

MINISTRY OF HEALTH, BRAZIL NATIONAL HEALTH SURVEILLANCE AGENCY - ANVISA

RESOLUTION BY THE BOARD OF DIRECTORS

RESOLUTION BY THE BOARD OF DIRECTORS – RDC No. 429 OF 8 OCTOBER 2020

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Provides on nutrition labeling of packaged foods.

The Board of Directors of the National Health Surveillance Agency, according to the powers assigned to it by articles 7, item III, and 15, items III and IV, of Law no. 9.782 of 26 January 1999, and considering the provisions of article 53, item V, and Paragraphs 1 and 3 of its Bylaws, approved by Board of Directors Resolution (RDC) no. 255 on 10 December 2018, hereby adopts the following Resolution by the Board of Directors, hereinafter "RDC 429/2020", as approved in the meeting held on 7 October 2020, and I, the Executive Chairman of the Board, hereby order its publication:

CHAPTER I PRELIMINARY PROVISIONS

Article 1. This Resolution provides on the nutrition labeling of packaged foods.

Article 2. This Resolution applies to foods packaged without the consumers' presence, including beverages, ingredients, food additives, and technology adjuvants, including those exclusively for industrial processing or food services. Sole paragraph. This Resolution does not apply to the following products:

I - natural mineral water, natural water, and water with added salts, as provided in Resolution RDC no. 274 of 22 September 2005; and

II - desalinized sea water, potable and bottled, as provided in Resolution RDC no. 316 of 17 October 2019.

Article 3. For the purposes of this Resolution, the following definitions are adopted: I - added sugars: all monosaccharides and disaccharides added to the food's processing, including fractions of monosaccharides and disaccharides from addition of the ingredients cane sugar, beet sugar, sugars from other sources, honey, molasses, *rapadura*, sugar cane juice, malt extract, saccharose, glucose, fructose, lactose, dextrose, inverted sugar, syrups, maltodextrins, other hydrolyzed carbohydrates, and ingredients with the addition of any of the previous ingredients with the exception of polyols, added sugars consumed by the product's fermentation or non-enzymatic darkening, and sugars naturally present in milks and dairy products and sugars naturally present in plant products, including fruits, whole or in pieces,

powdered, dehydrated, in pulps, purees, whole juices, reconstituted juices, and concentrated juices;

II- total sugars: all monosaccharides and disaccharides present in the food that are digested, absorbed, and metabolized by human beings, excluding polyols;

III - nutrition claims: any statement except for the nutrition facts table and front-of-package nutrition labeling that indicates that the food has positive nutritional properties pertaining to its calorie content and nutrient content, including absolute and comparative content and without addition claims;

IV - nutrition claims of absolute content: nutrition claims that describe the level or amount of calorie content and nutrients contained in the food;

V - nutrition claims of comparative content: nutrition claims that compare the levels or amount of calorie content or the same nutrients contained in the reference food;

VI – no-addition nutrition claims: nutrition claims stating that an ingredient was not added directly or indirectly;

VII – reference food: the conventional version of the same food with the comparative content nutrition claim and that serves as the standard for comparison to perform and highlight a modification pertaining to reduced or increased nutritional characteristics;

VIII - carbohydrates: all monosaccharides, disaccharides, oligosaccharides, and polysaccharides present in the food, including polyols, that are digested, absorbed, and metabolized by human beings;

IX - cholesterol: sterol that presents a cyclopentanoperhydrophenanthrene nucleus with a hydroxyl group at C3 and a carbon chain at C17;

X - consumer: any physical or legal person that acquires or uses foods;

XI - elements in the nutrition facts table: elements to which are applied formatting rules with the purpose of guaranteeing the table's visual identify and adequate legibility, including the outer borders, lines, and separating bar, margins, spacings, symbols, and stated information;

XII – individual packaging: packaging whose food content is less than or equal than two servings defined in Annex V of Normative Ruling no. 75 of 8 October 2020;

XIII – multiple packaging: packaging that contains one or more units of packaged foods or that consists of two or more packaged products of an identical nature and nutritional value, whether or not for joint consumption;

XIV – dietary fiber: carbohydrate polymer with three or more monomeric units that are not hydrolyzed by the human digestive tract's endogenous enzymes;

XV – monounsaturated fat: triglycerides that contain fatty acids with a cis double bond, expressed as free fatty acids;

XVI – polyunsaturated fat: triglycerides that contain fatty acids with cis-cis double bonds separated by a methylene group, expressed as free fatty acids;

XVII - saturated fat: triglycerides that contain fatty acids without double bonds, expressed as free fatty acids;

XVIII – total fat: substances with plant or animal origin, insoluble in water, formed by triglycerides and small amounts of nonglycerides, mainly phospholipids;

XIX - trans fats: triglycerides that contain unsaturated fatty acids with one or more unconjugated double bonds in the trans configuration, expressed as free fatty acids;

XX – household measurement: form of quantification of food servings using utensils, units, or other forms commonly used by consumers to measure foods;

XXI - nutrient: chemical substance normally consumed as a component of a food, that provides energy, is necessary for growth, development, and maintenance of health and life, or whose deficiency results in characteristic chemical or physiological changes;

