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This is an informative newsletter produced by the **Life Sciences and Healthcare** practice of TozziniFreire Advogados.

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Anvisa Approves Changes to RDC on Food Additives

On May 15, 2025, the National Health Surveillance Agency (Anvisa in Portuguese) published Resolution RDC No. 975/2025, which amends RDC No. 778/2023 – regulation that outlines the general principles, technological functions, and conditions for the use of food additives and technological aids in food.

The main change introduced in the new RDC is the extension of the deadline for adjusting food labels that contain food additives declared in the ingredient list, whose INS number or denomination has been updated according to Annex III of Normative Instruction - IN No. 211. As a result, the new deadline is now March 31, 2026.

The regulation also stipulates that products manufactured until the end of the adjustment period may be sold until the end of their expiration date, provided that the manufacturing date is clearly indicated on the label.

RDC No. 975/2025 came into effect on the date of its publication in the Federal Register.[1]

Anvisa Publishes New Public Inquiry on the List of Over-the-Counter Medications (LIMP)

On May 14, 2025, the National Health Surveillance Agency (Anvisa) published Public Inquiry No. 1,331/2025 in the Federal Register. The goal of the proposal is to gather comments and suggestions on the draft of Normative Instruction (IN) that amends the List of Over-the-Counter Medications (LMIP in Portuguese), as well as to present the rejections related to requests for the inclusion of new medications.

This new initiative follows Public Inquiry No. 1,320/2025, published on April 14, 2025, which also addressed the update of the aforementioned list.

According to the Agency, the LMIP plays a strategic role in balancing easier access to medication and the rational use of medications. Furthermore, constantly obtaining new scientific data and inserting products into the national market make the review of the LMIP a periodic and necessary measure.

The period for providing inputs for the new inquiry is from May 21, 2025, to June 19, 2025. Interested parties should send their inputs by filling out the electronic form available on the "Anvisa Legis" portal.[2]

1 Avaliable at: https://www.in.gov.br/en/web/dou/-/resolucao-rdc-anvisa-n-975-de-14-de-maio-de-2025-629499532. Access on June 16, 2025.

2 Avaliable at: https://www.gov.br/participamaisbrasil/cp-n-1331-de-09-05-2025-alteracao-da-lista-de-medicamentos-isentos-de-prescricao-e-apresentacao-de-negativas-de-inclusoes-solicitadas-. Access on June 16, 2025.

Anvisa Launches Cycle for Monitoring Pesticide Residues in Food

On May 5, 2025, the National Health Surveillance Agency (Anvisa), along with the State and Municipal Health Surveillance Agencies and the Central Public Health Laboratory of Minas Gerais - Ezequiel Dias Foundation, began collecting samples for the Program for Analysis of Pesticide Residues in Foods (PARA in Portuguese).

Established as a project in 2001 and institutionalized in 2003 by Resolution RDC No. 119/2003, PARA is currently regulated by Anvisa Ordinance No. 1,081, dated September 27, 2023. It is an initiative of the National Health Surveillance System (SNVS in Portuguese), coordinated by Anvisa in collaboration with local health surveillance agencies and state public health laboratories.

The central objective of PARA is to monitor pesticide residues in plant-based foods, aiming to protect public health by reducing the population's exposure to these substances through food. The results obtained support risk assessments and guide actions of health surveillance at national level.

Collections will take place from May 5 to December 5, 2025, covering samples of 13 widely consumed foods: pineapples, peanuts, potatoes, broccoli, coffee (ground), beans, oranges, cassava (flour), passion fruit, strawberries, okra, cabbage, and wheat (flour). The 2023-2025 Multiannual Plan provides for the monitoring of 36 foods, which together make up about 80% of the national consumption of vegetables.[3]

3 Avaliable at: https://www.gov.br/participamaisbrasil/cp-n-1331-de-09-05-2025-alteracao-da-lista-de-medicamentos-isentos-de-prescricao-e-apresentacao-de-negativas-de-inclusoes-solicitadas-. Access on: June 16, 2025.

