

Regulatory Bulletin

Administrative Law | Regulation | News and Updates



ABOUT REGULATION IN NUMBERS

"Regulation in Numbers" is an institutional project of FGV Direito Rio, with three main missions: (i) to produce and disseminate knowledge about the regulatory activity in the country; (ii) to contribute to the improvement of the national regulatory environment; and (iii) to promote good regulatory practices.

Developed within the scope of the Research Center on Law and Economics (CPDE) of FGV Direito Rio, Regulation in Numbers brings together empirical research, mainly of a quantitative nature, on: (i) Mechanisms of Participation (public hearings and consultations) of federal regulatory agencies; (ii) normative production of regulatory agencies; (iii) Political/Legislative Control of regulatory agencies; and (iv) External Control of regulatory agencies.

Geral Coordinator: Sérgio Guerra

TEAM

Scientific Coordinator: Natasha Schmitt Caccia Salinas

Executive Coordinator: Péricles Gonçalves Filho

Research Professors:

Patrícia R. P. Sampaio

Eduardo Jordão

Researchers

Lucas Thevenard Gomes

Gabriela Borges Silva

Luiz Guilherme Pessoa Cantarelli

Luiza Castello Branco

Erick Sobral Diniz

Braulio Campos Mattos

Caio Assumpção

José Ronaldo de Castro S. Junior

News and Updates

Antitrust authority can also regulate 'big techs' in Brazil

The Treasury wants a proposal for the regulation of digital platforms by the end of the first semester.

Brazil can lead rapid and responsible development.

Climate risks take precedence on Davos agenda

Competition and regulation of financial crypto-assets

The regulation of neurorights as new human rights

Rights, regulation, and journalism: the new controversies of AI

A new regulation for a new industrialization

Energetic renewal

Regulation of artificial intelligence: a third way.

The financial sector advocates for a specific focus on potential regulation of AI

FINANCIAL SYSTEM

Open Finance: Central Bank simplifies consent renewal and extends the validity period of data sharing.

The Central Bank has issued Joint Resolution No. 7, which simplifies the process of renewing consents for data sharing in Open Finance. With the aim of providing greater convenience and ease for clients, the regulation allows participating institutions to offer longer validity periods than the current 12-month limit for sharing, while maintaining the requirement that clients can revoke sharing at any time.

The Securities and Exchange Commission is issuing a Resolution adopting reports on sustainability-related financial information issued by the International Sustainability Standards Board (ISSB).

The Securities and Exchange Commission (CVM) has published Resolution CVM 193, allowing, on a voluntary basis, publicly traded companies, investment funds, and securitization companies to prepare and disclose sustainability-related financial information reports based on the international standard (IFRS S1 and S2) issued by the International Sustainability Standards Board (ISSB). The regulation becomes effective from 1/11/2023.

The Securities and Exchange Commission (CVM) has issued a Resolution repealing normative acts

The Securities and Exchange Commission (CVM) has issued Resolution CVM 192, repealing normative acts that were already tacitly revoked. The regulations affected are all amendments to main Instructions and Resolutions that had previously been repealed within the framework of the review and consolidation process outlined in Decree 10,139. Resolution CVM 192 will come into effect on 1/11/2023.

The National Data Protection Authority has published the second analysis of the Artificial Intelligence Bill.

The National Data Protection Authority (ANPD) has released the second analysis (Technical Note No. 16/2023/CGTP/ANPD) of Bill No. 2338/2023, concerning the regulation of artificial intelligence (AI) usage in Brazil. The document provides concrete contributions for amending the bill and proposes, among other things, a new institutional model.

Woman in Regulation

Agency alters natural gas sales to free consumers in São Paulo

Conjur: Author: Maria Costa

The regulatory importance of fintechs against cybercrimes in Brazil

Jota. Authors: Isadora Collet, Rebeca Paiva e Tatiana Coutinho.

New (and old) challenges in sight for CADE in 2024

Jota. Authors: Ticiania Lima, Marcela Malttiuzo e Anna Binotto.

Defense of the environment and climate: the contribution of the Attorney General's Office (AGU) to a collective construction.

Jota. Author: Mariana Cime.

A Role for Antitrust in Online Content Moderation

Reg. Review. Author: Julia Englebert

FDA's Minimal Authority over Dietary Supplements

Reg. Review. Author: Victoria Hawekotte



National Waterway Transportation Agency (ANTAQ)

The National Waterway Transportation Agency has extended the public hearing on the tariff revision in a resolution addressing container demurrage.

