

RESOLUTION No. 14 511

MINISTRY OF INDUSTRIES AND PRODUCTIVITY

UNDERSECRETARY OF QUALITY

CONSIDERING:

That in accordance with the provisions of Article 52 of the Constitution of the Republic of Ecuador, "**People have the right to have access to goods and services of the highest quality and to choose them freely, as well as accurate and non-misleading information about their content and characteristics**";

That the Protocol of Accession of the Republic of Ecuador to the Agreement establishing the World Trade Organization - WTO, was published in the Official Gazette Supplement No. 853 of January 2, 1996;

That the Agreement on Technical Barriers to Trade - AOTC of the WTO, in its Article 2 establishes the provisions on the preparation, adoption and application of Technical Regulations by central government institutions and their notification to other Members;

That the Decisions and Recommendations adopted by the Committee on Technical Barriers to Trade of the WTO must be taken into account;

That Annex 3 of the TBT Agreement establishes the Code of Good Conduct for the preparation, adoption and application of standards;

That Decision 376 of 1995 of the Andean Community Commission created the "Andean System of Standardization, Accreditation, Testing, Certification, Technical Regulations and Metrology", modified by Decision 419 of July 30, 1997;

That Decision 562 of June 25, 2003 of the Andean Community Commission establishes the "Guidelines for the preparation, adoption and application of Technical Regulations in the Member Countries of the Andean Community and at the community level";

That through Law No. 2007-76, published in the Official Register Supplement No. 26 of February 22, 2007, amended in the Ninth Reform Provision of the Organic Code of Production, Trade and Investment, published in the Official Register Supplement No. 351 of December 29, 2010, constitutes the Ecuadorian Quality System, which aims to establish the legal framework for: "**i) Regulate the principles, policies and entities related to activities related to conformity assessment, which facilitate compliance with international commitments in this area; ii) Guarantee compliance with citizen rights related to safety, protection of human, animal and plant life and health, preservation of the environment, consumer protection against deceptive practices and the correction and punishment of these practices; and, iii) Promote and encourage the culture of quality and the improvement of competitiveness in Ecuadorian society**";

That through Resolution No. 14 413 of August 22, 2014, promulgated in the Official Gazette Supplement 2 No. 318 of August 25, 2014, the mandatory nature of the **FIRST CHECK** of the Ecuadorian Technical Regulation RTE INEN022 "**LABELING OF PROCESSED, PACKAGED AND PACKAGED FOOD PRODUCTS**", the same that entered into force on August 25, 2014;

That through Resolution No. 00004522, published in Official Register No. 134 of November 29, 2013 of the Ministry of Public Health, the Sanitary Regulations for the Labeling of Processed Foods for Human Consumption are issued;

That through Ministerial Agreement 00005199, signed by the Minister of Public Health on December 1, 2014, by means of which it reforms the fourth transitory provision of Ministerial Agreement No. 00005103 published in the Official Registry Supplement No. 318 of August 25, 2014,



by means of which the “Substitute Sanitary Regulation” for the Labeling of Processed Foods for Human Consumption was issued”;

That the Ecuadorian Standardization Service - INEN, according to the functions determined in Article 15, literal b) of Law No. 2007-76 of the Ecuadorian Quality System, reformed in the Ninth Reform Provision of the Organic Code of Production, Commerce and Investments published in the Official Registry Supplement No. 351 of December 29, 2010, and following the regulatory process established in Article 29, first paragraph of the same Law, where it states that: ***“The technical regulation includes the preparation, adoption and application of technical regulations necessary to safeguard the objectives related to safety, the health of human, animal and plant life, the preservation of the environment and the protection of the consumer against deceptive practices.***has formulated the draft**SECOND REVISION**of the Ecuadorian Technical Regulation PRTE INEN 022**“LABELING OF PROCESSED, PACKAGED AND PACKAGED FOOD PRODUCTS”**;

That through the Technical-Legal Report contained in the Revision Matrix No. of date of, if suggested proceeding with the approval and officialization of the Regulations that are the subject of this Resolution, which recommends the approval and officialization of the **COMPULSORY** nature of the**SECOND REVISION**of the Ecuadorian Technical Regulation**RTE INEN 022 “LABELING OF PROCESSED, PACKAGED AND PACKAGED FOOD PRODUCTS”**;

