Subjective right to efficient regulation: the dual character of the Regulatory Impact Analysis*

Direito subjetivo à regulação eficiente: a natureza dúplice da Análise de Impacto Regulatório

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ABSTRACT

The Regulatory Impact Analysis (RIA), created by the Law no. 13,869 of 2019 establishes a mandatory step for regulatory activity in order to mitigate its risk and make it legally tolerable, recognizing the potentially harmful nature of regulation. In this sense, AIR production would be a subjective right of the regulated market, in line with the duties of good administration and to mitigate the risks of the normative activity considered

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by itself and a duty to the State, showing that its dual character in public policies construction specially on crises just as in Covid-19 pandemic.

KEYWORDS

Regulatory Impact Analysis — Law no. 13,869 of 2019 — risk society

RESUMO

A Análise de Impacto Regulatório (AIR), criada pela MP nº 881 de 2019, convertida posteriormente na Lei nº 13.869 de 2019 (Lei de Liberdade Econômica), estabelece uma etapa obrigatória à atividade normativa estatal a fim de mitigar seu risco e torná-lo juridicamente tolerável, reconhecendo o caráter potencialmente nocivo da regulação. Nesse sentido, a produção da AIR seria um direito subjetivo dos integrantes do mercado regulado, em consonância com os deveres da boa administração e de mitigação de riscos da atividade normativa em si considerada, e um dever do poder público, evidenciando seu caráter dúplice na construção de políticas públicas, especialmente em momentos de crise, como o vivenciado durante a pandemia de Covid-19.

PALAVRAS-CHAVE

Análise de Impacto Regulatório — Lei nº 13.869 de 2019 — sociedade de risco

Introduction

Efficiency is a constitutional predicate for the exercise of public administration. The creation of mechanisms that promote more effective statutory functions is the duty of public bodies and agents, with an inevitable weighing of purpose and the means to achieve them, necessarily conveyed by law, and the subjective right of citizens.

In light of this understanding — and with a markedly liberal bias — Provisional Measure No. 881, of April 21, 2019, established the Declaration of Economic Freedom Rights, later transposed into Law no. 13,869, of September 20, 2019, a normative instrument of strong value and indeterminate concepts that deserve careful analysis.

Among the various "legislative tortoises" of this provisional measure, matters unrelated to the subject included in the aforementioned standardization, Regulatory Impact Analysis (RIA) is a healthy instrument to promote efficiency, thence becoming the subjective right of actors in the regulated market, i.e., it becomes a necessary step for the valid exercise of regulatory activity, under the terms of the regulation prescribed by the Executive Branch.

However, rather than a management tool, it will here be analysed as a tool to reduce regulatory risks, making the requirement of RIA a subjective right of any member of the regulated sector. Here there is a familiar interface between law and economics — not only because the RIA must consider risks other than merely economic ones, albeit this is its main scope. Thus, in addition to regulatory activity prevent risks, it, in itself, produces risk.

The efficiency required of the State is also demanded in regulatory activity. The imposition of RIA by law is a response to the low quality of regulatory activity in the most diverse sectors of state regulation, provoking economic and social crises with regulations which should, on the contrary, provide stimulus and dynamism to economic activity, regulating it according to the needs of the market, always in the light of public interest. The enactment of a formal law shows that technical-scientific studies have not been used satisfactorily, through regulatory acts of low quality, even though their production has ostensibly been neutral, without favour or prejudice.

The law innovates by proposing quality and consistency when issuing regulatory normative acts, based on technical knowledge and in line with the interests of all actors in the sector, balancing the vested concerns. RIA is instrumental to normative production, denoting greater transparency and decision-making balance. That is why regulated industry participants, including consumers, have a subjective right to influence the RIA — a corollary of a greater right to equitable regulation and state efficiency.

The power-duty binomial, which shapes the State in its entire structure, is central to the proposed debate (hence its dual character). More than a duty of good management, RIA is a legal and constitutional imperative — and if all power emanates from the people, who exercise it through their representatives, expressed through law, then the RIA is configured as an instrument imposed by the people to legitimize regulatory activity as a corollary to the principle of legality, a subjective right of the citizen.

The Covid-19 pandemic, which triggered a technical-discretionary option, can unbalance the forces based on other principles, causing damage to

health and economic activity. In this sense, social distancing led to reductions in contamination rates, but caused severe damage to the economy, subject to the decision-making of public health managers.

The article begins with an overview of RIA, to demonstrate its origins and objectives, and define its scope. Next, risk is addressed as an element of administrative action and the power-duty of efficiency i.e., how management exposes itself to risks in the regulatory activity while seeking to mitigate them. The RIA will be then addressed as the subjective right of the agents in the regulated market based on the democratic principle, isonomy and the power-duty to reduce administrative risk. Finally, AIR will be explained as an instrument to improve the business environment, promoting development and wealth generation.

The general objective of this work is to discuss the dual character of RIA, as a right of the citizen and the regulated market and as a duty of the State, to mitigate the risks of poor regulation carried out under the pretext of standardizing a given activity. As specific objectives, subjective rights are deduced from the principles of public administration in terms of the construction of an adequate management model, as well as promoting reflection on the risk of administrative-regulatory activity and, ultimately, analysis of the role of the State as a regulatory agent of economic activity.

The research was broadly bibliographical, based on the subsumption of contemporary texts and interpretations of the Federal Constitution, in the face of current needs, towards a move from the theoretical to the practical, free from ideology, enabling consolidation of the precepts proposed in the academic community and in the legal environment.

1. An overview of RIA

A is a common management,[1] especially in countries where regulatory activity is more robust, such as United Kingdom, Canada and the United

[1] "There is a clear upward trend in the use of RIA by OECD countries. in 1980 only three countries used RIA. In the year 2000, around 50% of OECD member countries adopted institutionalized RIA programs. According to an OECD survey carried out in 2005 and updated in 2008, all member countries now routinely carry out some form of RIA for introducing new regulations before publishing them." SOUSA, Renan Martins de. A Análise de Impacto Regulatório (AIR) e o papel do Tribunal de Contas da União na avaliação da regulação setorial. *Revista do Tribunal de Contas da União*, n. 123, p. 105, 2012.

States,[2] with special emphasis on regulation in the health area. In Brazil, AIR initially emerged in Anvisa.[3]

For the legal terms, see article 5 of the aforementioned Conversion Law.[4] It is understood, however, that the proposal of the Organization for Cooperation and Economic Development (OECD)[5] is more accurate and, therefore, provides elucidation of the proposed analysis.

RIA[6] is as an instrument used to foresee the possible positive and negative effects of regulation,[7] namely, the risks of technical or economic contingencies

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2 Sousa summarizes the UK model, which adopted RIA in 2001. There is a committee to analyse the effects of regulation independently, as an agency. (Renan Martins de Sousa, A Análise de Impacto Regulatório (AIR) e o papel do Tribunal de Contas da União na avaliação da regulação setorial, op. cit., p. 123). The OECD, on its website, reports that the broad adoption of governance instruments has been a priority for member countries since 1995. As the document shows, the RIA started first in health and later spread to other branches. ORGANIZAÇÃO PARA COOPERAÇÃO E DESENVOLVIMENTO ECONÔMICO (OCDE). *Regulatory policy*. Available at: www.oecd.org/regreform/regulatory-policy/ria.htm. Accessed on: 9 May 2021.

3 In this respect, see, PECI, Alketa; SOBRAL, Felipe. Regulatory Impact Assessment: how political and organizational forces influence its diffusion in a developing country. *Regulation and Governance*, Feb. 2011.

4 Art. 5. Proposals for editing and amending normative acts in the general interest of economic agents or users of the services provided, edited by a body or entity of the federal public administration, including municipalities and public foundations, will be preceded by regulatory impact analysis, which will contain information and data on the possible effects of the normative act to verify the reasonableness of its economic impact. Single paragraph. Regulation will provide for the start date of the requirement that deals with the "main clause" and on the content, the methodology of regulatory impact analysis, the minimum requirements to be examined, the relevant cases and the cases in which it may be waived. BRASIL. *Lei nº 13.874, de 20 de setembro de 2019*. Conversão da Medida Provisória nº 881, de 2019. Institui a Declaração de Direitos de Liberdade Econômica. Available at: www.planalto.gov.br/ccivil_03/_ato20192022/2019/lei/L13874.htm. Accessed on: 29 Sep. 2021.

5 According to the text*:* Regulatory Impact Analysis (RIA) is a systemic approach to critically assessing the positive and negative effects of proposed and existing regulations and non-regulatory alternatives. As employed in OECD countries it encompasses a range of methods. It is an important element of an evidence-based approach to policy making. OCDE, Regulatory policy, op. cit.