XXII - omega 3: polyunsaturated fatty acids in which the first double bond is located in the third carbon from the methyl (CH3) group of the fatty acid;

XXIII - omega 6: polyunsaturated fatty acids in which the first double bond is located in the sixth carbon from the methyl (CH3) group of the fatty acid;

XXIV - omega 9: polyunsaturated fatty acids in which the first double bond is located in the nineth carbon from the methyl (CH3) group of the fatty acid;

XXV – main panel: the part of the labeling that primarily presents the sales name and trademark or logotype, when existent;

XXVI - polyols: alcohols containing more than two hydroxyl groups;

XXVII - point (pt): unit of typographic measurement, known as **PostScript point**, equivalent to 0.353 millimeters or one-half inch;

XXVIII - serving: amount of food used as reference for purposes of nutrition labeling;

XXIX – dish prepared semi-ready or ready-to eat: food prepared, cooked, or pre-cooked that does not require addition of ingredients for consumption;

XXX - proteins: polymers of amino acids or compounds that contain polymers of amino acids; XXXI - nutrition labeling: any statement aimed at informing the consumer of the food's nutritional properties, including the nutrition facts table, front-of-package nutrition labeling, and nutrition claims;

XXXII - front-of-package nutrition labeling: simplified standardized statement of specific high nutrient contents on the main panel of the food's label;

XXXIII – food services: includes all institutional or commercial establishments where the food is handled, prepared, stored, distributed, or displayed for sale, where it may or may not be consumed on site, such as restaurants, snack bars, bars, bakeries, food and nutrition units in health services, schools, and daycare centers, among others;

XXXIV – bioactive substance: nutrient or non-nutrient normally consumed as a component of a food, which has specific metabolic or physiological action in the human body;

XXXV – surface available for labeling: total labeling area defined according to the packaging's specificities, excluding deformed or difficult-to-view areas;

XXXVI – nutrition facts tables: standardized list of the contents of energy, nutrients, and bioactive substances in the food, including the linear model; and

XXXVII – daily reference values (DRV): values based on scientific data on the nutritional needs or reduction of the risk of chronic noncommunicable diseases, applied to nutrition labeling and claims of functional and health properties.

CHAPTER II

NUTRITION FACTS TABLE

Article 4. Statement of the nutrition facts table is mandatory on labels of foods packaged without the consumers' presence, including beverages, ingredients, food additives, and technology adjuvants, including those exclusively for industrial processing or food services. Paragraph 1. The provisions in the **heading** apply voluntarily to the foods listed in Annex I of Normative Ruling no. 75 of 2020, as long as these foods do not have: I - addition of essential nutrients, according to Ruling SVS/MS no. 31 of 13 January 1998 by the Health Surveillance Secretariat of the Ministry of Health ; II- addition of bioactive substances, according to Resolution no. 16 of 30 April 1999; III - nutrition claims; or IV - claims of functional properties or health properties, according to Resolution no. 18 of 30 April 1999. Paragraph 2. In the case of products exclusively for industrial processing or food services, the statement described in the **heading** can be made in alternative form in the documents accompanying the product or by other means by common agreement between the parties.

Article 5. The nutrition facts table should contain a statement of the amounts of:

I - calorie content;
II - carbohydrate;
III - total sugars;
IV - added sugars;
V - protein;
VI - total fat;
VII - saturated fat;
VIII - trans fat;
IX - dietary fiber;
X - sodium;
XI - any other nutrient or bioactive substance that is the object of nutrition claims, claims of functional properties, or claims of health properties;

XII – any other essential nutrient added to the food, according to Ruling SVS/MS no. 31 of 1998 by the Health Surveillance Secretariat of the Ministry of Health, the amount of which per serving is greater than or equal to 5% of the respective DRV defined in Annex II of Normative Ruling no. 75 of 2020; and

XIII – any bioactive substance added to the food.

Paragraph 1. In the case of low-sodium salt, the nutrition facts table should contain a statement of the amount of potassium.

Paragraph 2. In the case of special-purpose foods, the nutrition facts table should contain a statement of the amounts of calorie content and of all the nutrients and bioactive substances added to the products.

Paragraph 3. In the case of dietary supplements, the nutrition facts table should contain a statement of the amounts of calorie content and all nutrients, bioactive substances, and enzymes added to the products.

Paragraph 4. In the case of foods for lactose-restriction diets, the nutrition facts table should contain a statement of the amounts of lactose and galactose.

Paragraph 5. In the case of alcoholic beverages, the nutrition facts table may be replaced by the statement of the amount of calorie content.

Paragraph 6. In the case of iodine-enriched salt, the statement of the amount of iodine should be made according to the statement specified in 5-A of Resolution RDC no. 23 of 24 April 2013.

Paragraph 7. In the case of wheat and corn flours enriched with iron and folic acid, the amounts of iron and folic acid should be indicated according to the statement specified in article 13 of Resolution RDC no. 150 of 13 April 2017.

Paragraph 8. In the case of products exclusively for industrial processing or food services, the provision in item XII applies to any amount of the added essential nutrient.

