saúde EM DEBATE

ORIGINAL ARTICLE

Contributions to inclusive evaluation processes: Social participation in the regulation of electronic cigarettes in Brazil

Contribuições para processos avaliativos inclusivos: a participação social na regulação dos cigarros eletrônicos no Brasil

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ABSTRACT Electronic Nicotine Delivery Systems (ENDS), especially electronic cigarettes, are a subject of debate in public health. Drawing on the 'Social Participation Menu in Regulation' developed by the Brazilian Health Regulatory Agency (ANVISA), this study aimed to characterize the social participation mechanisms mobilized in the regulatory process of ENDS in Brazil. This exploratory study was based on a documentary review of activities related to the regulatory process, using data from ANVISA's official website (2019–2024). The analysis followed an adapted model based on the participatory approaches of Cousins and Whitmore and Cousins and Chouinard. Five social participation mechanisms were identified. The model's dimensions proved interconnected and sufficient to explain disputes between the interests and values of stakeholders and the regulatory authority, although limited in examining interactions among participants. The model reinforces the importance of understanding the regulatory system itself, yet it does not fully capture the relationships among those involved and their interaction with ANVISA. The theorization of these mechanisms as a network of dispositives highlights the dynamics of the State in the control of health policies. The Brazilian case may contribute to theoretical approaches examining the role of social participation in negotiated and transparent valuation processes central to inclusive and democratic evaluations.

KEYWORDS Program evaluation. Stakeholder participation. Health policy. Public health surveillance. Electronic nicotine delivery systems.

RESUMO *Os Dispositivos Eletrônicos para Fumar (DEF), especialmente os cigarros eletrônicos, são objeto global de disputa em saúde. Objetivou-se caracterizar, entre os mecanismos apresentados no 'Cardápio de Participação Social em Regulação' da Agência Nacional de Vigilância Sanitária (Anvisa), aqueles mobilizados no processo regulatório dos DEF no Brasil. Estudo exploratório baseado em revisão documental de atividades relacionadas ao processo regulatório, com dados do sítio eletrônico da Anvisa (2019-2024). A análise seguiu um modelo adaptado, baseado nas abordagens participativas de Cousins e Whitmore e Cousins e Chouinard. Identificou-se a mobilização de cinco mecanismos de participação social. As dimensões do modelo mostraram-se interconectadas e suficientes para explicar disputas entre interesses e valores das partes interessadas e o órgão regulador, mas com limitações para examinar interações entre os participantes. O modelo reforça a importância de compreender o sistema regulatório em si, contudo, não abrange plenamente as relações entre os envolvidos e sua interação com a Anvisa. A teorização dos mecanismos como rede de dispositivos evidencia a dinâmica do Estado no controle de políticas públicas de saúde. O caso brasileiro pode contribuir para abordagens que analisem teoricamente o papel da participação social em processos de valoração negociados e transparentes, cerne de avaliações inclusivas e democráticas.*

PALAVRAS-CHAVE *Avaliação de programas. Participação dos interessados. Política de saúde. Vigilância em saúde pública. Sistemas eletrônicos de liberação de nicotina.*

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Introduction

This article aims to characterize, among the mechanisms presented in the National Health Surveillance Agency's (ANVISA) 'Menu of Social Participation in Regulation'[1], those that were mobilized in the regulatory process concerning Electronic Nicotine Delivery Systems (ENDS) in Brazil. In addition, it seeks to critically analyze the role of these mechanisms in possible stakeholder participation in ENDS regulatory policy and their implications for evaluations that take regulatory processes as their object (the evaluand)[2].

ENDS, mainly represented by electronic cigarettes (also referred to as Electronic Nicotine Delivery Systems – ENDS, e-cigarettes, e-ciggy, e-cigar, or vape), stand out as a current topic of debate in health both in Brazil and worldwide, whether as a tobacco-derived product promoted with claims of harm reduction, as a smoking-cessation strategy, or as a health risk factor[3].

In a global context marked by the predominance of diverse regulatory mechanisms[4], it should be emphasized that ANVISA leads the Brazilian case. According to Baird[5], regulatory agencies constitute central devices in the machinery of the State in Brazil, acting as key stakeholders in mediating power relations among the State, the market, and society.

Hood et al.[6] argue that the regulation of state activities and services occurs through control mechanisms such as governmental directives, competition through the valorization of market relations, and horizontal influence by peers and self-regulatory processes. In the Brazilian case, this allows situating the regulatory action on ENDS in specific contexts around state control mechanisms traditionally mobilized by the State to guide social behavior according to institutionally defined standards and purposes[7].

