

REPUBLIC OF COLOMBIA

MINISTRY OF HEALTH AND SOCIAL PROTECTION

RESOLUTION NUMBER \_\_\_\_\_ OF 2021

( )

Whereby the Technical Regulation is established on the Nutrition Facts and Front-Of-Package Labeling (FOPL) that Packaged Foods for Human Consumption Shall Comply With.

**THE MINISTER OF HEALTH AND SOCIAL PROTECTION**

In Exercise of his legal powers – particularly those conferred as per Articles 488 – section f) of Act 09/1979, Article 10 – Act 1355/2009, and Article 2 of Decree-Law 4107/2011, and

**WHEREAS**

Article 78 of the Political Constitution of Colombia provides as follows: “(...) *those who commit violations against the health, the safety and proper use by consumers and users in the production and marketing of goods and services shall be liable according to the law (...)*”.

Act 170/1994 approved the Agreement of the World Trade Organization in Colombia which contains – inter alia – the Agreement on Technical Barriers to Trade., The Agreement on Technical Barriers to Trade recognizes the importance for Member Countries to adopt the necessary measures for the protection of the essential interests in terms of safety of all products, including industrial and agricultural products, and the relevant technical regulations.

In pursuance of the provisions of Article 28 of Andean Decision 850/2019, Technical Regulations are established to ensure the following legitimate objectives – inter alia: the imperatives of national security; the protection of human health or safety; the protection of life; animal health; plant health; the protection of the environment and the prevention of practices that may lead consumers to errors.

In accordance with the provisions of Act 1480/2011, a producer is defined as “*one who routinely, directly or indirectly, designs, produces, manufactures, assembles or imports products (...) subject to technical regulations or Sanitary and Phytosanitary Measures (SPS)*”. Article 6 of said Act also sets forth the following provisions in matters relating to suitability and safety of products: “*every producer shall ensure the suitability and safety of the goods and services offered or placed on the market, and the quality of same. In no case shall these be lower than, or contravene, the provisions of technical regulations and sanitary or phytosanitary measures*”.

Decree 1074/2015, i.e. Single Regulatory Decree of the Commerce, Industry and Tourism Sector, defines the technical guidelines to adopt good practices of technical regulation. Chapter 7 and section 1 of chapter 8 under Title 1, Part 2 of Book 2 also establishes rules relating to the National Quality Subsystem, with a focus on the regulatory procedures required for the issuance of national standards.

The guidelines for the preparation, adoption and application of technical regulations in the Member Countries of the Andean Community and at the community level are contained in Decision 827/2018 of the Andean Community, and the administrative procedure for the preparation, adoption and application of technical regulations, sanitary and phytosanitary measures in the agri-food field, in Decree 4003/2004, which has been observed in the preparation of this technical regulation.

According to the burden of disease study carried out in 2017 by the Institute for Evaluation and Measurement of the University of Washington for Colombia, excess weight is related to serious health complications and healthy years of life lost (Healthy YLL). A high body mass index (excess weight) has a high risk attributable to cardiovascular disease (3.15%) and endocrine diseases (2.32%). Similarly, hypertension plays a fundamental role in cardiovascular disease (6.68%) and dietary factors that contribute to 5.96% of the risk attributable to cardiovascular disease.

According to the study on the effects on health of food-related risks in 195 countries, 1990-2017: Global Burden of Disease Study 2017, and published in the year 2019, worldwide dietary factors and high sodium intake, sweetened drinks and trans fatty acids have a direct relationship with deaths from cardiovascular diseases, cancer and diabetes.

According to figures of the National Administrative Department of Statistics – DANE (from its original Spanish language initials: *Departamento Administrativo Nacional de Estadística*) in 2018, cardiovascular disease in the country is within the ten first causes of mortality, and caused 27.6 % of the total number of deaths. Among the major factors of risk of cardiovascular disease are hypertension and hypercholesterolemia. According to the 2017 National Survey of Health, 22.82 % of the population aged 18 to 69 has high blood pressure and 7.82% presented hypercholesterolemia (total cholesterol above 240 mg/dl). It is estimated that approximately 62% of the hypertension cases are associated with excess intake of salt in food; as for hypercholesterolemia, it is associated with excess intake of saturated and trans fats, and is by its prevalence the second risk factor for cardiovascular disease.

The latest Survey of Food and Nutritional Situation in Colombia - ENSIN 2015 (from its original Spanish Language initials: *Encuesta de Situación Alimentaria y Nutricional en Colombia*), showed significant results regarding the high prevalence of processed food in all age groups – above 50% of the population, and even reaching 91.4%. In turn, there is increasing prevalence of overweight and obesity – especially in schoolchildren, who increased from 18.8% in 2010 to 24.4% in 2015. In addition, one in three young people and adults are overweight (37.7%), whilst one in every five is obese (18.7%). In this sense, 56.4% of the population is overweight, which means a 5.2% increase with respect to 2010. In addition, more than half of the adult women (59.6%), and 39.3% of men have abdominal obesity – a situation which favors the development of cardiovascular diseases and insulin resistance.

The World Health Organization - WHO and the World Cancer Research Fund (WCRF) agree that the most important factors that promote increased weight and obesity, as well as noncommunicable diseases (NCDs) are the increase in the consumption of low nutritional value products and products with high added sugars, fat and salt, such as snacks and fast food, the habitual intake of sugary drinks, and the decrease in physical activity.

The WHO's report to end with child obesity in the year 2016 recommended *“the implementation of front-of-package labeling which is easy to interpret, supported on public education so both adults and children possess basic knowledge in matters relating to nutrition”*.

The Pan American Health Organization - PAHO calls on governments to *“develop and establish standards for front-of-package labeling to promote healthy choices, allowing to quickly and easily identify foods which are high in calories and have low nutritional value”* in strategic line 3 of the Action Plan for the prevention of obesity in childhood and adolescence. (2014-2019)

In accordance with the provisions of Article 3 – Act 1480/2011, the consumer has the right to: *“Obtain complete, truthful, transparent, timely, verifiable, comprehensible, accurate and suitable information in regards to the products offered or put into circulation, as well as on the risks that may arise from their consumption or use, the mechanisms for the protection of their rights and the ways to exercise them”*.

The United Nations Special Rapporteur on the right to health issued a Declaration in 2020 urging the States to address the global impact of noncommunicable diseases, adopting front-of-package labeling policies as a warning of foods and drinks that contain excessive amounts of critical, non-healthy nutrients, recognizing it as an adequate regulatory measure, which contributes to the obligations of the State in matters of human rights and allows consumers to make informed choices about their diets without making additional efforts or requiring qualified knowledge.

In accordance with the results of the Regulatory Impact Assessment (RIA) with projections to 25 years, the cost of implementing this regulatory project would be COP \$ 697,758 million, which implies consumer studies, new labels, product designs, Inspection, Surveillance and Control actions, and conformity assessment processes, whereas savings in health – established as benefits – are estimated at COP 2,787,180 million, which implies mitigation of overweight prevalence and their contribution to the noncommunicable diseases and their associated cost, as direct costs and indirect health-pocket expenses, decreased premature deaths and consequently an improvement of productivity in the country. Thus, this measure has a 3.99 cost-benefit ratio, which indicates that it is the best alternative in comparison with information campaigns and status quo.

Nutritional information in food packaging is an element of support to nutrition policies in the country; therefore, it becomes necessary to establish these technical regulations along with requirements for nutritional labeling and front-of-package labeling as a protective measure for consumers.

In pursuance of Decree 210/2003, 1471/2014 and 1595/2015, the Ministry of Health and Social Protection requested the Ministry of Commerce, Industry and Tourism to conduct a prior technical assessment, which was delivered by the Regulatory Directorate as per XXXX. Said assessment concluded the following: XXXXXXXXXXXXXXXXXXXX.

The aforesaid act was notified to the World Trade Organization (WTO) with code no. G/TBT/N/COL/XXX issued on the X day of XX, 20XX.

A legal technical assessment was issued in regards to the Resolution draft, as under Article 7 of Act 1340/2009, regulated by Decree 1074/2015. The Delegate for the Protection of Competition of the

Superintendence of Industry and Commerce issued a report under filing No. XXXX of XX of XX of 201XX, and concluded the following: C) XXXX”.

In light of the above, it becomes necessary to establish a technical regulation to ensure the fulfillment of the health requirements to be met by packaged food for human consumption, a necessary measure in order to provide consumers with clear and understandable nutritional information, to promote a healthy and balanced diet, to protect human health and to prevent potential damages to it.

By virtue of the foregoing, the Ministry of Health and Social Protection,

**DOES HEREBY RESOLVE AS FOLLOWS:**

**Chapter I**  
**Object, Scope and Definitions**

**Article 1. *Object.*** The purpose of this resolution is to establish the technical regulation with the conditions and requirements to be met by nutritional labeling and front-of-package labeling of packaged food and beverages for human consumption, seeking to provide sufficiently clear and understandable nutritional information about the product, to prevent practices that may result misleading for consumers, and to allow consumers to make an informed choice.

**Article 2. *Scope.*** The provisions hereunder shall apply to all national and imported packaged food for human consumption to be marketed in the national territory.

**Paragraph 1.** The following products shall be exempt from the application of nutritional labeling:

- a) Infant formula for children aged 0 and 6 months.
- b) Infant formula for children aged 6 and 12 months.
- c) Special infant formula.
- d) Food for Special Medical Purposes (FSMP).
- e) Fruits, vegetables, grains, eggs, meats and edible meat products presented in their natural state, refrigerated or frozen.
- f) Products from a single ingredient.
- g) Iodized and fluoridated salt and substitutes of salt.
- h) Food with packaging made from materials of natural origin.
- i) Herbal and fruit teas, tea, decaffeinated tea, instant or soluble tea or tea extract or decaffeinated tea extract not containing any added ingredients.
- j) Foods in bulk.
- k) Food used as raw material for the industry and to not be sold directly to consumers.

**Paragraph 2.** The following foods shall be exempt from the application of nutritional front-of-label warnings:

- a) Infant formula for children aged 0 and 6 months.
- b) Infant formula for children aged 6 and 12 months.
- c) Special infant formula.
- d) Food for Special Medical Purposes (FSMP).

- e) Fruits, vegetables, grains, eggs, meats and edible meat products presented in their natural state, refrigerated or frozen.
- f) Products from a single ingredient.
- g) Iodized and fluoridated salt and substitutes of salt.
- i) Herbal and fruit teas, tea, decaffeinated tea, instant or soluble tea or tea extract or decaffeinated tea extract not containing any added ingredients.
- j) Foods in bulk.
- k) Food used as raw material for the industry and to not be sold directly to consumers.
- l) Packaged foods without added salt/sodium, fats and/or sugars.
- m) Hydrating drinks.

**Paragraph 3.** Packed raw meat with added food products, condiments or additives containing salt or sodium should only include a declaration of the sodium content, and whether it exceeds the limit set forth in Article 32 hereof; should this be the case, the sodium front-of-package labeling warning shall be applied.

**Article 3. Definitions.** The definitions below are established for the application of this Resolution:

**Essential fatty acids:** nutrients that the human body requires and cannot synthesize, so they must be supplied in the diet. Essential fatty acids include linoleic and alpha-linolenic fatty acids, as well as EPA and DHA, which shall be supplied in the diet due to their very low conversion rate.

**Sugar:** for nutrient declaration purposes, sucrose will be understood as the term “sugar”.

**Total sugars:** carbohydrates of the monosaccharides and disaccharides type naturally present in food, such as sugar in milk and fruits, or added thereto.

**Added sugars:** Sugars that are added during food processing or packaged as such, and include sugars such as monosaccharides and disaccharides, sugars from syrups and those naturally present in honey and fruit concentrates or vegetable juices. These do not include the natural sugars found in milk, fruits, and vegetables.

**Available carbohydrates:** total carbohydrates with exclusion of dietary fiber.

**Total carbohydrates:** all mono-, di-, oligo- and polysaccharides, including sugar alcohols present in food.

**Glycemic Carbohydrates:** Total of carbohydrates in food minus the content of dietary fiber, polyalcohols and non-glycemic carbohydrates.

**Non-glycemic Carbohydrates:** Carbohydrates that have various chemical forms, and despite being digested they do not provide glucose or other carbohydrates for cell metabolism. They must show a glycemic index lower than 15, corresponding to the lowest value presented by a glycemic carbohydrate (fructose).

**Cholesterol:** Sterol-type substance present in fats of animal origin.

**Nutrient function claims:** Declarations which describe the physiological function of the nutrient in growth, development and normal functions of the body.

**Nutrient declaration:** Normalized list of a food's nutrient content.

**Declarations of properties of other functions:** Specific beneficial effects of the consumption of foods and their (nutritional and non-nutritional) constituents on physiological functions or biological activities, but not including nutrient function property claims. Such declarations of properties relate to a positive contribution to health or a condition related to health, or the improvement of a function, or the modification or preservation of health.

**Health property claims:** any representation that declares, suggests or implies that a relationship exists between a food or a constituent/component of same and health.