Article 6. The nutrition facts table may contain a statement of the amounts of:

I - vitamins and minerals naturally present in the foods, as long as the amounts per serving are greater than or equal to 5% of the respective DRV defined in Annex II of Normative Ruling no. 75 of 2020; and

II – other nutrients naturally present in the foods.

Sole paragraph. In the case of products exclusively for industrial processing or food services, the statement specified in item I can be made for any amount of vitamin and mineral present in the product.

Article 7. The amounts in the nutrition facts table should be stated numerically, according to the following:

I – the rules for rounding off and for expressing the values defined in Annex III of Normative Ruling no. 75 of 2020; and

II – non-significant amounts of calorie content and nutrients and their form of expression defined in Annex IV of Normative Ruling no. 75 of 2020.

Paragraph 1. Calorie content and percent daily values (%DV) should be stated in whole numbers, according to the rules for rounding off defined in Annex III of Normative Ruling no. 75 of 2020.

Paragraph 2. The statement specified in item II does not apply to

the following products:

I – infant formulas;

II - formulas for enteral nutrition;

III - products exclusively for industrial processing; and

IV - products exclusively for food services.

Article 8. The amounts in the nutrition facts table should be stated on the basis of the product as displayed for sale, per:

I - 100 grams (g) for solids or semisolids, or 100 milliliters (ml) for liquids; and II– food serving defined in Annex V of Normative Ruling no. 75 of 2020, and corresponding household measurement.

Paragraph 1. The statement specified in item I does not apply to dietary supplements. Paragraph 2. The statement specified in item II does not apply to products exclusively for industrial processing or food services.

Paragraph 3. In the case alcoholic beverages, the statement specified in the **heading** may only be made per 100 ml or per serving.

Paragraph 4. In the case of foods that require preparation with the addition of other

ingredients, the statement specified in the heading should be made per:

I - 100 g for solids or semisolids or 100 ml for liquids, based on the ready-to-consume food, considering the nutritional value of the added ingredients according to the manufacturer's instructions for preparation stated on the label; per serving of the product as displayed for sale, necessary to prepare a serving of the ready-to-consume product, defined in Annex V of Normative Ruling no. 75 of 2020, according to the manufacturer's instructions for preparation stated on the label.

Paragraph 5. The statement specified in item I of Paragraph 4 should be accompanied by the following footnote: "**In the product prepared for consumption".

Paragraph 6. In the case of infant formulas and formulas for enteral nutrition, the statement specified in the **heading** should be made per:

I - 100 grams for solids or semisolids, for 100 milliliters for liquids of the product as displayed for sale; and

II - 100 milliliters of the ready-to-consume product, according to the manufacturer's instructions for preparation stated on the label, when applicable.

Paragraph 7. The statement specified in Paragraph 6 may be made complementarily per 100 kilocalories (kcal) of the product prepared for consumption, according to the manufacturer's instructions for preparation stated on the label.

Article 9. Without detriment to the provisions of Annex V of Normative Ruling no. 75 of 2020, for definition of the food's serving size stated in the nutrition facts table, the following requirements should be met:

I - In the case of individual packages, the stated serving size should correspond to the total amount of the product contained in the package;

II- In the case of products that require draining before consumption, the stated serving size should correspond to the amount of the drained product;

III - In the case of multiple packaging with distinct food units in nature or nutritional value, and that do not require joint consumption, the servings of each product should be stated;

IV - In the case de of multiple packaging with distinct food units in nature or nutritional value and that require joint consumption, a single serving should be stated, corresponding to the sum of the servings of the products;

V - In the case food additives and technology adjuvants, the stated serving should be defined by the food's manufacturer, according to the instructions for preparation listed by the manufacturer on the label;

VI - In the case of dietary supplements, the stated serving size should correspond to the daily amount recommended by the manufacturer for each of the specific population groups whose consumption of product is indicated on the label;

VII - In the case of special-purpose foods not contemplated in Paragraph 6, Article 8 of this Resolution, the stated serving size should be defined by the food's manufacturer, considering the purpose and form of use of the product and the characteristics of the population groups for whom the product is indicated;

VIII - In the case of foods that do not have servings defined in Annex V of Normative Ruling no. 75 of 2020, the stated serving size should correspond to the serving of that food which by its nutritional characteristics is comparable or similar; and

IX - In the case of foods that do not have servings defined in Annex V of Normative Ruling no. 75 of 2020, and which do not have comparable or similar food according to its nutritional characteristics, the stated serving size should be defined according to the mean calorie content of the group to which the food belongs.

Article 10. The number of servings contained in the food's packaging should be stated in the nutrition facts table according to the rules for rounding off and for expressing values defined in Annex VI of Normative Ruling no. 75 of 2020.

Sole paragraph. The provisions in the **heading** do not apply to individual packaging and to foods with variable weight that are weighed at the point of sale at the consumer's request.

Article 11. The stated household measurements should be the most appropriate for the product's characteristics, observing the following requirements:

I - When utensils are used, the dosing utensils provided in the food should be used when they exist, or the household utensils and their capacities defined in Annex VII of Normative Ruling no. 75 of 2020;

II - In the case of individual packaging, the household measurement is the package;

III – In other cases, the measurements should employ units, slices, pieces, fractions, section, or other similar forms; and

IV – To express non-whole amounts of household measurements, the corresponding irreducible fraction should be used.

