The use and exemption of Regulatory Impact Assessment by the National Health Surveillance Agency

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Regulatory impact assessment—RIA—is increasingly important for Brazilian Administrative Law, especially after the 'Economic Freedom Act' (*Lei de Liberdade Econômica*) extended its scope of implementation to all public bodies and federal administration entities. This work analyses the evolution of RIA under the purview of the National Health Surveillance Agency (Anvisa), a federal agency that stands out for being at the forefront of RIA implementation in Brazil. To this end, data published on the legislation section of the agency's website about the use of RIA to substantiate Directors' Collegiate Regulations (*Resoluções de Diretoria Colegiada*) and Normative Instructions (*Instruções Normativas*) between 2011 and 2020 were collected. The total number and proportion of cases in which the Directors' Collegiate approved the realization or dispensation of RIA, based on relevant normative acts collected in this period, are presented. It was found that, in most cases, there were exemptions from RIA, and this proportion was not reduced over time. Furthermore, in cases of exemption, it was observed that the urgency/severity of the process was used as justification in a high proportion of cases. Finally, it was also observed that the use of RIA and exemption justifications vary according to the subject of the regulatory norm in question. The results of this study advance the existing knowledge about the implementation of RIA in Brazil and suggest new avenues of qualitative research on the factors that influenced the use and exemption of RIA by Anvisa.

Keywords: regulatory reform, regulatory impact assessment, National Health Surveillance Agency, Anvisa, empirical research.

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O uso e a dispensa da análise de impacto regulatório pela Agência Nacional de Vigilância Sanitária (Anvisa)

A Análise de Impacto Regulatório (AIR) vem ganhando crescente importância para o Direito Administrativo brasileiro, sobretudo após a edição da Lei de Liberdade Econômica, que estendeu o seu escopo de realização a todos os órgãos e entidades da administração pública federal. Este trabalho analisa o uso e a dispensa desse instrumento no âmbito da Agência Nacional de Vigilância Sanitária (Anvisa), agência federal que se destacou como pioneira na implementação da AIR no Brasil. Para tanto, foi feito um levantamento, a partir de dados publicados no portal de legislação da agência, sobre o uso de AIRs para subsidiar a elaboração de Resoluções de Diretoria Colegiada e de Instruções Normativas, entre 2011 e 2020. Apresentamos, para os atos normativos relevantes coletados no período analisado, o número e a proporção de casos em que a Diretoria Colegiada da agência aprovou a realização ou a dispensa de AIR. Identificamos que na maior parte dos casos, houve dispensa de AIR e que essa proporção não foi reduzida ao longo do período estudado. Além disso, para os casos de dispensa, constatamos que a urgência/gravidade do processo foi utilizada como justificativa em uma alta proporção de casos. Por fim, constatamos também que o uso de AIR e a justificativa para os casos de dispensa variam de acordo com o tema da norma regulatória analisada. Os resultados obtidos neste trabalho, além de avançarem a atual compreensão da implementação da AIR no Brasil, sugerem novas linhas de pesquisas qualitativas acerca dos fatores que influenciaram o uso e a dispensa de AIR pela Anvisa.

Palavras-chave: reforma regulatória; análise de impacto regulatório; Agência Nacional de Vigilância Sanitária; pesquisa empírica.

El uso y la dispensa del análisis del impacto regulatorio por la Agencia Nacional de Vigilancia Sanitaria (ANVISA)

El Análisis del Impacto Regulatorio (AIR) adquiere importancia creciente para el Derecho Administrativo brasileño, especialmente después de la edición de la Ley de Libertad Económica, que ha extendido su alcance para todos los órganos y entidades de la administración pública federal. Este estudio analiza el uso y la dispensa de esta herramienta en el ámbito de la Agencia Nacional de Vigilancia Sanitaria (Anvisa), agencia federal que se ha destacado como pionera en la implementación del AIR en Brasil. Para ese propósito, hicimos una búsqueda, con datos publicados en el sitio de legislación de la agencia, sobre el uso de los AIRs para basar la elaboración de Resoluciones del Directorio Colegiado y de Instrucciones Normativas, entre 2011 y 2020. Para todos los actos normativos relevantes que hemos recopilado en el período del análisis, presentamos el número y la proporción de casos en los cuales el Directorio Colegiado ha aprobado la realización o la dispensa del AIR. Hemos identificado que en la mayoría de los casos hubo dispensa del AIR y que esta proporción no se redujo a lo largo del periodo del análisis. Además, para los casos de dispensa, constatamos que la agencia utilizó la urgencia/gravedad del proceso como justificación en una alta proporción de los casos. Finalmente, constatamos también que el uso del AIR y la justificación para los casos de dispensa varían en función del tema de la norma regulatoria. Los resultados de este trabajo no sólo adelantan el conocimiento actual a propósito de la implementación del AIR en Brasil, sino también sugieren nuevas líneas de investigación cualitativa sobre los factores que han influenciado el uso y la dispensa del AIR por la Anvisa.

Palabras clave: reforma regulatoria; análisis de impacto regulatorio; Agencia Nacional de Vigilancia Sanitaria; investigación empírica.

1 Introduction

In recent years, Regulatory Impact Assessment (RIA) has become increasingly important for Brazilian Administrative Law. Debates about this tool arrived in Brazil from the country's engagement with the regulatory reform agenda of the Organization for Economic Co-operation and Development—OECD[1]—which led to the creation of the federal Program to Strengthen Institutional Capacity for the Management of Regulation (Programa de Fortalecimento da Capacidade Institucional para Gestão em Regulação—PRO-REG), in 2008.

In 2019, RIA gained legal basis in Brazil after Law No. 13,848/2019 (General Law of Regulatory Agencies) was passed, providing for the use of RIA by 11 federal agencies. Shortly after, Law No. 13,874/2019 (Economic Freedom Act) extended its use to all bodies of the federal government, and Decree No. 10,411/2020 established specific rules of implementation and methodological guidelines for RIAs.

This paper intends to contribute to the current public debate with an empirical analysis of the use and exemption of RIA by Anvisa, a federal agency that stands out for being at the forefront of RIA implementation in Brazil. Anvisa's regulatory activities highly impact the Brazilian economy,[2] and the agency has maintained a strong engagement with the development of RIA practices in Brazil. This paper analyzes the proportion of cases in which the agency's Directors' Collegiate approved the use or exemption of RIA. The justifications offered in case of exemption are also analyzed.

