NORMATIVE INSTRUCTION – IN No. 281 OF 22 FEBRUARY 2024

It establishes the way to regularize the different categories of food and packaging, and the respective documentation that must be presented.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and item VII, paragraph 1 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Normative Instruction, as decided upon in a meeting held on 21 February 2024, and I, Director-President, determine its publication.

Article 1. This Normative Instruction establishes, in accordance with Collegiate Board Resolution – RDC No. 843 of 22 February 2024, the form of regularization of the different categories of food and packaging, and the respective documentation that must be presented.

Paragraph 1. Annex I defines the categories of food and packaging that are required to have marketing authorization with Anvisa.

Paragraph 2. Annex II defines the categories of food and packaging that are required to be notified to Anvisa.

Paragraph 3. Annex III defines the categories of food and packaging with mandatory communication to the health authority of the State, Federal District, or Municipality of the start of manufacture or import.

Paragraph 4. Annex IV defines the categories of food and packaging that are not subject to regularization with the Brazilian Health Surveillance System (SNVS, in Portuguese).

Paragraph 5. Annex V establishes the general documents required to support marketing authorization requests.

Paragraph 6. Annex VI establishes the additional documents required to support marketing authorization requests, per product category.

Paragraph 7. Annex VII establishes the documents required to support marketing authorization revalidation requests.

Paragraph 8. Annex VIII defines the types of post-marketing authorization changes, their purpose, implementation conditions, and the documents required to support post-marketing authorization change requests.

Paragraph 9. Annex IX defines the document that must be submitted with the justifications for making post-marketing authorization changes.

Paragraph 10. Annex X establishes the documents required to support notifications, according to product category.

Paragraph 11. Annex XI establishes the form with the mandatory information that must be included in the notice of the start of product manufacture or import.

Article 2. This Normative Instruction shall come into force on 1 September 2024.

ANTONIO BARRA TORRES

Director-President

ANNEX I

CATEGORIES OF FOODS WITH MANDATORY MARKETING AUTHORIZATION WITH ANVISA

1.	Dietary therapeutic formula for inborn errors of metabolism
2.	Follow-on infant formula for infants and young children
3.	Infant formula intended for specific dietary therapeutic needs
4.	Infant formula for infants
5.	Standard formula for enteral nutrition
6.	Modified formula for enteral nutrition
7.	Pediatric formula for enteral nutrition
8.	Module for enteral nutrition

ANNEX II

CATEGORIES OF FOODS AND PACKAGING WITH MANDATORY NOTIFICATION TO ANVISA

1.	Desalinated, potable, and bottled seawater
2.	Foods with claims of functional property and/or health
3.	Transitional foods for infant feeding
4.	Foods for weight control
5.	Cereals for infant feeding
6.	Food-grade PET-PCR resin
7.	Precursor article or final packaging of food-grade PET-PCR
8.	Food supplements

ANNEX III

CATEGORIES OF FOODS AND PACKAGING WITH MANDATORY COMMUNICATION TO THE STATE, FEDERAL DISTRICT, OR MUNICIPAL HEALTH AUTHORITY OF THE START OF MANUFACTURE OR IMPORT

1.	Sugar, inverted liquid sugar, confectionery sugar, candy, bonbons, cocoa powder, soluble cocoa, chocolate, white chocolate, chewing gum, cocoa butter, cocoa mass, molasses, and brown sugar
2.	Food additives, including chemical leavening agents, tabletop sweeteners, and dietary sweeteners
3.	Dietary foods with nutrient restriction, foods for diets with controlled intake of sugars, and low-sodium salt
4.	Starches, biscuits, whole grains, processed grains, bran, flours, whole grain flours, pasta, and breads
5.	Coffee, barley, teas, yerba mate, spices, seasonings, and sauces
6.	Technological adjuvants, including biological yeasts, microbial cultures, enzymes, and enzyme preparations
7.	Edible mushrooms, fruit products, and vegetable products
8.	Food packaging, including final food-grade PET-PCR packaging when these are made from a notified precursor article
9.	Edible ice cream and preparations for edible ice cream
10.	Ice, natural mineral water, natural water, and waters with added salts
11.	Mixtures for preparing food and ready-to-eat foods
12.	Vegetable oils and fats
13.	Salt enriched with iodine

