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# Contributions to evaluation of regulatory processes: the case of electronic cigarettes in Brazil

## Contribuições para avaliação de processos regulatórios: o caso dos cigarros eletrônicos no Brasil

**Cesar Luiz Silva Junior**[I,*]

**Elizabeth Moreira dos Santos**[I]

**Gisela Cordeiro Pereira Cardoso**[I]

## ABSTRACT

**Introduction:** The Electronic Nicotine Delivery Systems, represented by electronic cigarettes (e-cigarettes) are object of a global dispute in public health. In Brazil, they are forbidden but this interdiction is currently under a debate steered by the Brazilian Health Regulatory Agency (ANVISA, by its acronym in Portuguese). **Objective:** To characterize the regulatory model of ANVISA, in the case of e-cigarettes, and discuss its implications for evaluations that have the regulatory process as an object. **Method:** A desk review in ANVISA´s website was conducted through a qualitative content analysis in order to build a timeline about the regulatory process and distinguish significant issues, from 2009 to 2023. **Results:** The timeline includes 10 normative and non-normative publications and additionally 31 media publications available in the website. The Resolution of the Collegiate Board (RDC, by its acronym in Portuguese) No. 46/2009 was the first ANVISA decision, which prohibited the devices commerce, import and marketing. The year with highest frequency most publications was 2019, followed by 2022 and 2018. Since 2019, the regulatory agenda was based on a new regulatory model that catalyzed social participation. During the regulatory process, diverse stakeholders took their stances around the RDC that demanded a revision of the previous decision in face of new evidences. **Conclusions:** The Brazilian case, which includes diverse stakeholders and interests, contributes to the identification of approaches that allow exploring the regulatory processes as evaluation objects, re-signifying as a network of *dispositives* that emerge from strategic crises.

**KEYWORDS:** Health Regulatory Processes Evaluation; Health Care Coordination and Monitoring; Electronic Nicotine Delivery Systems; Brazilian Health Surveillance Agency

## RESUMO

**Introdução:** Os dispositivos eletrônicos para fumar, principalmente representados pelos cigarros eletrônicos, se destacam como objetos de disputa global em saúde pública. No Brasil, eles estão proibidos, mas esta interdição está sendo discutida pela Agência Nacional de Vigilância Sanitária (Anvisa). **Objetivo:** Caracterizar o modelo regulatório da Anvisa, no caso dos cigarros eletrônicos, e discutir suas implicações para avaliações que tenham o processo regulatório como objeto. **Método:** A pesquisa documental subsidiou a elaboração de linha do tempo, baseando-se em publicações relacionadas ao processo regulatório em sítio eletrônico da Anvisa, entre 2009 e 2023. **Resultados:** A linha do tempo apresenta os eventos críticos que presumidamente geraram consequências e levaram a uma reconfiguração do processo estudado. Além de 31 notícias, foram identificadas dez publicações normativas e não normativas que integram o processo. O ano de 2019 teve a maior concentração de publicações, seguido por 2022 e 2018. A Resolução da Diretoria Colegiada (RDC) N° 46, de 28 de agosto de 2009, marcou a primeira manifestação da Agência, proibindo a comercialização, a importação e a propaganda dos dispositivos. Em 2019, a inclusão do tema na Agenda Regulatória se deu a partir de um novo modelo de regulação da Agência, com destaque para a incorporação de componente de participação social. Durante o processo, houve o reposicionamento de diversos atores em torno da

[I] Escola Nacional de Saúde Pública Sergio Arouca (ENSP), Fundação Oswaldo Cruz (Fiocruz), Rio de Janeiro, RJ, Brasil

* **E-mail:** cesarluiz54@gmail.com

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RDC, que sinalizava a possibilidade de sua flexibilização a partir de novas evidências. **Conclusões:** O caso brasileiro, que inclui diversos atores e disputas de interesses, contribui para a identificação de abordagens que permitam explorar os processos regulatórios como avaliandos, ressignificando como uma rede de dispositivos que emergem de crises estratégicas.

**PALAVRAS-CHAVE:** Avaliação de Processos Regulatórios em Saúde; Regulação e Fiscalização em Saúde; Sistemas Eletrônicos de Liberação de Nicotina; Agência Nacional de Vigilância Sanitária

## INTRODUCTION

Electronic smoking devices (ESDs), mainly represented by electronic cigarettes also referred to as electronic nicotine delivery systems (ENDS), e-cigarettes, e-ciggy, e-cigar, or vape have emerged as an innovation for nicotine cessation and/or replacement[1].

