

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.

TEAM

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News and Updates

[The Superior Court of Justice \(STJ\) upholds the collection of port fees](#)

[The debate about the inclusion of court-ordered payments \(precatório\) in concessions concerns regulatory agencies](#)

[The Ministry of Health purchases R\\$ 392 million worth of medicines without registration from Anvisa \(Brazil's National Health Surveillance Agency\)](#)

[The National Land Transportation Agency \(ANTT\) reduces minimum road freight rates by 2.34% to 3.21%](#)

[The Chamber of Deputies concludes the vote on the new fiscal framework without any changes](#)

[According to experts, the regulation of social media is a natural path](#)

[Lula sanctions law allowing the trading of carbon credits in forest concessions](#)

[Minas Gerais prepares for the second round of road auctions.](#)

[Google and Microsoft rely on Nvidia chips for AI.](#)

[U.S. Regulator Vows Tough Line on Problem Banks](#)

[US Supreme Court rules against EPA in wetlands regulation challenge](#)

FINANCIAL SYSTEM

[Brazilian Central Bank announces list of selected participants to take part in the Digital Real Pilot](#)

The Central Bank of Brazil (BC) has received a total of 36 manifestations of interest in the Digital Real (RD) Pilot, involving over 100 institutions from various financial sectors. After evaluation, the Executive Management Committee (CEG) has selected 14 participants, including major banks, payment institutions, cooperatives, and cryptocurrency service developers. The next step involves incorporating these participants into the RD Pilot platform, which is expected to take place by mid-June 2023.

The RD Pilot will focus on testing the privacy and programmability features through the implementation of a specific use case involving the delivery-versus-payment (DvP) protocol for federal government securities between clients of different institutions. In addition to privacy, the test will also address the programmability and interoperability of the services offered. The participation of a wide range of financial institutions and companies in the sector aims to promote innovation and enhance the infrastructure of the Brazilian financial system.

[CVM opens public consultations for accounting standards update](#)

The Brazilian Securities and Exchange Commission (CVM) initiated, on May 12th, three public consultations aimed at reviewing and updating Technical Guidance OCPC 7 and Technical Pronouncements CPC 12 and 18 (R2).

These updated proposals are part of the work plan of the Accounting Pronouncements Committee (CPC) and aim to align these standards with the concepts and references of other regulations that were subsequently modified.

CVM invites public participation and requests suggestions and comments on the revisions until June 12, 2023. Interested parties should submit their contributions to the Superintendent of Accounting and Auditing Standards (SNC) of CVM.

Woman in Regulation

An ongoing monetary revolution: Digital Real and the tokenization of sovereign currency

JOTA – Authors: Camila Villard Duran

Social media and the timing of regulation

JOTA – Authors: Ana Lúzia Calil

Without state oversight, regulation of social media will be purely rhetorical

Conjur – Author: Vanice Valle

Content moderation

against women: How the LGPD can be an ally

Conjur – Authors: Ana Carolina Reis Figueiredo e Anna Sambo Budahazi

Green hydrogen in the port universe.

Conjur – Author: Ingrid Zanella Andrade Campos

Cracking Down on Overdose Deaths

TheRegReview, Author: Katie Cohen

Coining a Regulatory Framework for Digital Assets

TheRegReview, Authors: Elizabeth Yin, Caroline Hackley, and Alexandra Walsh

Fiduciary Governance for 401(k)s

TheRegReview, Author: Natalya Shnitsner

The Brazilian Securities and Exchange Commission (CVM) issues resolutions to modernize Brazilian Depository Receipts (BDR) programs

On May 11, 2023, the Brazilian Securities and Exchange Commission (CVM) announced the issuance of Resolutions CVM 182 and 183, which bring important changes to the Brazilian Depository Receipts (BDR) programs in Brazil. The objective of these changes is to modernize the mechanisms for protecting the Brazilian capital market and investors.