The text is divided into 5 sections. After this short introduction, section 2 briefly presents theoretical foundations for the use of RIA in the public administration's rulemaking process. Section 3 describes the legal implementation of RIA in Anvisa, calling attention to the regulatory milestones the were most important for the evolution of the instrument over time. Section 4 presents the results of the empirical survey. The methods employed to collect the data and the criteria applied to select relevant observations[3] were indicated. Next, the results for the use of RIA and the justifications used by the agency

1 In 2007, Brazil was invited to a program of "enhanced engagement" with OECD and was included in the group of "key partnerships" of the Organization.

2 According to the webpage of Anvisa's economic advisory department, the production value in 2013 of activities related to food products, drugs, cosmetic products, agrotoxins, sanitizing products, health products and tobacco was in the order of 261.2 billion reais, which corresponds to approximately 10.5% of the value of the domestic product in that year. See: http://antigo.anvisa.gov.br/assessoramento-economico. Last accessed on June 24, 2021.

3 This paper intends to follow the directives of the reproducible research movement (Stodden, 2014).

in case of exemption are presented, drawing attention to a high level of variation in both cases when considering normative acts related to different subjects. Finally, section 5 presents final remarks, pointing to the fact that other lines of research could complement the efforts made in this study.

2 Reasons for the adoption of RIA

The academic literature offers three main reasons for the adoption of RIA at the beginning of the decision-making process: (i) an increase in rationality; (ii) political control of the bureaucracy; and (iii) legitimacy (Radaelli & De Francesco, 2010).

RIA makes use of a rational model of decision making to direct the law-making process. In this model, every rational decision implies choosing a solution that is the most suitable for accomplishing the objectives intended by the decision-maker. The decision-maker must also choose, among different possible solutions, the one that maximizes his or her goals. For the decision-maker to be ready to choose the best option, he or she must have information that will allow him or her to foresee the impacts of each alternative.[4]

Therefore, RIA is rooted in an instrumental mode of rationality that is different from Weberian, formal-logic rationality. In RIAs, proposed normative rules are not analyzed considering only their formal-logic characteristics; they are, above all, analyzed on the basis of their teleological virtues (Atienza, 1997, p. 37–38). Consequently, RIA is at the center of a movement towards the rationalization of the law-making process (Chevallier, 1992, p. 18). Any additions or adjustments to the content of the intended rule, in any steps of the regulatory rulemaking process, must guarantee that the final regulation is suitable for achieving certain objectives.

The potential of RIA to promote instrumental rationalization of the rulemaking process is controversial. RIA is criticized for relying on studies based on imprecise information and for producing inferences of questionable validity and reliability (Shapiro & Schroeder, 2008, p. 446). Its rationality can also be compromised because of the political use of RIA by politicians.

It is important to bear in mind that RIA can also be understood as an instrument for political control of the Public Administration. Legislators and other elected officials do not have adequate means to legislate on technically intricate issues. Furthermore, due

4 Simon (1997) was one of the people responsible for disseminating the characteristics and the limitations of the model. The idea of the use of scientific principles to guide rational decision making, however, dates more than one century back (Shapiro & Schroeder, 2008, p. 437).

to information asymmetry problems, they do not have enough knowledge to assess if the regulatory activity of the Public Administration is in accordance with the public policy goals they should serve (McCubbins et al., 1987).

Since it is not feasible, for the abovementioned reasons, for political agents to decide on intricate technical issues, they delegate their decision-making power to agencies without, however, losing control over the regulatory activity. In this regard, RIA can provide a means for political agents to control the decision-making process without having to fully understand the content of these decisions.[5]

This control mechanism becomes even more effective if RIA, besides being monitored, is also revised by political agents. In the United States, where RIA was originally conceived in the 1970s, it functions, above all, as an important instrument of political control by the Administration, deployed by the President, who has the prerogative to revise normative acts of significant economic impact (Morall, 1997, p. 71–87).

It is worth observing, however, that there is no consensus in the literature regarding the potential of procedural instruments, such as the RIA, to act as a means of controlling the rulemaking activities of regulatory agencies. The most controversial issues are those concerning the enabling or obstructing of the execution of administrative procedures involved in regulatory decisions (Moe, 1989).

In addition to its strategic political use, RIA can also fulfill a legitimizing role, given that it submits the normative rule to a comprehensive analysis and forces its creator to explain and document the problems and objectives that motivated the proposed regulation. RIA can therefore be understood as an answer to an alleged democratic deficit resulting from the delegation of decision-making powers to agencies.

The three reasons for the adoption of RIA can be complementary to each other, but they can also become mutually exclusive. When RIA is used as an instrument of political control, its root rationality can be neglected. Furthermore, an excess of transparency can disrupt the rationality of regulatory decisions in cases in which access to confidential information is relevant to inform the decision-making process of the regulator (Coglianese et al., 2009).

According to Salinas and Cerqueira (2020), tensions of this nature have become

5 This argument differs considerably from traditional scholarship on administrative procedures that guide the decision-making process of the Administration. The traditional legal view understands administrative procedures as a means of ensuring the legitimacy of administrative decisions, of limiting the discretion of public agents, and of protecting citizens against arbitrary actions by the State (Medauar, 2008).

a salient trait of the RIA institutionalization process in Brazil. At first sight, one might suppose that RIA was introduced by both the General Law of Regulatory Agencies and by the Economic Freedom Act, based on the same principles of rationality and legitimacy. Both laws establish that the lawmaking process must be preceded by RIA and that they should contain information and data on the possible effects of the proposed rule.

This does not mean, however, that RIA has not been deliberately used as a tool for political control. From this standpoint, it is important to highlight a fact rarely addressed in the literature: the provisions for the use of RIA in the General Law of Regulatory Agencies were an initiative of the Legislative Power, while the provisions from the Economic Freedom Act were an initiative of the Executive Power.

The Executive Power's control is more focused on the adoption of least-intrusive regulation and regulatory red tape reduction, while the Legislative Power's control predominantly aims to improve accountability, transparency, and the application of informed (evidence-based) expertise to regulatory issues. While rational policymaking and low-intervention regulation are not necessarily in contradiction, there can be tensions between them. The potential clash between more expert, evidence-based regulation and the desire for less intrusive styles of control will be more accentuated if the institutions in charge of creating and implementing a specific regulatory policy do not share a single vision of how regulation should be made. For further development on this issue, see Baldwin (2010).