A National Waterway Transportation Agency (Antaq) approved the extension of Public Consultation 06/2023, related to the Regulatory Result Evaluation (ARR) proposal of Resolution-ANTAQ 62/2021.

ANTAQ and MPor launch the 1st General Plan for Waterway Grants.

The National Waterway Transportation Agency (Antaq) and the Ministry of Ports and Airports (MPor) announced on 25/10 the approval of the first Hydroviary General Grant Plan (PGO), developed by Antaq and approved by the supervising ministry. On this occasion, the Agency and the Ministry announced the opening of a public call for studies on the Paraguay River.

The hydroviary plan aims primarily to increase Brazil's competitiveness and development. The approved document establishes that the exploration of navigable or potentially navigable waterways will be carried out through concession or by means of a public tender.

National Land Transportation Agency (ANTT)

ANTT adopts precautionary measures to ensure compliance with road passenger transportation

The National Land Transportation Agency has issued Ordinance SUFIS No. 52, containing precautionary measures in cases of non-compliance with provisions outlined in Resolution No. 4,770/2015 for companies in the road passenger transportation sector.

Based on the normative provisions of Resolution No. 5,083/2016 and Law No. 9,874/1999, ANTT's precautionary measures aim to address situations involving multiple infractions and the inappropriate and recurrent behavior of carriers, especially those that have not made necessary adjustments following routine inspections.

CASE LAW

Supreme Federal Court

ADI 7.458/PB, rapporteur Minister Gilmar Mendes, virtual trial finalized on 11.12.2023.

Theme: Administrative Law - Public tender; differentiated treatment; origin criterion; bonus in the score. Public tender: rules benefiting residents naturally located in the state..

Summary: It is unconstitutional—due to constituting disproportionate differential treatment, lacking reasonable justification—for a state law to grant, in favor of naturally resident candidates within its territorial scope, a 10% bonus in the score obtained in public tenders in the area of public security

National Civil Aviation Agency (ANAC) Public consultation opened on the compensation of carbon dioxide (CO2) emissions in international flights.

The National Civil Aviation Agency (ANAC) has opened a public consultation on the new regulation for monitoring and offsetting carbon dioxide (CO2) emissions in international flights. Contributions will be accepted until December 6th through the electronic form provided for the consultation.

Public consultation opened for the simplification of air taxi operations.

The National Civil Aviation Agency (ANAC) has proposed an innovation for air taxi services: the categorization of operators based on the size of the company and the complexity of the operation. This change will bring proportionality to requirements for air transporters, allowing new businesses to start with a simplified certification that adds requirements as the company grows.

Aligned with international best practices, the proposal creates four categories based on operational characteristics, authorization, the number of professionals involved, and the quantity and complexity of the aircraft used. The category with the simplest certification is dedicated to individual operators with only one aircraft and one pilot. The other categories must meet more requirements, which correspond to the size of the operator.

Proposals for the revision of Brazilian Civil Aviation Regulation (RBAC) No. 135 and Supplementary Instruction No. 119-004, which regulate the certification and operation of air taxi transport, are open for contributions until December 6.

ANAC and FAA sign a cooperation agreement for the certification of eVTOL (electric Vertical Takeoff and Landing) aircraft.

The National Civil Aviation Agency (ANAC) signed a letter of intent with the Federal Aviation Administration (FAA) for the certification of electric Vertical Takeoff and Landing (eVTOL) vehicles. Popularly known as "flying cars," eVTOLs are expected to bring improvements to short and medium-distance air transportation..

SUPERIOR COURT OF JUSTICE

EREsp 1.725.030-SP,
Rapporteur Minister Raul
Araújo, Special Court,
unanimously, judged on
12/14/2023, DJe
12/20/2023.

Subject: Public company providing essential public service. Non-profit and competitive nature. Prescription. Five-year term. Application of the same regime as legal entities of public law (Decree No. 20,910/1932 and Decree-Law No. 4,597/1942)

Highlight: The prescriptive regulatory regime of legal entities of public law, as provided for in Decree No. 20,910/1932 and Decree-Law No. 4,597/1942, applies to entities of the Indirect Administration with legal personality of private law that operate in the provision of essential public services without profit-making purposes and without competitive nature

HEALTH SURVEILLANCE

National Health Surveillance Agency (Anvisa)

Anvisa updates the list of Brazilian Common Denominations

The National Health Surveillance Agency (Anvisa) has published Collegiate Board Resolution (RDC) 822/2023, which updates the list of Brazilian Common Denominations (DCBs). Seventeen new denominations were included, and one was modified. The consolidated list of DCBs is available on a specific page of the Agency's portal.