In the course of their dissemination, they have acquired a leading role in several countries due to a series of controversies related to safety, efficacy for smoking cessation[2], and regulation methods[3], with repercussions on public health[4,5].

Given the current situation, there are a variety of approaches used by countries to regulate these devices[6]. The Institute for Global Tobacco Control[7] identifies, as of July 2022, 109 countries or other jurisdictions that regulate or ban e-cigarettes, considering different classifications and regulatory mechanisms.

As a term that encompasses various interpretations, Black[8] defined regulation as a continuous and targeted attempt to modify behavior in accordance with public standards or pre-established purposes.

The diversity of regulatory environments is characterized by the degree of State involvement in market decisions. In this context, the new governance of the regulatory state, including the origin and functioning of regulatory agencies, has been highlighted as one of the options increasingly adopted by governments[9]. In Brazil, regulatory agencies stand out as one of the most important parts of the country's state machinery. Created at the end of the 1990s, they have generated and influenced important work in recent years[10].

Considering international experiences in the regulation of electronic cigarettes, the regulatory process in the United States of America (USA) stands out. In the US case, the pre-market evaluation process was extended by the U.S. Food and Drug Administration (FDA) on the grounds that the products were low risk[11]. However, the increase in use among teenagers and young people, including the epidemic of pneumonia associated with the devices (known as E-cigarette or Vaping use-Associated Lung Injury - EVALI), led to specific decisions being taken by American states and cities[3].

To this day, the FDA has reviewed the marketing of specific brands, permeated by a series of controversies, such as the case of JUUL® - which uses nicotine salt in its formula and makes it possible to deliver up to 20 times higher concentrations of the substance to the consumer[12,13].

In the Brazilian case, the Brazilian Health Regulatory Agency (ANVISA) made its first statement on the subject in 2009, through the Resolution of the Collegiate Board (RDC) No. 46, of August 28, which banned the trade, import, and advertising of ESDs, based on the lack of scientific data on the claims made by these products[14]. Since then, efforts have been made to update information on these devices.

Under the influence of recent scientific studies[15] and international experiences, ANVISA included the issue in its 2017-2020 Regulatory Agenda, with discussions already starting within the framework of the agency's new regulatory model[16]. Among its main guidelines, even before any regulation proposed an in-depth study of the problem and the participation of the interested actors should be required.

Considering the regulation of electronic cigarettes, which is immersed in a permanent flow of evidence production, the process of monitoring the construction periods of scientific facts is fundamental. From this perspective, Weiss[17] points out that evaluation is inherently a political process, works with objects of interest, and must examine the entire context in which interventions operate. In short, evaluation takes place in an arena where the various players interact, support each other, and engage in disputes[17,18].

In a current scenario, influenced by the need to update the evidence, studies focusing on the uses and effects of electronic cigarettes have been widely produced[2,19]. However, it is noteworthy that regulatory processes, which are an arena for disputes over interests and values, are rarely addressed as object of evaluative processes.

This article, which is part of a study evaluating the regulatory process for electronic cigarettes in Brazil, aims to characterize ANVISA's regulatory model, taking ESDs as a case, and its implications for evaluations that have the regulatory process as their object (evaluand).

The relevance of this study comes from the inclusion in the historical debate on public health decisions of evaluation processes based on scientific evidence for decision-making.

## METHOD

The trajectory of regulatory processes includes various actors and disputes over interests, making their evaluation complex.

Therefore, it is necessary to identify approaches that allow this complexity to be explored, as a first step in a relevant evaluation study.

This article is the result of a thematic content analysis undertaken on publicly accessible documents from ANVISA's website[20]. The inclusion criteria involved the Agency's normative documents related to the regulatory process under study, from 2009 to 2023. Publications that did not meet these criteria, such as summaries, consolidated reports, and recordings, for example, were excluded.

Criteria of legitimacy and hierarchy between publications were considered. According to Decree No. 10.139, of November 28, 2019, normative acts other than a Decree encompass different forms, such as Ordinances (normative acts issued by one or more singular authorities), Resolutions (normative acts issued by collegiate bodies), or Normative Instructions (normative acts that, without innovating, guide the execution of current rules by public agents)[21]. They may be released by different bodies and entities of the direct, autarchic, and foundational federal public administration.