Article 12. The statement of amounts in the nutrition facts table should also be done in %DV, determined on the basis of the DRV defined in Annex II of Normative Ruling no. 75 of 2020, and based on the rounded-off amounts of nutrients stated in the food serving.

Paragraph 1. For nutrients without defined DRV, the space for statement of the respective %DV should be left empty.

Paragraph 2. When the amount of calorie content or nutrients is not significant, according to Annex IV of Normative Ruling no. 75 of 2020, the %DV should be stated zero.

Paragraph 3. In the case of individual packaging, the statement specified in the **heading** should be made according to the total food content in the package.

Paragraph 4. In the case of special-purpose foods not contemplated in Paragraph 6 of Article 8 of this Resolution which have indication for specific population para groups on their label and of dietary supplements, the %DV should be determined on the basis of the DRV defined in Annex VIII of Normative Ruling no. 75 of 2020 for each of the specific population groups indicated on the label.

Paragraph 5. The statement specified in the **heading** should accompanied by the following footnote: "*Percent daily values furnished by serving".

Paragraph 6. The statement specified in **heading** does not apply to the following products: I – infant formulas;

II - formulas for enteral nutrition;

III - products exclusively for industrial processing;

IV - products exclusively for food services; and

V – alcoholic beverages whose statement of nutritional facts is only done per 100 ml.

Article 13. Without detriment to the provisions in Paragraph 1° of Article 4 of this Resolution, the nutrition facts table should be stated on the labels of the multiple packaging and each food unit contained in it.

Paragraph 1. In case the food units are of the same nature and nutritional value, only one nutrition facts table should be stated on the multiple packaging label.

Paragraph 2. In case the food units are distinct in nature or nutritional value and do not require joint consumption, one nutrition facts table should be stated for each distinct unit on the multiple packaging label.

Paragraph 3. In case the food units are distinct in nature or nutritional value and require joint consumption, one nutrition facts table should be stated for the units' combination n the multiple packaging label.

Paragraph 4. The statement specified in the **heading** is not mandatory on multiple packaging when it is possible to read the nutrition facts table stated on the label of each food unit contained in it without opening the packaging.

Paragraph 5. The statement specified in the **heading** is not mandatory in the food units when it is to possible to supply them separately and the nutrition facts table of these units is stated on the multiple packaging label.

Article 14. The statement of the nutrition facts table should be located on a single continuous surface of the packaging and on the same panel as the list of ingredients.

Paragraph 1. The nutrition facts table may not be located on covered areas or deformed places such as sealing and twisting or hard to see, such as cracks, angles, corners, or seams.

Paragraph 2. In the case packages with multiple sides with obtuse angles in which it is possible to follow label's information over the angles, two or more panels may be considered continuous surfaces.

Paragraph 3. When the packaging space is insufficient for statement of the information specified in the **heading** on the same panel, the information should be displayed on adjacent panels.

Article 15. The statement of nutrition facts table should follow one of the models defined in Annex IX of Normative Ruling no. 75 of 2020.

Paragraph 1. The models specified in the **heading** should be adapted for:

I – exclusion of the 100 g, 100 ml, or serving column for the foods specified in Paragraphs 1, 2, 3, and 6 of article 8 of this Resolution;

II – exclusion of the %DV column for the products specified in Paragraph 6 of Article 12 of this Resolution.

Paragraph 2. The aggregate model may be used for statement of the nutrition facts table:

 $\rm I-$ on the multiple packaging specified in Paragraph 2 of Article 13 of this Resolution; and

II – in the foods indicated for more than one population group, as addressed in Paragraph 4 of Article 12 of this Resolution.

Paragraph 3. When or more nutrients or calorie contents are present in non-significant amounts, according to Annex IV of Normative Ruling no. 75 of 2020, the nutrition facts may be stated in simplified form according to the specific formatting requirement defined in Annex X of Normative Ruling no. 75 of 2020.

Paragraph 4. The provision in the **heading** does not apply to alcoholic beverages with statement of the calorie content only, according to Paragraph 5 of Article 5 of this Resolution.

Article 16. The formatting of the nutrition facts table should:

I – use 100% black characters and lines on a white background;

II – adopt the names of the components or their alternative names and the respective order of statement, indentation, and measurement units defined in Annex XI of Normative Ruling no. 75 of 2020;

III – use spacing between lines so as to prevent the characters from touching each other or the bar, lines, or symbols of separation, when present;

IV – use the protective edge, bars, lines, and symbols of separation and inner margins according to the selected model; and

V – comply with the specific requirements for standard formatting defined in Annex XII of Normative Ruling no. 75 of 2020.

Paragraph 1. The formatting requirements specified in item V represent minimum limits, and it is permitted to use larger dimensions as long as the other elements of the nutrition facts table are increased proportionally, in order to maintain the table's visual identity and its adequate legibility.

Paragraph 2. The provision in the **heading** does not apply to alcoholic beverages with statement of the calorie content only, according to Paragraph 5 of Article 5 of this Resolution.