Anvisa creates a monitoring panel for the Regulatory Agenda.

Starting this October, Anvisa's Regulatory Agenda will feature a Monitoring Panel, enabling the visualization of data regarding the progress, performance, and advancement curve of regulatory proposals within the Agenda. The information stems from quarterly monitoring initiated in July 2023, aimed at tracking the progress of regulatory proposals, assessing adherence to the planned schedule, and identifying critical points that could jeopardize the execution of the Agenda.

The amendment to Collegiate Board Resolution 53/2015 and the Normative Instruction on qualified impurities has been published.

The National Health Surveillance Agency (Anvisa) has announced that Collegiate Board Resolution (RDC) 821/2023 and Normative Instruction (IN) 258/2023 will come into effect on November 1st. RDC 821/2023 amends RDC 53/2015 to include in Article 10, Section IV, a provision specifying that impurities and degradation products are qualified when exposure is equal to or less than the limits stated in the list published in a specific Normative Instruction and its updates. The Qualified Impurities List has been published through IN 258/2023, covering 19 impurities from 17 drugs. These impurities, regardless of their origin, are considered qualified by Anvisa, provided all attributes defined in the annex of the mentioned IN are met.

Anvisa has published the Personal Data Protection Policy.

The National Health Surveillance Agency has published Ordinance 1,184/2023, which addresses the Personal Data Protection Policy of the Agency. This ordinance represents a significant step by Anvisa in aligning its processes with the General Data Protection Law (Law 13,709/2018). The policy aims to establish guidelines for the protection of personal data within the Agency.

FEDERAL COURT ACCOUNTS (TCU)

Decision 2445/2023
Plenário (Request for
Reconsideration, Reviewer
Minister Benjamin Zymler)

Theme: Public concession.
Restriction. Object of the
contract. Suppression.
Unilateral alteration.
Requirement.

Summary:

It is regular to unilaterally alter, through the reduction of the scope of the concession, with the purpose of granting the suppressed portion to a third party in a new bidding process, provided there is a motivated advantage, especially regarding tariff moderation, maintaining the economic and financial balance of the current contract and reasonably preserving its size and nature, so as not to characterize takeover.

[President Lula sanctions law regulating the TCU's role in the UN Board of Auditors.](#)

[TCU completes audit of the Brazilian electoral system](#)

[The Annual Budget Law may have overestimated the net federal revenue](#)

[TCU approves regulatory instruction to enhance transparency of special transfers made to states and municipalities](#)

HEALTH SURVEILLANCE

National Health Insurance Agency (ANS)

ANS releases sector data up to July 2023.

The National Supplementary Health Agency (ANS) has released the second edition of the Panorama Bulletin - Supplementary Health, featuring updated data on the health insurance sector until July 2023. The number of health insurance plan users increased by 1.9% compared to July 2022, marking once again the highest number of health plan beneficiaries in history, with 50.7 million users of medical assistance and 31.5 million customers with exclusively dental plans.

The board approves the holding of a public consultation on the composition of the Supplementary Health Chamber.

The proposal to amend the Normative Resolution that deals with the internal regulations of the Supplementary Health Chamber (CAMSS), with the aim of including representation from the pharmaceutical industry segment in its composition, was approved. The approval included the exemption from Regulatory Impact Analysis regarding the change, as well as the decision to conduct a public consultation to gather contributions from society and regulated entities on the matter.

ANS discussed assistance for beneficiaries with Global Developmental Disorders.

The National Supplementary Health Agency (ANS) held Public Hearing 36 to discuss assistance for beneficiaries in supplementary health with Global Developmental Disorders (GDD), including Autism Spectrum Disorder (ASD), and gather contributions on the subject. The remote meeting had 400 participants interested in the impacts of supplementary health assistance.

The hearing featured representatives from various professional sectors, as well as entities and associations in the health and civil sectors, who provided testimonials and contributions. Public Hearing 36 had 72 proactive interventions and almost 30 thematic presentations, highlighting the significance of the subject and the Agency's concern with this complex issue.

Opinion

Regulating innovation requires more brains and fewer bureaucratic minds.
Conjur. Author: Isac Costa

Rethinking health insurance plans
Jota. Author: Jose da Silva

Regulatory challenges of artificial intelligence in healthcare
Jota. Author: Fernando Aith.

