

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 National Electric System Operator (ONS) has identified a failure in wind and solar power plants as the cause of the blackout and is expected to propose regulations.

The government seeks to address disputes between workers and companies in the regulation of gig economy work.

The Central Bank (BC) will regulate cryptocurrency exchanges and require a physical presence in Brazil.

Dispute over betting revenue obscures the goal of regulation.

It is urgent to regulate streaming platforms in Brazil.

Investors will be able to share data with banks in the new phase of open banking; here's how it works.

The Modi government in India is moving forward against big tech companies and expanding internet censorship

Brazil was the second country to propose the regulation of artificial intelligence but is struggling to approve it.

FINANCIAL SYSTEM

Susep releases Monthly Summary with sector data up to July.

Susep has released its Monthly Summary report, containing data from the insurance sector for the month of July. The document is produced by Susep based on data submitted by the companies supervised by the Authority. The document can be accessed on the Susep website.

CVM is proposing a reform of the rules regarding shareholder meetings.

The Brazilian Securities and Exchange Commission (CVM) initiated a public consultation on September 21st with proposed changes to Resolution CVM 81, which governs shareholder meetings. The mechanisms for remote participation and voting in shareholder meetings will be expanded and improved based on input from stakeholders affected by the regulation and the experience of CVM's technical areas. The public consultation follows a Regulatory Impact Analysis (Análise de Impacto Regulatório or AIR), which estimates that any increase in compliance costs for companies is justified by the overall reduction in costs for affected parties. Suggestions and comments can be submitted until November 24th.

The Public Consultation on International Personal Data Transfers has been extended.

The Public Consultation on the Regulation of International Personal Data Transfers has been extended until October 14th. Society has the opportunity to contribute to the regulation of international personal data transfers and the presentation of the model of standard contractual clauses. Contributions must be submitted exclusively through the Participa + Brasil Platform. The draft resolution aims to regulate the transfer of personal data to foreign countries or international organizations of which Brazil is a member, as well as the models of Standard Contractual Clauses (SCC), the approval process for Specific Clauses (CE), and Global Corporate Rules (GCR), in addition to the Adequacy Decision mechanism.

Woman in Regulation

The conceptual confusion surrounding regulation in Brazil.

Jota. Author: Ana Luiza Calil.

Mental integrity and neurorights

Jota. Authors: Eduarda Chacon e Roberta Guerra.

Decrypting Deception in the NFT Market.

Reg. Review. Author: Elizabeth Yin



National Waterway Transportation Agency (ANTAQ)

ANTAQ has approved a public consultation on the access channel of the Port of Paranaguá.

On September 20th, the Brazilian National Agency for Waterway Transportation (ANTAQ) approved a public consultation to gather contributions, subsidies, and suggestions for the improvement of studies related to the project for concession of waterway access to the Port of Paranaguá in Paraná. This marks the first proposal for the concession of a port access channel in the country. The proposed contract duration is 25 years, with the assumption of the specified area in 2024, and the possibility of successive extensions up to a maximum of 70 years. The estimated Capex is R\$ 1.07 billion, Opex is R\$ 2.35 billion, and the total gross revenue is projected to be R\$ 8.85 billion.

ANTAQ and GIZ sign Technical Cooperation Agreement (TCA) for the development of a study on port decarbonization.

The Brazilian National Agency for Waterway Transportation (ANTAQ) and GIZ (Deutsche Gesellschaft für Internationale Zusammenarbeit) signed a Technical Cooperation Agreement (TCA) on September 18th. This agreement is focused on the development of a project aimed at decarbonization in the port sector under the International Hydrogen Ramp-Up Programme (H2Uppp), financed by the German Federal Ministry for Economic Affairs and Climate Action (BMWK). The study aims to assess the readiness of the national port infrastructure, among other aspects, to accommodate vessels using zero-carbon fuels, to support the production and export of green hydrogen and its derivatives (PtX), and to provide renewable energy to docked vessels.

National Land Transportation Agency (ANTT)

ANTT publishes the mandatory schedule for updating the RNTRC, which is the National Registry of Road Cargo Transporters.

ANTT has released the schedule for the Ordinary Revalidation of the National Registry of Road Cargo Transporters (RNTRC), as outlined in Resolution ANTT No. 5,982/2022, for updating the registration information of cargo transporters. Transporters who do not complete the ordinary revalidation by the specified date will have their registrations suspended and will not be eligible to engage in remunerated cargo transport.