6 The RIA was not created by the Provisional Measure. There are already experiences with the institute in regulatory agencies, especially at Anvisa. In this sense, see: Alketa Peci and Felipe Sobral, Regulatory Impact Assessment, op. cit., p. 6-7.

7 In the light of Rafael Oliveira's teachings, regulation works to correct failures in the market (Chicago School), such as monopolies and externalities. However, state intervention can lead to government failures, such as the "Nanny State", which takes away the autonomy of individuals, and regulatory asphyxia, defined by him as the "impossibility of exercising economic activities due to excessive state restrictions, configuring, in some cases, indirect expropriation of the right to exercise a certain economic activity". OLIVEIRA, Rafael Carvalho Rezende. *Curso de direito administrativo*. 5. ed. rev., atual. e ampl. Rio de Janeiro; São Paulo: Forense; método, 2017. p. 661-663. Rômulo Leitão and Alessandro Gouveia, in turn, explain that regulatory activity is imminently technical: "Thus, the regulatory choice would be the result of the technical competences of the agents, different from the discretionary choices of public administration, since the core of the choice is not based on convenience and opportunity, but on a decision technique closer to reality, built from a process of important participation of those interested in or affected by the results of regulation". LEITÃO,

that may arise from this standardization.[8] For example, when regulating the collection of a particular fee in a regulated market, the State may establish a series of benefits and penalties, especially for entrepreneurs and consumers, since all economic activity promotes externalities.[9]

In this text, the harmful potential of the activity is recognized, a trade-off between the desired and created risk,[10] as shown below, notably in markets that demand greater state regulation.[11] What is not acceptable, however, is the normative vacuum of the post-modern scenario, with risks previously unimaginable, generating uncertainties that escalate towards potential disaster.

As already highlighted, as a management tool, RIA has both positive and negative effects — in particular, economic reflexes. The instrument is a clear product of the interdisciplinarity that marks the regulatory law, recognizing the harmful potential of regulatory activity, especially from a financial point of view.

Rômulo Guilherme; GOUVEIA, Alessandro Samartin de. Escolha regulatória, controle judicial e a nova LINDB. *Revista de Direito Administrativo*, Rio de Janeiro, v. 278, n. 2, p. 103, set. 2019. ISSN 2238-5177. Available at: http://bibliotecadigital.fgv.br/ojs/index.php/rda/article/view/80051/76585. Accessed on: 21 Sept. 2021.

8 The regulatory choice is a prior decision-making process, but the recognition that a certain sector has complexity and specific needs, with a high technical load, which demand dynamism and neutrality superior to what the Legislative Power is capable of imprinting. According to Guerra, cited by Leitão and Gouveia, the regulatory choice is understood as "the exercise of the technical capacity of these decentralized entities to act, with greater weight, on the matters that compete to balance the regulated subsystem, different from the laws that, passed by the Legislative Power, assume a generic character, without concreteness". Ibid., p. 104.

9 Externality is the production of effects in relation to third parties for the sole fact of the activity, whether positive or negative.

10 John Oberdiek discusses, in chapter 4 of his work, whether or not there is a moral right against risk. OBERDIEK, John. Imposing risk. *Oxford Scholarship Online*, Oct. 2017. Available at: www.oxfordscholarship.com/view/10.1093/oso/9780199594054.001.0001/oso-9780199594054. Accessed on: 22 May 2021. More than that, it is believed that there is a legal duty of protection. In this sense, zero risk would be the closure of any and all economic activity; as this is not possible, a balance is sought between the tolerable and the desired risk so that there is always the necessary balance.

11 The Lei Geral de Agências, of June 2019, incorporates RIA into the decision-making process of regulatory agencies, the stage in which most regulatory activity takes place. It is understood, however, that art. 6, which introduces RIA in this field, is quite redundant, since there is a legal provision applicable to all state activity in the law which is the object of analysis in this article. The wording of that law confirms what has already been said: "Art. 6. Adoption and amendment proposals of normative acts of general interest to economic agents, consumers or users of services provided will be, under the terms of the regulation, preceded by the performance of a Regulatory Impact Analysis (RIA), which will contain information and data on the possible effects of the normative act." BRASIL. *Lei nº 13.848, de 25 de junho de 2019*. Lei Geral de Agências Reguladoras. Available at: www.planalto.gov.br/ccivil_03/_ato2019-2022/2019/lei/L13848.htm. Accessed on: 29 Sept. 2021.

The relevance of RIA and management based on science and statistics became even clearer during the Covid-19 pandemic. Social isolation proved to be the most effective way to contain the virus; however, this isolation has devastating effects on the economy and the State cannot support, alone, all the financial costs.

In this sense, any and all normative acts aimed at social welfare should be based on scientific study and cost-benefit analysis, to avoid mass starvation, rather than the invisible enemy, the virus. This is not an ideological discussion, but an eminently technical one. Social isolation should not be practiced blindly, without planning, but through setting the epidemiological impact against social economics, to determine in a gradual and preferential way where the impact on public health would be low and the economic and social impact high, not least as intervention in fundamental rights must always be minimal.[12]

By way of example, industrial activity has a high economic and social impact, with massive job creation, high revenue, and low epidemiological impact, since contact is with machinery more than people. Workers in this field should, in theory, be released earlier than, for example, academies, whose economic impact is low (not generating taxes or many jobs) and, at the same time, have a very high epidemiological risk.

Determining the risk of a given activity is the task of RIA. The impact on revenue should be measured and an estimation of the contamination index, to achieve an optimal point of the most economic activity with the least risk to public health.

It should be noted, however, that the technical-discretionary choice, in itself, is of high risk to the public administrator, since wrong choices can lead to disastrous results. Thus, minimizing risk to society, the decision to relax social distancing should be based on statistical, epidemiological and economic data and not essentially political aspects, such as the need to obtain legislative office.

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[12] The need for intervention in the right to circulated is limited to the minimum possible, inferred from Law no. 13,979, of February 6, 2020, which provides for measures to address the public health arising from the 2019 coronavirus outbreak. The aforementioned text, in art. 3, § 1, states that "The measures provided for in this article can only be determined based on scientific evidence and analyses of strategic health information and must be limited in time and space to the minimum necessary for the promotion and preservation of public health." BRASIL. *Lei n. 13.979, 6 de fevereiro 2020*. Provides for measures to address public health emergencies of international importance arising from the coronavirus outbreak. Available at: www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/lei/L13979.htm. Accessed on: 22 April. 2021.

The creation of this instrument, a task for the administration, gives rise to a concomitant subjective right for citizens: that of demanding that any normative regulatory act, even if general and abstract,[13] is preceded by analysis, to mitigate the potential risks of normative activity[14] as long as necessary under the terms of the regulation to which the law alludes, giving substance to the right to just administration and the duty of efficiency[15] of the public authority.[16]

Especially in the context of the Covid-19 pandemic, it is the right of the citizen to know why economic activity should adopt certain precautions and even stop and on what data and information that regulatory decision was based, in line with the democratic principle — and it is through the democratic path, at the polls, that poor discretionary choices are punished.

The risk of poor regulation, in the case of Covid, is destruction of economic activity, without even containing the contamination rate. The taking of informed decisions may not prevent its devastating impact, but it will certainly mitigate it. Regulation in times of crisis demonstrates, more than ever, how poor decisions can implode under the pretext of standardizing.

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[13] General and abstract normative acts are those that do not have specific recipients and that are not exhausted in the first application, functioning according to the logic of subsumption of the fact to the norm.

[14] About these risks: "The empirical evidence is sometimes challenged on the grounds that the disappointing performance of the regulatory process is the result not of any unsoundness in the basic goals or nature of the process but of particular weaknesses in personnel or procedures that can and will be remedied (at low cost) as the society gains experience in the mechanics of public administration. (…) The agencies are asked to do the impossible and it is not surprising that they fail, and in attempting to succeed distort the efficient functioning of the regulated markets". (POSNER, Richard. Theories of economic regulation. *The Bell Journal of Economics and Management Science*, v. 5, n. 2, p. 335-358, 1974. Available at: https://pdfs.semanticscholar.org/f7ce/e2b1bc06f593ca36bb972f438ff7fbbd0dbf.pdf. Accessed on: 22 May 2021.

[15] Efficiency is achieved through good governance — and, in the case of public authority, popular participation is a core element in this equation. Ismail Filho considers that "Good governance, on the other hand, means to govern with transparency, making informed decisions, where the public service user, whenever possible, must be heard and must have access to reasons for the governmental decision. This is because one must always take into account, permanently, the need for accountability. There thus emerges the need for prior planning of administrative decisions and a permanent dialogue (communication channel) between public service executives (administrators or public managers) and users/recipients of the provision". ISMAIL FILHO, Salomão. Boa administração: um direito fundamental a ser efetivado em prol de uma gestão pública eficiente. *Revista de Direito Administrativo*, Rio de Janeiro, v. 277, n. 3, p. 117, nov. 2018. ISSN 2238-5177. Available at: http://bibliotecadigital.fgv.br/ojs/index.php/rda/article/view/77679. Accessed on: 21 Sept. 2021.