Paragraph 3. In case there is not enough space display the nutrition facts table on a single continuous surface of the packaging, having excluded the main panel, it is permitted to use one of the following compacting resources:

I – simplified statement of vitamins and minerals, according to criteria defined in Annex X of Normative Ruling no. 75 of 2020;

II - abbreviation of the nutrients' names according to Annex XI of Normative Ruling no. 75 of 2020];

III - alteration of the font size up to the limits of reduced formatting defined in Annex XII of Normative Ruling no. 75 of 2020; and

IV - application of the condensed fonts for reduced formatting defined in Annex XII of Normative Ruling no. 75 of 2020.

Article 17. In case the compacting resources specified in Paragraph 3 of Article 16 of this Resolution are not sufficient for statement of the nutrition facts table on a single continuous surface of the packaging, the nutrition facts table should be stated:

I – using the linear model provided in Annex XIII of Normative Ruling no. 75 of 2020;

II – according to the formatting rules established in items I through III of article 16 of this Resolution;

III – according to the specific formatting requirements defined in Annex XIV of Normative Ruling no. 75 of 2020.

Sole paragraph. For packaging with a surface available for labeling less than or equal to 100 cm^2 , the nutrition facts table may be stated on a covered surface as long as it is accessible or on the secondary packaging, if the latter exists.

CHAPTER III

FRONT-OF-PACKAGE NUTRITION LABELING

Article 18. The statement of front-of-package nutrition labeling is mandatory on the labels of foods packaged without the consumer's presence whose amounts of added sugars, saturated fat, or sodium are greater than or equal to the limits defined in Annex XV of Normative Ruling no. 75 of 2020.

Paragraph 1. For the foods listed in Annex XVI of Normative Ruling no. 75 of 2020, it is prohibited to the display the information specified in the **heading**.

Paragraph 2. In case the foods mentioned in items 1 through 6 of Annex XVI of Normative Ruling no. 75 of 2020 include the addition of ingredients with added sugars or significant nutritional value of saturated fat or sodium to the product, according to Annex IV of Normative Ruling no. 75 of 2020, the statement specified in the **heading** only applies to nutrients that have their original value altered by the addition of these ingredients.

Paragraph 3. The statement specified in the **heading** is optional for the following products:

I - foods in packaging with a main panel area less than 35 cm²;

II – foods packaged at the points of sale, at the consumer's

request; and

III - packaged foods that are prepared or fractionated and marketed at the establishment itself.

Article 19. The limits established in Annex XV of Normative Ruling no. 75 of 2020 should be applied to the food displayed for sale.

Sole paragraph. In the case of foods that require preparation with the addition of other ingredients, the limits specified in the **heading** should be applied on the basis of the food prepared and ready-for-consumption, according to the instructions for preparation stated by the manufacturer on the label, without considering the nutritional value of the added ingredients.

Article 20. Without detriment to the provisions in Paragraphs 1 and 3 of Article 18 of this Resolution, front-of-package nutrition labeling should be stated on the labels of the multiple packaging and on that of each food unit contained in it.

Paragraph 1. In case the food units are of the same nature and nutritional value, only one front-of-package nutrition labeling should be stated on the multiple packaging label.

Paragraph 2. In case the food units are distinct in nature or nutritional value and do not require joint consumption, one front-of-package nutrition labeling should be stated for each distinct unit on the multiple packaging label, identifying the corresponding food.

Paragraph 3. In the cases specified in Paragraph 2, it is permitted to use grouped identification of the distinct units that have the same front-of-package nutrition labeling.

Paragraph 4. In case the food units are distinct in nature or nutritional value and require joint consumption, one front-of-package nutrition labeling should be stated for the combination of units on the multiple packaging label.

Paragraph 5. The statement specified in the **heading** is not mandatory on the multiple packaging when it is possible to read front-of-package nutrition labeling stated on the label of each food unit contained in it without opening the packaging.

Paragraph 6. The statement specified in the **heading** is not mandatory on the food units when it is not possible to display them separately and the front-of-package nutrition labeling of these units is stated on the multiple packaging label.

Article 21. The statement of the front-of-package nutrition labeling should:

I - be made with 100% black print on a white background;

II - be located on the upper half of the main panel on a single continuous surface;

III – have the same orientation of the text as the other information displayed on the label;

IV – follow one of the models defined in Annex XVII of Normative Ruling no. 75 of 2020, as applicable;

V – comply with the specific formatting requirements defined in Annex XVIII of Normative Ruling no. 75 of 2020;

Sole paragraph. The front-of-package nutrition labeling may not be displayed on places that are covered, removable for opening the seal, or difficult-to-view, such as areas of sealing or twisting.

Article 22. The minimum area of the front-of-package nutrition labeling should be determined by the percent occupation of the main panel, defined in Annex XVIII of Normative Ruling no. 75 of 2020.

Sole paragraph. In cases in which the percent occupation of the main panel requires the use of fonts smaller than the minimum size or larger than the maximum size, the minimum area of the front-of-package nutrition labeling should be determined by the fonts' minimum or maximum size.

Article 23. Other front-of-package nutrition labeling models, different from that defined in this Resolution, cannot be visible on the label.