3 Implementation of RIA by Anvisa

Anvisa is considered a pioneer in the use of regulatory impact assessment instruments in Brazil. In October 2006, Anvisa held an international seminar on "Regulatory Impact Assessment: experiences and contributions for the improvement of regulatory quality," which was the first event organized by a body of the federal government to discuss this issue in Brazil.[6]

The initiative marks the institutional cooperation between Anvisa and the Program for Strengthening the Institutional Capacity for Management in Regulation—PRO-REG (Alves & Peci, 2011)—which was created in March of the same year by Decree No. 6,062/2007.[7] In the years that followed the creation of PRO-REG, Anvisa approved

6 National Health Surveillance Agency - ANVISA (2013).

7 PRO-REG was created in the context of Brazil's increasing engagement with multilateral forums on regulatory reform, such as the Organization for Economic Co-operation and Development (OECD). OECD recommends

a series of regulatory rules to enhance its rulemaking process by improving the routines of formal rule standardization and by implementing instruments designed to ensure substantive quality control of its regulatory frameworks, including the establishment of public consultations and impact assessment.

Regarding RIA, in particular, Anvisa is considered an important reference for other Brazilian regulatory agencies. It was mentioned in PRO-REG case studies (Proença et al., 2009) and was also selected for a pilot project of the federal government to conduct the first systematic effort to measure the economic impacts of a federal agency's regulatory activities.[8] Recently, in the context of the approval of the Economic Freedom Act, Anvisa has, again, served as a case study in a research paper that circulated in the Senate (Meneguin & Saab, 2020).

RIA started being implemented by Anvisa after the passing of Ordinance No. 422/2008, which instituted Anvisa's Program on the Improvement of the Regulatory Process. RIA started to gradually be integrated into the agency's rulemaking processes, although at that point, there were no specific provisions determining the systematic and generalized implementation of the tool.

In 2011, RIA appeared for the first time in Anvisa's Internal Rules of Procedure. Ordinance No. 1,381/2011 created the Center for Regulation and Good Practices on Regulation, establishing as one of its attributions to "promote, coordinate and execute activities and procedures of Regulatory Impact Assessment to inform and subsidize, in advance, the decision-making process of the Directors' Collegiate on rulemaking and regulatory matters, in cooperation with other departments of Anvisa, depending on the degree of complexity and specificities established by the Directors."[9]

As of 2011, Anvisa started to regularly disclose whether the rules published on its legislation website were preceded by RIA, also publishing justifications when they did not.

In 2012, the Anvisa's Directors' Collegiate addressed the agency's impact assessment practices in the Ordinary Public Meeting—OPM No. 19[10]—in which it was established that RIA would become mandatory for all rules following common procedure and that a standardized form should be created in the FormSus system to guide RIA

that states implement AIR as a generalized tool for the approval of any regulatory rules that can create significant social-economic impacts (OECD, 2008, 2012, 2015).

8 National Health Surveillance Agency - ANVISA (2008).

9 Article 35-B, V of Anvisa's Ordinance n. 354/2006.

10 As shown in the records for Ordinary Public Meeting No. 19, of June 26, 2012.

procedures.[11]

Following the agency's initial experiences with RIA since 2011, a methodology was established within Anvisa based on different levels of complexity. In some cases, RIAs followed a simple method based exclusively on qualitative analysis (level-1 RIA); in complex cases, RIAs could include more extensive investigation and could entail a quantitative dimension (level-2 RIA and level-3 RIA).

OPM No.19/2012 determined the use of level 1 RIA (the so-called Report of Impact Assessment—REMAI) as the standard to be used in most cases and that RIAs of levels 2 and 3 should be used in cases the Directors' Collegiate determined them as necessary to better analyze the dimension of the impacts.

The method of assessment developed by Anvisa was based on a Multiple Criteria Decision Analysis (MCDA) methodology called MACBETH (Measuring Attractiveness by Categorical Based Evaluation Technique) (Bana e Costa et al., 2011; Costa et al., 2019). This methodology stipulates a phase in which qualitative evaluations on multiple decision-making criteria are collected. Those evaluations are then systematically processed in a standardized manner and generate quantitative, structured references to assess the alternatives for each decision.

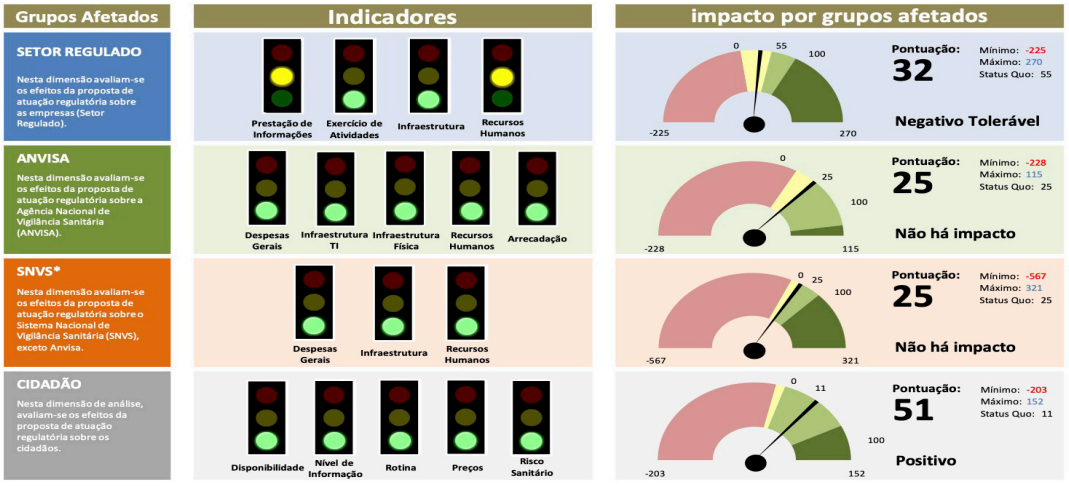
At Anvisa, this method consisted of a qualitative evaluation of the level of impact of the proposed rule regarding 4 possibly affected groups: (i) private regulated actors; (ii) Anvisa itself; (iii) the System of Sanitary Surveillance (SSS), except for Anvisa; and (iv) regular citizens.

For each of these groups, there are distinct dimensions of analysis to be associated with one of three possible levels of impacts (low, medium, and high), which are represented by the colors of a traffic light. At the end of the process, a panel is produced with a general synthesis of the expected impacts of the rule for the respective groups. The image below shows the impact panel for a revision of RDC No. 4/2012 regarding the criteria used for the Studies of Agrochemical Residues and the establishment of Maximum Limitations on Residues.[12]

11 Despite the importance of this advancement, it is worth noting the fragility of the instrument used to generalize the use of RIAs in Anvisa, as the sole documentation for this provision was the records for the Ordinary Public Meeting, which were not converted into a formal Ordinance.