**Nutritional property claims:** any representation that states, suggests or implies that a product has particular nutritional properties, including – but not limited to – the energy value and content of protein, fat, carbohydrates and dietary fiber, as well as the content of vitamins and minerals. Nutritional property claims do not constitute a statement of nutritional properties: the mention of substances in the list of ingredients; the name or brand of the packaged food; the mention of nutrients as a mandatory part of the nutrition labeling; or the quantitative or qualitative statement of some nutrients or ingredients in the labeling.

**Disease risk reduction property claims:** Statements of disease risk reduction properties are claims related to the consumption of a food or a component of the food in the context of the total diet, which can help reduce the risk of a disease or health-related condition. Risk reduction means significantly altering a risk factor or factors recognized as involved in the development of a chronic disease or health-related adverse condition.

**Total diet:** habitual diet of a person or population.

**Packaging made from materials of natural origin:** Element designed to contain a food that includes – but is not limited to – banana leaves, bijao plant leaves, corn leaves, and gourds.

**Dietary or diet fiber:** Edible carbohydrates that will not be digested or absorbed in the small intestine of human beings. Dietary fiber consists of one or more of the following carbohydrates: edible carbohydrates naturally found in food in the form in which it is consumed, carbohydrates obtained from food raw material by physical, enzymatic or chemical means, and synthetic carbohydrates.

**Insoluble fiber:** Insoluble fiber is the fraction of dietary fiber which is water-insoluble.

**Soluble fiber:** Soluble fiber is the fraction of dietary fiber which is water-soluble.

**Infant formula for children aged 0 to 6 months:** Product in liquid or powdered form intended for feeding children aged 0 to 6 months used when indicated by a healthcare professional which, by itself, covers the child's nutritional needs, as the main liquid food supply until supplementary food is introduced in cases where breastfeeding is not possible.

**Infant formula for children aged 6 to 12 months:** Product in liquid or in powdered form especially manufactured according to the nutritional needs of children aged 6 to 12 months, used when indicated by a healthcare professional concomitantly with supplementary food.

**Special infant formula:** Product in liquid or powdered 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 a supplementary diet.

**Fortification:** It means the addition of one or more essential nutrients to a food, whether or not contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or in specific population groups.

**Voluntary fortification of nutrients:** Process whereby food manufacturers decide to add specific essential nutrients to certain foods or certain categories of foods.

**Total fat:** sum of saturated fat, monounsaturated fat, polyunsaturated fat (including trans fat).

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

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

**Monounsaturated fat or monounsaturated fatty acids:** Fats that have a double bond in their hydrocarbon chain. For purposes of labeling, monounsaturated fat shall be understood as fat that has a double bond in its Cis configuration.

**Polyunsaturated fat or polyunsaturated fatty acids:** Fats that have two or more double bonds in their hydrocarbon chain. For purposes of labeling, polyunsaturated fat shall be understood as fat that has a double bond in its Cis configuration.

**Transisomeric or trans fat or trans fatty acids:** All geometric isomers of monounsaturated and polyunsaturated fatty acids that have one or more unconjugated carbon-carbon double bonds in their trans configuration. For labeling purposes, trans fat will be understood as the sum of all the mono and polyunsaturated isomers in trans configuration that comply with the description above.

**Glycemic index.** Glycemic index is defined as the incremental area under the blood glucose response curve from a 50 g carbohydrate portion of 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 considered valid only when so determined **directly** following the official protocol established by the FAO / WHO Expert Panel, as this is a biological test which is susceptible to different factors.

**Household measure:** These are utensils or forms commonly used by the consumer to measure food, including – but not limited to – the following: cup, glass, slice, unit, tablespoon, and teaspoon.

**Minerals:** inorganic substances necessary for physiological processes and which are not a source of energy.

**Nutrient:** any substance normally consumed as a component of a food that provides energy, or is necessary for growth, development and/or maintenance of health, or whose absence will produce characteristic chemical or physiological changes.

**Essential nutrient:** nutrient that is not synthesized by the body or that is synthesized in insufficient quantities and shall be consumed to ensure growth, development and/or maintenance of health.

**Serving:** A serving is the amount of a food normally consumed on one occasion by people over 4 years of age and adults, or by children over 6 months and under 4 years of age, which shall be declared on the label and is expressed using common household measures appropriate for that food. The serving of the food to be declared on the label shall be determined upon the basis of the amount of reference of the food normally consumed at one time or portion of usual consumption, whose list appears in the annex hereto.

**Prebiotics:** Substrates used selectively by guest microorganisms that confer a benefit to health.

**Probiotics:** Living microorganisms which, when administered in the appropriate amounts, confer to the host a benefit to health.

**Product from a single ingredient:** Packaged food whose list of ingredients only contains one ingredient, including – but not limited to: bottled water, coffee, coffee beans, ground coffee, sugar, olive oil, inter alia.

**Protein:** L-á (sic) amino acid polymers linked by peptide bonds. Proteins are denominated *simple proteins* when formed only by amino acids, and *compound proteins* when they include other substances such as lipids, carbohydrates, minerals, inter alia.

**Nutritional labeling:** Any description contained in the tag or label of a food intended to inform consumers about nutrient contents, nutritional properties and health-related properties of a food.

**Front-of-package warning labeling:** information system located on the main display face, which shows truthfully, clearly, quickly and simply when a packaged product has a high content of nutrients of public health interest (added sugars, saturated fat, and sodium).

**Positive seal:** A check-shaped logo that indicates that the food contains low contents in the nutrients of interest in public health (added sugars, saturated fat and sodium) and that does not use sweeteners in their formulation.

**Symbiotic substances.** Symbiotic substances are understood as the combination of prebiotic substances with probiotic cultures present in one and the same food.

**Main meal time:** Within the framework of daily meal planning, main meal time refers to the moments in which the food is distributed in greater proportion – i.e. breakfast, lunch and dinner.

**Nutrient Reference Value (NRV) or Reference Value:** Nutrient Reference Value (NRV) or Reference Value are a set of numerical values based on scientific data for the purposes of labeling or nutritional labeling and declarations of relevant properties. Nutrient Reference Value (NRV) or Reference Value include the following two types of NRVs:

- Nutrient Reference Values - needs (NRV-N): those which make reference to the NRV based on levels of nutrients associated to needs of nutrients.
- Nutrient Reference Values – non-communicable diseases (NRV-NCD): those which refer to the NRV based nutrient levels associated with reduced risk of diet-related



noncommunicable diseases, excluding diseases or disorders caused by nutrient deficiencies.

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

**Article 4. *Scope.*** Nutrition labeling consists of nutrient declaration and the supplementary nutritional information, which includes the nutritional property claims, health declarations and front-of-package labeling.

**Article 5. *Purposes and characteristics of nutritional labeling or labeling.*** Nutritional labeling shall be implemented in fulfillment of the following characteristics:

5.1 Providing an effective mechanism to indicate the content of nutrients of the food on the label, making it easier for the consumer to make an informed decision.

5.2 The information shall not describe or present the food in a false, confusing or misleading way or in any way likely to create an erroneous impression regarding the food's nutritional content, nutritional properties and health, in any respect.

5.3 The information shall not induce consumers to believe that there is quantitatively accurate knowledge of what people should eat in order to maintain health. The information should state the amount of nutrients that the product contains. A more accurate quantitative delimitation for individuals is not valid, as there is no significant manner to use the knowledge about individual requirements in the labeling.

5.4 Applying the nutritional principles based on strong scientific evidence and in pursuance of social ethics and responsibility, without conflicts of interest in the design, production and processing of food products, for the benefit of public health.

5.5 All the information presented on the label shall be complete, truthful, verifiable, and shall not lead to confusion or deceit.

5.6 Ensuring that the information presented on the label will not contravene the promotion of healthy eating habits, in accordance with public health policies.

**Article 6. *Prohibitions on nutritional labeling.*** The use of the following statements is prohibited on nutrition labeling:

6.1 Declarations of nutritional or health properties not based on scientific evidence.

6.2 Declarations that indicate, represent, suggest or imply that the food is useful, adequate or effective to alleviate, treat or cure any disease or physiological disorder.

6.3 Medical or of Health Associations shall not endorse food products for purposes of advertising and marketing.

6.4 Declarations that promote excessive consumption of any food, or which are contrary to good eating habits.

6.5 Declarations that affirm that the food by itself fully fits the recommendations of energy and nutrient intake, or which in itself can replace a main meal time.

6.6 Declarations that express or suggest that the intake of food, any of its ingredients or nutrients provides persons with extraordinary characteristics or skills.

## **Chapter II**

### **Declaration of nutrients**

**Article 7. Application of the declaration of nutrients.** The declaration of nutrients shall be mandatory for all packaged food hereunder, and shall comply with the provisions of this chapter. The declaration of nutrients shall also be included nutritional information table provided for in Chapter VI hereof.

**Article 8. Declaration and presentation of the nutrients.** The nutritional information table shall only present a declaration of the requisite and optional nutrients listed in this chapter. The declaration of nutrient contents shall be done in a numerical form.

**Article 9. Expression of the values.** The nutrients will be declared in accordance with the provisions of the table below. A mathematical approximation shall be made to the nearest whole number or decimal point, as shown in the example below:

**Table 1. Expression of values**

<i>Value ranges</i>	<i>Form of expression</i>	<i>Mathematical approximation (example)</i>
Values greater than, or equal to, 100	These values shall be declared in whole numbers with three digits	237.8 is rounded to 238 237.3 is rounded to 237
Values less than 100 and greater than, or equal to, 10	These values shall be declared in two digits	54.6 is rounded to 55 54.2 is rounded to 54
Values less than 10 and greater than, or equal to, 1	These values shall be declared in one decimal point	9.82 is rounded to 9.8 9.87 is rounded to 9.9
Values less than 1	Values for vitamins and minerals shall be declared with two decimals points, and with one decimal point for the rest of nutrients.	0.843 is rounded to 0.84 0.848 is rounded to 0.85

**Paragraph 1.** If the value is exactly half of the established interval, it shall be rounded to the nearest upper number.

**Paragraph 2.** The nutritional information shall include “zero”, or “0” or “none” for energy value and/or nutrients, whenever the food contains amounts less than or equal to those established as “not significant” in accordance with the following table:

**Table 2. Non- significant quantities**

<b>Energy value or nutrient</b>	<b>Non-significant quantities per 100 g or 100 mL (expressed in kcal, g or mg)</b>
Calories	Less than or equal to 4 kcal or less than 17 kJ
Total carbohydrates	Less than or equal to 0.5 g
Total sugars	Less than or equal to 0.5 g
Protein	Less than or equal to 0.5 g
Total fat	Less than or equal to 0.5 g
Saturated fat	Less than or equal to 0.1 g
Trans fat	Less than or equal to 100 mg
Cholesterol	Less than 5 mg
Dietary fiber	Less than or equal to 0.5 g

Sodium	Less than 5 mg
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**Article 10. General conditions for the declaration of nutrients.** The declaration of nutrients shall meet the general conditions below:

10.1 The declaration of nutrients shall be made per every 100g of the food and per serving, for solid and semisolid foods, and per 100 mL of product and per serving for liquid foods.

10.2 The declaration shall be made based on the expressions established in Article 9 hereof.

10.3 The number of servings per package shall be declared on the main display face of the label, along with the net content of the food or drink. The size of this legend shall be commensurate to the size of the net contents as set out in the technical Annex of Resolution 5109/2005 or any regulations amending or superseding it.

10.4 The nutrient values listed in the table of nutritional information shall be average values obtained from analysis of representative samples of the product to be labeled or tagged. This process will be repeated whenever there is any change in the formulation and technical data, and shall be previously authorized by the National Institute of Food and Drug Surveillance - INVIMA (from its original Spanish language initials: *Instituto Nacional de Vigilancia de Medicamentos y Alimentos*). The manufacturer shall be responsible for the accuracy of the values declared. The following criteria shall be met:

- a) Nutrients added to the food: The content of vitamins, minerals, protein, dietary fiber, monounsaturated or polyunsaturated fat, shall be at least 80% of the value declared in the label.
- b) Nutrients naturally present in the food: The content of vitamins, minerals, protein, total carbohydrate, dietary fiber, other carbohydrates, monounsaturated or polyunsaturated fat, shall be at least 80% of the value declared in the label. In the case of calories, sugars, total fat, saturated fat, trans fat or sodium, an excess of no more than 20% over the declared value on the label is accepted.
- c) To determine the nutrient content, it shall be guaranteed that the analytical methods used comply with the particular requirements to their specific use, using methodologies endorsed by international, regional or national organizations with competence in this field, which shall be verified by the health authority.
- d) As for foods packed in water, brine or oil, whose liquid is not normally consumed, the declaration of nutrients shall be made based on the drained mass or drained solid.