CASE LAW

Supreme Federal Court

ADPF 1.031/DF, rapporteur Justice Nunes Marques, virtual trial concluded on September 15, 2023

Theme: Installation and sharing of telecommunications infrastructure at the municipal level - ADPF 1.031/DF.

Summary: It is unconstitutional—because it encroaches upon the exclusive competence of the Federal Government to operate telecommunications services (CF/1988, Article 21, XI) and its prerogative to legislate on the subject (CF/1988, Article 22, IV)—for a municipal law to regulate the implementation and sharing of telecommunications infrastructure

Public hearing discusses the improvement of the user complaint process.

On September 18th, the National Land Transport Agency (ANTT) held Public Hearing No. 8/2023, in a hybrid format, to gather suggestions and contributions regarding the proposal to revise the process of receiving user complaints by the ANTT's Ombudsman Office concerning road passenger transportation and road and railway concessions. The goal is to enhance the service for citizens using services regulated by the agency and promote efficiency in serving the regulated sector. Interested parties can still contribute until 6th October at 6:00 PM through the ParticipANTT system.

National Civil Aviation Agency (ANAC)

The deadline for the consultation on warehousing and stevedoring fees has been extended.

The National Civil Aviation Agency (Anac) has extended the deadline for the public consultation on the proposed resolution regarding warehousing and stevedoring fees for imported and exported cargo until October 6th. The consultation has been open since August 7th and addresses the resolution that will replace Portaria nº 219/GC-5, dated March 27, 2001. Among the points under discussion are the prohibition of differentiation between domestic and international airlines, updates on tariff exemptions, and the timelines for fee exemptions and charges for the use of infrastructure dedicated to international cargo.

August has the best results in the domestic market for the month since 2000

In terms of passenger movement and passenger demand per kilometer, domestic civil aviation in Brazil recorded its best August since the beginning of the historical data series in 2000. This information is available in the latest update of the Demand and Supply Report, which is already available for consultation on the ANAC (National Civil Aviation Agency) portal. In August 2023, there were 8.2 million paid passengers in the domestic market, representing a 12.8% increase compared to August 2022, while flight demand (RPK) increased by 7.9% compared to the same month in 2022. Compared to August 2019, passenger movement increased by 4.3%, and demand growth was 6.4%. On the other hand, the supply (ASK) increased by 5.5% compared to August 2022 and 5.3% compared to August 2019.

SUPERIOR COURT OF JUSTICE

AREsp 1,708,364-RJ, Rapporteur Minister Gurgel de Faria, First Panel, unanimously decided on September 12, 2023

Theme: The commercialization of medications provided by hospitals and the profit margin are regulated by Resolution No. 2/2018 of the Chamber of Regulation of the Medicines Market. This regulation aligns with the provisions of Law No. 10,742/2003. Legality Principle. Innovation.

Highlight: Resolution No. 2/2018 of the Chamber of Regulation of the Medicines Market did not exceed its regulatory authority when it established a zero-margin overcharge for medications provided by hospitals in the provision of medical care services and established penalties in the event of a violation.

HEALTH SURVEILLANCE

National Health Surveillance Agency (Anvisa)

Sectoral dialogue: confidentiality of information received during CP 1.158/2023.

On October 5th, Anvisa (the Brazilian Health Regulatory Agency) will hold a sectoral dialogue with the aim of discussing the confidentiality and disclosure of information received during Public Consultation (CP) 1.158/2023. Other topics related to the draft resolution will be addressed in subsequent sectoral dialogues. The public consultation discussed a proposed regulation regarding the safety assessment and authorization for the use of new foods and new ingredients. The in-person meeting will take place at Anvisa's headquarters in Brasília, from 2:00 PM to 6:00 PM.

A new regulation on hair pomades came into effect on September 15th.

Resolution of the Collegiate Board of Directors (RDC) 814/2023, which deals with temporary conditions for regularization, commercialization, and use of hair pomades, came into effect on September 15th. With the publication of this regulation, Anvisa initiates a new regulatory phase related to the health crisis involving hair pomades for braiding, styling, and fixing hair. The implementation of RDC 814/2023 will provide more security to the regularization process for new hair pomades, which had been suspended since February, while also allowing ongoing investigations to clarify the so-called root cause of the issue.