That in accordance with the Law of the Ecuadorian Quality System and its General Regulations, the Ministry of Industry and Productivity is the governing institution of the Ecuadorian Quality System, consequently, it is competent to approve and make official the**SECOND REVISION**of the Ecuadorian Technical Regulation**RTE INEN 022 “LABELING OF PROCESSED, PACKAGED AND PACKAGED FOOD PRODUCTS”**;

That through Ministerial Agreement No. 11446 of November 25, 2011, published in the Official Gazette No. 599 of December 19, 2011, the Undersecretary of Quality is delegated the power to approve and make official the proposals for standards or technical regulations and conformity assessment procedures proposed by INEN within the scope of its competence in accordance with the provisions of the Ecuadorian Quality System Law and its General Regulations; and,

In exercise of the powers granted by law,

RESOLVES:

ARTICLE 1.-Approve and**make official**with the **MANDATORY** character the following:

**ECUADORIAN TECHNICAL REGULATION RTE INEN 022 (2R)
“LABELING OF PROCESSED FOOD PRODUCTS, PACKAGED AND
PACKAGED”**

1. OBJECT

1.1This Technical Regulation establishes the requirements that must be met by the labeling of packaged and packaged processed food products in order to protect people's health and to prevent practices that may mislead consumers.

2. FIELD OF APPLICATION

2.1This Technical Regulation applies to packaged and packaged processed food products, aimed at the final consumer, that are marketed in Ecuador, whether they are nationally manufactured or imported, except for those that are marketed in Duty Free.



3. DEFINITIONS

3.1 For the purposes of these Technical Regulations, the definitions contained in the standards NTE INEN 1334-1, NTE INEN 1334-2, NTE INEN 1334-3 and in the Organic Law on Consumer Protection and its Regulations apply, as well as the following:

3.1.1 *processed food*.- It is all food material, natural or artificial that for human consumption has been subjected to technological operations necessary for its transformation, modification and conservation, which is distributed and marketed in containers labeled under a specific factory brand.

For the purposes of this Regulation, alcoholic and non-alcoholic beverages, bottled water, condiments, spices and food additives, starter and continuation preparations for infant feeding, complementary foods and for special diets will also be considered as processed food.

3.1.2 *sugars*.- It is understood to be the monosaccharides and disaccharides present in the processed food, from all sources, whether their own or added.

3.1.3 *Energy drink*.- They are drinks that in their composition include one or more components of amino acids, carbohydrates, vitamins, minerals, caffeine, taurine and glucuronolactone.

3.1.4 *marketer*.- It is the natural or legal person, public or private, dedicated to the commercialization, wholesale or retail, of processed foods referred to in this Regulation.

3.1.5 *Consumer*.- It is any natural or legal person who, as final recipient, acquires, uses or enjoys goods or services, or receives an offer for it.

3.1.6 *Declaration of nutritional properties*.- It is understood any representation that affirms, suggests or implies that a food has particular nutritional properties, including but not limited to its energy value and content of proteins, fats and carbohydrates, as well as its content of vitamins and minerals.

3.1.7 *Health claim*.- It is any representation that declares, suggests or implies that there is a relationship between a food or a constituent of a food, and health.

3.1.8 *Non-caloric sweetener*.- It is any natural or artificial substance used to sweeten and that does not provide energy.

3.1.9 *Label (Label)*.- Label or label is understood as any expression, brand, image or other descriptive or graphic material that has been written, printed, stenciled, marked, embossed, attached to the container of a processed food, which identifies and characterizes it.

3.1.10 *Labeling (Labeling)*.- Any written, printed or graphic material that contains the label or label.

3.1.11 *Nutritional labeling*.- It is any description intended to inform the consumer about the nutritional properties of a food that includes: the declaration of nutrients and complementary nutritional information.

3.1.12 *Maker*.- Natural or legal person responsible for the manufacture of a processed food that is put up for sale in labeled containers, regardless of whether said manufacture is carried out by the same person, or by a third party.

3.1.13 *fats or lipids*.- Substances insoluble in water and soluble in organic solvents, especially constituted by esters of fatty acids; this term includes triglycerides, phospholipids, glycolipids, waxes, and sterols.

3.1.14 *Ecuadorian Technical Standard, NTE INEN*.- It is the document issued by the INEN, which provides, for common and repeated use, rules, guidelines or characteristics for products or processes and methods



of related production, and the observance of which is not mandatory. It may also include terminology, symbol, packaging, marking or labeling requirements applicable to a product, process or production method, or deal exclusively with them.