Anvisa Approves New Normative Instruction on Labeling of Dietary Supplements

On May 15, 2025, Normative Instruction (IN) No. 361/2025 was published in the Federal Register, amending IN No. 28/2018, the regulation responsible for defining lists of constituents, usage limits, permitted claims, and supplementary labeling applicable to dietary supplements.

Some of the main changes introduced are:

1. **Inclusion of Calcidiol as a Source of Vitamin D:** The new regulation includes Calcidiol, derived from Saccharomyces cerevisiae (CAS 63283-36-3), as a source of vitamin D in dietary supplements intended for individuals over 11 years old, including pregnant and lactating women, as provided for in ANNEX I. The requirements for supplementary labeling are included in ANNEX VI.
2. **Change of Footnotes:**

   Footnote iii of ANNEX III and footnote ii of ANNEX IV from: "As Cholecalciferol. 1 µg cholecalciferol = 40 IU vitamin D." to "As Cholecalciferol. 1 µg cholecalciferol = 40 IU vitamin D = 0.3333 µg of calcidiol;"
3. **Inclusion of Opuntia ficus-indica Extract** as a Source of Phenolic Compounds of Opuntia ficus-indica in ANNEX I, with limits defined in ANNEXES III and IV and the requirements for supplementary labeling in ANNEX VI;
4. **Inclusion of Xylo-oligosaccharides as a Source of Xylo-oligosaccharides** in ANNEX I, with limits defined in ANNEXES III and IV and the requirements for supplementary labeling in ANNEX VI;
5. **Inclusion of Authorized Claims for Use in Dietary Supplements of Astaxanthin,** and the requirements for composition and labeling of this substance, included in ANNEX V.

The IN established a period of 24 months for adjusting the labeling of dietary supplements regularized until the date of its publication and that include any of the constituents covered by the new regulation. IN No. 361/2025 came into effect on the date it was published.[4]

4 Avaliable at: https://www.in.gov.br/en/web/dou/-/instrucao-normativa-in-n-361-de-14-de-maio-de-2025-629483562 . Access on: June 16, 2025.

Anvisa Launches Targeted Inquiry on Regulation of Single-Use Medical Devices

On May 13, 2025, the General Management of Health Service Technology (GGTES) and the General Management of Health Product Technology (GGTPS) of the National Health Surveillance Agency (Anvisa) initiated a Targeted Inquiry (CD in Portuguese) exclusively to the National Health Surveillance System (SNVS) regarding proposals for regulation concerning the classification of medical devices as reusable or single-use devices.

The initiative also includes guidelines related to the good practices of processing these medical devices, both in health services and in processing companies.

The objective of the inquiry is to preliminarily share the regulatory proposals with health surveillance agencies throughout the country, in order to evolve them technically before they are submitted to the Collective Board for a Public Inquiry to be opened.

The deadline for inputs is 30 days from May 13, 2025, exclusively for entities of the National Health Surveillance System.[5]

5 Avaliable at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/anvisa-lanca-consulta-dirigida-sobre-dispositivos-medicos-de-uso-unico-e-boas-praticas-de-processamento#:~:text=SNVS-,Anvisa%20lan%C3%A7a%20consulta%20dirigida%20sobre%20dispositivos%20m%C3%A9dicos%20de%20uso%20%C3%BAnico,13%20de%20maio%20de%202025 . Access on: June 16, 2025.

ANS Announces the Launch of the Panel of Policyholders of Collective Plans

On May 8, 2025, the National Agency of Supplementary Health (ANS in Portuguese) announced the launch of the "Panel of Policyholders of Collective Plans," a digital tool that gathers key information about policyholders of collective health plans, a contracting type responsible for over 80% of beneficiaries in Brazil, according to ANS.

The panel will allow users to use different filters to search the database, such as number of policyholders and beneficiaries, as well as specific characteristics related to purchasing companies (business sector, size, and state), plans taken out, operators, and length of stay on the plan.

