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ANVISA Publishes Public Consultations on Food Labeling

The National Health Surveillance Agency (ANVISA) launched two public consultations in early November aimed at modernizing the labeling regulations for packaged foods. These proposals are part of the Regulatory Agenda 2024–2027 and seek to revise both general labeling and nutritional labeling of products.

(i) Public Consultation No. 1,357/2025 addresses the general labeling of packaged foods, while (ii) Public Consultation No. 1,358/2025 specifically deals with nutritional labeling.

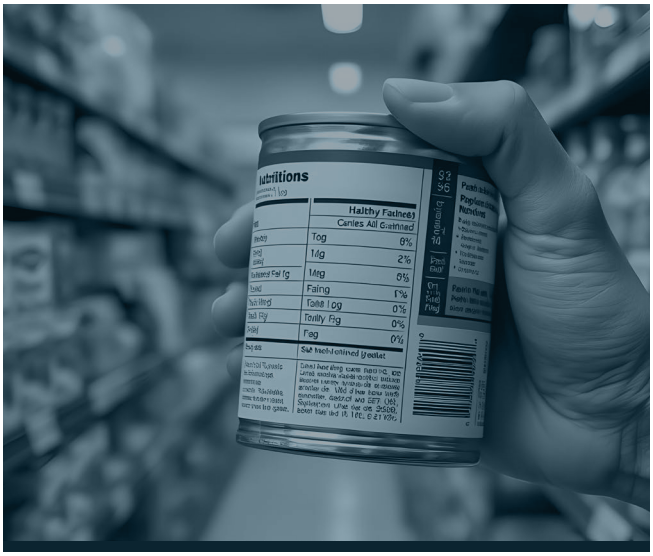
Both proposals for the regulations suggest new definitions, prohibitions, and exemptions in specific cases.

The first establishes changes to the declaration of allergens and derivatives, the origin and responsibility for the products, the use of the expression "EXCLUSIVELY INDUSTRIAL USE" or another equivalent term for foods intended solely for industrial processing, and reduces the threshold for the percentage presence of composite ingredients from 25% to 5% to exempt the description of their constituents in the ingredient list, among other changes.

Additionally, the proposed draft includes a specific section on the location and legibility of mandatory information, including information and models regarding font, size, contrast, specific to each mandatory textual element, etc., as well as regulating exceptional cases (such as reduced labeling surface).

A general adjustment period of 36 months from the publication of the regulation is proposed, reduced to 12 months for products intended exclusively for industrial processing or food service, and extended to 48 months for small-scale, artisanal manufacturers, etc.

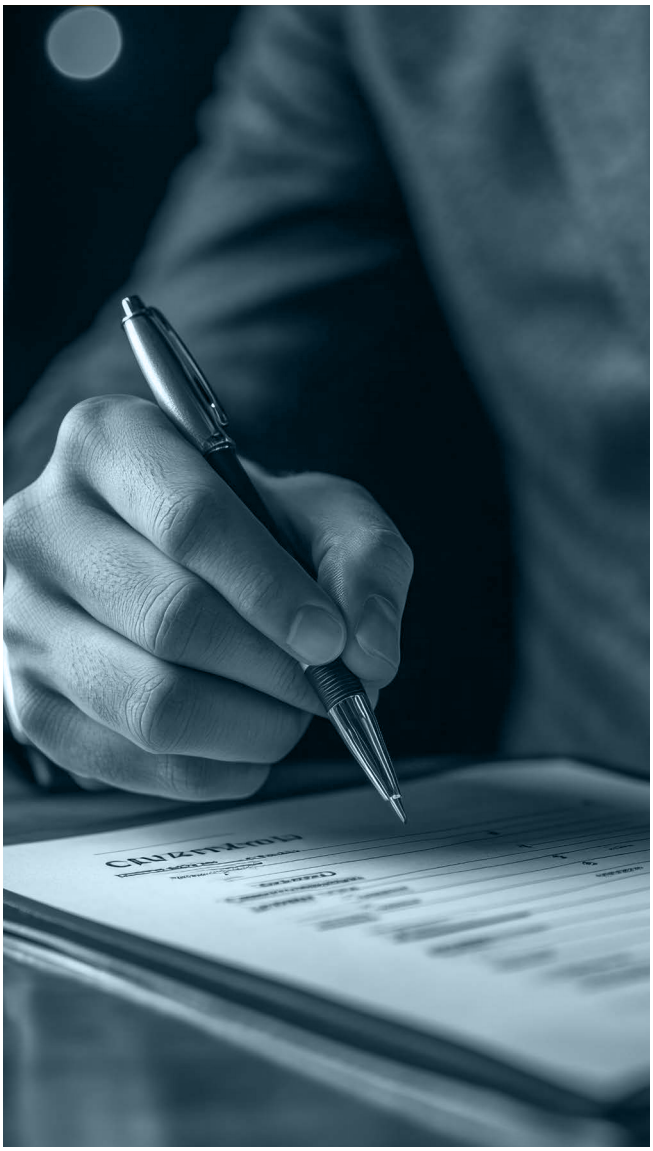
The draft regarding nutritional labeling introduces new guidelines on rounding energy and nutrient values, declaration of non-significant amounts of energy and nutrients, number