3.1.15 Nutrient.- It is any chemical substance normally consumed as a component of a food that: provides energy, or is necessary for growth, development and maintenance of health and life, or whose lack produces characteristic chemical and physiological changes.

3.1.16 Health Register.- Certification granted by the National Health Authority for the import, export and marketing of products for human use and consumption indicated in article 137 of the Organic Health Law. Said certification is granted when the requirements of quality, safety, efficacy and aptitude to consume and use said products are met, complying with the procedures established in the aforementioned law and its regulations.

3.1.17 Ecuadorian Technical Regulation.- Document issued by the INEN, which establishes the characteristics of a processed food or service, or the processes and production methods related to them, including the applicable administrative provisions, and whose observance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements applicable to a processed food, process or production method. Additionally, it can refer to the destination of processed foods after they are put into circulation or commercialized and cover aspects related to use, recycling, reuse, elimination or disposal.

3.1.18 Salt.Means sodium chloride and all food sources containing sodium, including additives.

3.1.19 Graphic System.- Representation of the levels of fat, sugars and salt (sodium) that the processed food contains.

3.1.20 Transgenic.Said of a living organism that has been modified by the addition of foreign genes to achieve new properties.

4. GENERAL CONDITIONS

4.1 Processed foods that have the "healthy food" logo must remove said logo from their labels and comply with the provisions established in this Technical Regulation.

4.2 For those components that do not have a reference value in the Ecuadorian Technical Standard, the reference values established in the CODEX ALIMENTARIUS will be considered.

4.3 The language of the information on the labeling of processed foods for human consumption will be in accordance with the provisions of the NTE INEN 1334-1 standard and may also use predominant local languages, in clear and easily understandable terms for the consumer to which they are addressed.

4.4 The labeling of processed foods for human consumption will be adjusted to its true nature, composition, quality, origin and quantity of the packaged food, in such a way as to avoid any misconception of its qualities or benefits and will be based on the characteristics or specifications of the food, approved in its Sanitary Registry.

5. REQUIREMENTS

5.1 The labeling of packaged and packaged processed food products must comply with the provisions of the Requirements chapter of the current NTE INEN 1334-1 and NTE INEN 1334-2 standards, and with Article 14 of the Organic Law on Consumer Protection.



5.2 For processed foods that contain transgenic ingredients, it must be declared on the product label, on the main panel, in duly highlighted letters and in accordance with the provisions of Annex B of the NTE INEN 1334-1 standard, **"CONTAINS TRANSGENICS"**, as long as the content of transgenic material exceeds 0.9% in the product.

5.3 When transgenic ingredients are used, the name of the ingredient must be declared in the list of ingredients, followed by the word **"TRANSGENIC"**, as long as the content of transgenic material exceeds 0.9% in the product.

5.4 For traceability purposes, the manufacturer must request that the supplier declare that the ingredient is or is not transgenic.

5.5 Packaged and packaged processed foods that have a sanitary registration must also comply with:

5.5.1 For the evaluation of the processed food in reference to the components and permitted concentrations of fats, sugars and salt, it must be referred to as established in Table No. 1.

TABLE 1. Content of components and concentration are allowed

Level Components	CONCENTRATION "LOW"	CONCENTRATION "HALF"	CONCENTRATION "HIGH"
total fat	Less than or equal to 3 grams in 100 grams	Greater than 3 and less than 20 grams in 100 grams	Equal to or greater than 20 grams in 100 grams
	Less than or equal to 1.5 grams in 100 milliliters	Greater than 1.5 and less than 10 grams in 100 milliliters	Equal to or greater than 10 grams in 100 milliliters
sugars	Less than or equal to 5 grams in 100 grams	Greater than 5 and less than 15 grams in 100 grams	Equal to or greater than 15 grams in 100 grams.
	Less than or equal to 2.5 grams in 100 milliliters	Greater than 2.5 and less than 7.5 grams in 100 milliliters	Equal to or greater than 7.5 grams in 100 milliliters
salt (sodium)	Less than or equal to 120 milligrams of sodium in 100 grams	Greater than 120 and less than 600 milligrams of sodium in 100 grams	Equal to or greater than 600 milligrams of sodium in 100 grams.
	Less than or equal to 120 milligrams of sodium in 100 milliliters	Greater than 120 and less than 600 milligrams of sodium in 100 milliliters	Equal to or greater than 600 milligrams of sodium in 100 milliliters.