The new platform will use official data from the Beneficiary Information System (SIB in Portuguese), the official source of ANS to consolidate information provided monthly by operators regarding the admission and exit of beneficiaries. It also integrates registration data of the purchasing companies, as recorded in the Federal Revenue Office's database.

According to ANS's Director of Sector Development, Maurício Nunes, the tool aims to increase transparency and enhance the debate about the profile of the economic sectors that dominate the purchase of plans, while also improving market transparency. ANS's Deputy Director of Sector Development, Angélica Carvalho, emphasized that, in addition to being a regulatory requirement of the Agency, matching data from the Federal Revenue Office's databases and from SIB adds greater reliability to the tool while meeting the Agency's regulatory requirements.[6]

Anvisa Publishes Second Edition of Questions and Answers on RDC No. 894/2024

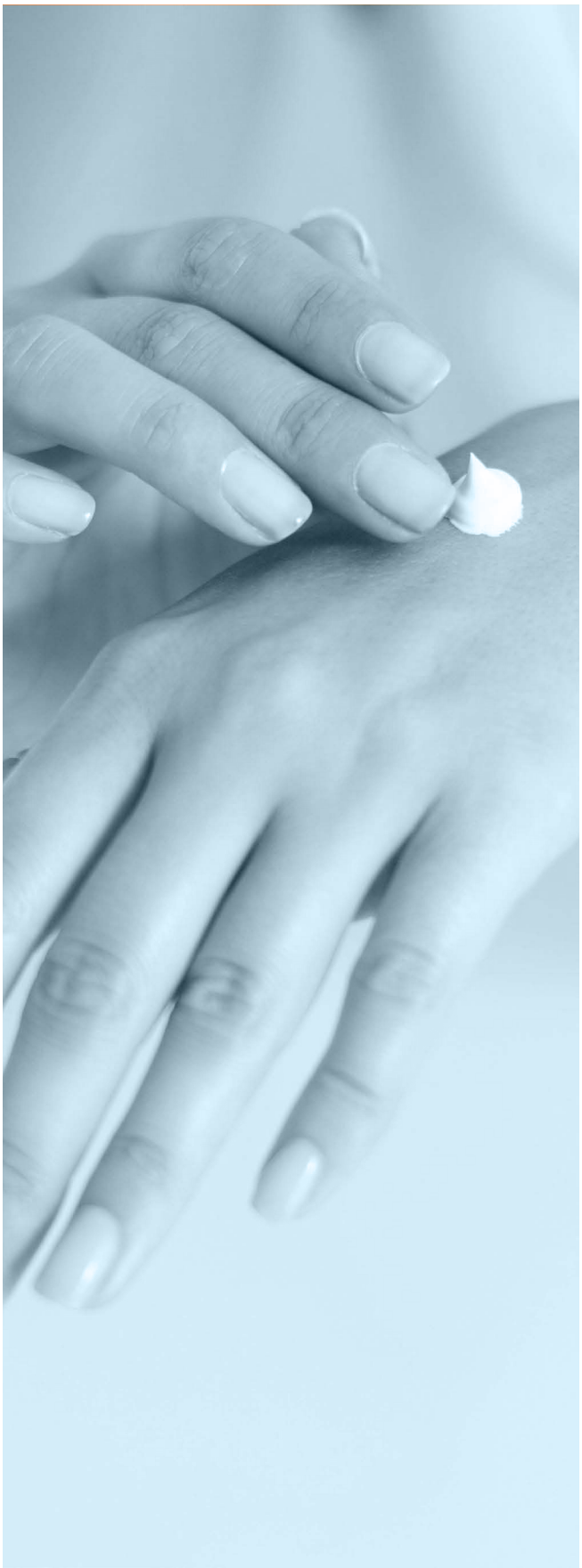
On May 13, 2025, the National Health Surveillance Agency (Anvisa) published the second edition of the "Questions and Answers" material regarding RDC No. 894/2024, which addresses Good Practices in Cosmetics Surveillance and comes into effect on August 28, 2025.