In order to help characterize the regulatory process, a timeline was drawn up. It was not limited to a factual chronology but presents critical events[22] which are characterized as those that generate consequences and lead to a reconfiguration of the process under study. Critical events can be understood as connections that reconfigure existing strategies or interventions and can mobilize elements from the micro, meso, and macro technical-political context[23]. The timeline usually materializes the controversies about the intervention or one of its components. Although not all of the controversies generate critical events, some of them, from a systemic perspective, can destabilize pre-existing certainties[22].

Besides the normative and non-normative publications, the timeline included media news published on the Agency's website[24] between 2009 and 2023 that mentioned the terms: "electronic cigarette" or "electronic smoking devices". A search tool was used to mine the data from the news. After reading all the media news, the data that earlier did not refer to electronic cigarettes or ESDs in their content or were duplicated were excluded. The tag limits of the search tools were taken into consideration when the data was analyzed.

In November 2022, ANVISA's digital platform went through several changes. This had direct consequences on the available material since the news were reported with the date of the website updating. However, that did not affect the present study because all the material was previously saved.

The publications were organized in a table according to date, title, and link of each publication. After reading all the material, themes were identified and organized mapping the controversies regarding to the use, effects, and risks of electronic cigarettes. A thematic content analysis was conducted[26], aggregating similar contents and exploring the relationship among them.

The study was registered at the Research Ethics Committee of the Sergio Arouca National School of Public Health, Oswaldo Cruz Foundation (CEP/ENSP/Fiocruz), and obtained Ethics Waiver No. 12/2022.

## RESULTS

Overall, ten documents were identified on the Agency's website: two notices, two guidance documents, a plan, an Ordinance, two reports, a Resolution, and a term.

Additionally, 61 media news were described. Of these, 25 duplicates were removed and five were excluded for not referring to electronic cigarettes or ESDs in their content.

In total, 31 media news and ten publications were available to describe the stages of ANVISA's regulatory process, and used to create the timeline.

Figure 1 shows that 2019 had the highest concentration of publications, followed by 2022 (n = 8) and 2018 (n = 7).

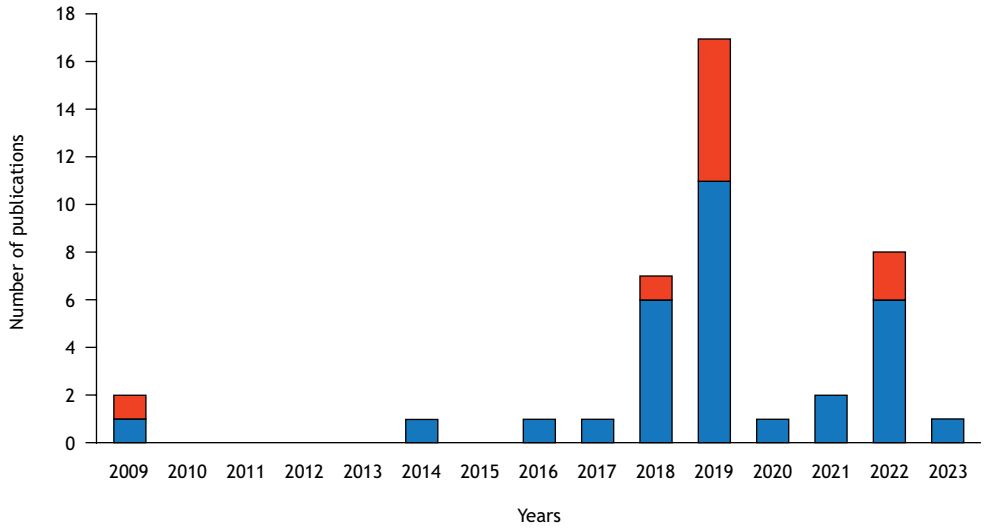
Figure 2 shows the timeline of critical events in the regulatory process for electronic cigarettes in Brazil.

Among the main critical events, ANVISA's first manifestation was in August 2009, with RDC No. 46, which "prohibits the sale, import, and advertising of any ESDs, known as electronic cigarettes"[14].

It was only in December 2016 that a new critical event was identified in the regulatory discussion of these devices in the country, with the publication of the document "Electronic cigarettes: what do we know?"[15]. This material was based on a partnership between the Pan American Health Organization, ANVISA, and the National Cancer Institute (INCA). The publication gathered information on the composition of the vapor, the damage to health, the role of these products in harm reduction and in the treatment of nicotine addiction. An effort was made to produce a synthesis of the state of the art, taking into account the knowledge available at the time.