Resolution CVM 182 regulates aspects related to the underlying assets of BDRs, classification into different levels, and registration requirements for the programs, replacing CVM Instruction 332. On the other hand, Resolution CVM 183 introduces complementary changes to Resolutions CVM 80 and 160, especially regarding the registration of foreign issuers in BDR Level II and III programs.



National Waterway Transportation Agency (ANTAQ)

ANTAQ approves first terminal bidding processes of 2023.

On May 19th, the National Waterway Transportation Agency (ANTAQ) approved the bidding process for the leasing of terminals in the states of Alagoas and Rio Grande do Sul. Three terminals have been authorized for auction, including two terminals at the Port of Maceió (AL) for fuel handling, with estimated investments of over R\$ 20 million and over R\$ 37 million, respectively. The third terminal, located at the Port of Porto Alegre (RS), will be used for handling and storage of vegetal bulk solids, with estimated investments of R\$ 17 million and a lease term of 10 years. The terminals will be auctioned through a simplified leasing process, with exemption from public hearing and merit analysis by the Federal Court of Auditors (TCU).

This approval marks the first terminal bidding process approved by ANTAQ in 2023. After approval by the agency, the process will move on to the Ministry of Ports and Airports (MPor) for final approval and subsequent scheduling of the auction.

CASE LAW

Brazilian Federal Supreme Court (STF)

ADI 3.236/ DF - ADMINISTRATIVE LAW - ADMINISTRATIVE ACT; FISCALIZATION; FUEL STATIONS; FUEL DISTRIBUTORS; CONSUMER PROTECTION

SUMMARY: The district law that requires fuel distributors to install electronic seals, at their own expense, on the storage tanks of branded gas stations that display their brand, while exempting unbranded gas stations (not affiliated or committed to a specific distributor) from this requirement, is unconstitutional due to its violation of the principles of proportionality, equality, and reasonableness.

National Land Transportation Agency (ANTT)

ANTT changes deadline for compliance of Electronic Freight Payment Institutions (IPEF)

On May 4th, the National Land Transportation Agency (ANTT) approved, through Resolution No. 6,015/2023, the amendment of Article 25-B of Resolution No. 5,862/2019, which regulates the registration of Transportation Operations required for the generation of the Identification Code of Transportation Operations (CIOT) for autonomous freight carriers and their equivalents.

The change extends the deadline for Electronic Freight Payment Institutions (IPEF) to comply with Law No. 14,206/2021 until July 31, 2023, for providing proof of formalization of their request to join the instant payment arrangement (Pix) established by the Central Bank of Brazil to ANTT.

MT PAR assumes concession of BR-163/MT.

The Government of Mato Grosso will invest R\$ 1.6 billion over the next two years to ensure improvement works on BR-163. The funds will be allocated through MT PAR, a mixed economy company from Mato Grosso, which took over majority ownership of Concessionária Rota do Oeste (CRO) on May 4th.

ANTT approves amendment to resolution regarding application for railway authorization

The National Land Transportation Agency (ANTT) approved, during the Board Meeting on April 27th, the amendment of Resolution No. 5,987/2022, which regulates the administrative process for applications for the exploration of new railways, new railway yards, and other related facilities through authorization grants.

The amendment aims to enhance Resolution No. 5,987 by providing clearer guidelines for the analysis of railway authorization processes. This topic is part of the Regulatory Agenda for the 2023-2024 biennium. The proposal aims to improve conflict resolution procedures in cases of locational incompatibility between projects, correct material errors, and achieve better alignment between the resolution and Law No. 14,273/2021.

Superior Court of Justice (STJ)

[Ag Int in RMS 68.803-CE - \(Rapporteur: Justice Mauro Campbell Marques\)](#)
ADMINISTRATIVE LAW.
Disciplinary Administrative Process. Nulity.

Highlight: The extension of the administrative disciplinary process, by itself, cannot be recognized as a valid cause for nullification, as long as the consequent detriment of this extension is not demonstrated.