6 Avaliable at: https://www.gov.br/ans/pt-br/assuntos/noticias/sobre-ans/ans-lanca-painel-de-contratantes-de-planos-coletivos. Access on: June 16, 2025.

RDC No. 894/2024 was created to strengthen the surveillance of adverse events and the management of risks associated with the use of personal hygiene products, cosmetics, and perfumes after they enter the market. The new regulation replaces RDC No. 332/2005, providing more robust guidelines for post-marketing monitoring of cosmetic products, focusing on consumer safety and on standardizing industry practices.

According to the Agency, the new material aims to facilitate the understanding of the regulation and support its practical implementation, reinforcing the importance of collaboration among all stakeholders in the production chain and use of cosmetic products, supporting the implementation of RDC No. 894/2024 and clarifying frequently asked questions from companies and other interested parties.

The new edition includes six new questions and answers, created based on the most recurring doubts from the regulated sector regarding the new RDC. The new version is already available for access on Anvisa's website (link).[7]



7 Avaliable at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/anvisa-lanca-segunda-edicao-das-perguntas-e-respostas-sobre-a-rdc-894-2024 . Access on: June 16, 2025.

FDA Launches Internal AI Tool

On June 2, 2025, the Food and Drug Administration (FDA), the health agency of the United States, announced the launch of an artificial intelligence tool that will help enhance the efficiency of its staff.

According to FDA Commissioner Marty Makary, the pilot program was very successful, and an accelerated schedule has been established for expanding the use of AI throughout the agency by June 30, 2025.

Named Elsa, the tool was developed in a Gov Cloud environment and allows FDA employees to access internal documents, ensuring that system information remains entirely within the agency's environment. The model does not use data from sensitive research or from regulated entities, providing additional protection for sensitive research and for information handled by agency staff.

According to FDA's AI Director, Jeremy Walsh, the launch of Elsa marks the beginning of the era of Artificial Intelligence at the agency, emphasizing that AI has transitioned from being a distant promise to becoming an active force that enhances individual performance. He also stated that the tool will evolve as it is used on a daily basis, incorporating functionalities based on the needs of the agency and its employees.

Currently, the FDA is using Elsa to speed up reviews of clinical protocols, shorten the time needed for scientific evaluations, and identify high-priority inspection targets. The idea is that as the tool matures, the agency will integrate more AI into various processes, such as data processing and generative AI functions to further support the FDA's mission.[8]

8 Avaliable at: https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people. Access on: June 16, 2025.

CMED Approves the New Internal Regulations of the Chamber and Promotes Changes to Resolution CMED No. 2/2004

On June 5, 2025, the Drug Market Regulation Chamber of the National Health Surveillance Agency (Anvisa) published Resolution CMED No. 02/2025, which approved the update of the Internal Regulations of the Chamber and amendments to Resolution CMED No. 2/2004, which governs the criteria for setting prices for new products and new presentations.

After 21 years in force, the Internal Regulations governed by Resolution CMED No. 3/2003 were replaced with the 2025 resolution. The Chamber's main objectives with the new regulation are:

1. Updating the tasks and attributions of the bodies that make up CMED;
2. Regulating the representation of bodies, the organization, and functioning of meetings;
3. Increasing predictability regarding administrative processes and procedures;
4. Imbuing modernity, agility, and improved governance to the administrative processes under its jurisdiction;
5. Optimizing the work developed by the Executive Secretariat (SCMED), in synergy with the Executive Technical Committee (CTE) and the Council of Ministers (CM); and
6. Strengthening legal certainty in the Chamber's decisions.