CHAPTER IV NUTRITION CLAIMS

Article 24. The statement of nutrition claims on the labels of foods packaged without the consumer's presence is voluntary, as long as:

I – used in the terms authorized for display of the nutritional characteristics established in Annex XIX of Normative Ruling no. 75 of 2020;

II – it meets the composition and labeling criteria for statement of nutrition claims established in this Resolution and in Annexes XX and XXI of Normative Ruling no. 75 of 2020; and

III - the nutritional properties claimed are maintained until the end of the product's

expiration date, considering the form of preparation of the food stated by the manufacturer on the label.

Paragraph 1. Nutrition claims cannot be displayed on alcoholic beverages.

Paragraph 2. Brands that make reference to the nutritional characteristics or terms authorized for use of nutrition claims may be used as long as they comply with the provisions in the **heading**.

Paragraph 3. The requirements specified in items I and II should comply with the provisions in:

I – Ruling SVS/MS no. 29 of the Health Surveillance Secretariat of the Ministry of Health, of 13 January 1998 for nutrition claims pertaining to the lactose content in foods for lactose-restriction diets;

II - in Resolution RDC no. 243 of 26 July 2018 for dietary supplements;

III – in Resolutions RDC no. 43, 44, and 45 of 19 September 2011 for infant

formulas; and

IV - in Resolution RDC no. 21 of 13 May 2015 for formulas for enteral nutrition.

Article 25. With the exception of the provisions in Paragraph 5 of Article 5 of this Resolution, the statements of the amounts of calorie content or nutrients outside the nutrition facts table can only be made when the amount stated meets at least one of the composition criteria specified in item II and Paragraph 3 of Article 24 of this Resolution, according to the case.

Article 26. The nutrition claims should be written in Portuguese, without detriment to the existence of texts in other languages.

Paragraph 1. Texts in other languages pertaining to nutrition claims that do not meet the criteria defined in this Resolution cannot be visible on the label.

Paragraph 2. The term **light** [in English] authorized for display of the nutritional characteristics established in Annex XIX of Normative Ruling no. 75 of 2020 does not need to be translated [into Portuguese].

Article 27. The composition criteria for the statement of nutrition claims defined in Annexes XX and XXI of Normative Ruling no. 75 of 2020 should be met in the food ready-forconsumption, when applicable, according to the manufacturer's instructions for preparation, according to the following criteria:

I - In case of nutrition claims of absolute content for the nutritional characteristics "low", "very low", "does not contain", or "without added…" should include the nutritional value of the ingredients added according to the manufacturer's instructions for preparation stated on the label; and

II- Nutrition claims of absolute content for the nutritional characteristics "source of..." or "high in..." cannot include the nutritional value of ingredients added according to the manufacturer's instructions for preparation stated on the label.

Article 28. The composition criteria for the statement of comparative nutrition claims defined in Annex XX of Normative Ruling no. 75 of 2020, should be met in relation to the reference food by the same manufacturer.

Paragraph 1. In case no reference food exists by the same manufacturer, the comparison should use the mean content value in three reference foods marketed in the country.

Paragraph 2. In case no reference food exists, no comparative nutritional claim can be made.

Paragraph 3. The comparative nutritional claim on the food's label should state whether it is compared to the reference food by the same manufacturer or to the mean of the reference foods on the market.

Paragraph 4. The sizes of the compared servings should be equal, considering the food ready-for-consumption.

Article 29. When the nutrition claims are based on common characteristics for all foods of the same type, the label should include a clarification following the statement, that all foods of this type also have these characteristics, with the same kind of lettering used in the nutritional claim, with at least 50% of its size, with a color contrasting with the label's background, and that guarantees the information's visibility and legibility.

Article 30. When there is a statement of front-of-package nutrition labeling, the nutrition claims and expressions that state the addition of essential nutrients cannot be located on the upper half of the main panel or use larger characters than those used on the front-of-package nutrition labeling.

CHAPTER V

DETERMINATION OF THE CONTENT OF NUTRITION LABELING COMPONENTS

Article 31. The stated nutritional values should be those that best represent their amounts in the food, considering:

I – the intrinsic properties of the substances;

II – their natural or added presence;

III - the seasonal variability in the nutritional content of the food or its ingredients;

IV - the characteristics of the food's production process;

V - the precision of the nutritional quantification methods;

VI – the food's expiration date; and

VII – the tolerance levels for purposes of inspection established in Article 33 of this Resolution.

Article 32. The product's nutritional values should by determined by applying at least one of the following methodologies:

I – the product's laboratory analyses, using validated analytical methods;

II – indirect calculation based on the amounts of components in the ingredients used in the product, provided by the suppliers; or

III - indirect calculation based on the amounts of components in the foods and ingredients present in food composition tables or other databases.

Paragraph 1. In the case of calorie content, the determination specified in the **heading** should be made by indirect calculation based on the conversion factors defined in Annex XXII Normative Ruling no. 75 of 2020, using the rounded-off values of the nutrients stated in the nutrition facts table.

Paragraph 2. In the case of foods with non-edible parts, the determination specified in the **heading** should be made for the edible part only.