**10.5 Nutrients with mandatory declaration:** The energy value and the amounts of the nutrients indicated below shall be declared in the nutritional table, per 100 g of food and per serving for solid foods, and per 100 mL of product and per serving for liquid foods, and with the provisions of article 9 of this technical regulation:

**Table 3. Forms of expression for nutrients with mandatory declaration**

Nutrient	Form of expression	Additional requirements
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Energy	Shall be expressed in kilocalories (kcal) (optional, between brackets: kilojoules (Kjul). The relevant declaration may use the terms or expressions energy, energy value, energy content, kilocalories.	The amount of total calories is the sum of the calories provided by fat, total carbohydrates, protein and dietary fiber, plus other energy sources as under Article 11 hereof, obtained from the amounts of these nutrients declared in the nutritional table according to the criteria of section 10.4.
Protein	It shall be expressed in grams	-
Total fat	It shall be expressed in grams	When making a declaration of nutritional properties in regards to the amount or the type of fatty acids, the amounts of monounsaturated, polyunsaturated, trans fatty acids and cholesterol shall be indicated immediately below the declaration of the total fat content.
Saturated fat	It shall be expressed in grams	It is not mandatory to include the declaration of saturated fat for foods containing less than 0.5 g Total fat per 100 g or 100 mL, unless declarations are made in regards to nutritional properties on the content of total fat total acids or cholesterol.
Trans fat	It shall be expressed in milligrams	-
Total carbohydrates	It shall be expressed in grams	-
Total sugars	It shall be expressed in grams	The declaration of total sugars is not mandatory for foods containing less than 1 g of sugar per 100 g food, except for cases in which declarations or references are made on artificial sweeteners, sugars or polyalcohols on the label; in this case, sugar will be declared as zero (0). If sugars are not declared, the following legend shall appear at the end of the nutritional information table. “Not a significant source of sugars”
Added sugars	It shall be expressed in grams	-
Dietary fiber	It shall be expressed in grams	The dietary fiber declaration is not mandatory for foods containing less than 1 g of dietary fiber per 100 g of food. In cases in which a declaration is made on nutritional properties in regards to dietary fiber, the quantity of its soluble and insoluble fractions shall be indicated.
Sodium	It shall be expressed in milligrams	-

vitamin A	It shall be expressed in ER micrograms	The declaration of vitamin A, vitamin D, iron and zinc is not mandatory for foods containing amounts less than 2% of the reference value per 100 g of the food. In cases in which these vitamins and minerals are not declared, the following legends shall appear at the end of the Nutritional Information Table: “Contains less than 2% of...” or ”Not a significant source of...” Followed by the vitamins and minerals that will not be declared.
Vitamin D	It shall be expressed in micrograms or IUs	
Iron	It shall be expressed in milligrams	
Zinc	It shall be expressed in milligrams	

**Paragraph:** if the food has an amount lower than the significant amount of the nutrients above, the abovementioned declaration shall not be necessary.

**10.5.1. Vitamins and minerals other than vitamin A, vitamin D, iron and zinc.** Vitamins and minerals other than vitamin A, vitamin D, iron and zinc can be declared when reference values have been established as under Chapter III hereof and they have been added to the food in amounts equal to or greater than 2% of the reference value per 100 g or 100 mL of the food.

**10.6 Nutrients of optional declaration.** Declaration of the nutrients listed below shall be optional. However, any declaration of nutritional properties on the nutrients below shall imply that the declaration of the nutrient ceases to be optional, and shall become mandatory.

**10.6.1 Monounsaturated, polyunsaturated fat, soluble and insoluble fiber and polyalcohols, cholesterol and potassium.** The amounts of monounsaturated polyunsaturated fat, soluble and insoluble fiber and polyalcohols shall be expressed in grams, and cholesterol and potassium shall be expressed in milligrams per serving, and per 100 g of solid food, and in grams per serving and per 100 mL of liquid food, according to the provisions under Article 9 hereof.

**Article 11. Calculation of energy and nutrients.** The energy calculation is made based on the actual values of the nutrients. The following criteria will be taken into account for the calculation of energy and nutrients, :

**11.1 Energy.** The amount of energy to be declared shall be calculated using the following conversion factors:

**Table 4. Conversion Factors**

Available carbohydrates	17 kJ / g (4 kcal / g)
Protein	17 kJ / g (4 kcal / g)
Fats	37 kJ / g (9 kcal / g)
Alcohol (Ethanol)	29 kJ / g (7 kcal / g)
Organic acids	13 kJ / g (3 kcal / g)

- a) For dietary fiber, the manufacturer shall use the calorie conversion factors referred to in documents of national or international scientific reference;
- b) For alcohols such as sorbitol, mannitol, xylitol and others, the manufacturer shall use the factors of caloric conversion referred to in documents of national or international scientific reference.

c) In the case of non-glycemic carbohydrates, manufacturers shall submit a request before the Special Food and Beverage Branch at the National Institute of Food and Drug Surveillance - INVIMA (from its original Spanish language initials: *Instituto Nacional de Vigilancia de Medicamentos y Alimentos*) with the respective scientific evidence, compared to the conversion factor.

11.2 **Proteins.** The amount of protein to be declared shall be calculated using the formula below: Protein = Total Content of Nitrogen Kjeldahl x 6.25 – unless a different factor is established in international standards or in the method of analysis for one food.

11.3 **Total Carbohydrates.** Total carbohydrates are calculated by subtracting the protein, the total fat, the moisture and the ash, from the total mass of the food.

**Article 12. Serving sizes and characteristics.** The following method shall be implemented in order to achieve standardization of the size of portions to be used in per-serving nutritional labeling, in accordance with the following requirements:

12.1 The size of the portion declared on the label of a food shall be determined upon the basis of the reference quantities normally consumed at a time or portions of regular consumption, as set out in Tables 5 and 6 below. A tolerance of plus or minus 30% of the amount of reference shall be accepted.

**Table 5. Amounts of reference for Children’s Food**

Food	Reference quantity
Instant dry cereals as a thickener or to prepare porridge or baby food	10 g
Cookies	10 g
Baby food	60 g
Milk (from age 1)	80 mL
Yogurt	60 g

**Table 6. Amounts of Reference for Foods in General**

Food	Reference quantity
Starch of corn, potato, cassava	10 g
Raw rice	30 g
Oat flakes <sup>3</sup>	24 g
Oat flour	25 g
Wheat Flours	25 g
Corn Flour	25 g
Pasta for Soup <sup>3</sup>	15 g
Simple grains – e.g. barley <sup>3</sup>	45 g
Flour as main ingredient <sup>3</sup>	50 g
Flour as a secondary ingredient <sup>3</sup>	20 g
Pizza dough	40 g
Regular bread	50 g
Loaf of white bread	22 g
Loaf of whole-wheat bread	32 g

Toasts	30 g
Croutons	7 g
Crackers	24 g
French bread	35 g
Bread Crumbs	30 g
Short and long raw pasta (as a single dish) <sup>3</sup>	55 g
Fresh, filled pasta (e.g.: ravioli, tortellini)	100 g
Precooked lasagna	140 g
Dry lasagna	55 g
Semolina as main ingredient <sup>3</sup>	70 g
Semolina as a secondary ingredient <sup>3</sup>	15 g
Corn / grain tortillas/tacos	30 g
Waffles	85 g
<b>PASTRY PRODUCTS</b>	
Cereal bars without filling	20 g
Cereal bars with filling	40 g
Brownies	40 g
Donuts, muffins	55 g
Cookies	30 g
Pastries / fruitcakes vegetable cakes, cheesecakes or similar	125 g
Cupcakes	50 g
Cake fillings or toppings	35 g
Tartlet	80 g
Baked Cakes without filling	55 g
Baked cakes with filling	80 g
Pastry mix	30 g
Baking Powder	0.6 g
<b>CEREALS FOR BREAKFAST</b>	
Cereal-based mixture to prepare drinks , ready to reconstitute (instant-beverage type)	Amount needed to make a glass (without ice)
Cereal for breakfast (cereal hot type), corn flakes	40 g dry; 55 g with flavor and sweetened
Cereal for breakfast (cereal hot type), oat flakes	1 cup prepared with 22 g of plain dry cereal
Ready-to-eat breakfast cereal	30 g
Ready-to-eat breakfast cereal weighing less than 20g per cup – e.g. single puffed cereal grains	15 g
Oat bran	21 g
Wheat bran or wheat germ	15 g
Wheat or corn flakes	30 g
<b>POTATOES</b>	
Pre-fried, frozen French fries	80 g

Fresh or frozen potato	80 g
<b>VEGETABLES WITHOUT SAUCE - FRESH OR FROZEN</b>	
Fresh or frozen vegetables <sup>3</sup>	85 g
Chili pepper, onion <sup>3</sup>	30 g
<b>OTHER VEGETABLES</b>	
Vegetables used primarily for seasoning (e.g. paprika, parsley) <sup>3</sup>	4 g
All vegetables without sauce canned in liquid	130 g
All vegetables with sauce, fresh, canned or frozen	110 g
Vegetable juice	200 mL
Olives <sup>4</sup>	15 g
Pickles – all types <sup>4</sup>	30 g
Vegetable paste (e.g. tomato paste)	30 g
Vegetable sauce (e.g. ketchup)	12 g
<b>FROZEN PREPARED DISHES</b>	
Mixed platter (meat or chicken with garnish)	250 g
Mixed platter with vegetables	135 g
<b>OTHER PREPARED DISHES</b>	
Measurable in cups (e.g. spaghetti with sauce, etc.)	1 cup
Not measurable in cup (e.g.: burritos, pizza, sandwiches, etc.)	140 g (add 55 g for products that have some type of sauce)
<b>PROCESSED FRUITS</b>	
All the fruits canned or frozen, except the listed in separate categories	140 g
Dehydrated (dried) plums	40 g
Dehydrated peach (dried)	60 g
Figs in syrup	100 g
Raisins	30 g
Peach halves <sup>4</sup>	85 g
Chopped peaches <sup>4</sup>	85 g
Raspberries <sup>3</sup>	85 g
Fruits for garnish or flavor (e.g. cherries)	4 g
Fruit for garnish (e.g., sauce or pureed plum)	70 g
Other fruits used as the main ingredient	55 g
Juices, nectars and fruit drinks	200 mL
Juices used as ingredients (e.g. lemon juice)	5 mL
Fruits in syrup or pickles <sup>4</sup>	30 g
Fruit-based Salsa (e.g. sauce of raspberry sauce on strawberry)	30 g
<b>DAIRY PRODUCTS</b>	



Milk candy	30 g
Whipped cream	10 g
Milk Cream	20 g
Spreadable sour cream	30 g
Ice creams	45 g (1 small scoop)
Ice cream in individual servings (e.g., popsicles, cup, cone, ice cream sandwich, etc.)	1 unit
Koumiss	150 mL / g
Cream yogurt	150 g
Liquid yogurt	200 mL
Fermented milk Drink	200 mL
Condensed milk	30 g
Evaporated milk	30 g
Powdered milk	Amount needed to make a glass (without ice)
Liquid milk	200 mL
Drinks with milk	200 mL
<i>Quesillo</i> – cheese snack	30 g
Cottage cheese	110 g
<i>Campefino</i> - fresh cheese	20 g
Cheese spread	13 g
Grated Cheese	18 g
Cheeses - except those listed in separate categories	30 g
Petit Suisse-type cheese	30 g
Dairy dessert	80 g
Dairy dessert with fruit	145 g
<b>FISHING PRODUCTS, MEATS AND THEIR DERIVATIVES</b>	
Canned anchovies	15 g
Caviar	15 g
Sausage meats	50 g
Chorizo and <i>Longaniza sausage</i>	55 g
Chopped Ham and Mortadella	38 g
Hot dog	40 g
Burger	70 g
Pate	15 g
Bacon	7 g
Fish, smoked seafood	55 g
Preserves of fish (e.g., salmon, mackerel or other)	100 g
Fish, canned seafood <sup>5</sup>	56 g
<b>EGG</b>	
Fresh egg <sup>3</sup>	50 g

Egg products (powdered egg)	Amount to replace a 50 g egg
<b>LEGUMINOUS BEANS IN DRY GRAIN</b>	
Peas, chickpeas, lentils, beans, broad beans <sup>3</sup>	60 g
<b>CANNED LEGUMES</b>	
Peas, chickpeas, lentils, beans	120 g
<b>OILS AND FATS</b>	
Oils	5 mL
Butter	7 g
Powdered butter substitutes	2 g
Margarine	7 g
Mayonnaise	6 g
Aerosol oil (spray type)	0.25 g
<b>WALNUTS AND SEEDS</b>	
Grated coconut	15 g
Walnuts	30 g
Peanut	30 g
Almonds	30 g
Nut mixes mixtures	30 g
Pastes and creams from nuts and seeds (e.g. peanut paste)	2 tablespoons - 20 g
<b>SUGAR, CHOCOLATE PRODUCTS AND OTHER SWEET PRODUCTS</b>	
Sugar	10 g
Substitutes of sugar	Amount equivalent to the reference amount of sugar to sweeten
Syrup used as main ingredient (e.g. corn syrup )	20 mL
Carbonated drinks	200 mL
Non-carbonated drinks	200 mL
Hydrating drinks	200 mL
Powdered Hydrating drinks	20 g - 30 g
Candies, sweets <sup>6</sup>	15 g
Chewing gum <sup>6</sup>	3 g
Marshmallows	30 g
Marmalade	20 g
Bee Honey	10 g
Pancake syrup	10 g
Chocolate syrup	30 g
Chocolate for direct consumption	25 g
Sugar-free drinking chocolate	8 g
Drinking chocolate with sugar	20 g
<i>Panela</i> (unrefined whole cane sugar)	25 g

Decorations for products - baked cakes, biscuits (e.g., colored sugar, chocolate chips).	1 teaspoon or 4 g if it cannot be measured in teaspoons
<b>MISCELLANEOUS</b>	
Soluble coffee	Amount needed to brew a cup
Ground coffee	Amount needed to brew a cup
<i>Achiras</i> snacks	25 g
Corn Extrudates	15 g
Corn Tortillas	30 g
Mixes (potato chips – plantain chips - pork rinds)	40 g
Pop corn	30 g
French fries / Fried plantain	30 g
Products of starch from cassava – baked ( <i>besitos</i> and <i>rosquitas</i> )	30 g
Pellet or puffed products of flour / rinds	15 g
Popsicles, frozen products with flavor and sweetened	85 g
Powdered mixtures for preparing drinks (without alcohol)	Amount needed to make 1 glass (without ice)
Dry mixes for coating meat, fish, seasoning mixes	12 g
Spices, herbs, (different from dietary supplements)	¼ teaspoon or 0.5 g if not measurable in teaspoons
Sauces for pasta	125 g
English sauce, soy sauce for meat	5 mL
Tartar sauce	15 g
Spicy sauces	6 g
Dressing for salads	30 g
Mustard	10 g
Vinegar	5 mL
Cooking wine	5 mL
<b>DEHYDRATED PRODUCTS</b>	
Dehydrated and concentrated broths	2.5 g
Powdered creams and dehydrated soups	20 g

12.2 For foods not defined in the tables in this Annex, it shall be the responsibility of the manufacturer to establish the size of the portion to declare on the label and its equivalence in household measures and units of the international system. In these cases, the serving shall comply with the definition established herein.