The main changes brought in by the New Regulation include:

- Exclusion of the Council of Ministers as a judging body in cases of omissions, amending Resolution CMED No. 2/2004.
- Appointment of up to four substitutes for representatives of the Executive Technical Committee (CTE).
- CTE's decision by simple majority in the judgment of administrative sanctioning processes.
- Expected annual ordinary meeting of the Council of Ministers.
- Redefinition of procedural deadlines.
- Possibility of making decisions via Virtual Decision-Making Circuit.
- New rules for situations of impediment.
- New rules for CTE to issue statements.
- New rules for cases of confidentiality and restricted access.
- New rules regarding the communication of CMED's procedural acts and the practice of procedural acts by the administrated party.

- Transparency measures: publication of an annual report of CMED's activities, publication of decisions, monitoring of processes by the parties.

The new Internal Regulations will come into effect on July 5, 2025 (30 days after publication, which occurred on June 5, 2025).[9]

Anvisa Publishes New RDC on Laboratory Tests (EAC)

On July 10, 2025, Collective Board Resolution RDC No. 978/2025 was published in the Federal Register (DOU in Portuguese), revoking RDC No. 786/2023 and establishing the technical and sanitary requirements for the operation of health services that perform activities related to Laboratory Tests (EAC in Portuguese).

The new regulation arises from the difficulties in implementing RDC No. 786/2023, which resulted in emergency amendments (RDC No. 824/2023) and, subsequently, in a textual and structural revision, aiming to enhance regulatory clarity without compromising the substantive regulatory content.

Key changes:

1. **New Wording:** The regulation has been rewritten in a clearer and more objective manner, replacing ambiguous terms and facilitating understanding and supervision.
2. **Regulation of Mobile EAC:** The parameters applicable to Mobile EAC Services have been improved, providing greater parity with other services (Type I, II, and III). Clear normative provisions have been created for quality control and the types of EAC and biological materials that can be collected.
3. **Reinforcement of Technical Requirements:** Type I and II Services must perform all stages of tests (pre-analytical, analytical, and post-analytical) on-site, including quality controls (CIQ and CEQ). Conducting controls outside the service is expressly prohibited.
4. **Classification of Isolated Offices:** Isolated offices are classified as Type I Service (ST I) or Type II Service (ST II), depending on the activity performed, with three defined categories:

   a) Office that does not perform EAC;

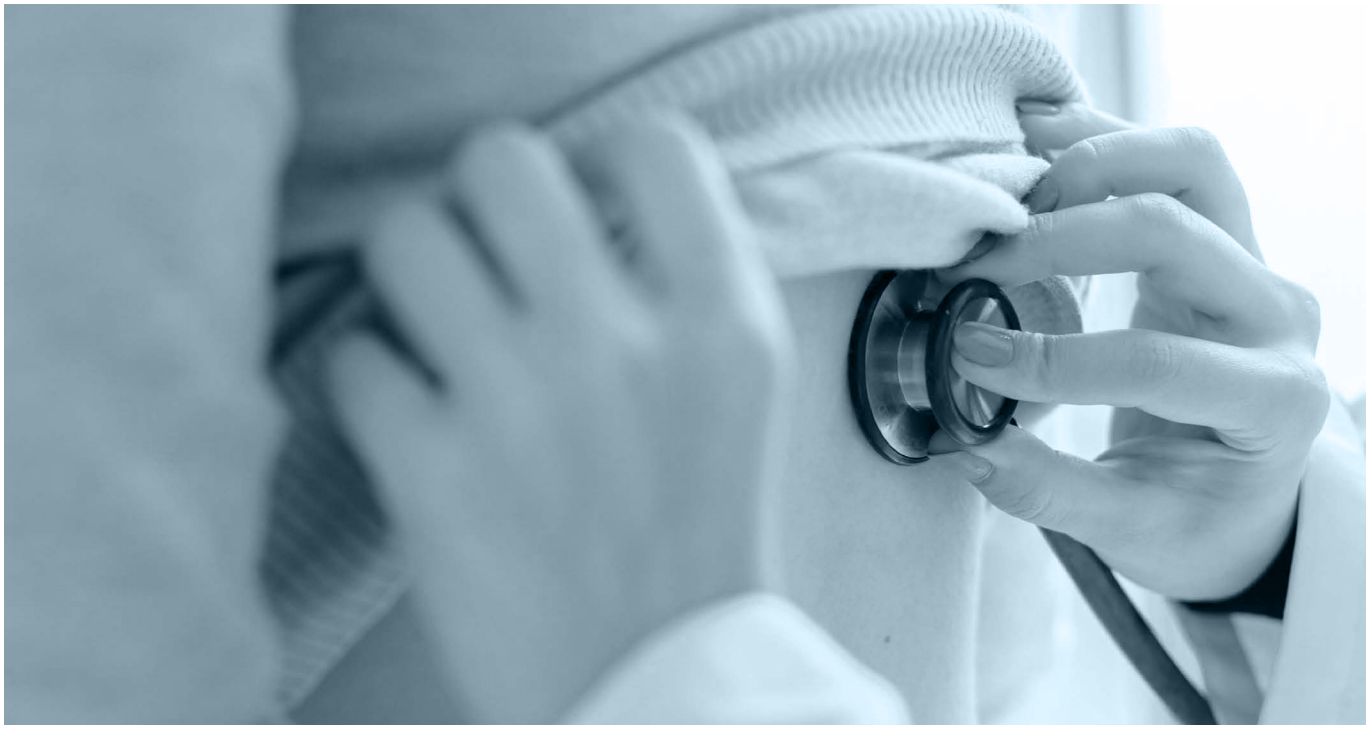
   b) Office that performs EAC sporadically (ST I);