of servings contained in the food packaging, declarations involving multiple individually packaged units, among others.

Besides revoking ANVISA Resolution No. 429/2020, the proposed regulation also aims to revoke the ANVISA Normative Instruction (IN) ANVISA No. 75/2020, updating and incorporating all the technical details brought by it.

The two public consultations are part of the process of reviewing and updating the regulatory framework applied to packaged foods in Brazil, which will define the format and content of labels to be adopted by the food sector in the coming years. Contributions should be made on the ANVISA website until March 9, 2026.



Federal Council of the OAB Requests ANVISA to Create a Dedicated Support Channel for Lawyers

The Federal Council of the Brazilian Bar Association (CFOAB) submitted a request to ANVISA for the creation of an exclusive support channel for lawyers, so that they are not contacted through the same channel as the general public.

This measure aims to ensure a swifter response for professionals in the field, especially regarding urgent demands.

The National Prosecutor for the Defense of Prerogatives, Alex Sarkis, highlighted that "without a specific channel, urgent requests get stuck in generic flows. A differentiated service ensures agility and efficiency in professional practice." He also stressed that the proposal does not represent institutional conflict but rather a collaborative construction between entities: "It is not about confrontation, but institutional dialogue. The aim is to build solutions that benefit the functioning of public service and justice as a whole."[1]

[1] Avaliable at: https://www.oab.org.br/noticia/63517/oab-solicita-a-anvisa-criacao-de-canal-exclusivo-para-advocacia-acessar-processos-administrativos

STJ Concludes Judgment on the Legal Nature of Discount Cards and Regulatory Competence of ANS

On October 14, 2025, the Superior Court of Justice (STJ) concluded the judgment of the last pending appeal in the Public Civil Action brought by the Federal Public Ministry (MPF), which discussed the legal nature of discount cards for health services and the potential omission of the National Supplementary Health Agency (ANS) regarding the regulation of this model.

The issue had been under review since a decision issued in October 2023 by Minister Herman Benjamin in the Internal Appeal in Special Appeal (REsp) No. 2.183.704. The minister had acknowledged that discount cards could mislead consumers due to their characteristics being similar to health insurance, concluding in favor of the requests made by the MPF.

However, ANS opposed the declaration of embargos, arguing that discount cards do not constitute health insurance since they do not involve coverage guaranteed by an operator but merely provide discounts on consultations and procedures paid directly by the consumer to the provider. Therefore, the Agency argued that such instruments do not fall under the regulatory framework governed by Law No. 9.656/1998, thus not being subject to its regulatory competence.

With the ruling on the embargos, the STJ closed the case analysis, consolidating the understanding already established by the Court, thereby requiring ANS to regulate and oversee the issue.

ANS Approves Amendment to RN No. 137/2006, Aiming to Modernize the Self-Management Model in Health Plans

On October 31, 2025, ANS approved Normative Resolution (RN) No. 649/2025, which proposes a revision of RN No. 137/2006, the standard governing the operations of self-managed operators in the supplementary health system.

The update follows a diagnosis by the Agency itself indicating that the previous regulation from 2006 generated disproportionate burdens and affected the economic sustainability of the entities.[2]

The new regulation modernizes the concept of self-management without straying from the main scope and expands the possibilities of organization for operators. Some updates encompass the inclusion of different professional categories within the same group of beneficiaries; the sharing of assistance networks with operators of other modalities; and an expanded definition of family groups.

Another relevant point is the provision that up to 10% of beneficiaries may use the health insurance outside the original coverage area, a case that is no longer restricted to temporary, work-related reasons and now encompasses retirement, study, or health conditions.

The proposal was approved by the Collegiate Board and is part of the process of revising standards applicable to different types of operators. The Agency expects that this update will contribute to greater regulatory security and strengthen the self-management model in supplementary health care.