5.5.2 For the comparison of the content of components and concentrations allowed in table 1 in processed foods for human consumption, the units established in the NTE INEN 1334-2 standard must be used. In the case of yogurts, ice creams, the calculation and comparison of said components will be done in milliliters (ml).

5.5.3 In foods that are consumed reconstituted, the content of components in the reconstituted portion will be evaluated, in accordance with the preparation instructions given by the manufacturer.

5.5.4A A graphic system with horizontal bars of red, yellow and green colors must be placed on the label, depending on the concentration of the components.

to) The red colored bar is assigned for high content components and will have the phrase "HIGH in..."

b) The yellow color bar is assigned for media content components and will have the phrase: "MEDIA in..."

c) The green color bar is assigned for low content components and will have the phrase: "LOW in..."

5.5.4.1 Depending on the nature of the product, each component will be represented by a bar as indicated in Table 1.

5.5.5 The graphic system must be properly framed in a square with a gray or white background, depending on the predominant colors of the label, and must occupy the corresponding percentage according to the area of the main or rear panel of the container in accordance with the provisions of table 2.

TABLE 2. Areas of the Graphic System

Graphic system area	main face area of display cm^{two}
≥2.5" ^{two}	19.5 - 32
twenty %	33 - 161
fifteen %	162 onwards

5.5.5.1 The graphics system area should be located in the upper left corner of the main panel or back panel.

5.5.5.2 The graphic system must not be hidden by any object or implement for its consumption or use, or by promotional products.

5.5.5.3 In processed foods contained in small packages, with a total area for labeling less than 19.4 cm^{two}, they must not place the graphic system in their container, and must include said system in the external container that contains them.

5.5.6 The provision to include the graphic system for foods described in the Chapter on Exceptions to Nutritional Labeling of the NTE INEN 1334-2 Standard is excluded, and all those processed foods that, due to their nature or composition of origin, have one or more of the components (fats, salt, sugars) and that none of the aforementioned components has been added in its process, to the initial and continuation formulas for infant feeding, complementary foods and foods for special diets, flours and food additives.

5.5.7 The inclusion of the graphic system in sugar, salt and fats of animal origin is excepted, however they must place the following message on their labels: "For your health, reduce the consumption of this product".

5.5.8 Products that contain two or more processed foods in their presentation must make the nutritional declaration for each of these, as well as the calculation and comparison of the content of components and concentrations allowed and place a graphic system of the highest levels of the three components in the largest container.

5.5.9 Products that contain one or more non-caloric sweeteners among their ingredients must include the following message on their label: "This product contains non-caloric sweetener."

5.5.10 Non-alcoholic beverages whose content is less than fifty percent (50%) of the natural food that characterizes it (based on its formulation), must include the following message on its label: "This product has less than 50% of the natural food in its content".

5.5.11 In the labeling of energy drinks that contain caffeine, taurine and/or glucuronolactone, the following messages will be included that will complement the warnings indicated in the Ecuadorian Technical Standard NTE INEN 2411:

to) "Product not recommended for infants, children, adolescents, pregnant women, lactating women, the elderly, diabetics, people sensitive to caffeine, people with cardiovascular and gastrointestinal diseases";

b) "Do not consume energy drinks before, during and after physical activity, or with alcoholic beverages.



5.5.12 The labeling of alcoholic beverages will contain the warning message indicated *in* the General Regulations of the current Organic Law on Consumer Protection.

5.5.13 Processed foods that include a property declaration that compares the nutrient levels and/or energy value of two or more foods must declare in accordance with the Ecuadorian Technical Standard NTE INEN 1334-3.

5.5.14 The messages to be declared must comply with:

5.5.14.1 Nutritional considerations. To determine if the processed food has a HIGH/MEDIUM/LOW content of components indicated in Table No. 1, proceed as follows:

to) Solid processed foods:

The results of the bromatological analyzes of the food must be directly compared with the parameters established in Table No.1 of this Technical Regulation. Said declaration must be in accordance with the units established in the NTE INEN 1334-2 Standard.

b) Liquid processed foods:

The results of the bromatological analysis of liquid processed foods, including yogurts, ice creams, must be compared with the volume references in Table No. 1 of this Technical Regulation, applying the density formula.

5.5.14.2 Characteristics of the graphic system for content of components and permitted concentrations established in table No.1.

The graphic system will be in the upper left corner of the main panel or back panel of the processed food container, occupying the corresponding area of said panel in accordance with table 2, including the following information:

one. Phrase: "STOP at..." followed by the component.