ANNEX IV

CATEGORIES OF FOOD AND PACKAGING EXEMPTED FROM REGULARIZATION WITH THE BRAZILIAN HEALTH SURVEILLANCE SYSTEM

1.	Food raw materials
2.	Natural food
3.	Food equipment, including those for domestic use
4.	Food products and ingredients, including food additives and technological adjuvants, prepared in accordance with standards that establish their composition, quality, safety, and labeling requirements and that are used exclusively in the production of processed foods
5.	Food products handled and prepared in food services when intended for direct sale to the consumer, such as bakery products, pasta products, pastries, confectionery products, sweets, rotisseries, ice cream products, bar products, restaurants, canteens, food and nutrition units of health services, schools, daycare centers, among others

ANNEX V

GENERAL DOCUMENTS REQUIRED FOR THE SUBMISSION OF MARKETING AUTHORIZATION APPLICATIONS

1.	Marketing authorization request form duly completed, according to the model available in Anvisa's system
2.	Copy of the valid health license of the manufacturer(s) that perform production, quality control, and storage activities, located in Brazilian territory or document proving regularity with the health authority of the country of origin, in the case of manufacturer(s) located abroad
3.	Proposed labeling information for the product
4.	Report containing qualitative and quantitative information on the added ingredients, including additives and technological adjuvants. The specifications adopted must be presented in accordance with specific technical regulations
5.	Analytical report/certificate of analysis of the ingredients, including additives and technological adjuvants, in accordance with specific technical regulations
6.	Analytical report/certificate of analysis of the final product object to the request (pilot batch or industrial batch)
7.	Report of stability studies that ensure maintenance of the nutritional properties of the product throughout their declared shelf life, including post-reconstitution studies in the case of dilution formulas
8.	Technological and safety justification for adopting an overdose, when necessary
9.	Proof of treatment to destroy *Clostridium botulinum* spores, when the product is added with honey and intended for children between 1 and 3 years old
10.	Proof that all ingredients are gluten-free, when the product is indicated for children under 3 years old

ANNEX VI

ADDITIONAL DOCUMENTS REQUIRED FOR THE SUBMISSION OF MARKETING AUTHORIZATION APPLICATIONS PER PRODUCT CATEGORY

Category	**Submission documents**
Diet therapy formula for inborn errors of metabolism	1 2 3 (when applicable)
Modified formula for enteral nutrition	3 4 5 (when applicable)
Pediatric formula for enteral nutrition	3 4 (when applicable) 5 6 (when applicable)
Standard formula for enteral nutrition	3
Module for enteral nutrition	3
Infant formula for infants and follow-on infant formula for infants and young children	7 (when applicable) 8 (when applicable)
Infant formula intended for specific dietary therapy needs	7 (when applicable) 8 (when applicable) 9 10 (when applicable) 11 (when applicable)
Submission document code	