[16] More than a duty, the search for efficiency is a necessity of the administration. So, "the challenges presented by postmodernity, especially the increase in risk, the speed of information, new technologies and the complexity of interests that must be satisfied by the State, demonstrate the insufficiency of traditional models of organization, performance and control of the Public Administration, guided by excessive formalities and the lack of concern with state efficiency." OLIVEIRA, Rafael. Governança e Análise de Impacto Regulatório. *Revista Eletrônica de Direito Administrativo Econômico*, Salvador, n. 29, p. 4, fev./mar./abr. 2012.

2. Risk as an element of administrative action and the power-duty efficiency

According to the International Organization for Standardization (International Organization for Standardization — ISO), risk is the effect of uncertainty on objectives.[17] These uncertainties may have various origins, such as ambiguity or lack of information, and the most diverse natures, such as legal risks, or physical risks (disasters, floods, for example).

According to the ISO 73:2009 Guide, which deals with risk management, the contemporary world may present a series of contingencies which are preventable if appropriate precautionary measures are taken. If they occur, their risk may be mitigated by adopting practices that are often simple.

If risk arises from ambiguity or lack of information, for example, it may also come from inexperience in the use of applied sciences, such as law and economics.[18] Its harmful potential emerges as the complexity and reach increase. As state action is largely exercised through legal acts, it is in their institution that government activity may err.[19] In terms of regulation, it is limited to the misuse of technical discretion.

With regard to regulatory law, there is an inevitable link between legal science and other branches of specialized technical knowledge, such as engineering, economics and medicine.[20] Regulatory activity arises with the challenge of, among other measures, promoting technical-legal changes with

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[17] The ISO 73:2009 Guide provides valuable instructions for professionals to assess the risk in the most diverse areas, dealing with risk communication from analysis to treatment. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO). *Guia* ISO 73. Available at: www.iso.org/obp/ui/#iso:std:iso:guide:73:ed-1:v1:en. Accessed on: 22 May 2021.

[18] The interaction between legal and economic sciences gave rise to the application of key concepts for the resolution of legal issues, from standardization to the application of law, in what is conventionally called "economic analysis of law".

[19] The imperfection of language, the raw material of law, leads to the subjective character of analysis of the norm, which may generate unwanted but inevitable distortions.

[20] On the regulation exercised by Central Banks, which is a notorious example of the combination of law and economics, it is stated that "As has already been happening in a large number of financially developed countries, based on the Anglo-Saxon model – with an efficient instrument of monetary and credit management, followed in the European Union after the adoption of the Euro as its currency — the institution of Central Banks, as constitutionally independent entities, to exercise, above political party pressures, partial interests of the market and, even, conjunctural public opinion, a technically autonomous regulatory activity, is a trend that, strengthened with the country's governmental practice, regardless of partisan views, sooner or later, will be incorporated into the Brazilian constitutional system." (MOREIRA NETO, Diogo de Figueiredo. Curso de direito administrativo: parte introdutória, parte geral e parte especial. 16. ed. rev. e atual. Rio de Janeiro: Forense, 2014. p. 617).

the agility that modern society demands, given the legislating function, by its very nature, follows the evolution of technical fields.

Thus, a technocracy anchored in law was created, to regulate technical aspects, concerned with activity output, notably financial. There is a need to know, in advance, the effect that standardization will have on the costs of an activity, the costs of compliance, product and service price, among others, to balance the risk of the activity and the benefits it brings collectively — considering that every activity has positive and negative externalities, even in terms of the very regulation that seeks to balance it.

The Covid-19 pandemic provides valuable lessons in this regard, as social isolation and the drop off in economic activity were triggered by the need to flatten the contamination curve. There is certainly an optimum point at which social and economic activity is affected the least without causing the contamination curve to run out of control.

Markets require certain regulation for their proper functioning, which must be carried out on a technical basis, so as not to fall into the same sins as the legislative function. It must be more agile, supported by technical discretion, with politics having a guiding role, although the law remains a core element in establishing the limits of regulatory activity.

Thus, a State that was essentially a provider of public services would be essentially regulatory. Its main function would be, with regard to art. 174 of the Federal Constitution,[21] to establish a beacon for the proper functioning of the market and the provision of services that the State, could or should provide, but does not do so at its own expense, through incapacity or simply political choice.

[21] Art. 174. As a normative and regulatory agent of economic activity, the State will exercise, in the form of the law, the functions of inspection, incentive and planning, determinant for the public sector and indicative for the private sector. BRASIL. *Constituição da República Federativa do Brasil*. Available at: www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm. Accessed on: 29 May 2021.

Articles 20[22] and 22[23] of *Lei de Introdução às Normas do Direito Brasileiro* (LINDB),[24],[25] supplemented by Law no. 13,655 of 2018, following the lessons of consequentialist doctrine,[26] determines that normative-regulatory acts consider the practical effects of the decision, in recognition of the harmful potential of the law and the need for analysis, necessarily, of the effectiveness of law, from formation to realization, as it is not possible to admit the existence of an applied social science that completely disregards, precisely, the consequences of its practices.

It also determines, in its article 21, that the administrative action will be guided by legal certainty.[27] Acting efficiently is acting with planning — and RIA is nothing more than a component of responsibility administrative.[28]

It is undeniable that normative activity appears to reduce the risks of mis-regulation of a certain activity due to political influence, i.e., so that the options are made with mostly technical, not political, support, as is inherent

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[22] Art. 20. In the administrative, controlling and judicial spheres, no decision will be made based on abstract legal values without considering the practical consequences of the decision. BRASIL. *Decreto-Lei nº 4.657, de 4 de setembro de 1942*. Lei de Introdução às normas do Direito Brasileiro. Available at: www.planalto.gov.br/ccivil_03/decreto-lei/del4657compilado.htm. Accessed: 23 May 2021.

[23] Article 22. When interpreting rules on public management, obstacles and the real difficulties of the manager and the demands of the public policies, without prejudice to the rights of administrators. Ibid.

[24] Although this article touches on analysis of the innovations of the *Lei de Introdução às Normas do Direito Brasileiro* (LINDB) of 2018, its scope is primarily the recognition of a subjective right of the members of the regulated market to conduct the RIA, within the ambit of a dialogic and participatory administration and of a larger context in which good management is required by the citizen. Ibid.

[25] The correlation between LINDB and regulatory activity is central to understanding the consequentialism required of regulatory law.

[26] The General Law on Agencies further reinforces such conclusions, attesting in art. 4 that the agency "shall observe, in its activities, due adequacy between means and ends, imposition of obligations, restrictions and sanctions to a greater extent than necessary to serve the public interest", and in art. 6, that the RIA "will contain information and data about the possible effects of the normative act". Consequentialism is essential to an applied social science, at the cost of losing its practical character and making it merely theoretical.

[27] MOREIRA, Egon Bockmann; PEREIRA, Paula Pessoa. Art. 21 da LINDB — o dever público de incrementar a segurança jurídica. *Revista de Direito Administrativo*, Rio de Janeiro, p. 243-274, nov. 2018. ISSN 2238-5177. Available at: http://bibliotecadigital.fgv.br/ojs/index.php/rda/article/view/77657. Accessed on: 21 Sept. 2021. It The quality of regulation is often closely linked to legal certainty. However, it is broader, as it analyses the developments of that norm from a technical, economic and social point of view. The normative risk to which it refers causes legal uncertainty, although it is not to be confused with it.

[28] Good public management is a subjective right of the citizen, legally enforceable, in a republic.

in parliamentary activity.[29] Here, then, normative risk arises,[30] understood as the possibility of a decree issued by the public administration causing damage to the regulated market on the pretext of standardizing it.[31]

As article 174 of the Charter suggests, the indicative role of regulation produces effects on the expectations of economic actors. Using sound technique to reduce the risks of errant standardization tends to produce positive effects for the economy, such as the increase in the solidity of the markets, the improvement of the business environment and the reduction of the ratings of international agencies. On the other hand, if inadequacy of this regulation is expected, this may have deleterious economic and social effects.