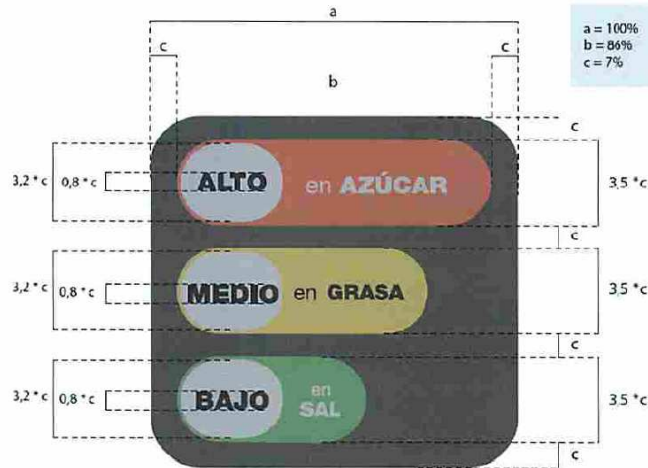
two. Phrase: "MIDDLE in..." followed by the component.

3. Phrase: "LOW in..." followed by the component.

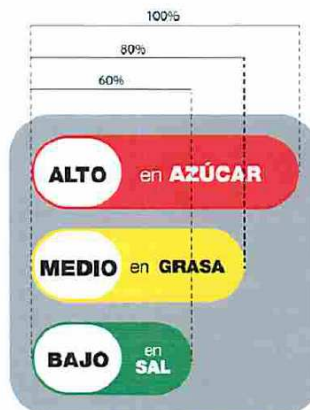
The graphic system must respect the percentages (%) of the proportions indicated in the following graphics:

GRAPHIC SYSTEM

Relative percentages of the label in relation to the overall size



Actual percentages of bars relative size



5.5.14.3 In addition, the graphic system must meet the following characteristics:

to) It must be framed in a gray background square (CMYK code; C 0%, M 0%, Y 0%, K 80%) or white in order to create contrast with the predominant color of the label and delimited with a black line (1-2 points)

b) The order of colors from top to bottom will always be red, yellow and green.

c) The colors for the bars should be:

one. For the bar that represents the high content, the color red should be used (CMYK code; C 0%, M 100%, Y 100%, K 0%).

two. Yellow should be used for the bar that represents the average content (CMYK code; C 0%, M 0%, Y 100%, K 10%).

3. For the bar that represents the low content, green should be used (CMYK code; C 75%, M 0%, Y 100%, K 0%).

d) The words "HIGH..." "MEDIUM...", "LOW..." will be written in Helvetica Neue or Arial font, in capital letters, in black, with Black style, without condensation in the typographic spacing, inserted in a white circle.



- and)** The word "en" will be written in Helvetica Neue or Arial font, in lower case, white for the red and green bars, and black for the yellow bar, in Roman style, without condensation in the typographic spacing.
- F)** The components (SUGAR, FATS and SALT) will be written in Helvetica Neue or Arial font, in capital letters, white for the red and green bars, and black for the yellow bar, with Black style, without condensation in the typographic spacing. .
- g)** The sizes of the words "in" and of the components are relative to the space of the bar; the word "in" can be placed above the component, if space requires it in order to be legible.
- i)** If a color is repeated two or more times, the description order will be as follows: sugar, fat and salt.
- i)** In the event that the processed food does not contain any of the components, only the bar that corresponds to the component that contains the processed food will be included in the graph, and the words "does not contain..." will be written in Helvetica typography Neue or arial, in lowercase, white, in the case of a gray background square, or in black, in the case of a white background square, in Roman style, without condensation in the typographic spacing, on the gray or white background of the box.
- g)** Characteristics of the messages to be declared
- one.** The messages that must be included in the label or labeling and described in these Technical Regulations, will be subject to the following characteristics:
- If there is more than one message, they must go together.
 - The messages must be in a box with a white background delimited with black borders.
 - The letter will be Helvetica neue or arial, regular non-condensed black.
 - The messages must be placed horizontally and legible to normal vision, in accordance with the respective Ecuadorian Technical Standards.
- two.** In the case of the messages that processed foods must contain, indicated in numerals 5.2; 5.5.7; 5.5.9 and 5.5.10 of these Technical Regulations, these must be located in the lower part of the main panel of the container.
- 3.** In the case of the messages that energy drinks must contain, indicated in numeral 5.5.11 of this Technical Regulation, these must be located on the rear panel of the container.