1.	Technical-scientific report presenting full scientific evidence supporting the safety and necessity of the presence or absence, in the formula, of substances associated with inborn errors of metabolism for which the product is indicated.
2.	Technical-scientific report presenting full scientific evidence supporting the suitability, safety, and benefit of the product to meet the nutritional needs of the individuals for whom it is intended, considering the product ready for consumption, according to the preparation and use instructions indicated by the manufacturer on the label, and the specific age groups for which the product is indicated.
3.	Report containing the results of studies ensuring that the product presents adequate homogenization and viscosity for administration in a tube.
4.	Technical-scientific report presenting all modifications made to the product and full scientific evidence supporting its safety and suitability to meet the special needs of patients due to physiological changes, metabolic changes, diseases, or health problems.
5.	Technical-scientific report presenting the references used to justify the limit of each constituent in order to meet the specific nutritional needs of the age groups for which the product is indicated, including full scientific evidence proving its safety and suitability to the specific nutritional needs of the individuals for whom it is intended.
6.	Technical-scientific report presenting proof and full scientific evidence that, for the nutritional claims used, the criteria defined in the specific technical regulation are appropriate for the indicated age group, considering the specific nutritional needs of the public for whom the product is intended; or full scientific evidence supporting criteria different from those established in the specific technical regulation, in order to consider any specific nutritional needs for which the product is intended.
7.	Technical-scientific report presenting full scientific evidence proving the safety and suitability of the formula for the growth and development of infants and young children (in the age range for which the product is intended).
8.	Technical-scientific report presenting full scientific evidence demonstrating that the addition of optional ingredients is done in a way that provides compounds normally found in human milk and necessary to ensure that the formulation is suitable as the sole source

	of nutrients for the infant or, when intended for use from the 6th month onwards, as a source for a mixed food diet.
9.	Technical-scientific report presenting full scientific evidence supporting the safety and efficacy of the formula to meet specific needs resulting from physiological changes and/or temporary or permanent diseases and/or to reduce the risk of allergies in predisposed individuals, according to the age range for which it is intended.
10.	Technical-scientific report presenting full scientific evidence demonstrating the effectiveness of adding chromium and/or molybdenum to the formula for its intended purpose and for the age group for which it is intended.
11.	Technical-scientific report presenting full scientific evidence demonstrating that the addition of optional ingredients is done in a way that provides dietary management resulting from physiological changes and/or temporary or permanent diseases and/or to reduce the risk of allergies in predisposed individuals.

ANNEX VII

DOCUMENTS REQUIRED FOR SUBMITTING MARKETING AUTHORIZATION REVALIDATION REQUESTS

1.	Revalidation request form duly completed, according to the model available in Anvisa's system.
2.	Copy of the valid health license of the manufacturer(s) that performs production, quality control, and storage activities, located in Brazilian territory or document proving regularity with the health authority of the country of origin, in the case of manufacturer(s) located abroad.

ANNEX VIII

TYPES OF POST-MARKETING AUTHORIZATION CHANGES, THEIR PURPOSE, IMPLEMENTATION CONDITIONS, AND DOCUMENTS REQUIRED FOR SUBMITTING POST-MARKETING AUTHORIZATION CHANGES REQUESTS

Type of post-marketing authorization change	**Purpose of the post-marketing authorization change**	**Submission documents**	**Implementation Condition**
Change in product designation	Include or exclude information about the nature or characteristics of the product in its designation.	2	After a 30-day analysis period.
Inclusion of brands	Include or replace brands or trade names of the product.	2	After a 30-day analysis period.
Exclusion of brands	Exclude brands or commercial names of the product	1 2	Without prior approval from Anvisa.
Change in instructions for use	Change information on the label that guides the consumer on the preparation, handling, or consumption of the product.	2 9	After approval by Anvisa.
Change of the indicated population group	Expand or restrict the population group for which the product is indicated.	2 9	After approval by Anvisa.
Change of labeling	Change mandatory and optional labeling texts that are not covered by another specific type of post-marketing authorization change.	2 3	After a 30-day analysis period.
Extension of the expiration date	Extend the expiration date stated on the label of the product granted marketing authorization. Including the consumption period after opening.	2 6	After approval by Anvisa.
Reduction of the expiration date	Reduce the expiration date stated on the label of the product granted marketing authorization. Including the consumption period after opening.	2 6	After a 30-day analysis period.