In 2017, the Brazilian Medical Association (AMB) sent a document to the director-president of ANVISA. The document reinforces the ban on the devices, considering the context that the tobacco industry was campaigned to persuade people to make RDC 46/2009 more flexible, as depicted from a media news from July 28, 2017:

> In the document, the AMB draws attention to the "recent moves by the tobacco industry with segments of the media, medical societies, and society in general in an attempt to convince health authorities to modify RDC No. 46/2009, with the clear aim of freeing the production and sale of electronic cigarettes".




Source: Prepared by the authors, 2023.
Blue: media news published on ANVISA's website; Red: publications that are part of the stages of ANVISA's regulatory process.

**Figure 1.** Distribution of publications related to the regulatory process of electronic cigarettes, on ANVISA's website, from 2009 to 2023.

In April 2018, ANVISA organized a technical panel to discuss electronic cigarettes. The panel involved the participation of the regulated sector, actors involved in reducing smoking in Brazil, national and international researchers, organized civil society, parliamentarians, and other authorities, including the head of the Secretariat of the World Health Organization's Framework Convention on Tobacco Control. The panel, as a proactive mechanism of the Agency, is characterized by the discussion of a given topic, regardless of the existence of an ongoing regulatory process.

In 2019, under the influence of updated scientific studies and international experiences, the theme was included in item 11.3 (New types of smoking products) of the 2017-2020 Regulatory Agenda. The publication of Administrative Regulatory Process Opening Term (TAP) No. 22, related to ESDs, started several discussions within ANVISA's new regulatory model. Established by Ordinance No. 1741, of December 12, 2018[16], the model's guidelines initially call for a more in-depth study of the problem and the participation of the interested public before any regulation would be proposed.

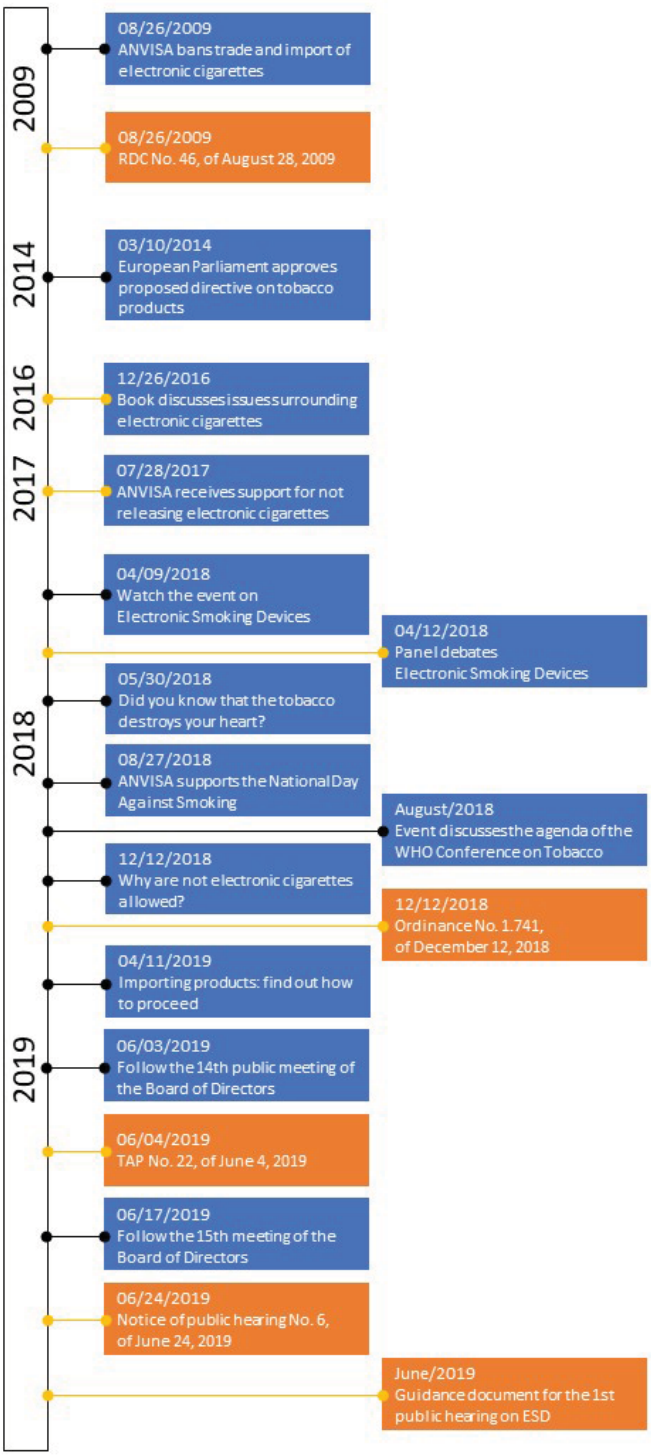
As one of the main critical events, the implementation of public hearings on electronic cigarettes was the subject of most publications in 2019. These hearings aimed to obtain technical and scientific input related to the devices and their controversies. The first hearing took place on August 8, 2019, in Brasilia, and the second on August 27, 2019, in Rio de Janeiro. Simultaneously, the publication of the Social Participation Plan for the topic has reinforced the importance of involving affected and interested agents in the regulatory process, considering Ordinance No. 1741 of December 12, 2018.