[2] Avaliable at: https://www.gov.br/ans/pt-br/assuntos/noticias/operadoras/ans-divulga-nova-regulamentacao-para-operadoras-de-autogestao

New ANVISA Ordinance No. 1.385/2025 Establishes the Regulatory Monitoring Committee for Health

On November 7, 2025, ANVISA published Ordinance No. 1.385/2025, which establishes the Regulatory Monitoring Committee for Health Innovation.

According to the new regulation, the Committee's mission is to monitor and track products or technologies deemed innovative and of strategic interest to public health, enabling partnerships with universities, research institutions, *ad hoc* specialists, and cooperation with other national and international agencies, as well as proposing regulatory adjustments it deems appropriate.

It is proposed that the Committee monitor five (or more) innovative products or technologies, which may include new medications, medical devices, advanced diagnostics, advanced therapy products, and regenerative medicine, digital solutions, and health services based on artificial intelligence and machine learning, among others.

According to the Ordinance, the Committee will be composed of representatives from each Agency Directorate, ensuring a multidisciplinary approach in the analyses.

The products monitored by the Committee will be assessed regarding their risk-benefit by the respective technical areas, with the support of the Committee.

During the regulatory analysis, the Committee may apply Agile Regulation tools, which will be regulated in specific normative act(s): such as the prioritization of analyses involving clinical research or product regularization; the possibility of adapting regulatory requirements; and the staggered submission of parts of the approval dossier as they are completed.

The initiative is certain to accelerate the introduction of new products and technologies into the Brazilian market more quickly and effectively.

New Decree Consolidates Regulation of Plant-Based Products in Brazil

Decree No. 12,709/2025 was published on October 31, 2025, establishing a new regulation for the inspection of plant-based products in Brazil. The regulation consolidates previously dispersed rules in various decrees into a single document and regulates legal provisions applicable to the plant chain, revoking nine decrees that addressed beverages, wines, and other plant products in a fragmented manner.

The new regulation broadens the normative scope and defines processed plant-based products; plant-based beverages; plant products analogous to animal products; algae and fungi; raw materials and plant ingredients intended for animal food and feed; and agricultural products of economic interest.

In line with Law No. 14,515/2022, the Decree establishes the mandatory implementation of self-control programs, which must include procedures for traceability, risk management, internal audits, and product recalls in cases of non-compliance.

The regulation requires companies to maintain auditable records of production and marketing and to formalize their registration with the competent authorities. It also mentions the Compliance Incentive Program for Agricultural Defense and guides the adoption of Codex Alimentarius guidelines whenever there is no specific national regulation.

The Decree further strengthens the Brazilian System of Inspection of Plant-Based Products (Sisbi-POV), which is part of the Unified System for Agricultural Health Attention (SUASA), by providing for the sharing of competencies among the Union, States, the Federal District, Municipalities, and public consortia, with voluntary adherence and equivalence among inspection regimes. The text outlines precautionary measures applicable to products and establishments, as well as infractions and penalties.

Although it takes effect on the date of publication, the Decree establishes different deadlines for certain provisions: articles related to labeling and e-commerce will take effect after 90 days, while changes to the registration denomination of beverages will have a 730-day adjustment period. The other articles will have immediate effect.

Decree No. 12,651/2025 Published, Regulating the Law on Clinical Research Involving Human Beings

On October 8, 2025, Decree No. 12,651/2025 was published, regulating Law No. 14,874/2024 and establishing guidelines for the operation of the National System of Ethics in Research involving Human Beings. The regulation clarifies points left pending by the Law that were generating uncertainty for institutions and researchers, especially regarding the transition of competencies among the involved agencies.

The Decree confirms that the norms of the National Health Council (CNS) that do not contradict the new legislation remain temporarily valid until the National Research Ethics Body publishes its regulations. It also states that the National Research Ethics Committee (CONEP) will continue to act as an appellate body until the members of the new body are in office while maintaining the accreditation of already recognized Research Ethics Committees (CEPs).

Among the main points, the regulation details the composition of the National Body, coordinated by the technical area of science and technology of the Ministry of Health, formed by representatives from various ministries, ANVISA, research support foundations, and experts selected through a public process.

The text further defines criteria for classifying research risks and provides specific norms for the accreditation of CEPs, post-study supply plans, monitoring of discontinued clinical trials, and the operation of biobanks and biorepositories.