Paragraph 3. The determination specified in the **heading** should apply the nutrient conversion factors defined in Annex XXIII of Normative Ruling no. 75 of 2020.

Article 33. The following tolerance levels are applied for inspection purposes:

I – the amounts of the food's calorie content, carbohydrate, total sugars, added sugars, total fat, saturated fat, trans fat, sodium, and cholesterol cannot exceed the values stated on the label by 20% or more; and

II – the amounts of protein, amino acids, dietary fiber, monounsaturated fat, polyunsaturated fat, vitamins, minerals, and bioactive substances in the food cannot be less than 20% of the stated value.

CHAPTER VI TRANSITIONAL PROVISIONS

Article 34. The documentation referring to compliance with the requirements set out in this Resolution should be provided to the health authority when requested.

Article 35. Item 6 of SVS/MS Ruling no. 54 by the Health Surveillance Secretariat of the Ministry of Health, of 4 July 1995, hereby takes effect with the following wording: "Labeling of low-sodium salt should meet the standards for general labeling, nutrition labeling, allergen labeling, lactose labeling, and 'contains:...' labeling." (NR – Regulatory Standard)

Article 36. Item 8 of SVS/MS Ruling no. 29 by the Health Surveillance Secretariat of the Ministry of Health, of 1998, hereby takes effect with the following wording: "Special-purpose foods should meet the standards for general labeling, nutrition labeling, allergen labeling, and lactose labeling and the specific standards for conventional food, when applicable." (NR - Regulatory Standard)

Article 37. Item 8 of SVS/MS Ruling no. 30 by the Health Surveillance Secretariat of the Ministry of Health, of 13 January 1998, hereby takes effect with the following wording: "Weight control foods should meet the standards for general labeling, nutrition labeling, allergen labeling, lactose labeling, and special-purpose food labeling." (NR - Regulatory Standard)

Article 38. Item 9 of SVS/MS Ruling no. 34 by the Health Surveillance Secretariat of the Ministry of Health, of 13 January 1998, hereby takes effect with the following wording: "Labeling of transition foods for infants and toddlers should meet the Brazilian Standard for Marketing of Foods for Infants and the standards for general labeling, nutrition labeling, allergen labeling, lactose labeling, special-purpose foods labeling, and 'contains:...' labeling." (NR - Regulatory Standard)

Article 39. Item 9 of SVS/MS Ruling no. 36 by the Health Surveillance Secretariat of the Ministry of Health, of 13 January 1998, hereby takes effect with the following wording: "Labeling of cereal-based foods for infant feeding should meet the Brazilian Standard for Marketing of Foods for Infants and the standards for general labeling, nutrition labeling, allergen labeling, lactose labeling, special-purpose foods labeling, and 'contains:...' labeling." (NR - Regulatory Standard)

Article 40. Items 10.3 and 10.3.1.1 of Ruling no. 31 of 1998, hereby take effect with the following wording: "10.3. Foods with added essential nutrients should meet the standards for general labeling, nutrition labeling, allergen labeling, and lactose labeling."

10.3.1

10.3.1.1. Labeling on enriched or fortified foods should specify the designation of the conventional food and one of the following expressions: "Enriched with Vitamin(s)", "Fortified with Vitamin(s)", "Vitamin-Enriched", "Enriched with Minerals", "Fortified with Minerals", "Fortified with Vitamins and Minerals", "Fortified with Vitamins and Minerals", "Enriched with Vitamins and Minerals", "Include with Vitamins and Minerals", "Include with Vitamins and Minerals", "Enriched with Vitamins and Minerals", "Include with Include with

Article 41. Articles 35, 37, and 38 of Resolution RDC no. 43 of 2011, hereby take effect with the following wording:

"Article 35. Nutrition labeling should comply with the provisions in Resolution RDC no. 429 of 8 October 2020 and Normative Ruling no. 75 of 8 October 2020."

Article 37. Claims of functional properties or health properties are not permitted.

Article 38. Only the following nutrition claims are permitted, having met the respective requirements." (NR - Regulatory Standard)

Article 42. Articles 35, 37, and 38 of Resolution RDC no 44 of 2011, hereby take effect with the following wording:

"Article 35. The nutrition labeling should comply with the provisions of Resolution RDC no. 429 of 8 October 2020 and Normative Ruling no. 75 of 8 October 2020."

.....

Article 37. Claims of functional properties or health properties are not permitted. Article 38. Only the following nutrition claims are permitted, having met the respective requirements." (NR - Regulatory Standard)

Article 43. Articles 33, 35, and 36 of Resolution RDC no. 45 of 2011 hereby take effect with the following wording:

"Article 33. The nutrition labeling should comply with the provisions of Resolution RDC no. 429 of 8 October 2020 and Normative Ruling no. 75 of 8 October 2020."

.....

Article 35. Claims of functional properties or health properties are not permitted. Article 36. Only the following nutrition claims are permitted, having met the respective requirements." (NR - Regulatory Standard)

Article 44. Resolution RDC no. 23 of 2013 hereby takes effect with the following Article 5-A added:

"Article 5°-A Labeling of salt for human consumption should contain the following phrase close to the nutrition facts table: "This product is enriched with 15 mg to 45 mg of iodine per kilogram." (NR - Regulatory Standard)

Article 45. Articles 26, 29, 32, and 33 of Resolution RDC no. 21 of 2015 hereby take effect with the following wording:

"Article 26. Claims of functional properties or health properties are not permitted.