A country with a high risk of capture,[32] for example, will have a higher investment risk, as, at any time, an unsuitable normative regulation can destroy

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[29] From a strictly theoretical point of view, the removal of political aspects means the technique can be preponderant in the regulatory activity. However, interference, especially from the Executive Power, is recurrent in decisions of regulatory authorities. Even if there are terms, the mere appointment to office by the head of government creates debts of "gratitude" that may interfere with regulatory decisions. It is a system that depends on the performance of the Legislative Power for its legitimacy, surpassing the model of the public tender, or of commissioning, free appointment and dismissal positions i.e., a nomination of a political nature. It is a political nomination to technical position, with a fixed term, pursuant to art. 3 of *Lei Geral das Agências Reguladoras* (SOUTO, Marcos Juruena Villela. Agências reguladoras. *Revista de Direito Administrativo*, Rio de Janeiro, v. 216, p. 125-162, abr. 1999. ISSN 2238-5177. Available at: http://bibliotecadigital.fgv.br/ojs/index.php/rda/article/view/47359/45378. Accessed on: 21 Sept. 2021).

[30] In English, the expression normative risk was coined by philosophers to designate the risk of correction of the evaluation parameter (the correct standard of evaluation itself) and not empirical evidence, as it once was. Risk has always been understood on the basis of facts, and the norm, by itself, is not a fact — but has material results that depend on the action of the addressees of that norm. Here, the normative risk is implicated in the "bad choice" of the administration among the possibilities presented at the limit of technical discretion. Note, however, that the authors link the possibilities of choice to moral and non-technical values, which will not always be possible with a regulatory act. (DIETRICH, Franz; JABARIAN, Brian. Decision under normative uncertainty. Available at: www.franzdietrich.net/Papers/DietrichJabarianNormativeUncertainty.pdf. Accessed on: 22 May 2021. p. 2).

[31] The proposed analysis focuses on the output of the standard, its practical corollary, and not on internal aspects of the norm — legal certainty in the strict sense. By normative risk it is understood the legal norm may cause damage to the recipients, focusing on the output of the norm, of its practical consequences, in the physical world. This is not to be confused with legal certainty, which is intrinsic to the norm itself, internal to it. Without prejudice, it is clear that the poor production of the norm, its material fragility, which leads to legal insecurity, can lead to the materialization of risks in the real world to which it refers. Such legal certainty is an element to be observed by the State, in terms of LINDB 21, AIR assists in fulfilling this role, with the production of clearer and more effective rules.

[32] Capture is the American terminology to designate the partial performance of the regulation agency in favour of the big players in the market, in view of the high political and economic power of these groups. According to Rafael Oliveira, "The strong autonomy and concentration of powers in regulatory agencies jeopardizes their democratic legitimacy and compatibility with the principle of separation of powers. There is a potential risk of interest capture (the capture theory) by economically and politically more influential groups, to the detriment of consumers and users of regulated public services". (Rafael Oliveira, *Curso de direito administrativo*, op. cit., p. 225).

the regulated market, with infeasible rules, based on politics or tainted by the excessive influence of dominant groups. Sectors with strong state regulation demand technical supervision so that everyone will benefit from the proposed standardization — as, after all, public interest guides all the actions of public administration. the capture promotes undesirable outcomes, such as rent seeking[33] and regulation based on economic and political interests, rendering it useless or, at least, reducing potential benefit.[34]

However, as highlighted, even if exercised lawfully, there is an intrinsic risk to regulation. As with any potentially damaging activity,[35] it is essential that those responsible and/or benefited, internalize the possible contingencies through economic compensation, adopting precautions that reduce the risk to a tolerable legal level,[36] by way of compensatory, reparatory or preventive mechanisms.

This same logic underlies, for example, the issue of environmental licenses based on previous impact studies. The risk, intrinsic to the normative activity, will never cease to exist, since the use of any technique brings the negative consequences of incompetence, lack of control or misapplication — and the law, as a means, is subject to such predicates.[37] As the ISO Guide 73:2009 suggests, agents must manage the uncertainties, anticipate contingencies and outline strategies in case they arise.

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[33] Rent seeking denotes "made to order" regulation, that, instead of regulating the market as it should, seeks to benefit certain economic agents, providing them with disproportionate gains.

[34] Richard Posner presents the Marxist version of the capture theory, according to which regulation would be developed to benefit a few, which the author vehemently refutes, as that regulation may benefit even those without economic or political power. There would be no "total and unrestricted capture", as that under analysis suggests. Accordingly, to the author, that theory is based on the following premise: "Big business capitalists control the institutions of our society. Among those institutions is regulation. The capitalists must therefore control regulation. The syllogism is false. The great amount of economic regulation serves the interests of small-business-or non-business-groups […]". Although there are normative diplomas with deviating purposes, it is agreed that this is not the rule. The author also presents economic theories and policies on regulation in the article in question. (Richard Posner, Theories of economic regulation, op. cit., p. 341).

[35] Ulrick Beck built a relevant thesis on risk society, through which the advance of modernity would imply the sharing of increasingly severe risks among more people, with a marked degree of exposure to disasters, pandemics and other threats to health and life. See: BECK, Ulrick. *Sociedade de risco*: rumo a uma outra modernidade. Tradução de Sebastião Nascimento. São Paulo: Ed. 34, 2010.

[36] Within the context of the risk society outlined by Ulrick Beck, it is understood that risk cannot be eliminated, but only reduced to tolerable levels, enabling activities that are important to the community, but which have intrinsic risks.

[37] At this point, legal certainty is assessed, as the misuse of language or techniques can lead to misinterpretations of the norm, making it intrinsically unsafe — and, consequently, with unsafe or unpredictable output.

In a context where the civil liability of the State is widely accepted, the existence of "incompetence niches" where "the king cannot go wrong"[38] is inadmissible. Those affected by general and abstract acts do not have, according to traditional paradigms, the legitimacy to argue nullity or to file compensation claims against the government that, through inadequate planning causes damage to the regulated market.[39] Rights may be damaged[40] and, in the face of this risk, the legal system establishes caution, an element implemented in the RIA. The absence of caution, in itself, is already harmful to the community and to the actors in the regulated market.

Admittedly, the State is immune to its own ineffectiveness. It is understood, however, that administrative efficiency has been viewed according to false premises by the Judiciary. The judicialization of health, for example, yields numerous convictions, based on the right to health enshrined in art. 196, not taking into account that this public policy is an obligation of means, i.e., if the State adopts all possible measures to ensure the health of citizens, it must not be condemned, where the protection granted was sufficient. There should be no judicial compulsion for the public entity.

For example, the State may, as the Supreme Court has already decided, be obliged to keep stores of medicine, to ensure continuous health treatment.[41] If it does so, rigorously, and yet, still, a certain medicine is lacking, due to unexpected circumstances, objectively unpredictable, the public entity cannot be held culpable, nor should it be forced to stock more (or less) than that recommended by hospital management.[42]

If health is the ultimate obligation, the public entity is obliged to avoid all and any deaths in the public system — which is absurd. It has the duty to save

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[38] Literal translation of the saying "the King can do no wrong", which summarizes the thesis of state irresponsibility in force in the *Ancien Régime*.

[39] In our opinion, the regulation adopted without legal precautions or without using the best technique is liable to compensation, especially if it causes abnormal damages, in the light of that prescribed by art. 27 of *Lei de Introdução às Normas do Direito Brasileiro* (LINDB), revised by Law no. 13,655 de 2018.

[40] Ulrick Beck points out, in his conclusions, that risks have the most varied forms. The speed with which wealth circulates is the same as which risks emerge, from all sources, including regulatory activity.

[41] SUPREMO TRIBUNAL FEDERAL. RE 429903/RJ. Rapporteur: min. Ricardo Lewandowski: 25/6/2014, First Session, Date of Publication: Electronic Judgement Dje-156, announced on 13 Aug. 2014, published 14 Aug. 2014. Available at: https://portal.stf.jus.br/processos/downloadPeca.asp?id=250762026&ext=.pdf. Accessed: 21 May 2022.

[42] It is not enough for the plaintiff, in this case, to say that the stock is insufficient. There should be discussion about the best technique to be adopted in order to safeguard the professionalism of the management of the hospital.

lives, according to best knowledge and techniques, encompassing hospital planning and management. If all precautions required by law are taken, the state should not be condemned.

Thus, it is understood that the power-duty[43] to implement normative acts is also an obligation of means, which must receive the same practical consideration. The State must adopt the appropriate precautions to mitigate the risks of its legal acts causing abnormal losses to the regulated market,[44] provided regulation is measured and does not result in harm. That is to say: there is a duty to support decisions on scientific grounds, based on solid data and information to ensure efficiency.[45]

It is possible, even likely, that regulatory acts will cause harm (normal or abnormal),[46] as there is an inherent risk — either through the misuse of language, or legal stratagems, or even by external factors, such as corruption and the deliberate intention to distort. What must be required of the government is the adoption of precautions to avoid materialization of damages caused by failure to comply with the duties of planning and efficiency, making use of

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[43] A state duty inexorably corresponds to a citizen's subjective right to demand fulfilment of that duty. Therefore, "as in a reciprocal relationship, the individual/administered/citizen (which, in democratic and social states of law, integrates the concept of the people, the holders of political power) also has a right to demand from civil servants the fulfilment of the duty of good public administration." (Ismail Filho, Boa administração, op. cit., p. 113).