AI Predictions in the Private Insurance System
Jota. Authors: Bernardo Santos e Ronaldo Gallo.

Electric triathlon: the regulatory challenges of market opening
Jota. Author: João Assis.

Artificial intelligence and civil liability.
Jota. Author: Filipe Medon.

Extremism, artificial intelligence, and democracy in peril.
Jota. Author: Edilene Lôbo e Jorge Messias.

Infrastructure and sectoral regulation in Brazil: key to development
Jota. Authors: Victor Rufino, Victor Couto e Olavo Guimarães.

Perspectivas para a regulação do saneamento básico em 2024
Perspectivas para a regulação do saneamento básico em 2024
Jota. Autores: Leandro Andrade, Beatriz Godoy e

TELECOMMUNICATION

National Telecommunications Agency (Anatel)

Anatel has submitted a proposal to revise the General Competition Goals Plan for public consultation.

The Board of Directors of Anatel approved a process regarding the proposal for submission of the General Competition Goals Plan (PGMC) to Public Consultation. The proposal will be available for contributions for a period of 60 days after the adoption of measures determined by the Board of Directors to clarify specific points. In addition to the consultation, a public hearing will be held in Brasília/DF, in a hybrid format, allowing both in-person and remote participation of interested parties, in order to deepen the debate on the topic.

The revision of the General Regulation of Consumer Rights for Telecommunication Services has been approved.

The Board of Directors of Anatel has approved the revision of the General Regulation of Consumer Rights for Telecommunication Services (RGC). The new Regulation has changed the rules regarding service suspension in case of non-payment. Service providers will no longer be able to charge any fees in the first 30 days of the service suspension period.

Anatel promotes a public consultation for the revision of the Spectrum Use Regulation.

The Board of Directors of Anatel has approved the submission to public consultation of the Draft Resolution approving the new Radio Frequency Spectrum Use Regulation (RUE), as well as the holding of two public hearings, one in Brasília and another in Fortaleza, in a hybrid format, allowing both in-person and remote participation of interested parties, in order to deepen the debate on the topic.

Anatel approves regulation on pole sharing.

The Board of Directors of Anatel has approved regulations on pole sharing between electric power distributors and telecommunications service providers. A Public Consultation on a proposed methodology for pricing fixation points on poles was also approved for a period of forty-five days. According to the reevaluation proposal, Infrastructure Explorers, legal entities granted the right to commercially exploit spaces in infrastructure, are created.

Opinion

Inside the EU's Ambitious Anti-Deforestation Regulation.

Reg. Review. Author: Madeline Bruning.

How Patents Contribute to High Drug Prices.

Reg. review. Author: Laura Dolbow.

Let Us Not Raise a Ruckus Over Net Neutrality.

Reg. Review. Author: Randolph J. May

Small-Scale Solutions to the Large-Scale Drug Crisis.

Reg. Review. Author: Carolina Hackley.

Modern Romance Hinges on Dating App Self-Regulation.

Reg. Review. Author: Elizabeth Yin

The right for remuneration for the authors in the substitute for Bill 2370/2019.

Jota. Authors: Allan de Souza

Quantum technology on the agenda: reflections on legal issues and governance.

Jota. Author: Paula Rodrigues

ENERGY

National agency of Petroleum, Natural Gas and Biofuels (ANP)

RenovaBio: ANP will conduct a public consultation on rules for biofuel certification.

A board of the ANP has approved the holding of public consultation and hearings regarding the revision of ANP Resolution No. 758, 2018. The regulation addresses procedures for the efficient certification of biofuels and the accreditation of inspection firms under the National Biofuels Policy (RenovaBio).

Resolution ANP No. 758/2018 includes guidelines on the eligibility criteria for biomass producers to participate in RenovaBio and an annex with the technical regulations of RenovaCalc (a calculator that quantifies greenhouse gas emissions from biofuels from the agricultural phase to their use in transportation).

The purpose of the revision is to promote regulatory improvements identified after a regulatory impact analysis (RIA).

RenovaBio: ANP discloses data on compliance with the individual target for 2022 by fuel distributors.

The ANP has released information on the compliance with the compulsory individual targets for the reduction of greenhouse gas emissions established for the year 2022 for fuel distributors. These targets are part of RenovaBio, the National Biofuels Policy. Fuel distributors retired (permanently removed from circulation) 33.2 million decarbonization credits (CBIOs), which corresponds to 90.4% of the total individual targets assigned to them by ANP and 92.3% of the total target established by the National Energy Policy Council (CNPE) for 2022. Each CBIO represents one ton of equivalent CO₂ that has been prevented from being emitted into the atmosphere.