In September 2019, the North American scenario of a health crisis caused by e-cigarettes prompted ANVISA to request reports from hospitals and health professionals regarding problems related to the use of the devices. The request was also sent to the Federal Council of Medicine (CFM) and the AMB, alerting doctors to the importance of reporting any suspicions, as depicted from a media news from September 20, 2019:

> The action aims to gather information to anticipate and prevent a health crisis like the one that has been reported in the United States, where there are cases of a serious respiratory disease, leading to deaths, associated with the use of these devices. The monitoring involves electronic cigarettes, vaporizers, and heated tobacco cigarettes, among other electronic smoking devices (ESDs).

In December 2019, INCA, which is linked to the Ministry of Health, implemented a campaign warning about the use of electronic cigarettes. The campaign pointed out that these products contain numerous toxic substances, thus they are not safe for human use. Moreover, the report highlight that e-cigarettes might increase by four times the chances of young people starting to smoke with the use of these devices. The Institute also released a Technical Note reporting the cases of more than 2,200 hospitalizations and 48 deaths related to the use of electronic cigarettes in the USA. It is worth noting that the note reaffirmed INCA's support for maintaining RDC No. 46/2009, which bans these devices in Brazil.

A media news dated December 18, 2019, informed that ANVISA had not received any notifications about lung diseases related to the use of electronic cigarettes from September up to mid-December of the same year. The report reinforced the need to collect these data. As a result, the Agency developed an induction strategy, providing a specific form for data collection, with the support of AMB and the Brazilian Society of Pulmonology and Phthisiology (SBPT).




Source: Prepared by the authors, 2023.

**Figure 2.** Timeline of critical events in the electronic cigarette regulatory process, considering publications on the ANVISA website from 2009 to 2023.