12 Available at:
http://antigo.anvisa.gov.br/documents/10181/3445713/REMAI.pdf/178961a1-bbf0-4922-ac7a-e926a205da71. Last access on June 24, 2021.

Image 1 – Regulatory Impact Panel



Source: ANVISA – Report on Impact Survey

This methodology, however, was revised by Ordinance No. 1,741/2018 to harmonize Anvisa's practices with the guidelines provided by the Civil Office (Casa Civil, 2018) for the preparation of RIAs.

This Ordinance was passed in the context of a substantial change in the role of RIA in Brazilian Administrative Law. Soon after the release of the Civil Office's guidelines, the General Law of Regulatory Agencies made the RIA mandatory for 11 regulatory agencies at the federal level, including Anvisa, for the creation or revisions of rules of general interest for economic players, consumers, or users of regulated services.[13]

After that, the Economic Freedom Act expanded the obligation to carry out RIA, in similar cases, to all bodies of the Federal Administration.[14] Finally, RIA was regulated by Decree No. 10,411/2020, which established rules for cases in which RIA was inapplicable or exempted,[15] for the structure of RIA reports,[16] for different methodologies that could be used to measure economic impact,[17] for the submission of the RIA report itself or the proposed rule for social participation,[18] among other similar implementation rules.

In December 2019, when Ordinance No. 1,741 was issued, the Civil Office's

13 Article 6 of Law No. 13,848/2019 – General Law of Regulatory Agencies.
14 Article 5 of Law No. 13,874/2019 – Economic Freedom Act.
15 Article 3, p. 2 and Article 4, respectively, of Decree No. 10,441/2020.
16 Article 6 of Decree No. 10,441/2020.
17 Article 7 of Decree No. 10,441/2020.
18 Article 8 and Article 9, respectively, of Decree No. 10,441/2020.

RIA guideline highlighted the need for more complete analyses, which had to include a detailed exposition of the regulatory problem and a detailed evaluation of multiple regulatory alternatives. These new directives, which were being consolidated at the federal level, implied the need for greater institutional efforts for the collection and treatment of empirical data on regulatory issues. Consequently, Ordinance No. 1,741/2018 also determined a new workflow to integrate social participation with the preparation of RIA. This workflow included the possibility of submitting the RIA's Preliminary Report to public consultation.

In order to integrate these new directives into the practices of its organizational units, Service Orientation—SO No. 56/2018—was passed, specifying the workflow for the formulation and deliberation of regulatory instruments. The provisions determined a 2 (two) year transition period, between April 2019 and April 2021, in which ANVISA's organizational units could choose between executing the RIA based on the previous or new workflow.[19]

In March 2021, ANVISA's program for regulatory improvement would once again be revised, with the goal of complying previous regulations to the terms of Decree No. 10,411/2020 as well as specifying the division of responsibilities in the preparation of RIAs. This reform, however, does not fall within the time period analyzed in this article.

4 Empirical analyses of the use of RIA by ANVISA

To study the evolutions of Anvisa's RIA instruments, data published on the agency's website were collected using an automated tool for data collection (web scraping). The main source of this data was the legislation section of Anvisa's website. The data obtained from this source included information on the use or exemption of RIA as well as the justification used in cases in which RIA was exempted.

These data were cross-referenced with information on the classification of normative acts (regarding the theme and scope of the act) published by Anvisa itself. These classifications were also available on the legislation section of Anvisa's website in a spreadsheet used by the agency to consolidate information on its normative acts.[20] The whole process of data collection, including gathering a database through web scraping

19 Article 57 of Anvisa's Ordinance No. 1,741/2018.

20 This spreadsheet was downloaded on March 3, 2021, through the following link: http://antigo.anvisa.gov.br/documents/33880/3396406/Consolidado_Estoque+Regulatório_Portal2/7164cfed-0213-4c97-8f1c-f7ffff224683.

and cross-referencing it with Anvisa's spreadsheet, took place between February 17, 2021, and March 3, 2021.

4.1 Data collection criteria

The analyses below were made according to a consolidated database prepared with data obtained by the data collection methodology described above. The complete database contains 2,185 normative rules, 2,077 of which were issued by Anvisa, and 112 by other entities (Ministry of Health, Ministry of Agriculture, the President's Office, etc.). These regulations are available on Anvisa's website due to the high level of connection between these rules and the normative rules issued by Anvisa itself.

Among Anvisa's rules, the ones mainly found were Directors' Collegiate Resolutions (RDC)—1,656 cases—Normative Instructions (INs/INCs—181 cases). RDCs, INs, and INCs correspond to approximately 88% of Anvisa's rules in the database. These types are not the most common if we consider all acts published by Anvisa in the Federal Official Gazette. There are other types of acts, such as Ordinances and Special Resolutions, that are more common.

The agency's option to mainly publish these types of normative acts on its webpage relates to the fact that these acts contain regulatory rules with general effects for private regulated agents. According to Anvisa's Internal Rules of Procedure (RDC No. 255/2019), ordinances are used for issues related to the interest of the agency itself (administrative management); and Special Resolutions are usually concrete acts with no general effects, such as permissions, authorizations, etc.[21]

The database also included non-binding measures, such as guidelines, which are of interest to private regulated agents (and, therefore, are published in the legislation section of the webpage), but they are not normative acts *per se*.

Among the types of acts that compose the database, Directors' Collegiate Resolutions and Normative Instructions are the ones that best reflect the regulatory activity of the agency. As such, the analyses only include RDCs, Ins, and INCs from Anvisa itself. This first criterion reduces the universe of study to 1,837 normative acts.

In addition, as seen before, Anvisa started using RIA due to the establishment of

21 It is important to note that both Decree No. 10.411/2021 (article 3, p. 2, I e II) and Anvisa's Ordinance No. 162/2021 (article 17, I e II) have established the inapplicability of RIA for special acts with concrete effects (as opposed to general effects) and for internal acts (with effects related only to agency's internal administrative matters).

the Program on the Improvement of the Regulatory Process by Ordinance No. 422/2008. However, the agency has only started to disclose data on the use or exemption of RIA after 2011, when Ordinance No. 1,381 created the Center for Regulation and Good Practices on Regulation. At that time, RIA was included for the first time in Anvisa's Internal Rules of Procedure.