Publications

Market Reactions to the Announcements of Financial Risk Regulation from Basel II.5 to Basel IV: What Do Shareholders and Creditors Perceive?
Author: Jonas Krettek.

A Global Analysis of Land Use Regulation, Urban Form, and Greenhouse Gas Emissions.
Authors: Paavo Monkkonen, Erick Guerra, Jorge Escamilla e outros.

Climate Transition Risk and The Role of Bank Capital Regulation.
Authors: Salomon Garcia e Enric Martorell.

Global Finance in the Context of Climate Change. Author: Stephen Park.

Knowledge and Decisions in the Information Age: The Law & Economics of Regulating Misinformation on Social-Media Platforms.
Author: Ben Sperry.

Self-regulatory Measures as Securities Regulation: The Saga of Antitakeover Regulation in China.
Author: Sirui Hán

National Electric Energy Agency (ANEEL)

Regulatory Agenda for 2024/2025 will be the subject of a public hearing.

The edition for the biennium 2024/2025 of the Regulatory Agenda will be the subject of Public Hearing No. 20/2023. The development of the Regulatory Agenda for the next biennium was based on the concept of ESG - Environmental, Social, and Governance. In the first phase, Aneel collected data, requests, and information from society through a Public Consultation to develop a proposal. The second phase is the holding of a public hearing, where society can present contributions through oral statements. Finally, in a Public Meeting of the Board of Directors, the Agency will define the Regulatory Agenda 2024-2025. Public Hearing No. 20/2023, in virtual format, will be held on November 1st.

Public Consultation proposes a reduction in the residential tariff for Roraima starting in January 2024.

The National Electric Energy Agency (Aneel) has approved the opening of Public Consultation No. 040/2023 to discuss the Periodic Tariff Review of Roraima Energia S.A. The company serves more than 204 thousand electricity consumer units in the 15 municipalities of Roraima.

The Auction Notices for Existing Energy Auctions A-1 and A-2 have been approved by ANEEL.

The National Electric Energy Agency (Aneel) has approved the draft of the Notice and respective Annexes for the Existing Energy Auctions "A-1" and "A-2" in 2023. The auctions aim to contract electricity from existing generation projects, with the start of supply in 2024 and 2025.

Publications

ESG Regulation and Financial Reporting Quality: Friends or Foes?
 Authors: Dalit Gafni, Rimona Palas, Ido Baum e Dov Solomon

Hardening Corporate Accountability in Commodity Supply Chains under the European Union Deforestation Regulation.
 Author: Laila Berning e Metodi Sotirov.

Responsive Regulation: an alternative to the regulatory model of private security regulated by the Federal Police in the Brazilian context.
 Author: Carmino Eduardo.

Regulation of artificial intelligence based on risks and its responsiveness.
 Author: Maria de Almeida.

Trademark law and regulation: the Louboutin case.
 Author: Henrique de Castro

WATER AND SANITATION

National Water and Basic Sanitation (ANA)

Public consultations on risk matrix for contracts and governance practices for entities in the sanitation sector have new contribution deadlines.

The contribution deadlines for Public Consultations No. 05/2023 and No. 06/2023 have been extended. The National Water Agency (ANA) is still receiving suggestions from the public for these public consultations through the ANA Social Participation System. Public Consultation No. 05/2023 deals with the improvement of the proposed reference standard (RS) on the risk matrix for public water supply and sanitation service contracts. Contributions can be made until 11:59 PM on November 10th.

ANA reopens public consultations on the operating conditions of the Grande and Paranaíba rivers' water systems.

The public consultations by the National Water Agency (ANA) on the proposed operating conditions of the water systems of the Grande and Paranaíba rivers have been reopened. The new deadline for receiving contributions from the public is until 8 AM on December 11th, through the ANA Social Participation System.

Public consultations on universalization goals and tariff regulation for basic sanitation public services have been extended.

The National Water and Basic Sanitation Agency (ANA) has extended Public Consultation No. 03/2023 and Public Consultation No. 04/2023. Contributions from the public for these consultations can be submitted until November 10th through ANA's Social Participation System. Public Consultation No. 03/2023 addresses progressive universalization goals for public water supply and sanitation services, along with an evaluation system on the subject. Public Consultation No. 04/2023 focuses on the development of the reference standard (NR) on tariff regulation models for water supply and sanitation services.