Lançada The Anvisa Digital Library was launched on September 21st.

The Library is a platform dedicated to the storage, dissemination, access, and preservation of documents related to the technical and scientific production of the agency. Its aim is to share knowledge and information generated by Anvisa's collaborators to increase visibility and promote the exchange of work. The Anvisa Digital Library is the result of extensive work conducted through various stages and studies by the Agency's Document Management and Corporate Memory Department in collaboration with the Brazilian Institute of Information in Science and Technology (Ibict).

FEDERAL COURT ACCOUNTS (TCU)

Judgment 1797/2023
Plenary (Request for
Consensual Solution,
Written by Minister
Benjamin Zymler)

Theme: Competence of the TCU. Federal administration. Consensual resolution. Endorsement. Concurrent control. Principle of legal certainty.

Summary: In the context of a consensual solution agreement (as per TCU Normative Instruction 91/2022) signed by the parties involved, the TCU (Brazilian Federal Court of Accounts) acts as an endorsing authority. It endorses the agreement and conducts a broad legal assessment, both confirming the legality of the negotiated subject and evaluating its motivation in terms of convenience and opportunity, with the aim of serving the primary public interest. This represents an exceptionally concurrent control mechanism, parallel to the controlled act, and it is necessary to provide stability to the expression of intentions in substantive law, thereby enhancing the legal security of the transaction.

[International control institutions are discussing final adjustments to the ClimateScanner.](#)

[Climate change, energy transition, and artificial intelligence are highlights of the 7th National Control Forum.](#)

[Public Procurement Seminar: the second day addresses control, opportunities, and challenges of the legislation.](#)

HEALTH SURVEILLANCE

National Health Insurance Agency (ANS)

[ANS is conducting a Public Hearing to discuss data transfer in the context of portability of waiting periods.](#)

The National Supplementary Health Agency (ANS) will hold Public Hearing 35 on October 9th to gather input and discuss the transfer of healthcare data, extracted from the Supplementary Health Information Exchange (TISS), when a beneficiary opts for waiting period portability. This is aimed at ensuring that the health plan consumer is the true owner and bearer of their data.

[A Cosaúde is debating the inclusion of technologies in the list \(rol\) and in the commission's regulations.](#)

ANS held the 20th technical meeting and 6th administrative meeting of the Commission for Updating the List of Procedures and Events in Supplementary Health (Cosaúde) on September 19th and 20th. During the meetings, they evaluated five new technologies for incorporation into the mandatory coverage list for health insurance plans. They also reviewed the contributions received in Public Consultation No. 114 for two other technologies. The meetings had the participation of members and guests from Cosaúde, which is composed of entities representing insurance companies, service providers, consumer protection agencies, and civil society, among others. These participants contributed to the assessments of the technologies.

The discussions on the proposals covered aspects related to scientific evidence regarding the efficacy, effectiveness, and safety of all technologies. They also included economic evaluations of benefits and costs compared to the coverage already provided in the List of Procedures and Events in Health, as well as an analysis of the financial impact of coverage expansions by insurance providers.

Opinion

Administrative regulation by private entities and the case of ABNT.

Conjur. Authors: Mauricio Zockun e Carolina Zockun

It is necessary to advocate for the regulatory agency model.

Conjur. Author: Danilo Vital

The complex equation of AI regulation.

Conjur. Authors: Daniel Becker e Ludmilla Campos.

New limits on credit card revolving interest rates: one good idea doesn't justify another bad one.

Conjur. Author: Gustavo Binenbojm

Dynamics of the new regulation of sports betting.

Conjur. Author: Thiago Queiroz Jorge

Regulation of medical advertising and promotion in the age of digital health.

Jota. Author: Fernando Aith.

Institutions and regulatory model: differences between risk and uncertainties.

Jota. Authors: Felipe Tavares e Cintia Leal.

Regulation for innovation.

Jota. Authors: Maria Foss, Diogo Coutinho e Marcelo Miterhof.

TELECOMMUNICATION

National Telecommunications Agency (Anatel)

Anatel approves a study for the reassessment of fees and contributions.