Given that the specific interest of this article is to study the implementation of RIAs by Anvisa, a second selection criterion becomes necessary. Before 2008, the practice of RIAs did not exist within Anvisa. Between 2008 and 2011, there were only tentative debates regarding the implementation of this instrument, and data on RIA are very scarce, with very few examples of its actual use.

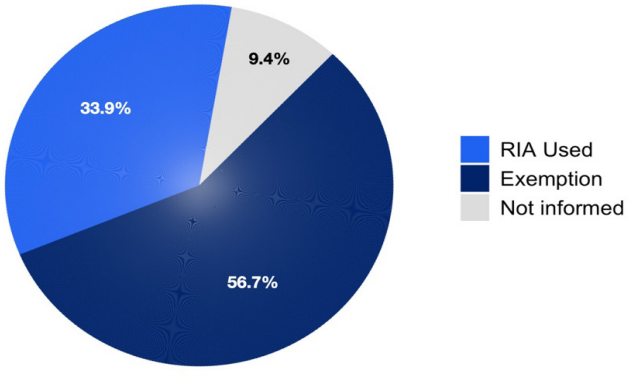
A second criterion was thus used to select, among Anvisa's RDCs, INs, and INCs, only the acts that were issued in the period from 2011 to 2020. The year 2021 was also excluded to avoid distortions in the analysis since the data are only available for the months of January and February.

Thus, using criteria regarding the origin of the act, the type of act, and the period of interest, a total of 843 normative rules (719 RDCs, 114 INs, and 10 INCs) are reached.

4.2 Use of RIA by the Agency

The first question that the data collected answers concerns the evolution of the use of RIA by ANVISA since 2011. It was observed that, among the 843 normative acts that compose the database, 286 used RIA (33,9% of the cases) to inform decisions; for 478 normative acts (56,7% of the cases), RIA was exempted; and for 79 normative acts (9,4% of the cases), there was no information available on the Agency's website about the use of RIA. The graph below shows these results.

Graph 1 – General proportion of use of RIA by Anvisa



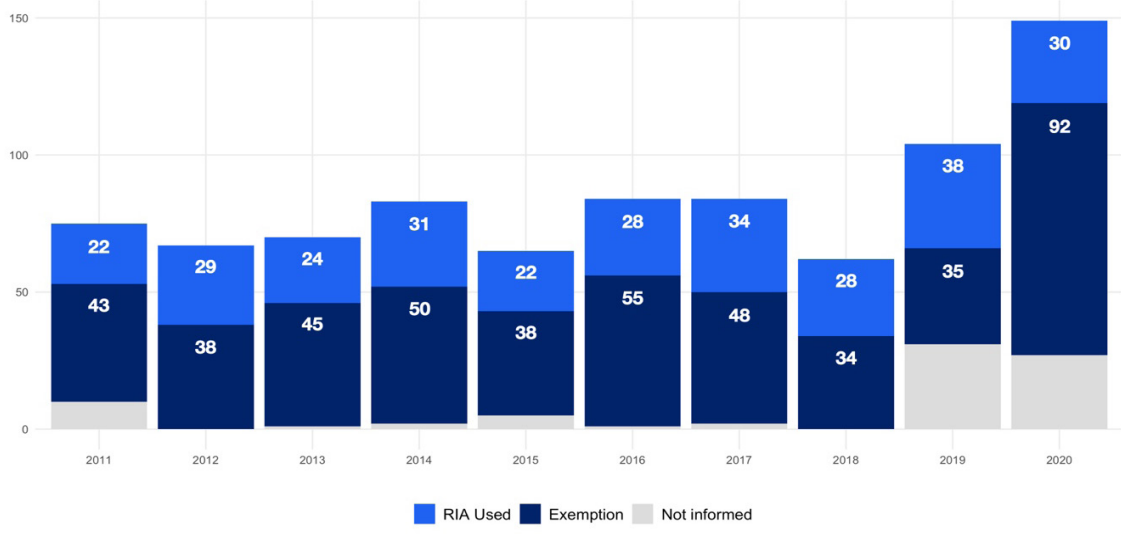
Source: elaborated by the authors.

During the period investigated, it was identified that the total number of normative acts per year and the proportion of use and exemption of RIAs have remained relatively constant between 2011 and 2016, with a slight upward trend in the use of RIAs in 2017 and 2018. In 2019, an increase in the total volume of normative acts was observed, with a decrease in the proportion of cases in which RIA was used and an increase in the proportion of cases with no information available.

This result may be related to the entry of the General Law on Agencies, which made RIA mandatory for ANVISA in certain cases. Another possible explanatory factor is the change in Anvisa's RIA methodology after the Civil Office guideline was issued and Ordinance No. 1,741/2018 was passed.

Finally, in 2020, a strong increase in the total volume of normative acts and a decrease in the proportion of cases in which RIA is used were observed. This result was expected due to the repercussion of the COVID-19 pandemic, especially considering that Anvisa was the regulatory agency that issued the majority of the direct measures that dealt with the pandemic (Guerra et al., 2020). The graphs below show the evolution of the use of RIA by ANVISA in absolute numbers and relative proportions.[22]

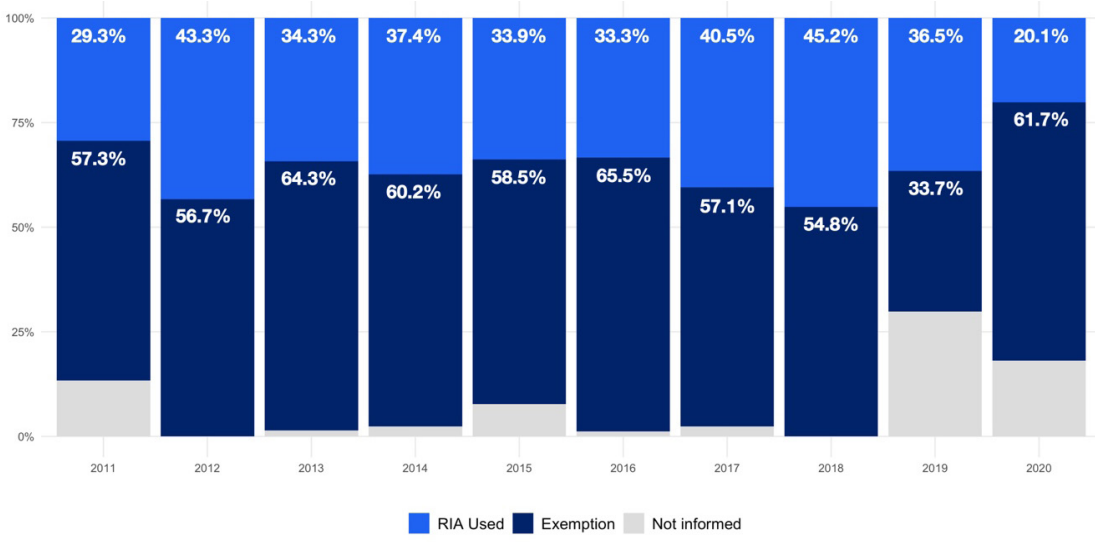
Graph 2 – Yearly Evolution of the use of RIA (absolute numbers)



Source: elaborated by the authors.