National Civil Aviation Agency (ANAC)

The regulation regarding the timeframe for flight simulator training is open for public consultation

The National Civil Aviation Agency (ANAC) initiated on May 15, 2023, Public Consultation No. 04/2023, which addresses the amendment to the Brazilian Civil Aviation Regulation (RBAC) No. 61. The proposed regulation is part of the Voo Simples Program and aims to simplify the rules related to flight simulator training. Contributions to the Public Consultation can be submitted until June 3, 2023, through a form available on the ANAC Public Consultation page on the Portal.

HEALTH SURVEILLANCE

National Health Surveillance Agency (Anvisa)

Management Report of Anvisa for 2022

On May 3rd, the National Health Surveillance Agency (Anvisa) released the Management Report for the year 2022, presenting the main activities and results achieved during that period. The document covers various areas of the agency's work, such as the registration and monitoring of medicines, food, personal hygiene products, cosmetics, as well as the control of ports, airports, and borders.

According to the report, Anvisa made significant progress in its regulatory activities, particularly in the prompt analysis and granting of authorizations, ensuring the availability of safe and high-quality products for the Brazilian population.

Normative update on requirements for clinical laboratory tests

The National Health Surveillance Agency (ANVISA) has approved a new regulation that establishes technical and sanitary requirements for the operation of clinical laboratories, pathological anatomy laboratories, and other services that perform clinical laboratory tests in Brazil. The normative update, which took place on May 3rd, aims to better align with the technological reality of the sector, aiming to enhance the quality and safety of the services provided.

Federal Court of Accounts (TCU)

Decision 752/2023 -

(Rapporteur; Justice Jorge Oliveira).

Privatization. Public concession. Investment. Compensation. Reversible assets. Relicensing. Fine. Investment Partnership Program

Highlight: In relitigation processes governed by Law 13.448/2017, it is irregular, in the calculation of the net amount to be reimbursed as compensation for reversible assets, to fail to deduct the amounts of fines owed by the concessionaire to the Union, related to proceedings initiated by the regulatory agency with final administrative decisions, regardless of whether they are or not enrolled in the active debt, except in cases of judicial or arbitral suspensions (Article 15, § 2 of Law 13.448/2017).

The court assesses the sustainability risk of the federal debt in 2023 as moderate

The audit identifies inappropriate use of resources from the Pre-Salt Social Fund

Revisions of concession contracts in Galeão and Viracopos airports have irregularities, according to the audit.

Inspection indicates the need to improve the planning of the operation of the Brazilian electrical sector.

HEALTH SURVEILLANCE

National Health Insurance Agency (ANS)

Updates to the ANS Resolutions in May 2023

In the 588th Collegiate Board Meeting (DICOL) of the National Supplementary Health Agency (ANS), held on May 2nd, various topics were addressed. These included the training of the Federal Prosecution Office alongside ANS, activities of Lab Inova ANS for modernizing work processes, and the evaluation of the Technical Cooperation Agreement between ANS and the Institute for Health Ethics. Additionally, the approval was given for conducting a public hearing and public consultation to evaluate a proposal for updating the List of Procedures and Health Events, including medications for cancer treatment. Administrative processes related to sanctions and reimbursement to the Unified Health System (SUS) were also analyzed and approved, among other relevant topics in the supplementary health sector.

On May 22nd, the 589th DICOL Meeting took place, where terms of commitment between ANS and three benefit administrators were approved: Classe Administradora de Benefícios Ltda.-ME, Benefit Administradora de Benefícios Ltda., and Plural Gestão em Planos de Saúde Ltda. These terms will be valid for 60 months and aim to provide periodic information about the number of covered lives managed by the companies. This will allow regulatory actions to be planned according to the economic size of each administrator.

ANS releases the Annual Management and Activities Report 2022.

The ANS has made available the Annual Management and Activities Report 2022. The document encompasses all actions carried out during the period, in compliance with recommendations from the Federal Court of Audit (TCU), with the aim of providing transparency and accountability to society.