[44] Renan Souza explains that there are several models of RIA. It is not the scope of this work to define the best AIR models, or the best methodology, a matter of the public administration. Renan Souza, A Análise de Impacto Regulatório (AIR) e o papel do Tribunal de Contas da União na avaliação da regulação setorial, op. cit. p. 107.

[45] Ismail Filho, quoting Diogo de Figueiredo Moreira Neto, states that constitutionalising the principle of efficiency made it a diffuse right of citizenship. However, it may be more appropriate to characterize it as a homogeneous individual right of each one of the members of the regulated market. The difference is significant in the field of procedural legitimacy, since considering it a diffuse right means subtracting the possibility of actors, individually, in court. Ismail Filho, Boa administração, op. cit., p. 113.

[46] Analysis of the (ab)normality of the damages is nothing more than a judgment of proportionality inherent to the conception of justice inseparable from the law itself. A disproportionate norm or decision is not well accepted and, therefore, does not reach the ideals of regulation and social harmony. This is why art. 4 of the General Agency Law places proportionality as a central element of regulatory activity, stressing "the imposition of obligations, restrictions and sanctions to a greater extent than necessary to meet the interests of the public". In general, the discussion about the occurrence of abnormal damages is limited to the realization of government acts. Odília Oliveira discusses the occurrence of this type of damage under this paradigm, which is considered valid to understand when a regulation will be applicable or not in view of the damages caused by it. See: OLIVEIRA, Odília Ferreira de Luz. Obra pública — dano anormal — responsabilidade do Estado. *Revista de Direito Administrativo*, Rio de Janeiro, v. 190, p. 194-200, out. 1992. ISSN 2238-5177. Available at: http://bibliotecadigital.fgv.br/ojs/index.php/rda/article/view/45432/47662. Accessed on: 25 May 2021. DOI: http://dx.doi.org/10.12660/rda.v190.1992.45432.

all reasonable preventive instruments. If this is done, there will be nothing to complain about, as the occurrence of "normative claims" is possible even if all precautions are taken, as imponderables are inevitable.

It is necessary to differentiate the burdens imposed by law from abnormal damages, as well as predicting the unpredictable. Tax burdens are expected, legally tolerable inconveniences, brought about by regulation. Such is the case with the adoption of new filters in cigarettes, for example, which increase industry costs in order to benefit the health of the consumer. This is acceptable to and expected by the whole community, respecting technical discretion.

It would be different if the standard required that filters be changed five times, without technical support. The loss experienced by that company would be abnormal, disproportionate, and therefore legally unacceptable.[47] Note that, in both examples, certain parties are benefited and harmed by the regulation,[48] all in the public interest.

There is no way to predict with absolute certainty who will bear the burden and reap the reward of a norm; it is possible, in that same example, that the industry increases its prices and still obtains a higher profit margin with the standard, although this is not the effect anticipated. Damages and costs of regulation can be predictable or unpredictable. RIA tries to reduce this spectrum of uncertainty, using prediction techniques, although the total reduction of uncertainties is an absolutely impossible task, limiting the incidence of unexpected "normative claims", also considering that this practice is an imperative of good governance.

Another example is given by Franz Dietrich and Jabarian:

> Ann, Bob, and Claire suffer from the disease. Ann has 2g of a medicine, which is just enough to cure her. Bob and Claire would each need just 1g of that medicine to be cured. The agent (e.g., the public health authority) may not intervene, so that Ann is cured while Bob and Claire are not. This is option "a". Or the agent confiscates Ann's medicine and redistributes it to Bob and Claire,

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[47] It is understood that, in the same way that no one can be forced to face abnormal damages, no one can be disproportionately benefited by the norm, as in the aforementioned rent seeking.

[48] Carl Cranor states that the regulation process, in general, involves pros and cons, benefited and harmed. Here, it would be concluded that it is up to the administration to exercise such an option, provided that they are at acceptable levels and always based on the public interest. CRANOR, Carl F. The normative nature of risk assessment: features and possibilities. *Risk*, v. 8, no. 123, 1997. Available at: https://scholars.unh.edu/cgi/viewcontent.cgi?article=1320&context=risk. Accessed on: 22 May 2021.

so they are cured while Ann is not. This is option "b".[49]

Option "a" is not acceptable, as Bob and Claire would die of that disease. Neither is option "b", as it would result in Ann's death. Neither are acceptable because they inflict abnormal harm. Ideally, without going into the legal merit of the example, vis-a-vis economic sciences, regulation should find a distribution of medicine that would cure all three, even if Bob and Claire were required to pay Ann some sort of compensation. Obviously, none would so graciously sacrifice themselves to save another.

The optimal solution would lie in the possibility that each one declared their needs but, at the same time, acquiesced with the others. Often the optimal solution is not perfect and embeds sacrifices: the public administrator must exercise technical discretion and competence, in the light of all available information. Reconciling interests would facilitate construction of the best decision, through broad discussion with all involved. If one or another were not heard, they would not accept that decision well. In this sense, the RIA should, legislatively, consider the imperatives applicable to public administration and the internal and external impact of that normative instrument — as relates to the international concept of the OECD, covered in this work.

All those potentially impacted, inside and outside the protected market, should have their interests protected as much as possible,[50] as a consensual and transparent solution tends to be the best and most efficient.[51] Furthermore, the practical effects of an abstract regulatory decision must be considered, in a predictive exercise preceded by scientifically based studies and broad popular participation,[52] mitigating (but not completely

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[49] Franz Dietrich and Brian Jabarian, *Decision under normative uncertainty*, op. cit. While economic science works, the authors use a lot with "numbering", that is, transforming abstract concepts into "units of utility" so that one can compare choices with no specific numerical value.

[50] Richard Posner states that the more homogeneous the interests, the easier it will be for the State to accommodate the interests of the regulated market. He warns, however, contrary to common sense, that highly concentrated markets tend to obtain less benefits of regulation than pulverized markets. (Richard Posner, Theories of economics regulation, op. cit., p. 341).

[51] Ismail Filho explains that the United Nations considers participatory democracy an ideal model for decision-making, with which we agree. Ismail Filho, Boa administração, op. cit., p. 117-118.

[52] Rafael Oliveira reinforces this idea, considering that "the RIA reinforces the legitimacy of the regulatory decisions, reinforcing the ideals of deliberative democracy. The legitimacy of the so-called 'Multiclass State' is not content with the traditional mechanisms of representative democracy. The homogeneity of interests to be protected — characteristic of the bourgeois Liberal State, which was supposed to meet the needs of a ruling class (the bourgeoisie) and which established the census vote — gives way to the heterogeneity of existing interests in today's complex society". Rafael Oliveira, Governança e Análise de Impacto Regulatório, op. cit., p. 12.

eliminating) the risks of normative activity[53] and increasing acceptance of the standard.

Regarding popular participation, it should be noted that regulatory agencies have sought to legitimize their decisions through dialogue with civil society, notably through media events.[54] Despite the critical arguments, such as the predominance of economic players at such events, it is understood that they are an important step towards the democratization of regulatory activity. Shared decisions tend to be better — even technically speaking.[55] Participation encourages an ethical approach and, if can improve efficiency.

RIA should support these meetings, demonstrating to the regulated market the expected impact of a certain measure, allowing less organized sectors of society to give their opinion vis-a-vis other participants, reducing the asymmetrical information that exists among the actors in the regulated market — in general, large companies and other key players, including those consumers who lack the knowledge or financial conditions to challenge market players.[56]

The responsibility of the State, for not taking all possible the precautions to mitigate the damage caused by regulatory activity, is key. Mandatory RIA provides an objective element to this analysis, with regard to a regulatory activity of great impact, as if the State does not adopt the necessary

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[53] Law no. 13,848, of June 25, 2019, provides for the management, organization, decision-making and social control of regulatory agencies. This is a significant legal framework for the performance of agencies, as it establishes clear standards for the performance of responsible entities, in most cases, for state regulatory activity. As highlighted, analysis of the risk society in postmodernity and its potential for democratic process, "with the recognition of risk and ambivalence, the possibility opens up both for a more than tolerant law and democracy, according to an inclusive and fraternal, deliberative and transparent model, a producer of a morally correct post-positivist law, as a way to reduce the risk or even to confer greater rationality of decision, so that this (risk) can live together". CARDOSO, Henrique Ribeiro. *Controle jurídico da legitimidade da atividade regulatória normativa.* Tese (doutorado em direito) — Faculdade Gama Filho, Rio de Janeiro, 2007. p. 81. The production of legitimate law, with wide participation of those affected is consistent with substantial democracy.