On September 15th, the Board of Directors of the National Telecommunications Agency (Anatel) approved a study for the reassessment of fees and contributions applicable to the telecommunications sector. The purpose of the study was to conduct a structured evaluation of the topic regarding cross-cutting aspects of institutional revenue balance, fiscal federal issues, and potential competitive impact on the sector. The study was prepared in the form of a Regulatory Impact Analysis Report and addressed three themes: the current tax system specific to the telecommunications sector, the redesign of the tax system specific to the telecommunications sector, and the redefinition of the tax burden.

Anatel approves a summary allowing the conversion of expiration into a more flexible penalty.

On September 15th, the Board of Directors of the National Telecommunications Agency (Anatel) approved a new summary that allows the conversion of the penalty of expiration, in cases of failure to put the telecommunications system into operation within the deadline, into a less severe penalty, provided that before the final judgment, the infringing party waives the corresponding Radiofrequency Usage Authorization or regularizes its conduct through the licensing of the corresponding stations. This specific summary applies to violations of Bid Notice No. 2/2015-SOR/SPR/CD-ANATEL, related to the bidding process for authorizations to use radio frequencies in the 1,800 MHz, 1,900 MHz, and 2,500 MHz bands.

Anatel maintains the prohibition of exclusivity in contracts between Telefônica and virtual operators.

On September 15th, the Board of Directors of the National Telecommunications Agency (Anatel) decided regarding the ORPAs (Authorization to Render Personalized Mobile Service) for MVNOs (Mobile Virtual Network Operators) of Telefônica, to maintain the decision expressed in Decision Dispatch No. 191/2022/CPRP/SCP that "exclusivity clauses should be excluded from MVNO ORPAs." It was also maintained the prohibition of charging a monthly subscription fee for machine-to-machine (M2M) terminals, such as card terminals and laptop modems, as well as for Internet of Things (IoT).

Opinion

Artificial intelligence: between sectoral regulation and centralized delusion.

Jota. Author: Rodrigo Ferria.

Regulatory consensus and the digital economy.

Jota. Authors: Bruno Dantas e Alexandre Freire.

MP 1175: Brazil on the outskirts of WTO rules on subsidy regulation.

Jota. Authors: Leonardo Matschlat e Gustavo Matschlat.

Does the Constitution Require Agencies to Use Biased Judges?

Reg. Review. Author: Richard J.

Who Favors Making ALJs At-Will Employees?

Reg. Review. Author: Alan B. Morrison

The Underused Field for Clean Energy.

Reg. Review. Author: Sam Wong.

Business Intimidation in the Rulemaking Process.

Reg. Review. Author: Soojin Jeong

Scarcity Issues in Water Rights.

Reg. Review. Authors: Jackson Nichols, Liam Kerr e Janaina Valle.

ENERGY

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

ANP will hold public consultations and hearings on the inclusion of dye in maritime diesel oil.

On September 14th, the ANP (National Agency of Petroleum, Natural Gas, and Biofuels) Board of Directors approved the regulatory impact analysis report and the holding of public consultations and hearings regarding the revision of Resolution ANP No. 903/2022, which establishes specifications for aquaviary fuels and their commercialization rules. The proposed amendment is the inclusion of the mandatory addition of dye to maritime diesel oil.

The Fuel of the Future Bill assigns topics to ANP

On September 14th, the government signed the Fuel of the Future Program Bill, which will be sent to the National Congress. Among other topics, the bill addresses synthetic fuels and the geological capture and storage of carbon dioxide, subjects that, according to the bill, would be assigned to ANP (National Agency of Petroleum, Natural Gas, and Biofuels).

National Electric Energy Agency (ANEEL)

The agency authorizes a Public Consultation to improve the rules of the Demand Response program

On September 19th, ANEEL authorized the opening of a Public Consultation (CP036/2003) to improve rules to enable the representation of the Demand Response program in the chain of electro-energetic optimization models used in the operation of the system and price formation from January 1, 2024, onwards. The proposal aims to enhance Regulatory Resolution 1030/2022 and revise Submodule 4.5 of the Network Procedures. The Demand Response Program allows for the voluntary reduction of electricity consumption by large consumers as an additional resource to meet the National Interconnected System (SIN) needs, aiming to achieve more advantageous results for both the reliability of the electrical system and the tariff moderation for end consumers.

Publications

Bridging Policy and Practice: A Pragmatic Approach to Decentralized Finance, Risk, and Regulation.

Author: Eric Hess.

Human Readability of Disclosures in a Machine-Readable World.