The Decree also establishes a digital platform by the Ministry of Health to integrate research information, with a public database, personal data protection mechanisms, and safeguards aligned with the General Data Protection Law (LGPD). The regulation reinforces the obligation of CEPs to ensure confidentiality and access control, in addition to requiring compliance with the LGPD at any stage involving personal data processing, including sensitive data.

Other provisions address the creation of a working group to draft complementary regulations by November 2025 and the possibility

of integrated ethical and sanitary assessment between the National Body and ANVISA for clinical research. The Decree also provides for advisory groups to support the accreditation processes and oversight of CEPs.

The practical application of the new rules will occur during a transition period, while the Direct Action of Unconstitutionality (ADI) 7,875 is pending before the Federal Supreme Court (STF), which challenges aspects of Law No. 14,874/2024, and in the Senate, the Legislative Decree Project (PDLS) No. 830/2025, which aims to suspend Decree No. 12,651/2025 for alleged violations of legal provisions in regulating the topic.

STF Launches Platform to Standardize Decisions on Judicialized Medications

On December 1, 2025, the STF held a hearing to present the National Platform for Centralization of Pharmaceutical Demands (SUSmed), aimed at centralizing requests regarding access to and acquisition of medications through the Unified Health System (SUS).

SUSmed, which is expected to be launched in 2025, will provide information on the current public policy for the application of a specific medication, and if it is not incorporated into SUS, the system will present information such as its unit and annual cost, the federative entity responsible for funding, etc.

Furthermore, the platform will allow "the request, monitoring, and decision-making regarding medications in a digitized and transparent manner," according to the CNS.[3]

After its implementation, the management of SUSmed will be transferred to the National Justice Council (CNJ), which will be responsible for establishing "rules for use, maintenance, support, and the physical and technical logistics of the platform."[4]

[3] Avaliable at: https://www.gov.br/conselho-nacional-de-saude/pt-br/assuntos/noticias/2025/dezembro/cns-pede-equidade-e-transparencia-para-os-usuarios-do-sus-no-acesso-a-plataforma-nacional-de-saude#:~:text=O%20Supremo%20Tribunal%20Federal%20(STF,SUS)%20em%20todo%20o%20pa%C3%ADs..

[4] *Ibidem.*

ABERT and ANVISA Decide to Suspend Process on Advertising Rules for Medications and Foods

In a conciliation hearing held on November 17, 2025, in the scope of ADI 7.788, ANVISA and the Brazilian Association of Radio and Television Broadcasters (ABERT) decided to suspend the procedural processing of the action, which discusses the constitutionality of sanitary norms applicable to the advertising of medications and foods.

The process began in 2025 when ABERT proposed an ADI against ANVISA Resolutions No. 96/2008 and No. 24/2010, arguing that such norms would constitute an overreach of the Agency's regulatory competence, as well as an infringement of constitutional principles such as free enterprise. However, at this moment, the parties propose to evaluate, together, points of convergence for defining a minimum regulatory framework.

Thus, a new hearing has been scheduled for February 9, 2026.

It is expected that the parties will develop a proposal based on the aspects they defend in common, without prejudice to the legal analysis of the issue by the STF.

New ANVISA Resolution Regulates Occupational Risk Assessment and Exposure to Agrochemicals

On November 25, 2025, ANVISA published Resolution No. 998/2025, which marks the establishment of a specific regulatory framework for the evaluation and management of occupational and environmental risks resulting from exposure to agrochemicals, environmental control products, related products, and bioinputs for plant protection use.

Until then, Brazilian sanitary regulation focused primarily on the risks posed by such products to the consumer through the control of residues in food. With the new resolution, the analysis now encompasses operators and workers involved in activities that involve contact with these products, as well as residents and bystanders in relevant areas.

The regulation establishes unprecedented technical parameters to support exposure risk assessment, requiring that companies registering agrochemicals submit to ANVISA the Occupational and Resident and Bystander Exposure Risk Assessment Dossier (DAROC) for each of their formulated products.

The model for the DAROC will be made available by ANVISA, along with the calculator that should be used to assess the risk for workers and residents and bystanders, considering Brazilian exposure scenarios.

Holders of registrations are required to review internal processes, update dossiers, and incorporate assessment and communication models proposed by ANVISA. Meanwhile, companies using the products must continue to comply with the specific guidelines in their management, which will be updated by registrants.

The regulation will come into effect only 180 days after its publication—allowing a transition period for registrants and users to adapt to the new requirements.

Partner responsible for the newsletter

Victor Hugo Callejon Avallone