Continue

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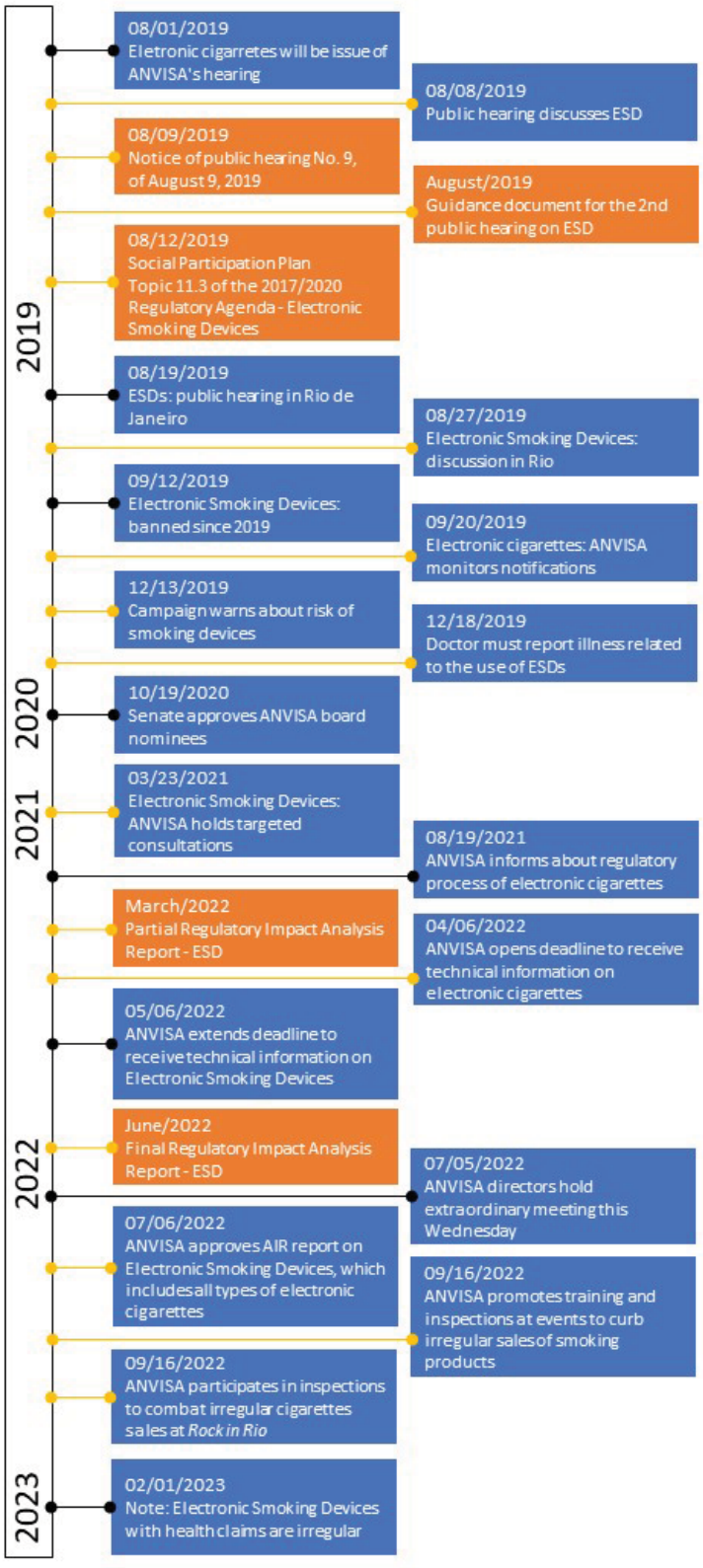


Source: Prepared by the authors, 2023.

**Figure 2.** Timeline of critical events in the electronic cigarette regulatory process, considering publications on the ANVISA website from 2009 to 2023.

Since 2021, the Agency has been prioritizing the implementation of the planned regulatory model through the recommended stages. In March of that year, ANVISA opened three consultations using a standardized electronic form: the first was addressed to state and municipal health surveillance managers; the second to educational and research institutions, as well as government entities; the third consultation included companies that trade these products in other countries.

In August 2021, ANVISA updated information on the regulatory process for electronic cigarettes. As reported, it was necessary to migrate the topic from the 2017-2020 Regulatory Agenda to the 2021-2023 Regulatory Agenda (Regulatory Project 16.4 - Regularization of smoking products) due to the complexity of the discussion and the needed compliance regarding the stages provided for in the Social Participation Plan.

In 2022, most of the publications referred to the ESD Regulatory Impact Analysis (AIR) Report. AIR partial and final versions were published in March and June, respectively. Between April and May, as another stage of social participation, the Public Subsidies Process (TPS) allowed interested parties to submit contributions to the partial report online.

As another important critical event, in July 2022, during the 10th Extraordinary Public Meeting, the AIR Report was unanimously approved by ANVISA. The approved document suggested the following alternative:

> Maintaining the prohibitions established by RDC No. 46/2009, improving the regulatory instrument and implementing additional non-normative actions, such as: carrying out educational campaigns, especially for young people and adolescents; inserting information on the risks of ESDs on ANVISA's website and in the curriculum of schools, to raise awareness among children and adolescents; improving inspection in the digital environment, borders, and points of trade, with greater interaction with the National Health Surveillance System and entities such as the Federal Revenue Service, Federal Police and Federal Highway Police, the Public Prosecutor's Office, among others.

In September 2022, ANVISA's actions to combat the irregular sale of electronic cigarettes became part of the publications on the Agency's specific website. In 2023, ANVISA issued a statement highlighting the consistency of the positive health claims made about the products. The Agency reinforced RDC No. 46/2009, extending the ban to food supplements (vitamins and other foods) that were delivered in the market displaying in the shape of these devices.

## DISCUSSION

Despite recognizing various types of regulation, the Brazilian case of ESDs is developed by State agents, making it important to contextualize the critical events presented in the discussions about the process of replacing disciplinary societies with control societies[27].