Authors: Andrew Call, Ben Wang, Liwei Weg e Qiang Wu.

Can Mandatory Disclosure Curb Greenwashing? First Evidence from the EU SFDR.

Authors: Jiyuan Dai, Gaizka Ormazabal, Fernando Penalva e Robert A. Raney.

Sustainability, Financial Inclusion and Efficiency: A Trilemma or a Trifecta for the Regulation of Digital Finance?

Authors: Dirk Zetsche, Douglas Arner e Ross Buckley.

Disclosure of Greenhouse Gas Emissions.

Author: Qi Gao Fritz.

Big Techs and Global Financial Regulation: Intersection, Challenges, and Solutions.

Authors: Steve Kourabas e Cheng-Yun Tsang.

ANEEL and ANATEL make progress in improving rules for pole sharing.

The technical departments of ANEEL and ANATEL have issued a proposal for a new regulation regarding the sharing of infrastructure between the electricity distribution and telecommunications sectors. The proposal aims primarily to modernize the rules to address irregularities in pole occupancy, resulting in increased safety for workers in distribution companies and telecommunications firms, as well as for the general population. Developed collaboratively by the agencies, the proposal takes into account input from stakeholders in the electricity and telecommunications sectors, as well as other interested parties.



National Water and Basic Sanitation (ANA)

ANA selects a civil society organization to serve as the executive secretariat for the Paranapanema River Basin Hydrographic Committee.

ANA has issued a Public Call for Proposals aimed at Civil Society Organizations (CSOs) to assume the role of the executive secretariat for the Paranapanema River Basin Hydrographic Committee (CBH Paranapanema). Non-profit private entities, as defined by Article 2 of Law No. 13,019/2014; cooperatives; and religious organizations can participate in the selection process by submitting their proposals until October 6th, through the Transferegov Portal.

After receiving the proposals, a Selection Committee to be established by ANA will choose a civil society organization to fulfill the responsibilities outlined in the notice between October 9th and 13th. The preliminary results are expected to be announced on October 16th. Both the approval and the publication of the definitive selection results are scheduled for November 13th.

With this initiative, ANA aims to provide structure and institutional support to CBH Paranapanema, enabling the selected organization to make decisions on relevant matters concerning the hydrographic basin.

Publications

Toward National
Regulation of Legal
Technology: A Path
Forward for Access to
Justice.

Author: Drew SimShaw

Affordable and Clean
Energy.

Authors: Elizabeth Warner
e Uma Outka

Carbon Pricing under
Competition and
Regulation in the
Extraction Industry.

Authors: Moustapha Pemy,
Bruno Kamdem e Hélyette
Geman.

Environmental
Regulations, Supply Chain
Relationships, and Green
Technological Innovation.

Authors: Xiaoqi, Jing Lin,
Xiyang e Yunbi An

A public consultation has been opened for the reference standard on regulatory governance practices of subnational regulatory entities.

On September 15th, the National Water and Basic Sanitation Agency (ANA) initiated the period for receiving contributions from the public as part of Public Consultation No. 06/2023. The ideas received will assist ANA in improving the reference standard (RS) concerning regulatory governance practices to be observed by subnational regulatory entities (ERIs) operating in the basic sanitation sector. Suggestions can be submitted until 8:00 AM on October 30th through ANA's Social Participation System.

To support public contributions, ANA has made available the Regulatory Impact Analysis Report (RAIR) on the subject of Public Consultation No. 06/2023, as well as a draft of the future reference standard.

Public consultation focused on the reference standard for tariff regulation models for water supply and sanitation is still open until October 1st.

ANA will accept contributions from the public until October 1st for the development of the reference standard (RS) on tariff regulation models for water supply and sanitation services in the context of Public Consultation No. 04/2023. Contributions can be submitted through ANA's Social Participation System.

The purpose of this standard is to define tariff regulation models that promote the appropriate incentive structure to enable universal access and satisfactory provision of water supply and sanitation services. Tariff regulation models encompass rules, guidelines, and procedures that guide regulation, aiming to ensure both adequate price levels and service provision through mechanisms that encourage efficiency.

To support the public's suggestions, the National Water and Basic Sanitation Agency has provided the Regulatory Impact Analysis Report (RAIR) on the subject of Public Consultation No. 04/2023, as well as a draft proposal for this future reference standard.