12.3 The quantities correspond to the food as it is marketed and only its edible part.

12.4 Food producers are required to convert the amount of reference into the serving size on the label, in an appropriate household measure for their specific product, using the procedures set forth in Chapter II hereof.

12.5 The amounts of reference make reference to the food as marketed – e.g. raw or processed products (cereals, legumes, etc.).

12.6 As for foods packaged with liquid, the amount of reference consists of the drained solids – except for foods in which both solids and liquids are consumed.

12.7 Reference quantities for ready-to-eat foods, or foods which are almost ready for consumption (e.g. heat-and-serve, or broil-and-serve).

12.8 The serving size of the label for all candies, sweets and chewing gum whose weight is different to the weight of the amount of reference will be considered a serving, provided it complies with the definition herein.

12.9 Common household measures constitute the basis required for the declarations of portion sizes and include: cup; glass; spoonful; teaspoon; slice; fractions of a unit; commonly used household containers such as a pitcher, tray or any other common household measure for packaged foods. However, in cases of foods where it is not possible to express a portion in these measurements, the following units can be used as a household measure: a slice, a fraction of the unit, ounces, or the number of units which is closest to the amount of reference.

12.10 The declaration of the serving size should express the amount in units in household units and parenthetically, in accordance with the International System of Units (value of the magnitude with its respective unit).

a) Liquids shall be declared using milliliters (mL) and any other food in grams (g). Grams shall be rounded to the closest whole number – except amounts smaller than 5 g. For amounts between 2 g and 5 g, the numbers should be rounded to the nearest 0.5 g; conversely, amounts under 2 g shall be rounded to the closest 0.1 g.

b) The size of the portions may also be declared in ounces (oz.) and fluid ounces (fl. oz.) in parentheses, after the measurement of the international unit system, separated by a diagonal line, when other common household measures are the main declaration for the serving of the food.

12.11 Declaration of household measures: Household measures shall be expressed in the form below:

- a) Cup: it is expressed in increments of 1/4 or 1/3 of cup;
- b) Tablespoon: It is expressed as 1, 1 1/3, 1 1/2, 1 2/3, 2, or 3 tablespoons;
- c) Teaspoon: It is expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons.

12.12 Number of servings per container: if a container contains more than one portion, the number of servings declared on the label can be expressed with the nearest whole number and use the word “approximately” or its abbreviation “approx.”. However, the following exceptions will be accepted:

- a) Packages containing between 2 and 5 servings can express so with the number closest to 0.5 of a serving, and the word “approximately” - e.g.: approximately 3.5 servings.
- b) When the portion is calculated based on the solid drained, and the number of portions changes due to the natural variation in the size of the unit (maraschino cherries, gherkins, pickles, inter alia), the declaration can present the usual number of portions in a container – e.g., “Usually 5 servings.”

12.13 Portions of food in individual units (e.g., biscuits, rolls, sliced bread, sliced pound cake): the serving size will be determined according to the sizes set out in Tables 4 and 5, with a tolerance of plus or minus 30% of the reference value.

**Paragraph.** Exceptions to the above criteria apply to foods with natural variation of sizes, such as preserve-type fruit in syrup (maraschino cherries, plums, peaches) vegetables in liquid, pickled products and other similar products, in which cases the declaration shall present the size of one portion on the closest weight to the corresponding reference value.

12.14 Food servings in large units normally divided for consumption (Examples: cakes, pies, pizza): The size of a portion is a slice, expressed as a fraction of the total which is closest to the reference amount. Slices can be expressed as 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be expressed by dividing these values by 2 or 3. It is allowed to use 1/8, 1/12 and 1/16 but not the fractions 1/7, 1/11, 1/13 and 1/14.

12.15 Portions of food in presentations not referred to in paragraphs 12.1 and 12.2 above (Examples: flour, rice, sauces in general, spreads, sugar, margarine), and ready-to-eat prepared meals, drinks and dishes ready for direct consumption, and prepared meals and dishes that necessarily require cooking:

- a) The size of one portion is the total amount expressed in the closest household measures to the amount of reference for the specific food;
- b) For ready-to-eat meals, beverages and prepared dishes ready for direct consumption, and prepared meals and dishes that necessarily require cooking, packaged in individual servings and in compliance with the provisions for individual servings, the serving size will be the entire edible content of the container;

12.16 Assorted food containers: for products that contain an assortment of individual servings or two or more compartments, with a different food in each compartment, they shall include the labeling or nutritional labeling for each variety of food, per serving size and per 100 g or mL, calculated based on the corresponding reference amount. The above does not apply to containers of food assortments in which the nutritional information on the products containing it can be read through their packaging.

**Article 13. *Equivalences of common household measurements.*** The following equivalences with the international unit system are established for the declaration of serving sizes:

- 1 teaspoon (tsp) equals 5 mL
- 1 tablespoon (tbsp) equals 15 mL
- 1 cup equals 200 mL or 240 mL
- 1 glass equals 200 mL or 240 mL
- 1 fluid ounce (fl. oz.) = 30 mL
- 1 weight ounce (oz.) = 28 g

**Paragraph:** These measures are exempt for foods that include their own unit of measure included in the package.

**Article 14. *Abbreviations allowed.*** Only the following abbreviations may be used for the declaration of energy, nutrients and serving sizes hereunder:

**Table 7. Abbreviations allowed in nutrients**

Energy and some nutrients	Abbreviation Allowed
Total fat	Fat
Saturated fat / saturated fatty acids	Sat. fat
Polyunsaturated fat	Polyunsat. fat.
Monounsaturated fat	Monounsat. fat.
Trans Fat / Trans Fatty Acids	Trans
Total Carbs	Total Carb.
Added sugars	Added Sg.
Dietary fiber	Fiber
Vitamin	Vit.

**Table 8. Abbreviations allowed in serving sizes**

Serving size	Allowed abbreviation
Teaspoonful	tsp
Tablespoon	Tbsp
Fluid ounce	Fl. oz./
Ounce	Oz.
Grams	g
Milliliter	mL
Size of the portion	Serving
Servings per container	Servings
Approximately	Approx.

### Chapter III Daily Nutrient Reference Values

**Article 15. Daily Nutrient Reference Values.** In order to comply with nutritional labeling in food, the following daily nutrient reference values are established for children older than 6 months and younger than four (4) years of age, and children older than four (4) years and adults.

**Table 9. Daily Nutrient Reference Values - Needs (DNRV-N)**

Energy / Nutrients	Unit of Measure	Children older than 6 months and younger than 4 years	Children over 4 years old and Adults
Energy / Calories	Kcal	1000 kcal	2 000 kcal
Total fat	Grams	33 g	66 g
Monounsaturated fat	Grams	NE	NE
Polyunsaturated fat	Grams	NE	NE
Carbohydrates	Grams	150 g	300 g
Dietary fiber	Grams	14 g	28 g
Protein	Grams	25 g	50 g
vitamin A	µg ER	300 µg ER	800 µg ER
Vitamin C / Acid Ascorbic	Milligrams	15 mg	83 mg
Calcium	Milligrams	700 mg	1 000 mg
Iron	Milligrams	11 mg	20 mg

Vitamin D	micrograms / International Units	15 µg / 600 IU	15 µg / 600 IU
Vitamin e	Milligrams ET	5 mg	9 mg
Vitamin B1 / Thiamine	Milligrams	0.5 mg	1.15 mg
Vitamin B2 / Riboflavin	Milligrams	0.5 mg	1.2 mg
Niacin / Nicotinic Acid	Milligrams	6 mg	15 mg
Vitamin B6 / Pyridoxine	Milligrams	0.5 mg	1.3 mg
Folic acid / Folacin / Folate	Micrograms	150 µg	400 µg
Vitamin B12 / Cobalamin	Micrograms	0.9 µg	2.4 µg
Match	Milligrams	460 mg	700 mg
Iodine	Micrograms	90 µg	150 µg
Magnesium	Milligrams	80 mg	310 mg
Zinc	Milligrams	3 mg	11 mg
Copper	Micrograms	340 µg	900 µg
Pantothenic Acid	Milligrams	2 mg	5 mg
Vitamin K	Micrograms	25 µg	65 µg
Selenium	Micrograms	20 µg	70 µg
Potassium	Milligrams	3000 mg	4700 mg

NS: Not Specified for nutritional labeling.

**Table 10. Nutrient Reference Values - Noncommunicable Diseases (NRV-NCD)**

Nutrients	Unit of Measure	Children older than 7 months and younger than 4 years old	Older children of 4 years old and adults old
Sodium, Max.	Milligrams	1000 mg	2000 mg
Saturated Fat, Max.	Grams	NE	20 g
Trans fat, Max.	Milligrams	NE	2200 mg
Added sugars, Max.	Grams	25 g	50 g
Cholesterol, Max.	Milligrams	NE	300 mg

NS: Not Specified for nutritional labeling.

**Paragraph 1:** In the case of Vitamin A, 1 ER is = 1 µg of Retinol or 6 µg of β-carotene or 12 µg of other carotenoids. When the provitamin A carotenoids (α-carotene, β-carotene, β-cryptoxanthin) contents in food is known, the µg of Retinol Activity Equivalent (µg RAE) shall be issued. 1 µg RAE = 1 µg of Retinol or 12 µg of β-carotene or 24 µg of α-carotene and β-cryptoxanthin.

**Paragraph 2:** In the case of Folate, 1 EFD = 1 pg of dietary folate = 0.6 µg of folic acid added to food or as a supplement ingested with meals = 0.5 µg of folic acid from supplements ingested on an empty stomach.

#### Chapter IV

#### Declaration of Nutritional Properties.

**Article 16. Requirements.** All foods that make use of declarations of nutritional properties shall meet the following requirements:

##### 16.1 General Requirements:

16.1.1 The only declarations of nutritional properties allowed will be those made based on the daily reference values established herein, and on the fatty acids established in articles 19.1 and 19.2 hereof.

**Paragraph:** Declarations of nutritional properties that had already been approved by the Specialized Chamber for Food and Beverages at the National Institute of Food and Drug Surveillance - INVIMA (from its original Spanish language initials: *Instituto Nacional de Vigilancia de Medicamentos y Alimentos*) will continue to be in force herein. Additionally, in the event that a declaration is needed for a nutrient which has no reference value, the manufacturer shall submit the relevant request before the Specialized Chamber for Food and Beverages at Invima.

16.1.2 The font size of the terms or descriptors used for the declarations of nutritional properties shall not be bigger than two times the size of the letters used in the name of the food, as established in Resolution 5109/2005, or any standard amending or superseding it.

16.1.3 When a product has one or more front warning seals, no declarations of nutritional properties will be made in relation to the content of these nutrients – in terms of comparison and non-addition – vis-à-vis the content of the nutrients referred to in the front warning seal (s). e.g.: if the food has high added sugars it cannot be stated that it has reduced sugars.

16.1.4 When a product has 1 or more frontal warning seals, the nutritional property declarations different from those established in numeral 16.1.3 may only be made on the face on which the nutritional information table is presented.