Brazilian regulatory action is aligned with the recommendations of the Framework Convention on Tobacco Control and has been regarded worldwide as a success story[8]. Initially grounded in the rationale of the Precautionary Principle, ENDS have been banned in the country since 2009. More recently, however, this decision was subjected to review by ANVISA, considering a range of criteria, such as comparisons between the Brazilian and international experiences, scientific evidence, and the various interests and values of stakeholders[9].

The Brazilian case of electronic cigarettes highlights ANVISA's incorporation of a new regulatory model that emphasizes 'good practices' and social participation as strategic means and conditions for achieving both longstanding and new state objectives[9,10]. In this new model, the Agency characterizes social participation as a set of actions and activities involving the collection of information, criticisms, suggestions, and contributions not only from those directly involved but also from the general public, thus emphasizing the importance of gathering such input through different means and channels[11].

This article assumes that regulatory processes are, par excellence, an arena of disputes over interests and values, and it addresses the relevance of valuation as a critical issue for evaluative research on regulatory processes. From this perspective, it examines how the mechanisms presented in ANVISA's 'Menu of Social Participation in Regulation'[1] and mobilized in the ENDS case operate these valuation processes for future evaluations.

Material and methods

This article stems from a documentary review based on publicly accessible documents related to the regulatory process concerning ENDS in Brazil. The source material was retrieved from ANVISA's website[12,13]. The inclusion criteria comprised the Agency's normative documents linked to the regulatory process under study, from 2009 to 2024. Publications that did not

meet these criteria, such as abstracts, consolidated reports, and recordings, were excluded.

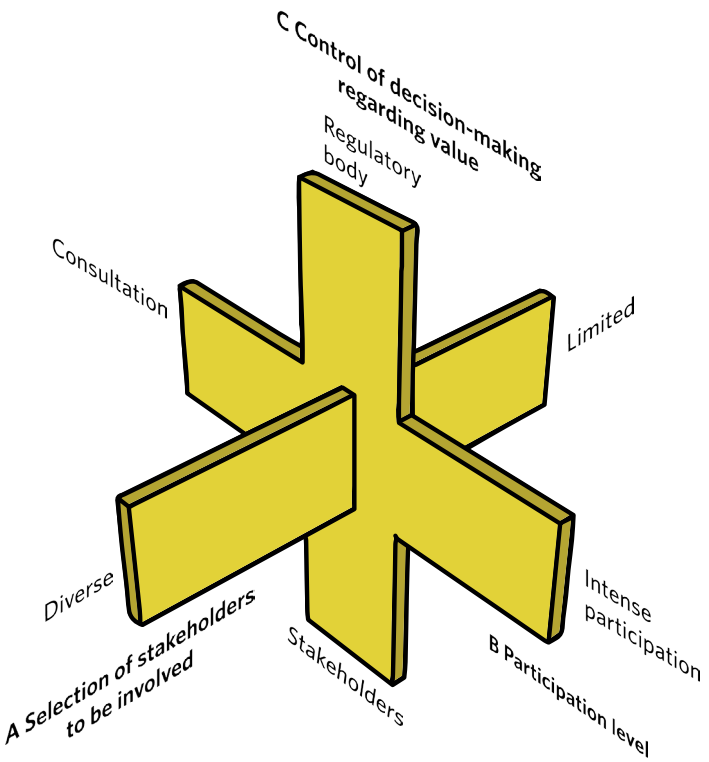
The documents were organized chronologically by year, subject, and access link, after which the evidence was analyzed, guided by the approaches of Cousins and Whitmore[14] and Cousins and Chouinard[15]. These approaches offer a robust three-dimensional framework for systematizing participatory evaluation and emphasizing the importance of involving all stakeholders in the process[16].

According to these authors, the three dimensions that should be considered in investigating participatory evaluative processes are: a) the selection of the stakeholders to be involved; b) the participation level; and c) control over decision-making regarding the evaluation process.

Building on this framework, an adapted model for the analysis of regulatory processes was developed and is presented in *figure 1*. While preserving the three dimensions proposed by the authors[14,15], the model reinterprets them in light of regulatory processes, particularly in relation to control over decision-making regarding value. In this adapted framework, the dimensions are understood as interconnected elements that play a critical role in shaping the participatory process and defining it as more or less inclusive.