Public Consultation 109: ANS receives contributions for the update of the Rol (Healthcare Procedures and Services Coverage List)

On May 5th, ANS announced the opening of Public Consultation No. 09 to receive contributions regarding the following technologies: a) Levomalate cabozantinib for the treatment of thyroid cancer (UAT 92); b) Ponatinib hydrochloride for treating patients with chronic myeloid leukemia (UAT 93)

Opinion

When fear dictates the pace of regulation of digital platforms.

Conjur – Authors: Daniel Becker e Luiza Pontes de Miranda Bretz

Anatel as a regulator of digital services.

JOTA – Authors: Alexandre Freire e Ricardo Campos

Regulation of social media: between remedies and poisons.

JOTA – Author: Gustavo Binenbojm

Regulation of social media

JOTA – Author: José Eduardo Faria

The Durability of Governance Reform: A Two-Wave Audit of Notice and Comment

Policymaking in China

GW, Authors: Steven J. Balla, Zhoudan (Zoey) Xie

Agile Regulation and the Future of Governance

TheRegReview , Author: Ayo Aladesanmi

The Cost of Data Protection Compliance

TheRegReview , Author: Isaac Rice

TELECOMMUNICATION

National Telecommunications Agency (Anatel)

Anatel approves Annual Management Report 2022

On May 3rd, Anatel published the Annual Management Report for the year 2022. The publication highlights the fulfillment of the public policy in the sector, including the expansion and provision of services, as well as the increased access with the implementation of 5G. It also mentions the results achieved by groups created to address issues of interference and financing of connectivity projects in schools.

Anatel has revised its strategic planning, establishing new objectives and focusing on the promotion of sustainable markets for communication, connectivity, and digital transformation. The fight against abusive telemarketing was emphasized, resulting in a reduction of over 30% in unwanted calls.

The report includes performance data, sectoral statistics, and budgetary, financial, and accounting information of Anatel, following international reporting standards and guidelines from the Federal Court of Accounts.

The National Telecommunications Agency (Anatel) and the Central Bank of Brazil (Bacen) are discussing regulatory sandbox

On May 11th, a meeting was held between Anatel and the Central Bank of Brazil (BCB) to discuss the regulatory sandbox. The initiative of BCB inspired Anatel to create its own sandbox project, which has already been submitted for public consultation and is currently being reviewed by the Specialized Federal Attorney's Office (PFE) before being sent for final approval by the Agency's Board of Directors.

The team from the Superintendence of Planning and Regulation (SPR), which developed Anatel's regulatory sandbox, along with the technical team from BCB, will work on drafting a cooperation agreement to be signed between the institutions. This agreement aims to enhance studies of mutual interest and promote the exchange of experiences between the two regulators..

New requirements for radiolocation and radionavigation.

On May 10th, the Board of Directors of Anatel approved Act No. 5,171, dated May 9th, 2023, which establishes the Technical and Operational Requirements for the use of frequency bands associated with radiolocation and radionavigation applications, specifically related to the use of radars.

Opinion

The Biden administration's recent regulatory review and analysis changes

Brookings - Connor Raso

Who Is Going to Regulate AI?

Harvard Business Review
Blair Levin; Larry Downes

ENERGY

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

ANP published a diagnosis of the Natural Gas industry aiming to develop a program to reduce market concentration

On May 25th, the Board of Directors of the National Agency of Petroleum, Natural Gas, and Biofuels (ANP) approved the publication of Joint Technical Note No. 2/2023, which presents the Competitive Diagnosis of the Brazilian Natural Gas Industry and proposes the Concentration Reduction Program (Gas Release).

The study aims to analyze the structure of the natural gas industry in Brazil and identify possible measures to promote competition and market deconcentration. The ANP also decided to conduct a regulatory impact analysis on the subject, which will be included in the Agency's Regulatory Agenda. This measure is aligned with the strategic guidelines of the National Energy Policy Council for the development of the New Natural Gas Market, aiming for an open, dynamic, and competitive market.

ANP implements measures for the opening of the natural gas market

The natural gas sector in Brazil has made significant progress towards a more open, dynamic, and competitive market in 2022 and during the first semester of 2023. The ANP has played a key role in these advancements by regulating the market, issuing licenses for the entry of new players, and disseminating information, in accordance with the New Gas Law.