22 A table with consolidated data on the yearly evolution of the use of RIA by Anvisa is available in the Appendix to this article.

Graph 3 – Yearly Evolution of the use of RIA (proportion)



Source: elaborated by the authors.

Based on these results, it can be concluded that, although ANVISA is an agency with a high degree of engagement with RIA, most general normative acts approved in this period did not rely on previous analyses of their regulatory impacts.

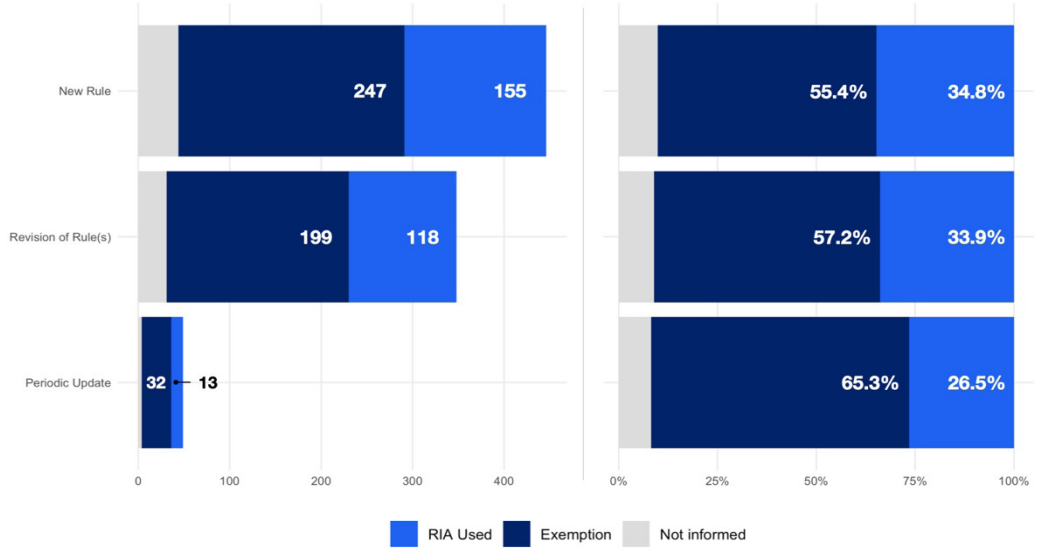
This is, however, a conclusion that is potentially compatible with the regulation of RIA, if one is to consider the general directives established by Decree No. 10,441/2020 and the internal rules of procedure established by Anvisa's Ordinances. This is because these rules establish cases in which RIA *does not apply* (material error corrections, normative consolidation, update/repeal of obsolete rules, etc.) and in which RIA *may be exempted* (procedures of great severity and urgency that represent high social risks, cases of notoriously low impacts, administrative simplifications without changes in the substance/merits of the normative rule, etc.).

Indications of the occurrence of these cases can be identified by cross-referencing data on the implementation of RIA with the categories of scope of the normative acts. In Anvisa's consolidation spreadsheet, the agency has classified its normative acts according to 3 (three) categories of scope: (i) new rule, (ii) revision of rule(s), and (iii) periodic update. Therefore, it is possible to assess if there is a substantially higher proportion of cases of RIA exemption among the rules that only revise or periodically update other rules, in comparison to entirely new normative acts.

The results obtained confirm that the high proportion of RIA exemption is also

present in rulemaking processes for entirely new normative acts. As shown in the graph below, the proportions of exemption and unavailability of information are practically equivalent among new rules and revision of rules. There is a higher proportion of RIA dismissal for periodically updating rules, which compose only a small number of cases.

Graph 4 – Implementation of RIA among scope categories



Source: elaborated by the authors.

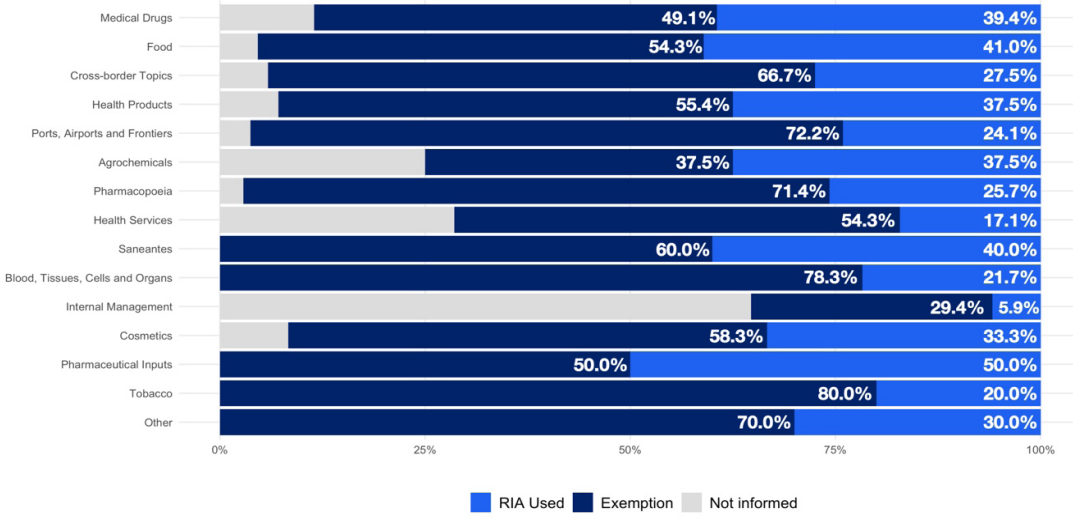
4.3 Variation of RIA implementation regarding the theme in the regulatory rule

On the other hand, more variation is seen when cross-referencing data on the use of RIA with the themes of the rules, a category also available in Anvisa's consolidation spreadsheet. The normative acts were classified by the agency, according to its theme, into 17 categories: medical drugs (218 cases); food (173 cases); cross-border topics (120 cases); health products (56 cases); ports, airports, and frontiers (54 cases); agrochemicals (40 cases); pharmacopoeia (35 cases); health services (35 cases); sanitizing products (30 cases); blood, tissues, cells, and organs (23 cases); internal management (17 cases); cosmetics (12 cases); pharmaceutical inputs (10 cases); tobacco (10 cases); organization and management of the SSS (7 cases); analytical laboratories (2 cases); and services of health interest (1 case).