Based on this configuration, this text discusses the dimensions presented in light of the literature and the findings, emphasizing the social participation mechanisms in the regulatory process under study.

Figure 1. Model representing the dimensions for investigating participatory evaluation processes, adapted from the regulatory process approach



Source: Adapted from Cousins and Whitmore[14] and Cousins and Chouinard[15].

By analogy with the original model, the dimension 'selection of the stakeholders to be involved' focuses on the choice of stakeholders who will take part in the regulatory process. It encompasses everything from participant selection to transparency and the activities shared at each stage of the process and in its products, so that selection ensures that multiple and relevant perspectives are considered.

Ultimately, each mechanism may encompass a variety of groups, such as opponents and allies, including parties affected by the regulatory problem. Whereas in the original model, selection was regarded as the sole responsibility of the evaluation team or as something shared with varying participation levels by the main stakeholders, this adapted model assumes that regulatory processes are highly context-dependent; therefore, they may include either diverse representatives or a selected group of interested participants.

The second aspect of the model is the 'participation level'. In the adapted model, this dimension refers to the level of stakeholder involvement in the regulatory process, which may range from more superficial levels, such as information gathering, to more decisive levels, such as defining the added value of the product in the health, economic, or symbolic-cultural sphere[17,18]. The participation level is related to adapting to context[19] and to possible stakeholder alignment with existing regulatory guidelines and controversies. In addition, the participation level is associated with organizational capacity to implement strategies intended either to facilitate or to hinder the regulatory issue.

In a direct adaptation of the original approach, the third dimension, 'control over decision-making regarding value', refers to the management of the regulatory process, emphasizing the importance of allowing stakeholders to exert control over and influence on how it is conducted. First, it is necessary to characterize whether control over the regulatory process is centralized in the regulatory body or whether it includes stakeholders at each stage of the process.

Next, considering the regulatory process as a technical-political movement of valuation, one may hypothesize that the power dynamics involved encompass two critical notions: relevance and pertinence. Relevance refers to the extrinsic quality of the object under evaluation, whereas pertinence concerns relevance regarding the sociotechnical context, that is, the technology's potential to meet the needs of the target audience. Thus, the valuation process materialized in evidence-based criteria of relevance and pertinence is dynamic, may change over time, and depends on technological innovations and contextual demands.

This study was submitted to the Research Ethics Committee of the Sergio Arouca National School of Public Health and received an Ethical Review Waiver Decision in 12/2022. Because of changes to ANVISA's website following the governmental elections in November 2022, all data available up to that month were backed up by the lead researcher in order to mitigate the consequences of any eventual problems in accessing the material made available.

Results

The ENDS case was the first to be guided by ANVISA's new regulatory model. Administrative Rule Nº 1.741 of December 12, 2018[20], which aimed to improve the process of drafting and revising normative acts, established new rules to promote public engagement and participation. In Brazil, between 2009 and 2024, 19 documents related to the regulatory process were produced. *Table 1* highlights the classification of these documents.

Table 1. Documents related to the regulatory process activities for Electronic Nicotine Delivery Systems in Brazil, on the ANVISA website, from 2009 to 2024