**Article 17. Types of declarations of nutritional properties.** Below are the types of statements of nutritional properties:

**17.1 Declaration of properties in relation to nutrient content:** a declaration of nutritional properties is understood to describe the level of a certain nutrient contained in a food. (Examples: “source of calcium”; “excellent content of fiber and low fat”; “fortified”)

**17.2 Nutrient comparison properties declaration:** This is a statement of properties that compares the levels of nutrients and/or the energy value of two or more foods. (Examples: “reduced”; “less than”; “less”; “more than”.)

**17.3 Declaration of non-addition properties:** Any statement declaring that an ingredient has not been added to a food, neither directly nor indirectly. The ingredient is one whose presence or addition is allowed in the food and that consumers would normally expect to find in the food. - e.g. “No added sugar” in a cookie.

**Article 18. General conditions for the declaration of properties related to the content of nutrients.** Below are the general conditions for the declaration of properties related to the content of nutrients:

18.1 The statement shall utilize the terms or descriptors that are fit to the content of the nutrient, dietary fiber or energy of the food. No terms, descriptors or synonyms other than those allowed herein may be used.



**18.2** The term “salt free” shall be compliant with the “sodium free” criterion. In the event that the food does not comply with the sodium free requirement, to express that the product does not have added salt, the declaration shall read “has no added salt” or “no addition of salt” – complying with the requirements of the declaration of nutritional properties **“No salt / sodium added”**.

18.3 It shall be understood that a food is solid or liquid according to the unit of measurement used in the declaration of the net content of the food, i.e. it will be solid if its net content is expressed in grams or another equivalent measure, or liquid if its net content is expressed in milliliters or another equivalent measure.

**Article 19. Terms or descriptors allowed for the statements of properties related to the nutrient content:** Excellent source, good source, \_\_\_ free, Low, Very Low, Lean, Extra lean, Fortified.

19.1 “Excellent source”: these descriptors shall comply with the following criteria:

**Table 11. Conditions for the following descriptor “Excellent source”:**

<b>Component</b>	<b>Conditions: not less than</b>
Protein	20 % NRV per 100 g (solids) 10% NRV per 100 mL (liquid) or 20 % NRV per serving of food
Vitamins and minerals	30 % NRV per 100 g (solids) 15 % of NRV per 100 mL (liquid) or or 30% of NRV per serving of food
Fiber	6 g per 100 g or 20% of the value daily of reference by portion
Omega-3 fatty acids	0.6 g of alpha-linolenic acid or 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g or 100 mL
Monounsaturated fats	At least 45% of the fatty acids present in the food come from monounsaturated fats and monounsaturated fats provide more than 20% of the energy value of the product
Polyunsaturated fats	At least 45% of the fatty acids present in the food come from polyunsaturated fat, and polyunsaturated fat provides more than 20% of the product’s energy value.
Unsaturated fats	At least 70% of the fatty acids present in food come from unsaturated fats, and unsaturated fats provide more than 20% of the product’s energy value.

19.2 Good source: shall comply with the following requirements:

**Table 12. Conditions for the following descriptor: “Good source”:**

<b>Component</b>	<b>Conditions: not less than</b>
Protein	10 % NRV per 100 g (solids) 5% NRV per 100 mL (liquid) or 10 % NRV per serving of food

Vitamins and minerals	15 % NRV per 100 g (solids) 7.5% of NRV per 100 mL (liquid) or or 15% of NRV per serving of food
Fiber	3 g per 100 g or mL or 10% of the daily reference value by portion
Acids fatty omega-3	At least 0.3 g of alpha-linolenic acid, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g or 100mL

The foods that comply with the descriptor “good source of” may also use the following synonyms: “provides”, “source”, “contains” or “with”.

19.3 **Free from:** to use the descriptor “free of”, the food shall meet the following requirements:

**Table 13 Requirements for the following descriptor. “Free of”**

Nutrient	Requirements for the descriptor ”Free from” (per 100 g for solid foods or 100 mL for liquid foods)
Calories:	<ul style="list-style-type: none"> <li>- Contains less than 4 kcal.</li> <li>- If a food complies with this condition without need for special processing or alteration, formulation or reformulation to reduce the calorie content, the label shall include a statement indicating that the natural food is calorie free;</li> </ul>
Fat:	<ul style="list-style-type: none"> <li>- Contains less than 0.5 g of total fat.</li> <li>- The food shall not contain ingredients that are fats, which can be interpreted by the consumer as containing fat.</li> <li>- If a food complies with this condition without need for special processing or alteration, formulation or reformulation to reduce the fat content, the label shall include a statement indicating that the natural food is fat free.</li> <li>The term “fat-free” may be used in skimmed milk, as long as it meets the requirements established herein.</li> </ul>
Saturated fat	<ul style="list-style-type: none"> <li>- Contains less than 0.1 g of saturated fat.</li> <li>- The food shall not contain ingredients that are fats, which can be interpreted by the consumer as containing fat.</li> <li>- If a food complies with this condition without need for special processing or alteration, formulation or reformulation to reduce the saturated fat content, the label shall include a statement indicating that the natural food is saturated fat free.</li> </ul>
Trans fatty acids:	<ul style="list-style-type: none"> <li>- The food contains less than 100 mg of trans fat.</li> <li>- The food shall not contain ingredients that are fats, which can be interpreted by the consumer as containing fat.</li> <li>- If a food complies with this condition without need for special processing or alteration, formulation or reformulation to reduce the trans fatty acids content, the label shall include a statement indicating that the natural food is free of trans fatty acids.</li> </ul>
Total	<ul style="list-style-type: none"> <li>- Contains less than 0.5 g of sugars.</li> </ul>

sugars	
Cholesterol	- Contains less than 5 mg per 100 g (solids) or per 100 mL (liquids) and, for both declarations less than 1.5 g of saturated fat per 100 g (solids), 0.75 g of saturated fat per 100 mL (liquids) and less than 10 % of energy from saturated fat
Sodium:	- Contains less than 5 mg of sodium. - The food shall not contain sodium chloride or any other ingredient or additive that contains sodium - If a food complies with this condition without need for special processing or alteration, formulation or reformulation to reduce the sodium content, the label shall include a statement indicating that the natural food is sodium free.

19.3.1 Foods that comply with the descriptor “\_\_\_\_\_ free”, may also use the following synonyms: “does not contain \_\_\_\_\_”; “Zero \_\_\_\_\_” (or its numerical expression); “No \_\_\_\_\_” or “non-significant source of \_\_\_\_\_”; or “Without \_\_\_\_\_”.

19.3.2 The use of the terms “free”, “low” means that the food has been modified in some way. These terms can only be used in foods that have been specially processed, modified or formulated, with the aim of reducing or removing an amount of a nutrient present in the food. E.g.: Canned peas usually contain sodium; consequently, if the food is processed in such a way that meets the requirements to be considered “low” or “free” sodium can be called in this way.

19.3.3 In the case of food which, by their nature, are exempt from the nutrient which is the object of the declaration, the terms or descriptors used to describe the level of the nutrient should not imply that it is a quality exclusive to that product, but that it is a natural quality of the food.

19.4 **Low in:** to use the descriptor “low in”, foods shall meet the following requirements:

**Table 14. Requirements for the following descriptor: “Low in”**

<b>Nutrient</b>	<b>Requirements for the descriptor ”Low in” (per 100 g or 100 mL)</b>
Calories:	- Contains a maximum of 40 kcal per 100 g or 20 kcal per 100 mL.
Grease:	- Contains a maximum of 3 g per 100 g (solids) or 1.5 g per 100 mL (liquids).
	The term “low fat” may be used in low-fat milk provided it meets the requirements set out herein.
Saturated fat	- Contains a maximum of 1.5 g per 100 g (solids), 0.75 g per 100 mL (liquids) and no more than and 10% of energy comes from saturated fat
Cholesterol	- Contains a maximum of 0.02 g per 100 g (solids) 0.01 g per 100 mL (liquids)
Sodium:	- Contains a maximum of 80 mg per 100 g or 100 mL of food. The term “low in salt” can be used if the product complies with the following criterion: “low in sodium.”

**Paragraph:** Foods that meet the descriptor “low in” may also use the following synonyms: “little”, “few”, “low source of” or ”contains a small amount of”.

19.5 **Very low in:** only allowed for sodium, if it contains a maximum of 40 mg per 100 g or 100 mL of food.

19.6 **Lean:** This descriptor is only applicable to meat and fish. The product shall contain less than 10 g of total fat, less than 4.5 g of saturated fat and less than 95 mg of cholesterol per serving declared on the label.

19.7 **Extra-lean:** This descriptor is only applicable to meat and fish. It shall contain a maximum amount of 5 g of total fat, 2 g of saturated fat and 95 mg of cholesterol per serving declared on the label.

19.8. **Fortified:** the food product shall meet the following requirements for the use of this descriptor:

19.8.1 **General principles for the use of the following descriptor: “Fortified” in food.** Fortification of essential nutrients in foods shall comply with the following general principles:

- a) Nutrients derived from foods included in the daily diet shall be considered in concentrations that do not lead to an excessive or insignificant intake of the fortified essential nutrient, as compared to its habitual content.
- b) Fortification of one essential nutrient does not lead to detrimental effects against the metabolism of any other nutrient content in the food.
- c) The sources of essential nutrients can be natural or synthetic and their selection shall be based on considerations such as the safety and the bioavailability of same. In addition, the criteria of purity shall take into account the national rules or, failing that, those of FAO / WHO standards, recognized international standards, and in default thereof, the international pharmacopoeia books.
- d) The essential nutrient shall be stable and available in the food under the usual conditions of packaging, processing, storage, distribution and use.
- e) The essential nutrient shall be bioavailable.
- f) Fortification of essential nutrients in foods should not be used to induce a mistake or to deceive the consumer, in terms of the food’s nutritional value.
- g) There shall be standardized methods – or measurement methods internationally accepted by organisms responsible for control and/or enforcement of the concentrations of essential fortified nutrients in foods.

19.8.2 **Essential nutrients which can be added to fortify food.** Foods may be fortified by one or more of the essential nutrients below. The vitamin and minerals compounds shall be as specified in the table below:

**Table 15. Allowed vitamin and/or mineral compounds to fortify foods**

Nutrient	Vitamin and/or mineral compound
vitamin A	-retinol -acetate of Retinyl palmitate of retinyl -beta-carotene
Vitamin D	- cholecalciferol - ergocalciferol

Vitamin E	<ul style="list-style-type: none"> <li>- D-alpha-tocopherol</li> <li>- DL-alpha-tocopherol</li> <li>- acetate of D-alpha tocopheryl</li> <li>- acetate of DL-alpha tocopheryl</li> <li>- succinate acid of D-alpha tocopheryl</li> <li>- Succinate of DL-alpha tocopheryl polyethylene glycol 1000</li> <li>- ALPHA-tocopherol &lt; 20 %</li> <li>- beta-tocopherol &lt; 10 %</li> <li>- gamma-tocopherol 50% - 70 %</li> <li>- delta-tocopherol 10 % - 30%.</li> </ul>
Vitamin K	<ul style="list-style-type: none"> <li>- phylloquinone (phytomedianone)</li> <li>- menaquinone-7 and menaquinone-6</li> </ul>
Vitamin B1	<ul style="list-style-type: none"> <li>- thiamine hydrochloride</li> <li>- thiamine isosorbide</li> <li>- thiamine chloride monophosphate</li> <li>- thiamine chloride pyrophosphate</li> </ul>
Vitamin B2	<ul style="list-style-type: none"> <li>- riboflavin</li> <li>- riboflavin 5'-phosphate sodium</li> </ul>
Niacin	<ul style="list-style-type: none"> <li>- nicotinic acid</li> <li>- nicotinamide</li> <li>- hexanicotinate of inositol (hexaniacinate of inositol)</li> </ul>
Pantothenic acid	<ul style="list-style-type: none"> <li>- Calcium D-pantothenate</li> <li>- Sodium D-pantothenate</li> <li>- Dexpanthenol</li> <li>- pantethine</li> </ul>
Vitamin B6	<ul style="list-style-type: none"> <li>- hydrochloride of pyridoxine</li> <li>- pyridoxine 5'-phosphate</li> <li>- dipalmitate of pyridoxine</li> </ul>
Folic acid	<ul style="list-style-type: none"> <li>- pteroylmonoglutamic acid</li> <li>- Calcium L-methylfolate</li> </ul>
Vitamin B12	<ul style="list-style-type: none"> <li>- Cyanocobalamin</li> <li>- Hydroxocobalamin</li> <li>- 5'-deoxyadenosylcobalamin</li> <li>- methylcobalamin</li> </ul>
Vitamin C	<ul style="list-style-type: none"> <li>- acid L-ascorbic</li> <li>- Sodium L-ascorbate</li> <li>- Calcium L-ascorbate</li> <li>- Potassium L-ascorbate</li> <li>- 6-palmitate of L-ascorbyl</li> <li>- L-ascorbate of magnesium</li> <li>- L-ascorbate of zinc</li> </ul>
Calcium	<ul style="list-style-type: none"> <li>- calcium carbonate</li> <li>- calcium chloride</li> <li>- calcium salts of citric acid</li> <li>- calcium gluconate</li> <li>- calcium glycerophosphate</li> </ul>