[54] "Unlike other decision-making processes, inaccessible to social participation, AIR reveals the merits of decisions and the impact of actions based on public consultation concerning documents that establish objectives and effects of a regulation proposal. This consultation increases the transparency of the regulatory process and favors public response toward important information, providing quality control of the identified impact and improving the quality of information on which decisions will be based." ALVES, Flávia Neves Rocha; PECI, Alketa. Análise de Impacto Regulatório: uma nova ferramenta para a melhoria da regulação na Anvisa. *Revista Saúde Pública*, p. 803, 2011. Available at: www.scielo.br/j/rsp/a/nLq8TdwdnRdWQZrtTcGWPNn/abstract/?lang=pt. Accessed on: 29 May 2021.

[55] Popular participation is part of the good governance required by the public power as an imperative of constitutional law (principle of efficiency).

[56] Information asymmetry is one of the market failures that legitimizes state intervention.

precautions for the exercise of its power, this is already an affront to the fundamental rights of citizens. Just administration is inherent to the concept of citizenship and RIA is a core instrument for the satisfactory performance of regulatory activity.

On the other hand, state omission in the elaboration of RIA would amount to an unacceptable and authoritarian abuse of the right to regulate a given activity.[57] The law determined this instrument as a working method, regardless of administrator options, i.e., the tool is fully binding. RIA integrates due legal process for the issue of regulatory acts, a formal and mandatory step, dependent on eligibility, under the terms of the regulation.

The effects may be halted in court, if they are not subject to legal action that ultimately culminates in the annulment of the act. The burden of proof in indemnity claims proposed by the injured parties may be reversed, vis-a-vis norms that have not been produced with the support of the RIA, thus requiring competent studies — the same logic that induces reversal of the burden of proof in the environmental field, notably with regard to measuring the impact of a venture when there is no scientific evidence as to its harmfulness (precautionary principle).[58]

That is to say: the actor responsible for creating the risk (in this regulatory case) has a legal duty to prove the adoption of all precautions prior to the publication of the normative act, under penalty of liability for the resulting effects, unless it proves, technically, the harmlessness of the act. if there is no support for standardization, this should not be carried out, as adventurous regulatory activity is not permitted.

From the power to create harm comes the right to mitigating measures, whence the duty of the administration, more than moral, is juridical. As with private agents, so with the State, which has the same (or even more) potential to destroy.

It would be the duty of the administration to prove it adopted the best rationale in passing a normative act, that all factors were considered — hence,

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[57] Abuse of rights is defined in art. 187 of the Civil Code, as an act formally lawful but materially unlawful.

[58] Reversing the burden of proof determines that the unknown risks of an activity are not tolerable, and it is up to the interested party to provide the information necessary to certify harmlessness. In this sense, note the jurisprudence of the Federal Supreme Court (STF) in the environmental field, using the precautionary principle to determine that the economic agent attests to the safety of their enterprise when there is no scientific certainty about the risks and harms of that activity.

the possibility of the Judiciary delving into the merits of regulation,[59] as regulatory normative activity is based on the technical discretion inherent to it.

In the wake of what the Chenery doctrine,[60] of American origin, teaches, acts based on the technique would be indiscriminate,[61] and the Judiciary should cling to formal aspects, to the possible adoption of precautions and liability studies and substantial legal factors,[62] such as proportionality and reasonableness (as in the case of abnormal damages). Still, it could only do so after ample probationary delay.[63]

This is because only the Executive Branch has the ability to bring together the variables for the production of a substantiated technical-discretionary decision. The Covid-19 pandemic at the beginning of the decade, provides precious insights into the topic. A macroeconomic, not merely political, analysis determines whether a given activity has low epidemiological impact and may work. Certain measures may attract votes, but the health impact must be balanced by necessary consideration of the economy.

There is no affront to the inexorability of jurisdiction (or to fair legal order), since the dispute would be validly analysed by the Judiciary within the spectrum of attributions expected in the Constitution of the State's functions.[64]

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[59] "A consequence of the recognition of the rules of the agencies as a kind of administrative act, is the possibility of their control by the Judiciary. Even if one adopts narrower view of the control of discretionary administrative acts, with incompatibility of merit — convenience and opportunity, within the motive and the object —, or even the proportional application of guidelines/objectives/principles, there is no denying control over the elements necessarily linked to any administrative act — competence, purpose and form — or even the criteria (sub-rules of adequacy, necessity and proportionality in the strict sense) of proportionality." Henrique Ribeiro Cardoso, *Controle jurídico da legitimidade da atividade regulatória normativa*, op. cit., p. 47.

[60] The "Chenery Doctrine" was expounded in its entirety in SLS 2240-SP, Rel. min. Laurita Vaz, unanimously judged on 7/6/2017, DJe 20/6/2017 (STJ, Informativo 605). Available at: www.stj.jus.br/docs_internet/informativos/PDF/Inf0605.pdf. Accessed on: 21 Sept. 2021.

[61] A (in)sindicabilidade dos atos regulatórios é objeto de análise detida in: Rômulo Guilherme Leitão e Alessandro Samartin de Gouveia, Escolha regulatória, controle judicial e a nova LINDB, op. cit.

[62] Regulatory activity is subject to legality both in its form, in this case, by instituting AIR, as well as in its content. According to Leitão and Gouveia, "[t]he regulatory competence, even when the result of a regulatory choice, ends up disciplining rights and obligations of regulated persons and this always requires compliance with the national legal system and, as it is the result of a state action, it is undeniably an act before and above all in line with the principle of legality, even if one recognizes the disintegration of the legality in the face of the speed and complexity of social and economic relations". Ibid., p. 106.

[63] Res judicata, in a system of single jurisdiction, such as the one adopted by Brazil, would confer certainty to the right claimed, since the judicial process would necessarily demand expertise.

[64] For Tércio Sampaio Ferraz Júnior, the principle of legality, reinterpreted in the sense of legitimation, is respected when the law is seen as an administrative instrument: "Its hermeneutic principle is in the solidarity between means and ends, whence the reasonableness of the administrative activity, then submitted to an evaluation of its efficiency", is not limited to the

The regulation may be analysed in the light of public interest, in terms of legal criteria, dependent on sound technique — a legality exam[65] that does not replace the administration in the choice of valid output of a certain norm,[66] i.e., in the choice of who will bear the burden and regulation onus, except for the occurrence of abnormal damages (which, after all, are disproportionate). Thus, there would be an examination of legality.

3. AIR as a subjective right of participants in a regulated market: the democratic principle, isonomy and the power-duty of administrative risk reduction

The RIA is, then, an optimal instrument for regulation and, based on the principle of efficiency, would be a subjective right of the regulated market according to the primacy of citizenship and republicanism. The duty of sound administration is materialized in the RIA, and the rights of the citizen who, after all, is the owner of public affairs. This subjective right has at least three pillars: the democratic principle, isonomy and the theory of risk.[67]

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discretion of a judgment of opportunity, but of reality, concerning evaluation of policies for the implementation of objectives, the adequacy of means chosen in view of the proposed purposes. FERRAZ JÚNIOR, Tércio Sampaio. Agência reguladora: legalidade e constitucionalidade. *Revista Tributária e de Finanças Públicas*, São Paulo, a. 8, n. 35, p. 154-155, nov./dez. 2000.

65 He summarizes it this way: "The normative technical power indicates that these autonomous bodies receive from the respective laws delegation to institute technical norms (not the basic norms of legislative policy), complementary and of a general nature, portraying broader regulatory power, insofar as such norms are introduced into the legal system as a new law (*ius novum*). […] What seems inescapable is verification, in each case, whether the exercise of the power was realized or, on the contrary, if it was abusive, with disrespect to the parameters that the law determined. Consequently, technical normative power cannot fail to be subject to administrative and institutional control." CARVALHO FILHO, José dos Santos. *Manual de direito administrativo*. 21. ed. rev., atual. e ampl. São Paulo: Atlas, 2016. p. 621-622.

66 The difficulty of comparing the options using technical discretion prevents the act being evaluated by the magistrate, in this regard. According to Franz Dietrich and Brian Jabarian, "*Options have uncertain value, for instance because of competing normative intuitions or theories*". Franz Dietrich and Brian Jabarian, *Decision under normative uncertainty*, op. cit., p. 3. In other words, objectively measurable numbers are not compared, but choices performed according to the best technique. If there is no malpractice or illegality, there will be no replacement of the manager by the judge, even if the results of regulation in one way or another are economically more favorable, as monetization cannot take over the entire complexity of public policies. Likewise, the expected result of one and the other option cannot be measured according to expected values, because at least one of them, that passed over, did not occur, and facts cannot be compared against expectations.