Year	Activity	Related documents
2009	Prohibition of the sale, import, and advertising of ENDS in the country.	Collegiate Board Resolution Nº 46 of August 28, 2009
2009	Public Consultation N°41 of June 23, 2009	-
2018	Holding a Sectoral Dialogue Technical Panel	Consolidated Report of the Panel on ENDS
2019	Publication of Opening Notice for Process N°22 of June 4, 2019	Opening Notice for Process Nº 22 of June 4, 2019
	Preparation of the Social Participation Plan	Social Participation Plan – Topic 11.3 of the 2017/2020 Regulatory Agenda – ENDS
	Holding of the 1st Public Hearing in Brasília/DF, on August 8, 2019	Notice of Public Hearing Nº 6 of June 24, 2019
		Guidance Document for the 1st Public Hearing on ENDS
	Holding of the 2nd Public Hearing in Rio de Janeiro/RJ, on August 27, 2019.	Notice of Public Hearing Nº 9 of August 9, 2019
		Guidance Document for the 2nd Public Hearing on ENDS
2021	Holding of the Targeted Consultation N°04/2021 on ENDS for State and Municipal Health Surveillance Managers	Report of the Targeted Consultation Nº 04/2021 – State and Municipal Health Surveillance Managers
	Holding of the Targeted Consultation N°05/2021 on ENDS for Research Institutions, Educational Institutions, and Government Agencies	-
2021	Holding of the Targeted Consultation N°06/2021 on ENDS for Companies that sell ENDS in other countries	Report of the Targeted Consultation Nº 06/2021 – Companies that sell ENDS in other countries
	Holding of Focus Groups	-
2022	Completion of the preparation of Preliminary RIA Report	Partial Report of Regulatory Impact Analysis on ENDS – March 2022
	Holding of the Public Acceptance of Subsidies for the Preliminary RIA Report	Call for Proposals Nº 10 of May 5, 2022
		Call for Proposals Nº 7 of April 5, 2022
		Report of the Public Acceptance of Subsidies Nº 06/2021 ENDS
	Completion of the preparation of the Final RIA Report	Report of Regulatory Impact Analysis on ENDS – June 2022
		Extract from the Dicol Resolution of July 11, 2022
2023	Drafting the Regulatory Instrument	Draft Collegiate Board Resolution
2023-2024	Holding of the Public Consultation	Call for Proposals for Public Consultation N°1.222 of December 4, 2023
		Report of the Public Consultation Nº 1.222/2023 – Topic 16.4 of the 2021-2023 Regulatory Agenda
2024	Deliberation on a regulatory instrument in a Collegiate Board	Collegiate Board Resolution Nº 855 of April 23, 2024

Source: Prepared by the authors.

RIA: Regulatory Impact Analysis; ENDS: Electronic Nicotine Delivery Systems; Dicol: Collegiate Board.

ANVISA's regulatory action regarding electronic cigarettes began in 2009, ten years before the issue was included in the Regulatory Agenda, with the publication of Collegiate Board Resolution (RDC) Nº46 of August 28[21]. The publication of this RDC was preceded by Public Consultation Nº41 of June 23, 2009, when ANVISA received contributions on the proposal to ban ENDS in the country[22].

Later, however, in 2018, the regulatory discussion occurred through the Sectoral Dialogue Technical Panel held in Brasília, as a proactive mechanism employed by ANVISA, in order to collect demands and perspectives, thereby suggesting a broad and participatory discussion on ENDS. In 2019, the topic was included in the 2017-2020 Regulatory Agenda, with the start of the discussions under ANVISA's new regulatory model.

Specifically, regarding ENDS, the Social Participation Plan, dated August 12, 2019[11], presented a preliminary view of the process under study, including the mapping of affected and interested parties, the projected social participation mechanisms (*table 2*), and their implementation schedule. As one of the pillars of regulatory policy, the document reinforced the importance of participatory regulatory action, considering that:

> The involvement of stakeholders guarantees their empowerment and confers legitimacy on the regulatory process, allowing regulators to collect better evidence to justify regulatory action and support decision-making[11(1)].

The Plan listed approximately 60 affected and interested stakeholders in the regulatory problem, organized into seven groups previously defined by ANVISA: a) Regulated sector; b) Associations representing the regulated sector; c) Governmental bodies; d) Organized civil society; e) Education and research institutions; f) International organizations; and g) Society in general[11].

In addition, six social participation mechanisms were projected in the document: a) Public hearings; b) Targeted consultations; c) Focus groups; d) Working group; e) Public Acceptance of Subsidies; and f) Public consultation[11]. Of these, only the working groups were not implemented because of the restrictions imposed by the COVID-19 pandemic. *Table 2* describes the social participation mechanisms mobilized in the regulatory process concerning ENDS in Brazil.

Table 2. Social participation mechanisms mobilized in the regulatory process of Electronic Nicotine Delivery Systems in Brazil

Mechanism	Objective*	Target Audience	Means
Public Hearing	To discuss the potential reduction of risks and the health risks related to ENDSs and to obtain evidence related to the topic	Open to anyone interested, without limitation of specific target audience	Public in-person session
Focus Group	To generate a better understanding of the usage patterns, perceptions, beliefs, attitudes, and behaviors of the individuals involved in the research	Open to anyone interested from a specific target audience	Online format
Targeted Consultation	To collect evidence relating to the several aspects to be evaluated regarding ENDSs	Open to anyone interested from one or more specific target audiences	Electronic form with a specific deadline, containing questions directed to the different affected and interested parties

Table 2. Social participation mechanisms mobilized in the regulatory process of Electronic Nicotine Delivery Systems in Brazil

Mechanism	Objective*	Target Audience	Means
Public Acceptance of Subsidies	To collect data and information about the Preliminary RIA Report in order to assist the decision-making process	Open to anyone interested, without limitation of specific target audience	Electronic form with a specific deadline
Public Consultation	To support decisions by ANVISA's Dicol based on the submission of draft regulatory acts for comments and suggestions from the general public	Open to anyone interested, without limitation of specific target audience	Electronic form with a specific deadline

Source: Prepared by the authors.