	<ul style="list-style-type: none"> <li>- lactate of calcium</li> <li>- calcium salts of orthophosphoric acid</li> <li>- calcium hydroxide</li> <li>- calcium malate</li> <li>- calcium oxide</li> <li>- calcium sulfate</li> <li>- calcium malate citrate</li> <li>- calcium acetate</li> <li>- Calcium L-ascorbate</li> <li>- calcium bisglycinate</li> <li>- calcium pyruvate</li> <li>- calcium succinate</li> <li>- calcium L-lysinate</li> <li>- calcium L-I pidolate</li> <li>- calcium L-threonate</li> </ul>
Magnesium	<ul style="list-style-type: none"> <li>- magnesium acetate</li> <li>- magnesium carbonate</li> <li>- magnesium chloride</li> <li>- magnesium salts of citric acid</li> <li>- magnesium gluconate</li> <li>- magnesium glycerophosphate</li> <li>- magnesium salts of orthophosphoric acid</li> <li>- magnesium lactate</li> <li>- magnesium hydroxide</li> <li>- magnesium oxide</li> <li>- magnesium sulfate</li> <li>- magnesium and potassium citrate</li> <li>- magnesium L-ascorbate</li> <li>- magnesium bisglycinate</li> <li>- magnesium L-lysinate</li> <li>- magnesium malate</li> <li>- magnesium L-I pidolate</li> <li>- magnesium pyruvate</li> <li>- magnesium succinate</li> <li>- magnesium taurinate</li> <li>- magnesium acetyl taurinate</li> </ul>
Iron	<ul style="list-style-type: none"> <li>- ferrous carbonate</li> <li>- ferrous citrate</li> <li>- citrate ferric of ammonium</li> <li>- ferrous gluconate</li> <li>- ferrous fumarate</li> <li>- diphosphate ferric of sodium</li> <li>- ferrous lactate</li> <li>- ferrous sulfate</li> <li>- ferric diphosphate (ferric pyrophosphate)</li> <li>- ferrous ammonium phosphate</li> <li>- ferric saccharate</li> <li>- elemental iron (carbonyl + electrolytic + dehydrogenated)</li> <li>- bisglycinate of iron</li> <li>- ethylenediaminetetraacetate of ferrous sodium (III) trihydrate</li> </ul>

Copper	<ul style="list-style-type: none"> <li>- cupric carbonate</li> <li>- cupric citrate</li> <li>- cupric gluconate</li> <li>- cupric sulfate</li> <li>- copper-lysine complex</li> <li>- Ferrous L-pidolate</li> <li>- ferrous phosphate</li> <li>- taurinate of iron (II)</li> </ul>
Chrome	<ul style="list-style-type: none"> <li>- chloride of chromium (III)</li> <li>- lactate of chromium (III) trihydrate</li> </ul>
	<ul style="list-style-type: none"> <li>- chromium nitrate</li> <li>- picolinate of chromium</li> <li>- sulfate of chromium (III)</li> </ul>
Zinc	<ul style="list-style-type: none"> <li>- zinc acetate</li> <li>- zinc bisglycinate</li> <li>- zinc chloride</li> <li>- zinc citrate</li> <li>- zinc gluconate</li> <li>- zinc lactate</li> <li>- zinc oxide</li> <li>- zinc carbonate</li> <li>- zinc sulfate</li> <li>- zinc L-ascorbate</li> <li>- zinc L-aspartate</li> <li>- zinc L-lysinate</li> <li>- zinc malate</li> <li>- zinc mono-L-methionine sulfate</li> <li>- zinc L-pidolate</li> <li>- zinc picolinate</li> <li>- zinc methionine</li> <li>- zinc histidine</li> </ul>
Selenium	<ul style="list-style-type: none"> <li>- sodium selenite</li> <li>- sodium selenite acid</li> <li>- sodium selenate</li> <li>- selenium-enriched yeast *</li> <li>- Seleniomethionine</li> </ul>
Potassium	<ul style="list-style-type: none"> <li>- potassium bicarbonate</li> <li>- potassium carbonate</li> <li>- potassium chloride</li> <li>- potassium citrate</li> <li>- potassium gluconate</li> <li>- potassium glycerophosphate</li> <li>- potassium lactate</li> <li>- potassium hydroxide</li> <li>- potassium salts of orthophosphoric acid</li> </ul>

\*Selenium-enriched yeast: yeast produced by culture in presence of selenite of sodium as a source of selenium. Its commercial dry presentation has a maximum amount of 2.5 mg Se/g. The species with organic selenium predominantly present in yeast is selenomethionine (between 60% and 85% of the extracted selenium present in the total product). The content of other organic

selenium compounds, including selenocysteine, shall not exceed 10% of total extracted selenium. Typically, the levels of inorganic selenium shall not exceed 1% of the total selenium extracted.

**Paragraph.** The vitamin or mineral compounds specified in Table 15 shall be approved by the Specialized Chamber for Food and Beverages at the National Institute of Food and Drug Surveillance - INVIMA (from its original Spanish language initials: *Instituto Nacional de Vigilancia de Medicamentos y Alimentos*).

**19.8.3 Reference value range for the use of the descriptor “Fortified”.** Foods voluntarily fortified shall comply with the range of 20% to 100% of the NRV set out in Table 9 hereof, per serving declared, without exceeding the Tolerable Upper Intake Level (UL) as outlines in Resolution 3803/2016, or any standards amending or superseding it.

**Paragraph 1.** Foods whose fortification is mandatory are excluded from compliance herewith.

**Paragraph 2.** The declaration of the descriptor “fortified” can be made as follows: “Fortified with Vitamins X and Minerals X”, “With Vitamins X and Minerals X”, “More Vitamins X and Minerals X”. The above shall comply with the ranges established per serving declared on the label.

**Article 20. General conditions for the declaration of comparative nutritional properties.** The general conditions for the declaration of comparative nutritional properties are as follows:

20.1 The comparative nutrition claim shall be based on food as offered when sold.

20.2 The foods compared shall correspond to different versions of one and the same food, or similar foods, and the foods compared shall be clearly identified, which means that it must be done in the same amount.

20.3 An indication shall be given as to the amount of difference in the energy value or the content of nutrients in accordance with the following:

20.3.1 The value of the difference expressed as a percentage, a fraction or an absolute amount.

20.3.2 The identity of the food or foods with which the food in question is compared, in such a way that the consumer can easily identify them.

20.3.3 The information in sections 20.3.1 and 20.3.2 shall appear together or immediately below the descriptor term used for the comparative claim, and its print size shall not be less than a half of the abovementioned term.

20.4 Foods with reduced saturated fat contents should not increase the content of trans fatty acids.

20.5 Foods with reduced trans fatty acid contents should not increase the content of saturated fatty acids.

**Article 21. Terms or descriptors allowed for declarations of comparative nutritional properties.**



21.1 Reduced \_\_\_\_\_: the comparison shall be based on a relative difference of at least 25 % in the energy value or in the content of nutrients, respectively between the foods compared and a minimum absolute difference, as shown in the following table:

**Table 16. Requirements for the descriptor “Reduced \_\_\_\_\_”**

<b>Nutrient</b>	<b>Minimum Relative Difference</b>	<b>Minimum Absolute Difference</b>
Calories	25%	40 kcal (Solid)
		20 kcal (Liquids)
Fats	25%	3 g (Solid)
		1.5 g (Liquids)
Saturated Fat	25%	1.5 g (Solid)
		0.75 g (Liquids)
Sugars	25%	3 g (Solid)
		1.5 g (Liquids)
Sodium	25%	80 mg
Cholesterol	25%	20 mg (Solid)
		10 mg (Liquids)

**Paragraph 1.** The term “Reduced” shall not be used if the reference food complies with the requirements to be a “low” source.

**Paragraph 2.** The term “Reduced” shall appear on the label immediately followed by the preposition “in” and the nutrient or calories that have been reduced. E.g. “Reduced in calories” (sic); “Reduced in fat” (sic).

**Paragraph 3.** The foods that comply with this descriptor may also use the following synonyms: “less \_\_\_\_\_” or “lower in \_\_\_\_\_”.

**Paragraph 4.** The term *light* only can be used for low in calories.

**Article 22. Terms or descriptors allowed for non-addition declarations.**

22.1 “No added sugars”: the descriptor is allowed if it meets the following characteristics:

- a) No sugars have been added to food, including – but not limited to: sucrose, glucose, honey, molasses, syrups, maltodextrins, panela (sugar cane), agave nectar, cane juice, dextrose, *turbinado* sugar, black molasses, cane juice crystals, evaporated cane juice,

- fruit concentrate, concentrated fruit juice, corn syrup solids, maltose, D-ribose, sucrose, glucose solids, barley malt, brown sugar, caramel, crystalline fructose.
- b) The food does not contain any sugar-based ingredient, including – but not limited to: jams, jellies, chocolate with caloric sweeteners, pieces of fruit with caloric sweeteners, sugary cereals, non-reconstituted fruit juice concentrates.
  - c) No means are used (e.g. enzymes) during processing that can increase the sugar content in the final product (example: using enzymes to hydrolyze starches and release sugars).

22.2 **“No added salt / sodium”**: the descriptor is allowed if it meets the following characteristics:

- a) The food shall not contain salt, or other salts or additives that contain sodium.
- b) The food does not contain salt/sodium based ingredients including – but not limited to: sauces, dehydrated broths, canned food, sausages, salt substitutes, meat marinades, inter alia.
- c) does not contain any sodium-based ingredients instead of added salt, including - but not limited to: sea algae.
- d) shall comply with the “low in sodium” requirement.

## **Chapter V**

### **Health property claims.**

**Article 23. Requirements.** All food that is the subject health property claims shall meet the requirements for the declaration of nutrients and declaration of nutritional properties hereunder.

**Paragraph:** Health claims that have already been approved by the Specialized Chamber of Food and Beverages at the National Institute of Food and Drug Surveillance - INVIMA (from its original Spanish language initials: *Instituto Nacional de Vigilancia de Medicamentos y Alimentos*) will remain in force for this technical regulation.

**Article 24. Types of health claims:** There are three types of claims: 1. Nutrient function claims, 2. Function property claims; and 3. Disease risk reduction property claims:

**24.1 Nutrient function claims:** describes the physiological function of the nutrient in the normal growth, development and functions of the body.

Example:

“Nutrient A (include a physiological role of nutrient A in the body with respect to maintaining health and promoting normal growth and development). X food is a source of / excellent in nutrient A”, with a complete diet.

**24.2 Other function property claims:** Property-related claims are related to specific beneficial effects of the regular consumption of food or its constituents in the context of the total diet, regarding the normal biological functions or activities of the body. These claims of properties are related to a positive contribution to health or improvement of a function, or modification – or preservation of health.

Example:

“Substance A (name the effect of substance A on the improvement or modification of one physiological function or biological activity associated with health). Food Y contains x grams of substance A”.

For purposes hereof, below are some declarations of properties of other functions and their general characteristics:

24.2.1. Statements that link the consumption of probiotics with a better digestive function:

a) The microorganism or bacteria shall:

- Be alive, not be pathogenic and its natural environment is the human digestive tract.
- Be able to survive in the intestinal tract –i.e. it shall be resistant to gastric juices and bile acids.
- Have the ability to adhere to the intestinal mucosa.
- Have the ability to colonize the intestine.
- Have the ability to survive during the shelf life of the product it is added to.

b) The food shall contain a greater or equal number of viable bacteria of probiotic origin at  $1 \times 10^6$  CFU / g in the finished product until the end of its shelf life.

c) The statement should indicate that adequate and regular consumption of probiotic microorganisms is not the only factor to improve digestive functions, and that there are other additional factors to be considered such physical exercise and the type of diet.

d) Model statement: “A proper diet and regular consumption of foods with probiotic microorganisms may help normalize digestive functions and regenerate intestinal flora”.

24.2.2. Statements of health properties that relate the consumption of prebiotics with a better intestinal function:

a) The substance regarded as a prebiotic shall comply with the following:

- The amount of food that must be consumed to obtain the beneficial effect shall be reasonable in the context of the daily diet.
- Being a preferred substance by one or more species of beneficial bacteria in the large intestine or colon.
- Being resistant to gastric acids (gastric acidity).
- Being fermentable by the intestinal microflora.
- Being resistant to endogenous enzymatic hydrolysis.
- Having the ability to produce changes in the lumen of the large intestine, or in the body of the host that shows benefits for the health.
- Selectively stimulating the growth and/or the activity of bacteria associated with health and wellbeing.

b) The declaration shall indicate that adequate and regular intake of prebiotics is not the only factor to improve digestive functions, and other additional factors have to be considered such as physical exercise and the type of food.

c) Statement Model: “An adequate diet and regular consumption of at least X g per day of Y prebiotics promotes a healthy / good / balanced intestinal flora”; “Benefits the intestinal flora”; “helps improve the intestinal / digestive function”

**24.3 Disease risk reduction property claims:** The claim consists of two parts: (i) information on the physiological role of the nutrient on a known relationship between health and diet; followed by (ii) information on the composition of the product relevant to the physiological role of the nutrient in this relationship.