   c) Office that performs EAC and collects, stores, and transports biological material (ST II).

9 Avaliable at: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/Regulacao/processo-de-revisao-da-resolucao-cmed-no-2-2004. Access on: June 16, 2025.

5. **Health Assistance Establishment (EAS) with Public Administration Legal Nature:** The nomenclature has been standardized to identify the EAS, with expected infrastructure adaptation while maintaining quality parameters for the public sector.
6. **Regulation of Distribution Center:** The Distribution Center (CD in Portuguese) is regulated as an integral part of the quality chain of tests and needs a sanitary permit and a technician responsible for storing and transporting biological material.
7. **Quality Control Management:** The regulation updates the documentary requirements, including a mandatory External Quality Control Performance report, which must be issued by a Proficiency Testing Provider at least annually.
8. **Updates and Monitoring:** Anvisa will update the "Questions and Answers" document to reflect the changes in the regulation and plans to conduct a new Regulatory Outcome Evaluation (ARR in Portuguese) to monitor implementation.

With these changes, Anvisa expects to reduce regulatory uncertainties, ensure greater legal certainty for the regulated sector, and facilitate oversight by local health authorities. Resolution RDC No. 978/2025 came into effect on June 10, 2025, and health services have until September 8, 2025, to comply with the new guidelines.[10]



10 Avaliable at: https://www.in.gov.br/en/web/dou/-/resolucao-anvisa-n-978-de-6-de-junho-de-2025-635044217 . Access on: June 16, 2025.

Anvisa Publishes New RDC on Infant Formulas and Transitional Foods

On June 11, 2025, the Collective Board Resolution RDC No. 976/2025 was published in the Federal Register. It addresses the sanitary requirements applicable to infant formulas, nutrient formulas for high-risk newborns, transitional foods, and cereal-based foods for infants and young children, enteral nutrition formulas, and dietary formulas for inborn errors of metabolism.

The new Resolution replaces nine normative acts, including RDCs No. 42 to 45 from 2011, No. 21 and 22 from 2015, and No. 460 from 2020, as well as SVS/MS Ordinances dated 1998.

