

RESOLUTION RDC NO. 487 OF 26 MARCH 2021

Provides for the maximum tolerated limits (MTL) of contaminants in foods, the general principles for their establishment, and the analysis methods for the purposes of conformity assessment.

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, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item VII, paragraphs 1 and 3 of Article 53 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 255 of 10 December 2018, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 25 March 2021, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Article 1. This Resolution provides for the maximum tolerated limits (MTL) of contaminants in foods, the general principles for their establishment, and the analysis methods for the purposes of conformity assessment.

Article 2. This Resolution incorporates Resolutions GMC/MERCOSUR no. 12/2011 and no. 103/1994 into the Brazilian legislation.

Article 3. This Resolution applies to the whole food production chain.

Sole paragraph. This Resolution does not apply to:

I – potable water, in accordance with Annex XX of Consolidation Administrative Rule no. 5 of 28 September 2017;

II – bottled water for human consumption, in accordance with Collegiate Board Resolution – RDC no. 274 of 22 September 2005 and Collegiate Board Resolution – RDC no. 316 of 17 October 2019;

III – contaminants from food additives and processing agents, in accordance with Administrative Rule SVS/MS no. 540 of 27 October 1997;

IV – constituents from dietary supplements, in accordance with Collegiate Board Resolution – RDC no. 243 of 26 July 2018, and Normative Instruction no. 28 of 26 July 2018;

V – bacterial toxins in foods, in accordance with Collegiate Board Resolution – RDC no. 331 of 23 December 2019, and Normative Instruction no. 60 of 23 December 2019;

VI – substances from the migration of materials in contact with foods, in accordance with Collegiate Board Resolution – RDC no. 91 of 11 May 2001; and

VII – macroscopic and microscopic foreign matters in foods and beverages, in accordance with Collegiate Board Resolution – RDC no. 14 of 28 March 2014.

CHAPTER II

DEFINITIONS

Article 4. For the purposes of this Resolution, the following definitions are adopted:

I – food production chain: all sectors involved in steps of production, industrialization, storage, fractioning, transportation, distribution, import, or commercialization of foods;

II – contaminant: any substance not intentionally added to foods and that is present as a result of production, industrialization, processing, preparation, treatment, packaging, transportation, or storage, or as a result of environmental contamination; and

III – maximum tolerated limit (MTL): maximum concentration of the contaminant legally accepted in food.

CHAPTER III

GENERAL PROVISIONS

Article 5. The quantities of contaminants must be the lowest possible, through the application of the best production practices and technologies available.

Article 6. Contaminant MTLs are defined in Normative Instruction no. 88 of 26 March 2021.

Sole paragraph. The contaminant MTLs referred to in the caption of this article apply to the edible part of foods, considering the food as displayed for sale, except when specified otherwise in Normative Instruction no. 88 of 2021.

Article 7. In the case of foods not provided for in Normative Instruction no. 88 of 2021, but which have been dehydrated, diluted, transformed, or compounded from one or more of the ingredients listed in such Normative Instruction, the contaminant MTLs must observe:

I – the relative proportions of such ingredients in the final product;

II – alterations in the concentration of such ingredients from the product's drying, dilution, or transformation process, when applicable; and

III – the analytical quantification limit.

Paragraph 1. The documentation related to compliance with the requirements provided for in the caption of this article must be available for consultation by the competent authority.

Paragraph 2. If the data referred to in item II are not provided or do not have an adequate justification, the competent authority shall define the factors to be applied, based on the information available.

Article 8. In the case of contaminants of food ingredients not provided for in Normative Instruction no. 88 of 2021, and which are not provided for in article 7 of this Resolution, the limits of contaminants defined in the specifications of identity, purity, and composition approved by Anvisa must be observed, or, in their absence, one of the following references:

I – Brazilian Pharmacopeia;

II – Officially acknowledged pharmacopeias, in accordance with Collegiate Board Resolution – RDC no. 37 of 6 July 2009;

III – Food Chemicals Codex – FCC; and

IV – Joint FAO/WHO Expert Committee on Food Additives – JECFA.

Article 9. The foods that do not comply with the MTLs of contaminants defined in articles 6 to 8 of this Resolution can not be intended for direct human consumption or used as ingredients in foods intended for human consumption.

Article 10. Contaminant MTLs shall be established based on the following information:

I – toxicological studies available for the contaminant;

II – risk assessments, conducted by internationally acknowledged organisms, for the contaminant;

III – magnitude and severity of the health adverse effects caused by the contaminant ingestion;

IV – analytical data on the contaminant incidence in the food;

V – the food consumption data;

VI – populational group for which the product is indicated;

VII – form of preparation and consumption of the food;

VIII – norms, recommendations, or directives by Codex Alimentarius or other internationally acknowledged organisms;

IX – good agricultural, livestock, industrial, and analytical practices;

X – commercial relevance of the food;

XI – technological possibilities, including the availability of analytical methodology;

XII – food contamination problem history; and

XIII – existing data in scientific literature.

Article 11. In order to verify contaminant MTLs, it is mandatory to use methodologies that comply with the performance criteria established in the latest version of Codex Alimentarius Manual of Procedures.

Paragraph 1. In order to verify inorganic arsenic MTL, methodologies quantifying total arsenic may be used.

Paragraph 2. If the provisions in paragraph 1 of this article are applied and the results are higher than the respective MTLs, trials for the quantification of inorganic arsenic must be conducted.

CHAPTER IV

FINAL AND TRANSITIONAL PROVISIONS

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, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 13. Article 2 of Collegiate Board Resolution – RDC no. 281 of 6 October 2003, is now effective with the following wording:

“Article 2. The maximum tolerated limit of benzopyrene must comply with the provisions in Normative Instruction no. 88 of 26 March 2021.” (new wording)

Article 14. The following are hereby revoked:

I – Administrative Rule SVS/MS no. 11 of 15 May 1987;

II – Administrative Rule SVS/MS no. 685 of 27 August 1998;

III – Collegiate Board Resolution – RDC no. 7 of 18 February 2011;

IV – Collegiate Board Resolution – RDC no. 42 of 29 August 2013;

V – Collegiate Board Resolution – RDC no. 138 of 8 February 2017; and

VI – Collegiate Board Resolution – RDC no. 193 of 12 December 2017.

Article 15. This Resolution comes into force on 3 May 2021.

ANTONIO BARRA TORRES

This content does not replace the one published in the certified version.