Given its low frequency, the themes of organization and management of the

SSS, analytical laboratories, and services of health interest were consolidated into the category "others," totalizing 10 cases. The graph below shows the frequencies of RIA implementation according to categories of themes.

Graph 5 – Use of RIA according to regulatory theme



Source: elaborated by the authors.

For some themes with a very small number of cases (low n) in the database, the significance of this variation must be analyzed with caution. This is the case for themes such as cosmetics, pharmaceutical inputs, and tobacco. However, one can identify that, even in themes that are very common in the database, such as medical drugs; products for health; or ports, airports, and frontiers, the variation in the proportion of cases of exemption is very significant.

This result may indicate different levels of engagement of internal departments of the agency with RIA or even reflect perceptions of the Directors' Collegiate of the Agency regarding themes of greater relevance and urgency. Again, complementary studies are necessary for a qualitative analysis of the results obtained here.

4.4 Justifications in cases of dismissal

Besides publishing information on the implementation of RIA, the Agency also offers a justification for the cases it has opted to exempt the use of RIA or public

consultation before the approval of the rule on its website.

There were 4 (four) different justifications published by the agency on its website for the universe of cases investigated in this article: "procedure with a high degree of urgency and severity;" "procedure of periodic update;" "procedure of notorious low impact;" and "procedure of revision of a normative rule that exclusively envisages administrative simplification, without altering substance/merits."

To simplify the presentation of our results, these justifications are codified as 'urgency/severity,' 'periodic update,' 'low impact,' and 'administrative simplification.' There are also cases in which the agency has not published a justification on its webpage, referred to as "not informed."

The table below shows categories of justification used by Anvisa in cases of RIA exemption, indicating the absolute number and percentage of rules that have received each justification.

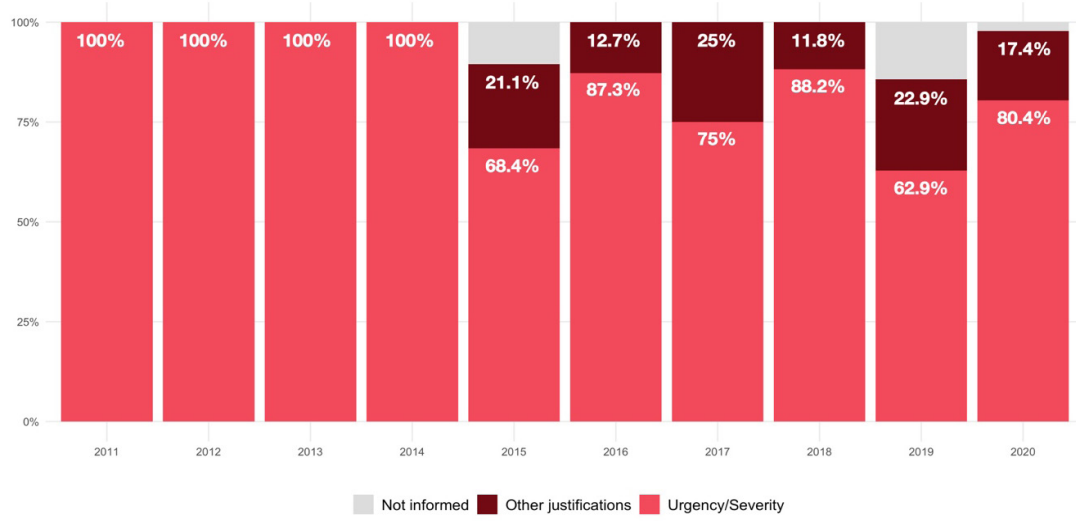
Table 1 – Justifications for RIA dismissal

Justification	No. of Cases	
	Total	%
Urgency/Severity	412	86.2
Periodic Update	31	6.5
Low Impact	22	4.6
Not Informed	11	2.3
Administrative Simplification	2	0.4

Source: elaborated by the authors.

There is a predominance of the justification urgency/severity, which is present in 86.2% of the cases in which RIA has been exempted for the universe of cases under investigation. In addition, when comparing justifications over the years, it was verified that, until 2014, urgency/severity was the only justification presented by the Agency for RIA exemption, as observed in the graph below.

Graph 6 – Justifications for RIA dismissal per year

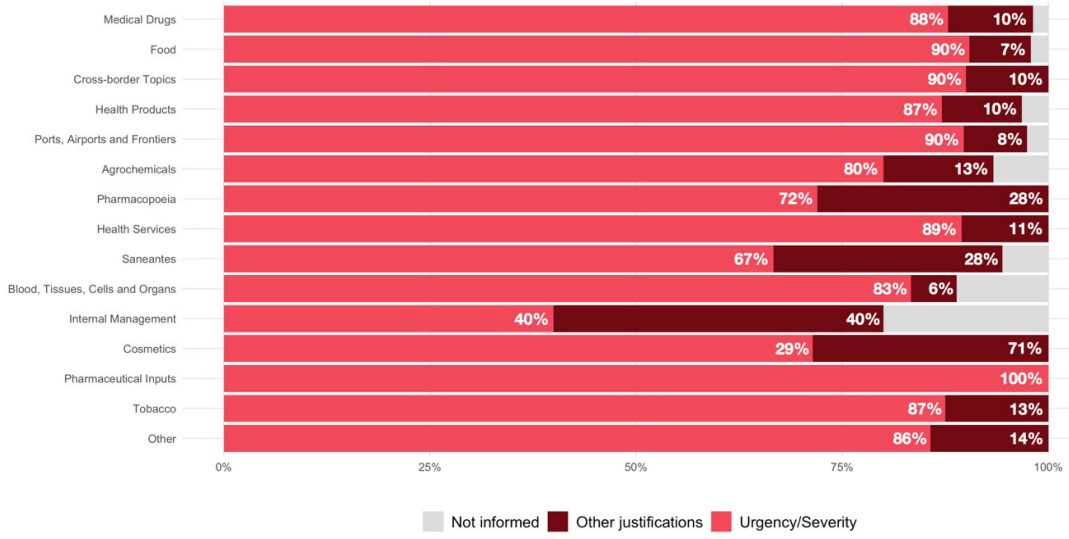


Source: elaborated by the authors.