Key changes:

1. **Normative Consolidation:** The new RDC unifies various separated regulatory norms, with clearer organization by product category and a structure adapted for periodic updates.
2. **Restriction on the Use of Sugars:** Based on recommendations from the WHO, the Dietary Guidelines for Brazilian Children Under 2 Years, and in accordance with the Codex Alimentarius, the new regulation:
   a. Prohibits the use of fructose, sucrose, maltose, and honey as carbohydrate sources in infant formulas.
   b. Allows the use of glucose syrup only in formulas with hydrolyzed proteins and under specific limits (maximum of 2g/100 kcal).
   c. Transitional foods and cereal-based products are also subject to sugar restrictions: the limit is 2.5g/100 kcal for sugars added in cereals, and the use of honey and sugar is prohibited in transitional foods.
3. **New Labeling Criteria:** The RDC requires the adoption of clearer and standardized language on labels, including the obligation to indicate the age range on the products and the prohibition of health and functional claims for transitional foods and cereals, aligning with international standards.
4. **Composition and Updates:** The lists of authorized constituents have been updated, incorporating new ingredients as indicated by the opinions provided. Updates will be made periodically based on technical-scientific evidence and petitions submitted to Anvisa.
5. **Enteral Nutrition Formulas:** The regulation revises the composition requirements for the various categories of enteral formulas, including:
   a. Permission for specific modifications in composition based on clinical needs.
   b. Restrictions on the use of certain sugars in pediatric enteral formulas.

c. Updates to legislative techniques and exclusion of redundant provisions.

6. **Dietary Formulas for Inborn Errors of Metabolism:** The restriction on the use of sugars such as honey, sucrose, and fructose has been maintained, except in cases where fructose is clinically indispensable.
7. **Adjustment Period:** The regulated sector will have 24 months to comply with the new requirements, especially regarding product labeling. The transition from registered products to notified products for cereal transitional foods has also been regulated.

The new regulation has low regulatory impact, according to the assessment of the National Health Surveillance Agency (Anvisa) itself, but brings in significant structural effects:

- Standardization and Simplification of Regulatory Obligations, enhancing predictability and legal certainty.
- Reduction of Risks to Child Health, especially related to excessive sugar consumption.
- Alignment with International Standards, facilitating exports and enhancing the competitiveness of the national industry.
- Increased Responsibility in Formulation and Labeling, requiring companies to take

immediate actions for marketing and portfolio review.

In addition to the RDC, a Normative Instruction (IN) was published establishing the lists of constituents, usage limits, and claims for products regulated by RDC No. 976/2025. Divided into annexes, the IN sets limits on various aspects:

- **Annex I:** Defines the constituents that are sources of nutrients, substances, and probiotics permitted in formulas for infants and young children, as well as pediatric formulas for enteral nutrition and dietary formulas for inborn errors of metabolism. It specifies that CAS numbers for constituents refer to anhydrous substances and accepts different degrees of hydration, as long as they comply with the specifications of Anvisa Resolution No. 976.
- **Annex II:** Establishes minimum and maximum limits and conditions for use of nutrients and optional substances in infant formulas.
- **Annex III:** Presents the authorized nutritional claims for infant formulas.
- **Annex IV:** Defines minimum and maximum limits of nutrients and optional substances in transitional foods and cereals for infants and young children.
- **Annex V:** Establishes authorized constituents for enteral nutrition and dietary formulas for individuals over 3 years old, with the same considerations regarding CAS numbers and hydration.
- **Annex VI:** Defines minimum and maximum limits of nutrients and optional substances for standard enteral nutrition formulas.
- **Annex VII:** Establishes limits for pediatric enteral nutrition formulas for individuals over 3 years old.
- **Annex VIII:** Presents the authorized nutritional claims for enteral nutrition formulas.

The new RDC represents a milestone for the sector of food regulated by Anvisa, especially in categories aimed at feeding populations such as infants and patients with specific nutritional needs. The normative consolidation, restrictions on sugar use, and the expected periodic updates of ingredient lists establish a more coherent, technical, and updated regulatory environment, demanding companies to pay greater attention when complying with the requirements.

Resolution RDC No. 976/2025 came into effect on June 11, 2025, date in which it was published.[11]

11 Avaliable at: https://www.in.gov.br/web/dou/-/resolucao-anvisa-n-976-de-5-de-junho-de-2025-635345132 . Access on: June 16, 2025.

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