67 Such aspects were addressed in previous studies and the conclusions on RIA presented here are supported, in part, by the work developed in: Henrique Ribeiro Cardoso, *Controle jurídico da legitimidade da atividade regulatória normative*, op. cit. Democracy, isonomy, in the context of uncertainties, is concretely related to the legitimacy of regulatory activity, under the premises established by Habermas and Alexy: "The discursive theory of law and deliberative

The democratic principle has already been touched upon but needs reiterating. The participation of the population in public administration is increasingly relevant, especially due to the facilities provided by Information Technology. At the same time, an increase of specialization, of technical expertise, can be seen — one of the factors that underlie the creation of regulatory agencies.

Accordingly, the production of information and knowledge remain in the hands of those few endowed with greater organization and economic power — in general, large companies in the regulated sector, at the expense of the most disadvantaged sectors, notably the average citizen. Although information and knowledge are more available, they are increasingly specialized and unintelligible, reinforcing information asymmetry between the various agents impacted by the norm.[68]

The RIA mitigates this asymmetry, rendering studies more palatable. In this way, in the midst of such an ocean of information, the administration organizes and systematizes it, democratizing the analytical aspect of the production of the norm, as already happens with environmental impact studies.[69] The participation of those affected by the standard is a fundamental element for it to be better accepted, understood and respected.

With regard to isonomy, it is understood that the paradigms that place the State as the higher body in formal and business relations are no longer a reality.[70] The large conglomerates wield political and economic

democracy establish direct contact with the sociology of risk, with its ambivalence, and the recognition of contingency as a common destiny". Ibid., p. 127.

[68] Despite the internet being celebrated as democratizing access to information and knowledge, specialization and technique are still guided by economic power. The great conglomerates have greater power to produce technical information, so that everything indicates that the diffusion of electronic means of communication has reduced the asymmetry of information is only true in terms of simple knowledge and information, largely because to produce technical information it is necessary to have financial resources, which most people do not have.

[69] This parallel is always relevant, as impact studies (normative, environmental) are aimed at mitigating the risks of an activity, recognizing its potential harmful nature to the collective.

[70] Flávia Piovesan demonstrates this reality with economic data: "With regard to the private sector, there is also a need to accentuate social responsibility, especially of multinational companies, insofar it is the main beneficiary of the process of globalization, suffice to say that of the 100 (one hundred) biggest world economies, 51 (fifty-one) are multinational companies and 49 (forty-nine) are national states". PIOVESAN, Flávia. *Direitos humanos e propriedade intelectual*. 2007. p. 34. Available at: http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/2665/CL01%20-%20Flavia%20Piovesan%20-Direitoshumanosepropriedadeintelectual.pdf?sequence=3. Accessed on: 2 May 2021. This scenario was certainly consolidated in the 12 years that followed the article, with recent reports that there are companies that are already valued at a trillion dollars (according to an *InfoMoney* report "The tragic story of the first company worth $1 Trillion — and it's not Apple."). INFOMONEY. *A trágica história da primeira empresa a valer US$ 1 trilhão — e não é a Apple*. Available at: www.infomoney.com.br/mercados/acoes-eindices/noticia/7544565/tragica-historia-primeira-empresa-valer-trilhao-nao-apple. Accessed on: 29 May 2021. Interestingly, in 2007, PetroChina reached this level but soon after steeply declined.

power unparalleled in history, and it is plausible to consider that the State and individuals, at times, are on the same political and economic plane. If precautions are required from individuals to mitigate the risk, the same is true in relation to the State — and regulation is one of its primary functions. From another perspective, RIA would provide, as already said, a greater equalizing of information between the various economic actors, including between the administration and the large conglomerates.

In the legal system there are a series of instruments required by individuals in order to validly exercise their actions within a risk society. In this sense, instruments such as the environmental impact study,[71] and the study of neighbourhood impact,[72] among others, were designed. RIA is such an instrument.[73]

These texts seek to assist informed decision making by the public authority. According to the democratic principle, and based on isonomy, state activities which give rise to risk are to be submitted for consideration by other public bodies and the population for validation.[74]

The production of prior studies is an onus of risk activity. Such studies are required, even by the government, in the exercise of dangerous, polluting activities, for example. Actions entailing legal risk are necessarily subject to regulatory precautions.

There is no practical or legal reason for the State, in high-risk activity, not to carry out adequate studies, with a scientific bases, based on broad

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71 The environmental impact study is supported by the Federal Constitution (art. 227 and items) for projects potentially causing a significant impact environmental.

72 The neighbourhood impact study is a document that aims to protect the urban environment, supporting the creation of large enterprises mentioned in previous studies that demonstrate it is beneficial to the community, including with regard to quality of life.

73 Peter Menell argues that, of their own accord, entrepreneurs would only be willing to avoid damages from the moment the cost of any litigation exceeds that of prevention, from which emerges the need to impose limits, including for the State. He says: "The approach taken here is to focus on the injurer's choice of damage level. The key observation is that it is possible for the injurer to preclude suit by setting the level of damages below the victim's litigation costs; that is, the victim will have no incentive to sue when his litigation costs exceed his expected gain from suit (recovery of damage). Therefore, the injurer can harm the victim up to the value of the victim's litigation cost without inducing suit. Consequently, when the injurer provokes suit, he sacrifices in profits that do not have to be paid out to the victim as damages an amount equal to the victim's litigation costs". (MENELL, Peter. A note on private versus social incentives to sue in a costly legal system. P. 41. Available at: https://poseidon01.ssrn.com/delivery.php?ID=850020098089104071002025122191021120028037009079051031109073107074027024000108009026118058007012054120046022187070092108075105007085094078038067078125011115015004042095066072121002002022012008088108020110076122-028085074090100102098091075112001093&EXT=pdf. Accessed on: 19 Jun. 2021).

74 This is the ideal, according to the canons of participatory democracy.

discussion in society, to prevent or mitigate the damage to the regulated market or the popular economy. If projects that harm the environment are embargoed or undone, likewise, a norm with damaging potential can and should be suspended or annulled.

Regulatory activity gives rise to consequences that can be measured within a reasonable range of possibilities — even as it seeks to discipline legal relationships. Escaping this prism, following an extraordinary path, is not feasible, as predictive activity is limited. The risk is managed, never eliminated.

It is the subjective right of market actors to demand elaboration of RIA as a management instrument, under penalty of suspension of the norm, for failure to comply with the technical discretion power-duty of the regulatory entity, and public authorities are required to prevent operations of enterprises that do not carry out environmental studies required by law, even in the private sector. The State should adopt measures that mitigate risks,[75] enabling the performance of a given activity, often with underlying socio-economic interest, for the benefit of all.[76] Anyone in a potentially harmful industry must bear a burden, such as carrying out prior studies which prove that, for the community, the activity is beneficial, even if it derives from controlled risks, and, therefore, is legally acceptable.

It is important to mitigate potential risks of high risk, albeit necessary, activities to an acceptable level. The operation of a nuclear power plant, for example, is important to generate energy for a society, despite carrying risks. Strong regulation is required, although this does not prevent disasters like that in Fukushima, Japan, in 2011. The country did not then ban the use of this energy source, since inherent public interest is involved. Although the plant

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[75] The danger must not be understood only in terms of disaster. The interruption of a service, by itself, can cause incalculable damage to society. Hence both hazardous operations in the strict sense, such as a nuclear power plant, and of general economic interest, such as natural monopolies (water, electricity, telephony, etc.) are the object of technical regulation.

[76] Contrasting the American with the French model, Rafael Oliveira states that "[t]he reasons for the liberal character of the American state, economic activities, with rare exceptions, have always been free to individuals (free enterprise). However, certain activities, because of the strong social importance involved, are highlighted by the State and subject to the most intense police power. These are the so-called public utilities, considered private activities subject to special regulations and controls (Regulatory State). It is possible to say that the main distinction between the French public service and public utilities lies in the ownership of the activity: while the public service is owned by the State, the public utilities are securitized by individuals, with limitations (police power) placed by the State". Rafael Oliveira, *Curso de direito administrativo*, op. cit., p. 373-374.

owners benefit directly from its operation, all parties, directly or indirectly, reap the benefits.

Whether regulatory activity is necessary to mitigate high risk operations or, even, to balance the regulated market, if it is a power-duty of the State to promote economic stabilization, then it must adopt plausible measures to prevent the inherent risk outweighing its potential benefits, even if it requires the adoption of a similarly risky manoeuvre. Disaster risk is substituted, for example, by risk of poor regulation.

At this point, the aforementioned parallel re-emerges. Regulatory activity is predictive and, as such, subject to a certain regulatory risk. The text under scrutiny seeks to mitigate these risks, but it does not have the power to eliminate them, like the others previously mentioned, notably environmental studies.