The benefit claimed should arise from regular consumption of a portion of a food, (as defined in Article 12 hereof), or constituent food in the context of a healthy diet.

If the alleged benefit is attributed to a constituent in the food for which a Nutrient Reference Value (NRV) has been established, the food in question shall be:

(i) An excellent source of the constituent, in the case in which an increase in consumption is recommended; or, (ii) low in \_\_\_\_\_, reduced \_\_\_\_\_; or \_\_\_\_\_ free regarding the constituent in the case in which a reduction in the consumption is recommended.

Whenever applicable, the conditions for the declarations of properties and nutritional comparisons will be used to determine the levels for “excellent” “low in \_\_\_\_\_”, “reduced in \_\_\_\_\_” or “\_\_\_\_\_ free”.

Examples:

“A healthy diet low in (nutritious substance) or (nutrient A) may reduce the risk of (disease D).

“(Food X) has a lower amount of (nutritious substance) or (nutrient A)”.

“A healthy diet rich in (nutrient or substance A) may reduce the risk of (disease D). (Food X) has excellent content of (nutritious substance) or (nutrient A)”

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

25.1 Health property claims shall not suggest that the food by itself is enough for a daily diet; neither shall health property claims suggest that a diet balanced based on common foods does not provide sufficient amounts of all the nutrients.

25.2 Health property claims shall not promote excessive consumption of any food, nor shall it be contrary to good eating habits as established in the Dietary Guidelines Based on Food for the Colombian Population.

25.3 Health property claims shall not cast doubt on the safety and quality of similar foods.

25.4 Whenever a product has 1 or more front-of-packaging warning seals, it shall not make any health property claims regarding the nutrient cataloged as “High in \_\_\_\_\_”, for any of the following nutrients: sodium, saturated fat and/or added sugars.

25.5 When a product has 1 or more front-of-packaging warning labels, the health property claims – different from those established in section 25.4 above – shall only be include in the face of the packaging showing the nutritional information table.

25.6 Quantifying the degree of risk reduction is not allowed.

25.7 In no case shall health property claims imply any curative, medicinal or therapeutic properties.

25.8 The term “healthy” or any term derived from it, such as: “health”, “salubrious”, “healthily”, “sanitary”, “good health”, “healthy status”, shall not be used in the labeling to describe a food as “healthy”, nor to present it in such a manner as to make it plausible to assume that the food itself communicates “health”. Similarly, the terms “complete food”, “balanced nutrition”, “complete nutrition” or equivalent shall not be used to the extent that they make it plausible to assume that a food by itself is enough for a daily diet.

Article 26. *Authorization for other health property claims.* After the product marketing stage, health property claims shall be accepted if they have already met the criteria for health property claims in relation to the nutrients established in SEAB Act No. 4/2017 and No. 13/2017. In the event of not meeting the criteria therein, the approval protocol outlined in Resolution 684/2012 shall be followed.

## **Chapter VI**

### **Specifications and formats of the nutritional information table and the front-of-package labeling.**

**Article 27. *Specifications of the Nutritional Information Table.*** The Nutritional information table shall abide by the following general and specific conditions:

#### **27.1 General conditions.**

27.1.1 The nutritional information shall appear grouped, presented in one frame, in a visible place of the label, with a minimum size of 25% of the area available for printing on the face on which it is located (preferably the back face), in legible print and with colors that contrast with the background in which it is printed.

27.1.2 The nutritional information shall include the numbers and the units corresponding to each nutrient declared.

27.1.3 The nutritional information shall appear in Spanish language, and may additionally appear in another language. In case the original label displays the information in a language different from Spanish, a supplementary label or tag shall be used and attached in a visible place, containing the translation and requirements hereof.

This supplementary label can be used in imported products originally labeled in Spanish whose nutritional information needs to be expressed in accordance with the requirements set out herein. The abovementioned adjustment may be performed before, during or after the nationalization process.

27.1.4 The font of the nutritional information shall be easy to read – i.e. Arial or Helvetica.

27.1.5 The information on energy and nutrients can be declared using the abbreviations permitted in accordance with the provisions in Chapter II hereof.

27.1.6 The use of nutritional table formats from another country is allowed in the case of imported products. However, the nutritional table for Colombia shall be included in compliance with all the requirements established herein.

**Article 28. *Specific conditions***

28.1 The title of the Nutritional Information Table shall be declared as “Información Nutricional” (*Nutritional Information*) or “Datos de Nutrición” (*Nutrition Facts*) using Arial or Helvetica font type, 10- point minimum size. The titles and names of the following nutrition facts: calories, saturated fat, trans fat, added sugars, and sodium, should appear in bold to distinguish them from the other nutrients. The nutritional table shall occupy at least 25% of the available printing area of the place on which the label is located.

28.2 With the exception of vitamins and minerals, the name of each nutrient shall appear in a column followed immediately by the amount by weight of the nutrient, using “g” for grams or “mg” for milligrams, “µg” for micrograms or IU (international units), as applicable.

28.2.1 Claims related to monounsaturated, polyunsaturated fat (omega-3 acids where appropriate), monounsaturated fat and trans fat should appear in this order, indented immediately below the total fat declaration.

28.2.2 The declaration of dietary fiber and total sugars should appear immediately indented below the declaration of total carbohydrates and – when applicable – the declaration of soluble and insoluble fiber should appear in this order, indented, immediately below the declaration of dietary fiber.

28.3 The information on vitamins and minerals – except sodium and potassium – shall be separated from the information on the other nutrients with a line, and presented vertically in one or two lines, using Arial or Helvetica font – 5-point size at least.

4.28 Nutritional data should appear in the following order: calories, total fat, saturated trans fat, carbohydrates, dietary fiber, total sugars, added sugars, protein, and sodium. The names and nutrition facts of the following nutrients: calories, sodium, saturated fat, trans fat, and added sugars, shall be in bold and font size shall be 1.3 times larger than the others.

28.5 Arial or Helvetica font type, 10-point size, shall be used in the fields “Serving Size” and “Number of servings per container”.

**Article 29. Nutritional Information Table Formats.** The Nutritional Information Table shall be submitted in one of the following format types – depending on the available print area on the label, nutrients declared, forms and other considerations of the food:

- a) Standard vertical;
- b) Simplified;
- c) Tabular and linear.

**Article 30. Specifications of the formats of the Nutritional Information Table.** Below are the specifications to be met by each of the Nutritional Information Table formats:

30.1 **Standard vertical format.** The standard vertical format shall present the information indicated in Article 10 hereof, in the form of columns, as shown in the example of Figure 1 below. The line width of the box lines separating the segments and nutrients defined for this format may vary; this shall also apply for the tabular, linear and simplified formats.

FIGURE 1 **Standard Vertical Format**

<b>Nutritional information</b>		
Per 100 g and per serving size		
Serving size : one unit (40 g)		
Number of servings per container: Approx. 2 servings		
<b>Calories (kcal)</b>	Per 100 g	Per serving
	<b>261</b>	<b>101</b>
Total fat	13 g	5.2 g
Polyunsaturated fat	3.0 g	1.2 g
<b>Saturated fat</b>	<b>6.0 g</b>	<b>2.4 g</b>
<b>Trans fat</b>	<b>820 mg</b>	<b>328 mg</b>
Total carbohydrates	31 g	12 g
Dietary fiber	0.8 g	0.3 g
Total sugars	5.0 g	2.0 g
<b>Added sugars</b>	<b>2.0 g</b>	<b>0.8 g</b>
Protein	5.0 g	2.0 g
<b>Sodium</b>	<b>560 mg</b>	<b>224 mg</b>
Vitamin D	5.0 µg	2.0 µg
Iron	4.0 mg	1.6 mg
Zinc	4.0 mg	1.6 mg
vitamin A	3.0 µg ER	1.2 µg ER
Calcium	400 mg	160 mg
Vitamin B1	1.0 mg	0.4 mg

**Paragraph:** In the case of raw meat with added food products, seasonings or additives containing sodium, the sodium content declaration shall be made in the manner below:

**FIGURE 2 Format for raw meats with added food products, seasonings or additives containing sodium**

<b>Nutritional information</b>		
Per 100 g and per portion		
Serving size : one unit (40 g)		
Number of servings per container: Approx. 2 servings		
<b>Sodium (mg)</b>	Per 100 g	Per serving
	<b>560</b>	<b>224</b>

**30.2 Simplified format.** The simplified format can be used when one food contains amounts which are not significant, or is not a significant source of six (6) or more of the following nutritional data: calories/kilocalories, total fat, saturated trans fat, sodium, total carbohydrates, dietary fiber, sugars, added sugars, protein, vitamin A, vitamin D, iron and zinc. To this effect, “no significant amount” or “not a significant source” is established in Chapter II hereof.

The simplified format should have the same graphical presentation (columns) as the vertical standard format – as shown in Figure 3 below, and shall include:

- a) The following information:
  - Total calories, total fat, saturated fat, trans fat, total carbohydrates or its abbreviation Carb. Total, protein, sodium and added sugars.
  - Any other nutrient of mandatory declaration – if present in quantities greater than the insignificant ones.
- b) The phrase “Not a significant source of (...)”. Indicating in lieu of the ellipsis the nutrients identified as insignificant amounts in the lower part of the nutritional information table;

FIGURE 3 Simplified format

<b>Nutritional information</b> Per 100g and per portion		
Serving size : one unit (40g) Number of servings per container: Approx. 2 servings.		
<b>Calories (kcal)</b>	Per 100g	Per serving
	<b>241</b>	<b>96</b>
Total fat	13 g	5.2 g
<b>Saturated fat</b>	<b>6.0 g</b>	<b>2.4 g</b>
<b>Trans fat</b>	<b>820 mg</b>	<b>328 mg</b>
Total carbohydrates	31 g	12 g
<b>Added sugars</b>	<b>2.0 g</b>	<b>0.8 g</b>
<b>Sodium</b>	<b>560 mg</b>	<b>224 mg</b>
Not a significant source of Protein, Vitamin D, Iron, Zinc, Vitamin A and fiber.		

30.3 **Tabular and linear formats.** The tabular or linear formats can be used in the case of packages whose available printing area on the product label is less than 225 cm<sup>2</sup>.

30.4 **Tabular format.** The Tabular format should present the nutritional information horizontally, in four sections, as is shown in Figure 4 below.

FIGURE 4 Tabular format

**Nutritional information (100 g or 100 mL):** **Calories 261**, Total Fat 13.0 g, **Sodium 560 mg**, Total Carbohydrates 31 g, **Added Sugars 2.0 g**, Protein 5.0 g, Vitamin A 4.0 µg ER, Vitamin D 5.0 µg, Iron 4.0 mg and Zinc 3.0 mg. Not a significant source of saturated fat, trans fat, and fiber.

**Nutritional information (serving):** **Calories 101**, Total Fat 5.2 g, **Sodium 224 mg**, Total Carbohydrates 12.0 g, **Added Sugars 0.8 g**, Protein 2.0 g, Vitamin A 1.2 µg ER, Vitamin D 2 µg, Iron 1.6 mg and Zinc 1.6 mg. Not a significant source of saturated fat, trans fat, and fiber.



### 30.5.2 Linear format

The linear format can be used only when it is not possible to include the format tabular in the label on account of size and shape. The Linear Format shall only list nutrients per 100 g - mL and per serving. The following nutrients shall be in bold: calories, saturated fat, trans fat, sodium, and added sugars.

The ingredients shall be followed, separated by commas.

FIGURE 5 Linear Format

Nutritional information Per 100 g and per portion	Calories	Per 100 g	Per portion
			<b>261 kcal</b>
	Total fat	1 3 g	5.2 g
	<b>Saturated fat</b>	<b>6.0 g</b>	<b>2.4 g</b>
	<b>Trans fat</b>	<b>820 mg</b>	<b>328 mg</b>
<b>Serving size:</b> 1 unit (40 g)	<b>Sodium</b>	<b>560 mg</b>	<b>224 mg</b>
<b>Number of servings per container:</b> Approx. 2 servings	Total carbohydrates	3 1 g	12 g
	Dietary fiber	0 g	0 g
	Total sugars	5.0 g	2.0 g
	<b>Added sugars</b>	<b>2.0 g</b>	<b>0.8 g</b>
	Protein	5.0 g	2.0 g
Not a significant source of Vitamin A, Vitamin D, Iron and Zinc.			

**Article 31. Nutritional Information Table for products that contain food assortments; products in multiple packages:** these products shall meet the following specifications:

#### 31.1 Assorted products:

- a) For food products consisting of two or more individual packages of ingredients, both contained in an outer container, both intended for sale to the public, the nutritional information table should appear on the outer packaging offered to the public;
- b) When two or more products are simply combined without using – or without the existence of – an outer container or package that contains them, or a transparent packaging, each product shall have its own table nutritional information table;

- c) When the product assortments are packaged individually, for users to consume the product at the same time, the nutritional information shall be specified for each product or to their mixture.

### 31.2 Multiple packages

For products that have two or more individually packaged foods, contained in an outer container and intended for their consumption separately, the nutritional information shall be specified for each food in a place that is clearly visible to the consumer.