5.5.15 Regarding the labeling of processed foods for human consumption, the following is prohibited:

- to)** Affirm that the consumption of a processed food by itself covers the nutritional requirements for a person;
- b)** Use logos, certifications and/or seals of associations, societies, foundations, federations or collegiate groups, which refer to health benefits from the consumption of a certain processed food;
- c)** Declare nutritional properties, failing to comply with the reference values established in the Regulations and Technical Standards for the labeling of processed foods;
- d)** Declare healthy properties that cannot be verified;
- and)** Attribute preventive properties or therapeutic action to alleviate, treat or cure a disease;



F) Use images of boys, girls, and adolescents, unless the provisions of the Code for Children and Adolescents are complied with;

g) Suggest the frequency of consumption of processed foods;

6. SAMPLING

6.1 The inspection and sampling to verify compliance with the labeling requirements of packaged processed foods will be done in accordance with the provisions of the current NTE INEN-ISO 2859-1 standard with a simple sampling plan, normal inspection, general inspection level II, with an AQL of 1.5%.

7. REFERENCE DOCUMENTS

7.1 Ecuadorian Technical Standard NTE INEN 1334-1 ***Labeling of food products for human consumption. Part 1. Requirements.***

7.2 Ecuadorian Technical Standard NTE INEN 1334-2 ***Labeling of food products for human consumption. Part 2. Nutritional labelling. Requirements.***

7.3 Ecuadorian Technical Standard NTE INEN 1334-3 ***Labeling of food products for human consumption. Part 3. Requirements for nutrition claims and health claims***

7.4 Ecuadorian Technical Standard NTE INEN 2411 ***Energy drinks. Requirements***

7.5 NTE INEN-ISO 2859-1 ***Sampling procedures for inspection by attributes. Part 1. Acceptable Quality Level (AQL) Rated Sampling Programs for Lot-to-Lot Inspection.***

7.6 Ministry of Public Health of Ecuador. Ministerial Agreement 00004522 Sanitary Regulations for the labeling of processed foods for Human Consumption. Quito, November 15, 2013. Published in Official Gazette No. 134 of November 29, 2013 (Second Supplement).

7.7 Ministry of Public Health of Ecuador. Ministerial Agreement 00004565 Reforms article 7 of the Sanitary Regulations for the labeling of processed foods for Human Consumption. Quito November 27, 2013.

7.8 Ministry of Public Health of Ecuador. Errata of the Ministerial Agreement 00004522 Sanitary Regulations for the labeling of processed foods for Human Consumption. Published in Official Gazette No. 136 of December 3, 2013 (Second Supplement).

7.9 Ministry of Public Health of Ecuador. Ministerial Agreement 00004832 Sanitary Regulations for the labeling of processed foods for Human Consumption. Published in the Official Registry of April 16, 2014 (Second Supplement).

7.10 Ecuadorian Technical Standard NTE INEN-ISO/IEC 17050-1 ***Conformity Assessment - Supplier's Declaration of Conformity. Part 1: General Requirements***."

8. PROCEDURE FOR THE ASSESSMENT OF CONFORMITY

8.1 In accordance with the provisions of Law No. 2007-76 of the Ecuadorian Quality System, prior to the commercialization of national and imported products contemplated in this technical regulation, manufacturers and importers must demonstrate their compliance through a certificate of inspection, issued by an accredited or designated inspection body in the country, or by those that have been issued in relation to the mutual recognition agreements in force with the country, according to the following:



a) For imported products. Issued at origin or destination by an inspection body accredited, whose accreditation is recognized by the Ecuadorian Accreditation Service - SAE, as established by the Ecuadorian Quality System Law.

b) For products manufactured nationally. Issued by an accredited inspection body by the SAE or designated as established by the Law of the Ecuadorian Quality System.

8.2 For the demonstration of the conformity of the products contemplated in this Technical Regulation, manufacturers and importers must demonstrate their compliance through the presentation of the inspection certificate of the sampled lot, in Spanish and, according to the following options:

8.2.1 Inspection certificate that demonstrates compliance with the requirements established in this regulation, issued by a product inspection body, accredited and recognized by the SAE, to which the current Sanitary Registry must be attached.