For 2023, the Agency will continue to work on regulating third-party access to essential infrastructure such as pipelines and LNG terminals, as well as improving transparency in the gas market information. The agency is also working on measures to simplify the capacity contracting for gas transportation and plans to address the movement of LNG and CNG through alternative modes.

Publications

Discretion, Regulation, and Reflexivity: A new theory on administrative choices

Author: Sérgio Guerra

Administrative Process - Constitutional Principles and Law No. 9.784/1999

Author: Egon Bockmann
Moreira

Sanctions in Administrative Law

Author: Yasser Gabriel

Green Bonds: A Legal and Economic Analysis

Sergio Gilotta - Thilo Kuntz (ed.), Research Handbook on Environmental, Social, and Corporate Governance, Edward Elgar, 2023

What 21st-Century Free Speech Law Means for Securities Regulation

Helen L. Norton - 99 Notre Dame Law Review



National Electric Energy Agency (ANEEL)

ANEEL conducts Public Consultation on treatment in the management of generation and CUST grants

Between May 11th and 22nd, the National Electric Energy Agency (ANEEL) conducted a Public Consultation to address the management of grants and the Contracts for the Use of the Transmission System (CUST) entered into by renewable energy generators.

ANEEL's proposal aims to resolve the difficulties of accessing the transmission grid due to the increasing expansion of these energy sources. The agency proposes a mechanism for amicable termination of the CUST, with the revocation of the grants and exemption from applicable fines. Interested parties can submit their intention to adhere to the proposal until June 6th. The situation arises from the increase in grant applications from renewable energy generators and the overload of requests for access to transmission and distribution.

ANEEL presents the 2022 Management Report

On May 3rd, ANEEL released the 2022 Management Report, providing a thorough analysis of the actions and results achieved by the Agency. This publication is part of ANEEL's Annual Accountability Report (PCA), in accordance with Instruction Normative No. 84 of the Federal Court of Auditors (TCU), and offers a detailed overview of the Agency's activities and accomplishments.

Resolution updates criteria and safety actions for dams regulated by ANEEL

On May 2nd, ANEEL approved the results of Public Consultation No. 082/2021, which discussed the improvement of Normative Resolution No. 696/2015 regarding criteria and safety actions for dams regulated by ANEEL.

The revision of the regulation was necessary due to an amendment in Law No. 12,334/2010, which addresses the National Policy on Dam Safety. The main improvements include issues related to the delimitation of the Self-Saving Zone (SSZ), flood maps and cascade breach studies, minimum requirements for safety inspections and issuance of the Declaration of Stability Condition, as well as the regulation of specific offenses and penalties for dam safety.

WATER AND SANITATION

National Water and Basic Sanitation (ANA)

ANA has initiated a public consultation on the risk matrix for contracts related to water supply and sanitation services

On May 10, the National Water and Basic Sanitation Agency (ANA) launched the Public Consultation No. 02/2023, which will be open until 6:00 PM on June 5. The purpose of this consultation is to gather suggestions from the public for the development of a reference standard on the risk matrix for contracts related to water supply and sanitation services.

Contributions received through ANA's Social Participation System will be crucial for the planning process of this standard, following the Dialogue on Regulatory Alternatives held in April. This topic is included in ANA's Regulatory Agenda, which aims to identify issues in the basic sanitation sector and implement regulatory actions to improve the provision of these services.

Agency initiates public consultation for the reference standard on general conditions for the provision of water and sanitation services

On May 8th, the ANA initiated Public Consultation No. 03/2023 for the planning of its reference standard on general conditions for the provision of water supply and sanitation services, particularly regarding issues related to customer service, metering, billing, and collection for these services.

The Water Governance Pact comes into effect with a focus on water resources, basic sanitation, and dam safety

The initiative aims to improve the institutional relationship between the National Water and Basic Sanitation Agency (ANA) and the federative units, with the purpose of integrating water resources management in hydrographic basins with shared responsibility between the Union and the federative units