### 31.3 Small containers and pyrography

Food in small containers with a total surface for labeling less than 77 cm<sup>2</sup>, shall include the nutritional information on the secondary container. These packages should include an email address or phone number or any other means, for consumers to obtain nutritional information. For the application of this exception, total surface shall mean the sum of the areas of all printed surfaces of the packaging materials, excluding the areas that will be sealed and closed.

**31.4 Returnable Packaging:** The products in returnable glass containers whose total area for labeling is greater than 77 cm<sup>2</sup> should include: a QR code, an email address or phone number where consumers can see the nutritional information and/or nutritional claims of the product.

**Article 32. Front-of-package labeling of warning:** Whenever a packaged food has added salt / sodium, sugars or fats, and their content exceeds the value set in Table No. 17, the label shall display the or nutritional characteristics concerning the nutrient added.

**Table No. 17 Nutrient content limits for the establishment of the warning seal**

Nutrient	Solids (100 g)	Liquids (100 mL)
Sodium (mg)	> = 400	> = 150
Added sugars (g)	> = 10	> = 5.0
Saturated fat (g)	> = 4.0	> = 3.5

- a) For purposes hereof, it will be understood that a food is solid or liquid according to the unit of measurement used in the declaration of the net content of the food – i.e. it will be solid if its net content is expressed in grams or another equivalent measure, or liquid if its net content is expressed in milliliters or another equivalent measure. In the case of packaged food which needs to be reconstituted for consumption, it will be understood as solid or liquid according to the conditions of use defined by the manufacturer.
- b) Packaged foods with added salt/sodium shall be understood as foods that have been added any salt or additive during the manufacture process, and contains sodium or any ingredient containing sodium aggregates. In the case of salt, compliance shall be given to the regulations in force in matters relating to fortification.
- c) Packaged foods with added sugars shall be understood as foods to which any sugar has been added as an ingredient or additive during the process of manufacture, including ingredients that contain added sugars.

- d) Packaged foods with added fats shall be understood as foods to which any vegetable or animal fat or partially hydrogenated vegetable oils (vegetable butter, vegetable cream or margarine) have been added as an ingredient, including ingredients containing said fats as aggregates.

32.1 *Shape of the warning seal:* The way to highlight the nutritional features indicated in the first paragraph of this article shall be by including seals in the label – specifically a round symbol with a black background and a white edge, and inside the text “HIGH” followed by: “SATURATED FATS”, “SALT/SODIUM” “ADDED SUGARS” of individually or with two or three seals (as applicable). The letters of the text shall be uppercase and white - ARIAL BOLD font type. In addition, the word “Minsalud” (Ministry of Health) shall be inscribed within the same symbol in black letters, according to figure 6 hereof.

**FIGURE 6. Shape of the warning seal**



**HIGH ADDED SUGARS**  
**HIGH SALT/SODIUM**  
**HIGH SATURATED FATS**

**Paragraph:** No other front-of-packaging label format or type of warning seal shape shall be used. In addition, the text, font type, and diagrams or drawings shall not be changed.

32.2 *Dimensions and location of the Warning seal:* The aforementioned symbols shall be located in the upper right part of the front face (or main display face) of the product label. The dimensions of the aforesaid symbol (s) shall be determined in accordance to the area of the main display face of the label, according to the table below:

**Table 18. Dimensions of the warning seal:**

Area of the main face of the label (cm <sup>2</sup> )	Dimensions of the symbol (diameter)
< 30	Labeled in secondary container
> = 30 and <60	1.6 cm
> = 60 and <100	2.1 cm
> = 100 and <200	2.7 cm

$\geq 200$ and $< 300$	3.3 cm
$\geq 300$	3.8 cm

Whenever it becomes necessary to label more than one symbol with the descriptor “ALTO EN” (HIGH \_\_\_\_), these labels shall be arranged together, next to each other or one below the other, taking into account the forms described in section d) of Article 32.3. If all 3 seals apply, they shall be labeled in the following order: added sugars, salt / sodium, and saturated fat. The symbol (s) shall be clearly, indelibly and easily readable under normal circumstances of purchase and use. In no case shall the seals be fully or partially covered.

**32.3 Measurements of the warning label:** All elements (text and icons) shall be centered on the axis and the black box. The measurements are presented below:

a) Added sugars



b) Salt / sodium



c) Saturated fat



d) Distance between 1 or more stamps





The letter “x” corresponds to the unit of proportion on which the icon of the label is built.

**Paragraph 1.** Adhesives may also be used indelibly on the label, provided that they meet the characteristics, size and location requirements defined in the regulatory proposal. The adhesive shall be securely fixed by adhesion, printing, sewing, embossing, printing, heat setting, or other analogical means, so as to ensure that it does not become removed from the product in normal conditions of use, preservation, storage, transport, and remain attached up to the moment of its commercialization and shelf life.

**Paragraph 2.** The use of another warning label or logo, or any image different from the provisions herein, is not allowed.

**Article 33. Positive Seal:** The positive seal can be applied to a packaged food voluntarily when it meets all the following technical criteria, complying with the characteristics, size and location defined in this technical regulation.

33.1 Complying with the following maximum levels for sodium, saturated fat and added sugars:

**Table 19. Maximum contents for sodium, added sugars and saturated fats**

Nutrient	Solids (100 g)	Liquids (100 mL)
Sodium (mg)	<= 80	<= 60
Added sugars (g)	<= 2.0	<= 1.0
Saturated fat (g)	<= 2.0	<= 2.0

33.2 The first ingredient in the list of ingredients cannot be: sodium or additives with sodium, fat and/or added sugars.

33.3 Not using calorie and/or zero-calorie sweeteners in its formulation.

33.4 **Shape of the positive seal:** The way to highlight the nutritional characteristics indicated in sections 33.1, 33.2 and 33.3 hereof shall be by labeling a check symbol with the following colors: RGB (34, 55, 98) or CMYK (100%, 87%, 33%, 22%) and a white checkmark in its interior, as shown in the figure below:

**FIGURE 7. Shape of the positive seal**



**Paragraph.** No other type of positive seal shape shall be used; neither will it be allowed to change its color, add letters or phrases, sizes, or location.

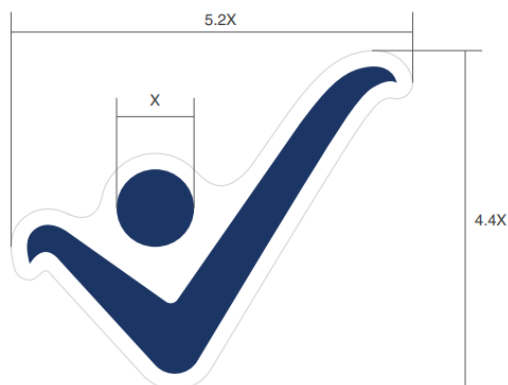
33.5 **Dimensions and location of the positive seal:** The abovementioned symbol shall be located in the bottom left part of the front face of the product's label. The dimensions of the aforesaid symbols shall be determined in accordance to the area of the main display face of the label, according to the table below:

**Table 20. Dimensions of the positive seal:**

Area of the main face of the label (cm <sup>2</sup> )	Dimensions of symbol (side more long)
< 30	Label to be placed in the product's greater container
> = 30 and <60	1.4 cm
> = 60 and <100	1.8 cm
> = 100 and <200	2.5 cm
> = 200 and <300	3.0 cm
> = 300	3.5 cm



## Proportions



The letter “x” corresponds to the unit of proportion on which the icon of the label is built.

## Chapter VII Conformity Assessment

**Article 34. *Conformity Assessment Procedure.*** For purposes of conformity assessment of these technical rules, the information of nutrition property claims, health property claims and the front-of-package labeling will be established as a firsthand declaration made by the producer, marketer, or importer, or the corresponding individual. This claim presumes that the declarant has carried out the requisite verifications, inspections and tests on their own, and therefore the declarant provides – under the latter’s responsibility – that the packaged foods comply with the provisions of this technical regulation.

**Article 35. *Document for conformity assessment.*** Manufacturers, marketers or importers shall submit only once – and for each presentation of the product – a firsthand statement in accordance with the requirements and formats set out in the following Standard: ISO / IEC 17050 – 1 version 2004 and Standard ISO/IEC 17050 – 2 2004 version.

**Paragraph 1.** The firsthand statement and supporting documentation shall be rendered available for monitoring purposes.

**Paragraph 2.** In the case of imported products, the importer shall attach the firsthand statement to the import license or registration, as applicable, at the time of its submittal in the Single Foreign Trade Window – VUCE (from its original Spanish language initials: *Ventanilla Única de Comercio Exterior*).

## Chapter VIII Responsibility, Inspection, Surveillance and Control

**Article 36. *Responsibility.*** Natural or legal persons engaged in the processing, marketing and/or import of packaged foods for human consumption shall be responsible for compliance with the health requirements referred to in the health regulations and the provisions herein.

**Article 37. *Inspection, surveillance and control.*** It shall be the responsibility of the National Institute of Food and Drug Surveillance - INVIMA (from its original Spanish language initials:

*Instituto Nacional de Vigilancia de Medicamentos y Alimentos*) to exercise the functions of Inspection, Surveillance and Control, in coordination with the territorial entities of the departmental or district order, and in development of the Sanitary Inspection, Surveillance and Control Model, as outlined by the Ministry of Health and Social Protection through Resolution 1229/2013 or any regulations amending or superseding it, for which purpose they may apply the security measures and impose the corresponding sanctions, in accordance with the provisions of Act 9/1979 and the punitive administrative proceedings provided for in Act 1437/2011.

## **Chapter IX Final provisions**

**Article 38. Authorization for label stock depletion and use of adhesives.** Depletion of labels and use of adhesives shall be authorized by INVIMA in accordance with the procedure indicated by this agency for this purpose.

**Paragraph 1.** Depletion of labels shall not require prior authorization by Invima during the transition period of this resolution.

**Paragraph 2.** Those responsible for packaged foods may make use of adhesives on the label as established in Article 32 with regard to the front-of-packaging warning labeling, provided that the adhesives comply exactly with the provisions contained herein. This alternative shall not require prior authorization by Invima.

**Paragraph 3.** Upon expiration of the transition period of this Resolution, the labels and tags of all the products in commercialization shall comply with all of the relevant requirements. Therefore, exhaustion of label stocks as under Resolution 333/2011 shall not be allowed.

**Paragraph 4.** For products imported upon issuance of the Certificate of Sanitary Inspection - CIS (from its original Spanish language initials: *Certificado de Inspección Sanitaria*) by Invima, the use of a supplementary label or tag containing the information required herein will be allowed, which shall be attached in a visible place. Its adjustment may be made before, during or after of the nationalization process.

**Article 39. Review and update.** In order to keep the provisions of the technical regulation established with this resolution up to date, the Ministry of Health and Social Protection, in accordance with national and international scientific and technological advances and existing evidence, will proceed to review them within a period of time not exceeding five (5) years from its effective date, or earlier if it is detected that the causes that substantiated its issuance were modified or have disappeared.

**Article 40. Notification.** This technical regulation shall be notified to the member countries of the World Trade Organization (WTO) through the TBT (Technical Barriers to Trade) PoC at the Ministry of Trade, Industry and Tourism.

**Article 41. Validity and repeal.** In accordance with section 12 of Article 10 of Andean Decision 827/2018, the provisions relating to the front-of-packaging warning labeling contained in Article 32 will come into effect eighteen (18) months after the date of its publication in the Official Gazette. During this period producers, importers and marketers of packaged food for human consumption and other sectors required to comply with the

provisions herein shall adapt their processes and/or products to the conditions established herein. Article 3 of Resolution 4135/1976, Resolution 333/2011, Section 5.2 and Article 6 of Resolution 2508/2012 shall be repealed eighteen (18) months after the date of publication hereof.

**Paragraph 1.** Up to a maximum period of eighteen (18) months from the date of publication of this resolution in the Official Gazette, manufacturers, importers and marketers of packaged foods for human consumption and other sectors required to comply with the provisions herein shall continue to abide by the provisions of Resolution 333/2011 and Articles 5.2 and 6 of Resolution 2508/2012.

**Paragraph 2.** Any packaged foods that are not in compliance with the nutritional labeling and front-of-packaging warning labeling requirements established herein after eighteen (18) months of entry into force of this standard – regardless of the date of manufacture, and in the event that the products are not exhausted during this term – shall be withdrawn by the manufacturer, marketer or importer.

**Paragraph 3.** In the case of returnable containers, an additional time of 5 years will be given after the eighteen (18) months following the date of publication to adjust to the provisions herein. However, eighteen (18) months after the date of effect of this standard – and as a temporary measure – the front-of-packaging warning seal shall be placed on the cap for returnable containers that cannot be labeled on the front face, or a sticker shall be placed in the secondary packaging.

**BE IT PUBLISHED, NOTIFIED AND ENFORCED.**

Issued at Bogotá, D.C. on this \_\_\_\_\_

**FERNANDO RUIZ GÓMEZ**  
Minister of Health and Social Protection