Article 29. The nutrition labeling should comply with the provisions in Resolution RDC no. 429 of 8 October 2020 and Normative Ruling no. 75 of 8 October 2020.

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Article 32. The amounts of probiotics added to the formula should be stated on the product's labeling as follows:

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Article 33. Only the nutrition claims provided in Annex IV of this Resolution can be used, as long as they meet the criteria defined in this Annex." (NR - Regulatory Standard)

46. Article 4 of Resolution RDC no. 135 of 8 February 2017 hereby takes effect with the following wording: "Article 4. Items 8.1.3 and 8.1.4 are included in Item 8 of the Annex of Ruling SVS/MS no.29 by the Health Surveillance Secretariat, of 1998, with the following wording:

8.1.3. Foods for lactose restriction diets that meet the classification established in item 4.1.1.4.1 should display the statement "lactose-free", "zero lactose", "0% lactose", "without lactose", or "does not contains lactose" close to the food's sales name.

8.1.4. Foods for lactose restriction diets that meet the classification established in item 4.1.1.4.2 should display the statement "low lactose content" or "low lactose" close to the food's sales name." (NR - Regulatory Standard)

Article 47. Article 15 of Resolution RDC no. 243 of 2018 hereby takes effect with the following wording:

"Article 15. The nutrition labeling should comply with the provisions in Resolution RDC 429 of 8 October 2020 and Normative Ruling no. 75 of 8 October 2020." (NR - Regulatory Standard)

Article 48. Failure to comply with provisions contained in this Resolution constitutes a public health violation under the terms of Law no. 6.437 of 20 August 1977, in addition to the applicable civil, administrative, and criminal liabilities.

Article 49. The following provisions are hereby revoked: I - item 6.1.2 of Ruling SVS/MS no. 54 by the Health Surveillance Secretariat of the Ministry of Health, of 1995; - items 8.2, 8.2.1.1, and 8.2.1.1.1 of Ruling SVS/MS Π no. 29 by the Health Surveillance Secretariat of the Ministry of Health, of 1998; III - items 8.2.1, 8.2.2, and 8.2.3 of Ruling SVS/MS no. 30, of 1998; IV - items 10.3.2.1. and 10.3.2.2 of Ruling SVS/MS no. 31 by the Health Surveillance Secretariat of the Ministry of Health, of 1998; V - item 7.3.2 of Resolution RDC no. 274 of 2005; VI - Paragraphs 1, 2, 3, and 4 of Article 35 of Resolution RDC no. 43 of 2011; VII - Paragraphs 1, 2, 3, and 4 of Article 35 of Resolution RDC no. 44 of 2011; VIII - Paragraphs 1, 2, 3, and 4 of article 35 of Resolution RDC no. 45 of 2011; IX - items I, II, III, and V of article 29 and Annex III of Resolution RDC no. 21 of 2015; X - items I, II, and III of Article 15 of Resolution RDC no. 243 of 2018; XI - Resolution RDC no. 359 of 23 December 2003; XII - Resolution RDC no. 360 of 23 December 2003; XIII - Resolution RDC no. 163 of 17 August 2006: XIV - Resolution RDC no. 48 of 5 November 2010; and XV - Resolution RDC no. 54 of 12 November 2012.

Article 50. A period of 12 (twelve) months is established for adjustment of the following foods after this Resolution takes effect:

I - foods produced by family farmers or rural family businesses, as defined by Article 3 of Law no. 11.326 of 24 July 2006, with gross revenue in each calendar year up to the limit defined in item I, Article 3 of Complementary Law no. 123 of 14 December 2006;

II- foods produced by economic solidarity projects, as defined by Article 2, item II, of Decree no. 7.358 of 17 November 2010, with gross revenue in each calendar year up to the limit defined in item I, Article 3, of Complementary Law no. 123 of 14 December 2006; III - foods produced by individual microentrepreneurs, as defined by Paragraphs 1 and 2 of Article 18-A of Complementary Law no. 123 of 2006;

IV - foods produced by small-scale agribusinesses, as defined by Articles 143-A and 144-A of Decree no. 5.741 of 30 March 2006;

V - foods produced by artisanal agribusinesses, as provided in Article 7-A of Decree no. 5.741 of 2006;

VI - foods with artisanal production, according to Article 10-A of Law no. 1.283 of 18 December 1950.

Sole paragraph. Products manufactured up to the end of the adjustment period can be marketed until their expiration date.

Article 51. For non-alcoholic beverages in returnable containers, the products' adjustment should observe the gradual process of the labels' replacement, which cannot exceed 36 (thirty-six) months after this Resolution takes effect.

Article 52. This Resolution takes effect 24 (twenty-four) months after its publication. Sole paragraph. Products manufactured before this Resolution takes effect can be marketed until their expiration date.

ANTONIO BARRA TORRES

Interim Executive Chairman