

RESOLUTION – RDC NO. 26 OF 2 JULY 2015 – ANVISA

Provides on the requirements for mandatory labelling of the main foods that cause food allergies.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV of Law no. 9,782 of 26 January 1999, item V, paragraphs 1 and 3 of Article 5 of the Internal Regulation approved in the terms of Annex I of Anvisa Administrative Rule no. 650 of 29 May 2014, published on the Federal Official Gazette of 2 June 2014, considering the provisions in Article 2, item III, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and the Agency's Regulation Process Improvement Program, created through Administrative Rule no. 422 of 16 April 2008, in a meeting held on 24 June 2015, adopts the following Collegiate Board Resolution, and I, Deputy Director-President, determine its publication:

Article 1. This Resolution establishes the requirements for mandatory labelling of the main foods that cause food allergies.

Article 2. This Resolution applies to prepackaged food, including beverages, ingredients, food additives, and processing agents, as well as those intended exclusively for industrial processing or food services.

Paragraph 1. In a complementary way, this Resolution applies to Resolution RDC no. 259 of 20 September 2002, which approves the technical regulation for the labelling of packaged foods, and its updates.

Paragraph 2. This Resolution does not apply to the following products:

I – packaged foods that are prepared or fractioned in food services and commercialized at the establishment itself;

II – foods packaged at the points of sale at the consumer's request; and

III – foods commercialized without packages.

Article 3. For the purposes of this Resolution, the following definitions are adopted:

I – food allergen: any protein, including modified proteins and protein fractions, derived from the main foods that cause food allergies;

II – food allergies: reproducible adverse reactions mediated by specific immunological mechanisms that occur in sensitive individuals after the consumption of a determined food;

III – cross contamination: presence of any food allergen not intentionally added to the food as a consequence of cultivation, production, handling, processing, preparation, treatment, storage, packaging, transportation, or preservation of foods, or as a result of environmental contamination;

IV – Allergen Control Program: program for identification and control of the main foods that cause food allergies and for prevention of cross-contamination with food allergens at any stage of their manufacture process, from primary production to packaging and commercialization;

V – food service: institutional or commercial establishment where food is handled, prepared, stored, and displayed for sale, whether or not it is consumed on site, such as restaurants, cafeterias, bars, bakeries, food and nutrition units of schools, daycare centers.

Article 4. The main foods that cause food allergies are listed in the Annex and must be mandatorily declared in accordance with the requirements established in this Resolution.

Sole paragraph. Declarations referring to foods that cause food allergies not provided for in the Annex may be made, as long as the requirements established in this Resolution are complied with.

Article 5. Alterations on the list of the main foods that cause food allergies must be requested through a specific petition and comply with the requirements provided for in Resolution no. 17 of 30 April 1999, which approves the technical regulation that establishes the basic directives for risk and safety assessment of foods, and its updates.

Article 6. Foods, ingredients, food additives, and processing agents that contain or are derived from the foods listed in the Annex must include the declaration “Allergic consumers: this food contains (common names of the foods that cause food allergies)”, “Allergic consumers: this food contains derivatives from (common names of the foods that cause food allergies)”, or “Allergic consumers: this food contains (common names of the foods that cause food allergies) and derivatives”, as applicable.

Paragraph 1. In the case of crustaceans, the declaration must include the common name of species as follows: “Allergic consumers: this food contains crustaceans (common name of the species)”, “Allergic consumers: this food contains derivatives from crustaceans (common name of the species)”, or “Allergic consumers: this food contains crustaceans and derivatives (common name of the species)”, as applicable.

Paragraph 2. For the products exclusively intended for industrial processing or food services, the information required in the caption of this article may be provided, as an alternative, in the documents that accompany the product.

Paragraph 3. Ingredients, food additives, and processing agents derived from the main foods that cause food allergies may be excluded from the obligation of declaration provided for in the caption of this article, as long as the provisions in Article 5 of this Resolution are complied with.

Article 7. In the cases where it is not possible to ensure the absence of cross contamination of foods, ingredients, food additives, or processing agents by food allergens, the label must include the declaration “Allergic consumers: this food may contain (common names of foods that cause food allergies)”.

Paragraph 1. The use of the declaration established in the caption of this article must be based on an Allergen Control Program.

Paragraph 2. In the case of crustaceans, the declaration must include the common name of the species as follows: “Allergic consumers: this food may contain crustaceans (common names of the species)”.

Paragraph 3. For the products exclusively intended for industrial processing or food services, the information required in the caption of this article may be provided, as an alternative, in the documents that accompany the product.

Article 8. The warnings required in articles 6 and 7 of this Resolution must be grouped immediately after or below the list of ingredients, and with legible characters that comply with the following declaration requirements:

I – upper case;

II – bold;

III – color contrasting with the label background; and

IV – minimum size of 2 mm and never smaller than the font size used in the list of ingredients.

Paragraph 1. The declarations referred to in the caption of this article may not be placed in covered locations that may be removed by opening the seal or that are difficult to see, such as sealing and folding areas.

Paragraph 2. In the case of packages with main panel area equal to or smaller than 100 (one hundred) cm², the minimum size of the characters is 1 (one) mm.

Paragraph 3. If more than one of the warnings provided for in the caption of this article are applicable to the product, the information must be grouped in a single phrase, starting with the expression: “Allergic consumers:” followed by the respective content indications.

Article 9. Foods, ingredients, food additives, and processing agents must not declare any type of claims related to the absence of foods that cause allergies or food allergens, except for the cases provided for in specific technical regulations.

Article 10. The documentation related to the compliance with the requirements provided for in this Resolution must be available for consultation by the competent authority and forwarded to Anvisa, when applicable, for the purposes of health marketing authorization.

Article 11. A period of 12 (twelve) months is hereby established for the necessary adequacy of the labelling of the products covered by this Resolution, counting from the date of its publication.

Sole paragraph. The products manufactured by the end of the adequacy period referred to in the caption of this article may be commercialized until their expiry date.

Article 12. Failure to comply with the provisions contained in this Resolution shall be considered an infraction of health regulations, pursuant to Law No. 6,437 of 20 August 1977 and its updates, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 13. This Resolution comes into force on the date of its publication.

IVO BUCARESKY

Deputy Director-President

ANNEX

1. Wheat, rye, barley, oats, and their hybridized strains.
2. Crustaceans.
3. Eggs.
4. Fish.
5. Peanut.
6. Soybean.
7. Milk from all mammal animal species.
8. Almond (<i>Prunus dulcis</i> , sin.: <i>Prunus amygdalus</i> , <i>Amygdalus communis</i> L.).
9. Hazelnuts (<i>Corylus</i> spp.).
10. Cashew nut (<i>Anacardium occidentale</i>).
11. Brazil nut (<i>Bertholletia excelsa</i>).
12. Macadamias (<i>Macadamia</i> spp.).
13. Walnuts (<i>Juglans</i> spp.).

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