Change of preservation precautions	Change of reservation precautions related to the product's exposure conditions (temperature, light, and humidity) stated on the label of the product granted marketing authorization.	2 6	After approval by Anvisa.
Inclusion of Presentation	Include a new presentation for the product with: · Different type or quantity of coloring or flavoring additive or other ingredient used to give color, flavor, or aroma to the product; or · Different material or type of packaging for the product.	2 3 5 6 or 7 8 (when applicable)	After approval by Anvisa.
Change in product packaging	Change the type of packaging or materials used in the production of the product packaging.	2 6 or 7	After approval by Anvisa.
Inclusion and/or replacement of establishments involved in manufacturing	Inclusion and/or replacement of an establishment involved in the production, quality control, or storage of the food granted marketing authorization.	2 4 6 or 7 (when applicable)	After a 30-day analysis period.
Exclusion of establishments involved in manufacturing	Exclude an establishment in production, quality control, or storage of the food granted marketing authorization.	1 2	Without prior approval by Anvisa.
Change in activities of establishments involved in manufacturing	Change the activities carried out by an establishment involved in production, quality control, or storage of the food granted marketing authorization.	1 2	Without prior approval by Anvisa.
Change in formula	Quantitative change of ingredients and/or addition of a new ingredient and/or exclusion of an ingredient.	2 3 5 6 or 7 8 (when applicable)	After approval by Anvisa.

		9	
Change in product specification	Change the specification of the product granted marketing authorization without changing its formulation and composition and safety requirements.	2 5 6 or 7	After approval by Anvisa.
Change in ingredient specification	Change the specification of the product ingredient (including change of supplier) without changing the formulation and specification of the product granted marketing authorization.	2 6 or 7 8	Without prior approval by Anvisa.
Codes for submission documents			
1.	Marketing authorization request form filled out only with the information applicable to the proposed change.		
2.	Justifications for the post-marketing authorization change, including a detailed description and rationale for the proposed change, in accordance with Annex IX.		
3.	Labeling information.		
4.	Copy of the valid health license of the manufacturer(s) that perform production, quality control, and storage activities, located in Brazilian territory or document proving regularity with the health authority of the country of origin, in the case of manufacturer(s) located abroad.		
5.	Analysis report demonstrating compliance with the specifications adopted for the product.		
6.	Stability study report that guarantees the nutritional properties of the product throughout its declared shelf life, including post-reconstitution studies in the case of formulas for dilution.		
7.	Technical report with rationale supporting the non-performance of prior stability studies, accompanied by a statement that stability studies will be performed to monitor the product under the new conditions, with due communication to Anvisa in cases of out-of-specification results.		
8.	Ingredient analysis report demonstrating compliance with the adopted specifications.		

9.	Documents established in Annexes V and VI that ensure maintenance of the composition and safety requirements of the product granted marketing authorization.

ANNEX IX

DOCUMENT WITH JUSTIFICATION FOR MAKING THE POST-MARKETING AUTHORIZATION CHANGE

Justifications for making the post-marketing authorization change
Description of the request (Report containing the proposed change requested, including a comparison of the product's situation before and after. When there are interdependent changes, indicate linked petitions).
Reason for the request (Motivation for the proposed change, including the technical argument for making the change. When applicable, supporting documentation for the reason must be attached).
I declare that no change other than that proposed above will be made and that the information contained in the labeling text will be changed in accordance with the request described above.
Name of the legally responsible person

ANNEX X

DOCUMENTS REQUIRED FOR THE SUBMISSION OF NOTIFICATIONS, PER PRODUCT CATEGORY

Category	**Submission Documents**
Desalinated, potable and bottled seawater	1 2 4 8
Foods with functional and/or health claims	1 2 3 4
Transitional foods for infant feeding	1 2 3 4 7
Weight control foods	1 2 3 4
Cereals for infant feeding	1 2 3 4
Food-grade PET-PCR resin	1 2 5 9