8.2.2 First Party Certificate of Conformity according to the NTE INEN-ISO/IEC 17050-1 Standard, duly legalized by the competent Authority, attaching the current Sanitary Registry, issued or recognized by the Competent National Authority of the country of destination. In this case, the importer must attach the Registry of Operators, established by Ministerial Agreement No. 14114 dated 2014-01-24.

9. SURVEILLANCE AND CONTROL AUTHORITY

9.1 In accordance with the provisions of Law No. 2007-76 of the Ecuadorian Quality System, the Ministry of Industry and Productivity and the Ministry of Public Health, which, based on their constitutive laws, have control and supervision powers, are the authorities competent to carry out the tasks of surveillance and control of compliance with the requirements of this technical regulation, and will demand from the national manufacturers and importers of packaged and packaged processed food products, the presentation of the respective inspection certificates.

9.2 The market surveillance authorities shall exercise their functions independently, impartially and objectively, and within the scope of their powers.

10. PENALTIES REGIME

10.1 Suppliers of these products that fail to comply with the provisions of this Technical Regulation will receive the sanctions provided for in Law No. 2007-76 of the Ecuadorian Quality System and other current laws, depending on the risk involved for users and the severity of the breach. .

11. RESPONSIBILITY OF THE CONFORMITY ASSESSMENT BODIES

11.1 The inspection agencies, or other instances that have issued erroneous inspection certificates or that have deliberately adulterated the data of the inspection certificates, will have administrative, civil, criminal and/or fiscal responsibility in accordance with the provisions of Law No. 2007 -76 of the Ecuadorian Quality System and other current laws.

12. REVIEW AND UPDATING

12.1 In order to keep the provisions of this Ecuadorian technical regulation updated, the Ecuadorian Standardization Service, INEN, will review it within a period not exceeding five (5) years from the date of its entry into force, to incorporate advances technological or additional safety requirements for the protection of health, life and the environment, in accordance with the provisions of Law No. 2007-76 of the Ecuadorian Quality System.



ARTICLE 2.-Provide the Ecuadorian Standardization Service, INEN, that in accordance with Ministerial Agreement No. 11256 of July 15, 2011, published in the Official Gazette No. 499 of July 26, 2011, publish the **SECOND REVISION** the Ecuadorian Technical Regulation **RTE INEN 022 (2R) "LABELING OF PROCESSED, PACKED AND PACKAGED FOOD PRODUCTS"**, on the website of that institution, (www.normalizacion.gob.ec).

ARTICLE 3.-This Ecuadorian Technical Regulation RTE INEN 022 (Second Revision) replaces RTE INEN 022:2014 (First Revision) and will enter into force from the date of its promulgation in the Official Registry.

TRANSITORY DISPOSITIONS

FIRST TRANSITORY:The requirements established in numerals 5.2 and 5.3 of this Technical Regulation will come into force as of August 29, 2014, through additional permanent adhesive labels, indelible or printed seals, which can be placed at origin or destination.

SECOND TRANSITORY:The requirements established in numeral 5.5 of this Technical Regulation will be mandatory as of August 29, 2014 for medium and large companies that manufacture, import or market processed food products. Through additional permanent adhesive labels, indelible or printed seals, which can be placed at origin or destination.

THIRD TRANSITORY.-Processed foods that have the "healthy food" logo must remove said logo from their labels and comply with the provisions established in this Regulation.

FOURTH TRANSITORY:The requirements established in numeral 5.5 of this Technical Regulation will be mandatory as of November 29, 2014 for small and micro-enterprises established in Art. 106 of the Regulation for the Structure of Investment Productive Development of the Organic Code of the Production, Commerce and Investments and natural persons who carry out commercial activities and take advantage of the Special Tax Regime (RISE) or are obliged to keep accounts subject to current tax regulations. Through additional permanent adhesive labels, indelible or printed seals, which can be placed at origin or destination.

FIFTH TRANSITORY: *"The deadline for the exhaustion of processed foods produced before August 29, 2014, by large and medium-sized companies; and before November 29, 2014 for micro and small businesses, it will be the same as the expiration date of said products declared on the label".*

SIXTH TRANSITORY: For companies that have used a bar with the words "Does not contain..." in the graphic system, their products may remain on the market until inventory is exhausted.

COMMUNICATE AND PUBLISH in the Official Registry.

Given in Quito, Metropolitan District, 2014-12-17

Mgs. Ana Elizabeth Cox Váscquez
UNDERSECRETARY OF QUALITY