According to Deleuze[27], disciplinary societies reached their height at the beginning of the 20th century and proceeded to organize several mechanisms of confinement. In the midst of a generalized crisis of means of confinement, signs of new control mechanisms of social relationships emerged. A new frame of these mechanisms emerged through modulation which respond continuously and in an unlimited manner to the short term and rapid changes of the social life.

In this context, the State has been developing modes of "command and control" that shape both its practices and the relationship between the state and social subjects. In short, the sustainability of State intervention involves restructuring the objectives and methods it employs[28,29].

According to Foucault[30], the survival and limits of the State must be understood based on general tactics of governmentality, which allow it to define at every moment what should or should not be its responsibility. Considering a sovereignty-discipline-management triangle, these tactics make it possible to exercise a very specific and complex form of power, which has the population as its main target and dispositives as its essential mechanisms. For the author, e.g., "in short, the said and the unsaid are the elements of the dispositive. The dispositive is the network that can be woven between several of these elements"[30].

It should be noted that the characterization of the timeline allowed us to identify, from the point of view of the historicity of the event studied, the context of emergence of the dispositives[30,31,32] to solve the controversies taken as crises of valuation. In the regulatory case, the mobilization of different dispositives - Ordinances and Resolutions, e.g. - shows the possibility of characterizing them as a network that maintains connections of discourses, practices, and power.

Not falling into the trap of ratifying the traditional separation between the sphere of private interests and that of the State, Dardot and Laval[29] stated that "neoliberalism not only does not exclude but calls for government intervention". In this context, it is important to emphasize the influence of the regulatory agency in the significant transformation in power relations between the State and society[33].

Besides that, the influence of the market must be emphasized. With regard to regulatory agencies in Brazil, Ferraz Júnior[34] said that they represent the replacement of the management model based on formal controls and direct intervention with the managerial model, based on performance evaluation in which the efficiency of intervention is subject to regulation. The author adds that in this way the state assumes its regulatory role which, through regulatory processes, contributes to improving market efficiency.

Dardot and Laval[29] point out that the state is no longer judged by its ability to ensure its sovereignty, categories that have been overcome historically, but by its alignment with legal norms and economic "good practices" of governance. It is worth noting that the introduction of the notion of "good practices" is one of the

points that marks the need to monitor and evaluate benchmarks, such as timeliness of action and compliance to a standard of quality and adequacy.

In contrast to an authoritarian bias aimed at compelling individuals to comply with a certain State order, the emergence of consensus mechanisms, with a democratic bias, began to highlight "good practices" as a means and condition for achieving its old and new objectives[28]. The trajectory of the Brazilian case shows the incorporation of a new regulatory model by ANVISA, with emphasis on the introduction of a participatory component to the process, considering different mechanisms for social participation, bringing different actors and values to the discussions.

The literature points out that regulatory action can take place through normative and non-normative acts. Normative action aims to change the behavior of the agents affected by the regulatory problem through acts of "command and control", traditionally represented by the imposition of rules of conduct or standards to be observed, under penalty of punishment. Non-normative action, on the other hand, takes place through induction mechanisms that do not involve the issuing of a normative act, represented mainly by recommendations, guidance, and education campaigns, e.g.[35].

As with the RDC in the Brazilian case, it can be seen that explicit regulation, of a normative nature, is preferred by regulators, since they consider that the implementation of standardized solutions facilitates the monitoring of compliance with the rule and the clarity of information for affected agents[35].

From a disciplinary perspective, the RDC is characterized as a normative act that implies sanctions for infractions. In other words, it represents one of ANVISA's core activities, expressing a final decision for regulatory purposes. However, according to a survey by the Agency itself, approximately 90% of lawsuits directly involve its final activities. Regarding the RDCs, most of them generate some dissatisfaction among the regulated entities. The sanctions for infractions are usually subject of lawsuits[36], since they are a provisional legal decision, characterizing an arena of continuous debate and struggle.

Furthermore, Kolieb[37] pointed out that excessively prescriptive actions, which create unnecessary barriers or costs for the regulated, can generate a culture of disincentives and resistance to compliance. RDC No. 46/2009, which has remained unchanged since its publication, already signaled the possibility of more flexible processes based on new evidence. In short, it can be characterized as a dispositive, agreed and provisional, while the regulatory process based on evidence tends to mirror the evolved mechanisms of the knowledge society.