Precursor article or final packaging obtained from food-grade PET-PCR resin	1 2 6
Food supplements	1 2 3 4
Codes for submission documents	
1.	Notification form duly completed, according to the specific model for the category available in Anvisa's system.
2.	Copy of the valid health license of the manufacturer(s) that perform production, quality control, and storage activities, located in Brazilian territory or document proving regularity with the health authority of the country of origin, in the case of manufacturer(s) located abroad.
3.	Report of stability studies that guarantee the nutritional properties of the product throughout its declared shelf life, including post-reconstitution studies in the case of products for dilution.
4.	Technical report/Certificate of analysis or calculation report of the product proving compliance with the composition requirements established by the specific technical regulation.
5.	Technical reports proving that the packaging obtained from food-grade PET-PCR resin complies with the health regulations for plastic materials.
6.	Technical reports proving that the packaging obtained from the precursor article or the final packaging, as applicable, comply with the health regulations for plastic materials.
7.	Analytical report on solid matter, pH, and nitrate expressed in NO3 ions, for the purpose of verifying the requirements established in the specific technical regulation.
8.	Copy of the authorization for water collection and licenses issued by the competent environmental agencies.
9.	Special authorization for use (letter of no objection, approvals, or decisions) of food-grade PET-PCR, issued by the **Food and Drug Administration (FDA)**, the **European Food Safety Authority (EFSA)**, the **Directorate General of Health and Consumer Protection** of the

	European Commission, the Competent Health Authorities of the Member States of the European Union or by an authority agreed upon within the scope of MERCOSUR.

ANNEX XI

FORM FOR NOTIFICATION OF START OF PRODUCT MANUFACTURE OR IMPORT

Notification of start of product manufacture or import	
1.	Data of the regularization holder: CNPJ: Corporate name:
	Address: (Street, number, neighborhood, city, state, and zip code) Telephone: E-mail:
2.	Data of the manufacturing unit(s) **1** of the food or packaging, or of the storage unit(s) of the food or packaging for imported products: CNPJ: Corporate name:
	Address: (Street, number, neighborhood, city, state, and zip code) Telephone: E-mail: Corporate name of the manufacturer abroad and country of origin (when applicable): **1** when the product has more than one manufacturing unit
3.	Product(s) data **2**: Category: (as described in Annex III of this Normative Instruction) Product designation: (as defined in specific technical regulation) Brand(s) or trade name:
	Type(s) of packaging: Validity period: (may be informed in years, months or days) **2** products that have the same manufacturers or the same importer and storage units may be included in a single form.
4.	Data on the trademark(s) holder **3**: Trademark:

	CNPJ: Corporate name:
	Address: (Street, number, neighborhood, city, state, and zip code) Telephone: E-mail: **3** Fill in only when the trademark holder is different from the regularization holder.
5.	Commercial perspective: (municipal, state, national, and/or export)
	Term of Responsibility: I hereby inform that as of ____ /_____ /_____, the company identified above, duly licensed for (manufacturing/importing food/packaging), began manufacturing/importing the product(s) described above, and its commercialization will begin within _____ days.
	I hereby declare that I comply with the current health regulations applicable to the above product(s), and that the product(s) complies with all the composition, quality, safety, and labeling requirements set forth in specific technical regulations.
6.	I further declare that all the evidence required to prove the quality and safety requirements of the product(s) has been provided and is available for consultation by the health authority at any time. Finally, I am aware that the company identified above may be inspected by this health authority and that failure to comply with the requirements set forth in the health legislation constitutes a violation of federal health legislation, with the offending company being subject, in the administrative sphere, to the penalties provided for in Law No. 6,437 of 20 August 1977, without prejudice to any applicable civil or criminal sanctions. In the legal sphere, its Legal Representatives are responsible for acts of infraction committed by the company, in accordance with the infractions and sanctions provided for in Decree Law No. 2,848, of 7 December 1940 (Criminal Code – Chapter III: Crimes against Public Health).