Even so, regulatory activity must be carried out in the public interest. The State is bound to take all precautions to prevent harm, but where extraordinary risks arise, if the studies have been carried out assiduously, the public entity is not culpable, legally. The risks of an activity may only be mitigated, not eliminated — affecting notions of accountability with regard to normative activity.

As the ISO 73:2009 Guide suggests, there should be a margin of tolerance that promotes a balance between the legally acceptable risk and the right of citizens to have a regulated environment, based on public studies enshrined in a formal text.

The duty of sound and prudent administration corresponds, indubitably, to the subjective right to risk mitigation, by constitutional imperative. The Economic Freedom Act, furthermore, concerns possible effects of the regulatory act — hence, unforeseen circumstances do not denote inefficiency, but a path not supported by the State,[77] unforeseen and thus unpreventable.

There is no practical reason to exclude a wide spectrum of regulatory activity in the risk society. The elaboration of a formal document, with the broad participation of all the actors involved, gives greater legitimacy to the rule, reinforcing the technical nature of the regulation. Thereafter, the public administration is supported in the fulfilment of its institutional duties to the citizen. The instrument gains its validity from the richness of this interface.

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[77] Here, it is for this reason of full responsibility in environmental matters. Having adopted all possible and imaginable precautions, the occurrence of unpredictable damages could not be imputed to anyone, for unpredictability is not accepted by the entrepreneur.

The importance of pragmatism[78] over abstract discourse is evidenced by the aforementioned articles from LINDB, added in 2018. According to that text, it is possible to infer the need for RIA from the necessary study of the elements that require analysis of the act, as already mentioned before.

Management, more than ever, must adopt scientific, evidence-based, measures to enable the effective realization of rights. It should also be noted that article 27[79] expressly states the need to prevent unfair or abnormal damages in all administrative activity, lending more importance to RIA in its predictive task. Consequentialism is bound up with democracy in the mitigation of regulation risks.

4. Positive impact of RIA on the business environment

It is understood that the RIA is an instrument for the improvement of the business environment business and reduction of regulatory risks in Brazil. It is quite common in environments with inadequate regulation, that some market actors bear abnormal damage, while others, purposely or not, are disproportionately benefited (rent seeking). This phenomenon should be avoided, as a marker of justice. In this system of ideas, RIA can contribute to the strengthening of democracy, and to economic growth in an environment with acceptable regulatory risks.

The presence of high levels of regulatory risk implies disinvestment in the regulated markets, as sudden changes in legislation are a factor of unacceptable unpredictability in a competitive landscape. As rent seeking may occur, benefiting some to the detriment of others — notably when those responsible for the regulatory activity are captured — so it is possible that regulation exacerbates damage to all those involved, which should be avoided at all costs.

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[78] Some people see this pragmatism as one of the negative points of RIA. Rafael Oliveira observes: "From one perspective, part of the doctrine maintains that the instrument has an intimate relationship with utilitarianism, concerned with maximizing social welfare from the economic perspective (maximization of wealth). The contempt for ethical values, as well as the difficulties in quantifying and qualifying the costs and benefits involved are issues raised in the implementation of the RIA". Rafael Oliveira, Governança e Análise de Impacto Regulatório, op. cit., p. 12.

[79] Art. 27. The decision of the process, in the administrative, supervisory or judicial spheres, may impose compensation for undue benefits or abnormal or unfair losses resulting from the process or the conduct of those involved.

Benefit to some is inherent to the regulatory activity, and should always be guided by technical aspects and proportionality,[80] since standardization seeks, precisely, to correct the imperfections of the marketplace. It is evident, however, that the ideal is a context in which everyone is benefited by regulation: more satisfied consumers, lower prices, an increase in profit margins or in the safety of products and services, among other consequences.

The above equation is not always financial. It is possible that, according to other factors, a general increase in prices is fostered, for example, to the financial loss of both producers and consumers — as the case of the tobacco industry, already mentioned. Regulatory activity will therefore always be affected by economic issues,[81] although this may yield to other social values, according to the technical possibility defined by an impartial body.

This is the case with the adoption of environmental policies — e.g., the determination of the California State Government to phase out fossil fuel buses by 2040.[82] The policy leads to an increase in car prices and shrinking profit margins in the industry. On the other hand, gains are promoted in areas such as health, environment and safety.[83] Here, the normative activity, through technical assessment, opted for quality of life at the expense of the financial sector, like the hypothetical case of the tobacco industry.

There is an inherent cost to regulation, which it is up to the RIA to balance against the expected benefits of the proposed standard.[84] The legitimacy of this

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[80] It is what determines art. 4 of the General Law on Regulatory Agencies.

[81] This interaction between law and economics was highlighted elsewhere. (Henrique Ribeiro Cardoso, *Controle jurídico da legitimidade da atividade regulatória normativa*, op. cit.). There are several currents of thought on this relationship between applied sciences and how positive law can cause distortions in the economy. "The law, in establishing rules of conduct between people, must take into account the economic impact their norms will have, the effects on the distribution or allocation of resources and the incentives that influence the behaviour of economic agents". Ibid., p. 20.

[82] JORNAL DO CARRO. Califórnia terá todos os ônibus elétricos até 2040. Available at: https://jornaldocarro.estadao.com.br/carros/california-onibus-eletricos-ate-2040/. Accessed on: 29 May 2021.

[83] The social cost does not always materialize as a financial equation. Expression in a single unit is a convenience of public policies. The financial cost is often compared to a system of incommensurate aspects, such as health and education, summarized as indicators without properly attributing direct economic value to them. COASE, Robert. *The problem of social cost*. Available at: https://www2.econ.iastate.edu/classes/tsc220/hallam/Coase.pdf. Accessed on: 29 May 2019.

[84] According to the *States' use of cost-benefit analysis report*, by the MacArthur Foundation, "Cost-benefit analysis is an analytical approach that evaluates the costs of public programs relative to the benefits they achieve for taxpayers. By projecting and assigning current dollar values to predicted outcomes, ideally including all direct and indirect effects, and comparing those with the costs, cost-benefit analyses determine whether each program would generate a net positive benefit to society. The results are usually reported as a benefit-cost ratio. For example, a 5.4-1 ratio indicates $5.40 of net value for taxpayers for every $1 in funding". MACARTHUR FOUNDATION. States' use of cost-benefit analysis. Jul. 2013. Available at: www.pewtrusts.org/-/media/legacy/uploadedfiles/pcs_assets/2013/pewresultsfirst50statereportpdf.pdf. Accessed on: 22 May 2021.

option is backed by public consultations, inherent to democratic coexistence, and by technical aspects. RIA is the formalization of this technical knowledge in a text that should be easy and comprehensive, available to the entire regulated market, including less influential parties, such as consumers and small businesses. These actors have little or no impact on decision-making structures and their participation is encouraged, especially in formal frameworks.

It is clear, therefore, that the normative activity, under the pretext of mitigating risks, carries in itself considerable harmful potential, which must be mitigated by instruments such as RIA, thus promoting qualitative gains in decision making, with a view to meeting public interest and conciliating existing antagonistic interests within the regulated market. The adoption of clear technical criteria is a step towards a healthier democracy and an efficient, effective regulatory state that helps realize the fundamental rights of citizens — notably, to fair administration and, specifically, to risk reduction of regulatory activity.

Final considerations

The mitigation of risks inherent to regulatory activity is the duty of management, and the RIA is formal recognition that all possible precautions must be adopted to avoid resulting damage, without, however, responsibility for the effects of this regulation where these deviate from the legally required predictability.

Compliance with the rules is conditioned, therefore, by a technical, democratic and isonomic construction that prevents, on adequate grounds, the risk of regulatory activity. This is identical to private actors who fail to comply with the duties of risk prevention: without adequate studies, they cannot act; without adequate studies, the State cannot promote the regulation validly. Regulatory activity is key to mitigating risks. Still, it is, itself, a source of normative risks, so it must always be guided by technical discretion, with public interest always paramount.

In this sense, participatory and substantial democracy gains strength in the technical wellsprings of our modern world. Mitigation is the duty of any person who carries out risky activities, regularity included. RIA is a state instrument that privileges the democratic principle, isonomy and the theory of risk, enabling reduction of possible contingencies caused by regulatory activity, opening space for the strengthening of institutions, democracy and

public debate on regulatory activity, and promoting greater acceptability of rules built with other social actors.

Sound administration emerges, in this context, as both a duty of the State and a citizen right. In the regulatory sphere, the RIA is an instrument to achieve this, involving, therefore, the compliance of market participants, with a view to optimal regulation, which promotes the least distortion, and to reduce, as much as possible, risks which may causing abnormal or disproportionate damage.

The fundamental right to sound administration is instrumentalized by the RIA and, therefore, may be required of each member of the regulated market as a corollary of republican principles and citizenship, becoming, thus, a subjective right demanded of the public authority in any of its spheres and functions.

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