There are significant influences from the national and international contexts in the process of discussing the regulation of electronic cigarettes. It is worth noting that, since February 2020, when the first case of COVID-19 was confirmed in Brazil, the country has experienced a scenario of intensified health, political and organizational instability, including important repercussions on ANVISA's actions during the pandemic. Despite the "disappearance" of ESD in the Agency's publications during the period, the migration of the topic to the 2021-2023 Regulatory Agenda reinforced the complexity of the discussion (still current) in the national and international context of public health debate. In fact, the update of the topic in the political agenda highlights the importance of the participatory process of evidence assessment and decision-making, and the interesting contribution of the Brazilian case.

Evidence-based regulation is one of the main guidelines for improving regulatory quality at ANVISA[16]. With the sufficiency and credibility of evidence always in consideration, the case of electronic cigarettes is yet another current issue permeated by a process of permanent generation of doubts, focusing on the mechanism of construction of scientific facts[38].

According to Latour[18], by itself, a claim is neither fact nor fiction, becoming one or the other thanks to other claims. Based on this, the process of monitoring the construction of scientific facts is fundamental, since it is around these claims that the various actors interact, support each other and dispute values. In the case of electronic cigarettes, it is essential to discuss the values that are placed at the center of the arena in the evaluation processes that subsidize the regulatory dispositives.

The valuation process stands out as an important point in the conceptualization of evaluation and how it should be conducted[39]. Valuation is presented as a process that assesses and discusses the added value of actions, objects, and/or interventions of organized systems that aim to respond to a need or a problematic situation, i.e., it puts forward a hypothesis about the added value and then tests it using the scientific method[40,41]. In turn, the process of valuation considers the wise (science) and jurisprudence (the fact in context)[42,43], once again reinforcing the role of context in evaluative processes and, consequently, in the relationship between evaluation, judgment and its application.

Based on the construction of spaces for the articulation and mediation of interests[44], ANVISA's regulatory action in the case of electronic cigarettes, developed with mechanisms for social participation, mainly represented by public hearings, signals the proposal for a more flexible process, which opens the way for an approach that, according to Patton[45,46], is situated in a sphere of pluralistic, democratic valuation.

The pluralist approach has implications for the time required and for the actors involved, reconfigures the role of the evaluator, the criticism of evaluation criteria and the influence of the findings of evaluation processes on regulatory processes.

In other words, findings from the various models and designs used in the uses and effects of ESDs are key to monitoring the construction of scientific facts involved in evidence-based regulation.

## CONCLUSIONS

During the regulatory process under study, it is important to observe the repositioning of the different actors around movements that show the emergence of interaction between peers as a possible alignment in the search for a shared valuation.

Like any intervention, a regulatory model expresses theories of change, action and/or interaction. Several authors highlight the importance of representing contextual factors or external influences that can change the conceptualization and models of the intervention. Santos et al.[47] discussed the processes involved in producing the effects expected by the intervention, including the relationship with the context in which they take place, thus mobilizing approaches that explore them from a micro, meso, and macro point of view in order to highlight the relationships of influence.

It is essential to debate the need to identify, build and implement new regulatory alternatives, seeking to theoretically characterize the regulatory process as an object of analysis, making transparent its potential added value to the practices of the regulatory State. The analysis of the context with the identification of critical events, whether as strategic crises or devices that reposition them technically or politically, subsidizes these processes.

In short, the movements of representation of controversies and mobilization for their intentional "solution", identified through social participation, underline the theorization of the regulatory process, now conceived as a network of dispositives. In this socio-technical network[48], the negotiation and "consensual" resignification of added values can make the transvaluation process viable, materializing it in a new regulatory dispositive, be it an Ordinance, Resolution or other[49].

The incorporation of a new regulatory model by ANVISA, considering a social participation component, in contexts of health, political and organizational instability, makes its evaluation approaches even more complex.

Considering the first steps of an evaluation process, in terms of understanding the object being evaluated and clarifying the theory that supports their apprehension, it is thought-provoking. Therefore, to theorize the case of regulatory processes as a network of dispositives, in their disciplining and/or modulating perspectives, is a very interesting challenge.

This article contributes to identifying approaches that make it possible to explore the evaluand theoretically, as well as suggesting further discussions on the role of social participation for regulatory processes through shared valuation among peers. This last point highlights the importance of evaluation and regulation.

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## Authors' Contribution

Silva Junior CL, Santos EM, Cardoso GCP - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. All the authors approved the final version of the work.

## Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.