Interestingly, compared to the year 2020, when the COVID-19 pandemic started, years 2014 and 2018 had a larger proportion of cases in which RIA was dismissed due to urgency/severity. It is worth noting, however, that the total number of normative acts issued in 2020 was substantially higher than those of the years 2014 and 2018. But it is a fact, in any case, that the high prevalence of urgency/severity as justification for RIA exemption does not relate to the COVID-19 pandemic, given that this trend was already present years before the start of the pandemic.

Furthermore, it is observed that the themes of the normative rules are also associated with variations in the justifications presented for RIA exemption. Cases involving themes such as agrochemicals, pharmacopoeia, and sanitizing products presented higher proportions of justifications other than gravity/severity. The graph below shows this result.

Graph 7 – Justifications for the dismissal of RIA according to theme



Source: elaborated by the authors.

Again, one must bear in mind that the number of cases (n) of some categories is excessively low and does not allow the reaching of robust conclusions. In any case, the data do show indications that the Directors' Collegiate of the Agency perceives gravity/severity differently for different thematic areas that fall within the agency's regulatory agenda. Further qualitative analysis of justifications for RIA dismissal may contribute to the understanding of this occurrence.

5 Final remarks

As a pioneer in the implementation of RIA in Brazil, Anvisa might be the best agency to systematically integrate this tool into its regulatory practices. Nevertheless, this paper finds that the agency has dismissed the use of RIA for 56.7% of its general normative acts with external effects.

The gravity/severity of the rulemaking process has been used massively by the agency to exempt studies of RIA, totaling 86.2% of exemption cases.

The use of RIA and exemption justifications tend to vary depending on the theme of the normative act as demonstrated. This result can indicate institutional differences between the different organizational unities of Anvisa. It can also point to differences in the way the Directors' Collegiate evaluates the complexity and severity of different recurring themes in its regulatory agenda.

In addition to contributing to the rationality and legitimacy of administrative decisions, RIAs can be used as a mechanism for political control of the Public Administration. It is beyond the scope of the article to confirm whether the use of RIA by Anvisa fulfills its different functions and purposes.

This article has accomplished a far simpler but essential task for future studies on the efficacy and effectiveness of this instrument—that of identifying the circumstances under which the agency used or did not use RIAs. In order to meet its rationality standards, RIA should only be exempted exceptionally, such as in low-impact rulemaking or when the costs of adopting RIA in urgent/severe situations supersede its benefits. Likewise, RIA will only serve as an instrument of political control if it is used as a rule of thumb by regulatory agencies.

In this article, it was not confirmed whether the situations in which Anvisa exempted RIA really met the urgent/severity or low impact criteria. This analysis is exclusively based on the justifications presented by Anvisa; verification of the justifications presented by the agency is yet to be made. However, the data collected do show that Anvisa uses this justification often and that different regulatory themes are treated differently by the agency. Hopefully, these results have set the ground for further investigations into Anvisa's RIA effectiveness.

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APPENDIX

I. COMPLEMENTARY TABLES

YEARLY USE/EXEMPTION OF RIA

	Use of RIA		Exemption of RIA		Not informed	
Year	Use (total)	Use (%)	Exemption (total)	Exemption (%)	N/I (total)	N/I (%)
2011	22	29.33	43	57.33	10	13.33
2012	29	43.28	38	56.72	0	0.00
2013	24	34.29	45	64.29	1	1.43
2014	31	37.35	50	60.24	2	2.41
2015	22	33.85	38	58.46	5	7.69
2016	28	33.33	55	65.48	1	1.19
2017	34	40.48	48	57.14	2	2.38
2018	28	45.16	34	54.84	0	0.00
2019	38	36.54	35	33.65	31	29.81
2020	30	20.13	92	61.74	27	18.12

Source: elaborated by authors.

USE/EXEMPTION OF RIA BY THEME

Tema	Use of RIA		Exemption of RIA		Not Informed	
	Use (Total)	Use (%)	Exemption (Total)	Exemption (%)	N/I (Total)	N/I (%)
Medical Drugs	86	39.4	107	49.1	25	11.5
Food	71	41.0	94	54.3	8	4.6
Cross-border Topics	33	27.5	80	66.7	7	5.8
Health Products	21	37.5	31	55.4	4	7.1
Ports, Airports and Frontiers	13	24.1	39	72.2	2	3.7
Agrochemicals	15	37.5	15	37.5	10	25.0
Phamacopoeia	9	25.7	25	71.4	1	2.9
Health Services	6	17.1	19	54.3	10	28.6
Saneantes	12	40.0	18	60.0	0	0.0
Blood, Tissues, Cells and Organs	5	21.7	18	78.3	0	0.0
Internal Management	1	5.9	5	29.4	11	64.7
Cosmetics	4	33.3	7	58.3	1	8.3
Phamaceutical Inputs	5	50.0	5	50.0	0	0.0
Tobacco	2	20.0	8	80.0	0	0.0
Other	3	30.0	7	70.0	0	0.0

Source: elaborated by authors.

USE/EXEMPTION OF RIA FOR ACTS OF DIFFERENT SCOPES

Act	Use of RIA		Exemption of RIA		Not Informed	
	Use (total)	Use (%)	Exemption (total)	Exemption (%)	N/I(total)	N/I(%)
New Rule	155	34.75	247	55.38	44	9.87
Periodic Update	13	26.53	32	65.31	4	8.16
Revision of Rule(s)	118	33.91	199	57.18	31	8.91

Source: elaborated by authors.

II. RESOURCES

The complete data base, as well as the code used in this research can be freely accessed[23] at: https://drive.google.com/drive/folders/1crxqKuRnFp39yJdh_oBoDwWNI4ikn7Ft?usp=sharing.

If you have any problems gaining access to these resources from the address given above, please contact us through the e-mail: lucas.gomes@fgv.br. All the code used to collect the data, clean the data and produce graphical visualizations was developed in the R language, using the packages and versions detailed below.

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23 Most files were stored in R's native format (.rds), but you will find the final version of the database (before selection cuts) in CSV format at './dados/ anvisa_legis_consolidada.csv'. You will also find PDFs with the full texts of a large proportion of the normative acts on the database at './dados/PDFs/.*'.