(*) According to the Social Participation Plan11. RIA: Regulatory Impact Analysis; ANVISA: National Health Surveillance Agency; ENDS: Electronic Nicotine Delivery Systems; Dicol: Collegiate Board.

The public hearing emerges as a mechanism intended to introduce and debate matters of relevant interest, generally controversial issues, through in-person sessions open to any interested party[1]. In the case of ENDS, two public hearings were held in Brasília/DF and Rio de Janeiro/RJ on August 8 and August 27, 2019, respectively. According to the Final Regulatory Impact Analysis (RIA) Report[22], several participants attended the hearings, totaling 161 in the first and 155 in the second.

As prescribed, information on the public hearings was published in the Federal Official Gazette. To guide the debate, the guidance documents contained 13 guiding questions prepared by ANVISA, which were to be addressed during the hearings[22]. The hearing agenda was organized into two sessions. An initial presentation session was dedicated to stakeholders invited by ANVISA to present evidence, their positions, and claims regarding ENDS, followed by an open session for the general interested public to present positions and questions on the topic.

The focus group, in turn, was held on the basis of interviews with specific groups to discuss the regulatory topic of interest, defined and introduced beforehand by a moderator. It aimed to capture perceptions, beliefs, and attitudes about the topic under regulation[1]. The study was independently conducted by the Federal University of Rio de Janeiro in remote format, covering five capitals in different Brazilian regions that had been selected because of their highest prevalence of ENDS use: São Paulo, Curitiba, Campo Grande, Teresina, and Porto Velho[22]. Ten focus groups were conducted with ENDS users, assessed in two age groups: young adults (18–28 years) and adults (35 years or older). The study was supported by the Pan American Health Organization and held from November 2021 to March 2022.

Targeted consultations, in turn, were conceived to capture or validate information, evidence, and data through written contributions from specific target audiences[1]. Three targeted consultations were conducted from March to April 2021. The first was directed to Health Surveillance managers in states and municipalities and received 7 contributions, all from municipal surveillance agencies; the second targeted education and research institutions and government bodies and received 31 contributions, of which 20, 3, and 8 came from those groups, respectively. The third consultation, lastly, addressed companies marketing these products in other countries and received 7 contributions.

The Public Acceptance of Subsidies, an open consultation mechanism that allows interested parties to provide data, information, and evidence regarding ANVISA's

Preliminary Regulatory Impact Analysis (RIA) Report, was conducted from April to May 2022. The information on the conduct of this mechanism, described in the Social Participation Plan, was published on ANVISA's website through official notices. In total, 1,567 participants from within and outside Brazil were registered: 1,488 were citizens; 30 were from non-governmental organizations; 22 were from academia/research; 10 were from government; and 17 were from the regulated sector.

Finally, the public consultation aimed to receive contributions on the draft regulatory normative instrument through an electronic form open to any interested party[1]. ANVISA recommended the activity through the Final RIA Report, which received contributions from December 2023 to February 2024. According to the Report on Public Consultation N°1.222/2023, ANVISA received 13,930 contributions through electronic forms: 13,614 from individuals and 316 from legal entities, with 850 contributions specifically concerning ENDS, besides general suggestions and 86 files attached to the forms as supplementary material[23].

Among individual participants, 83% identified themselves as citizens and 9% as health professionals. Among legal entities, 46% identified themselves as members of the regulated sector and 6% as public entities. Of the participants identifying themselves as belonging to the regulated sector, 94% were companies and 6% were representative entities. Regarding responses, 37% reported that they were in favor of the proposed rule, 59% stated that they held a different opinion, and 4% did not comment. According to the Report, only 2% of participants contributed specifically to the normative text under consultation[23].

In April, RDC N°855/2024, as the newly deliberated normative instrument, prohibited the sale, importation, storage, transport, and advertising of ENDS and reinforced the prohibition of their use in public or private enclosed collective environments[24].

Discussion

In the case of regulatory policy, it is challenging to perceive the paradox in a context in which, on the one hand, there is a trend toward reducing the role of the State in public policy and, on the other, a growing concern with controlling and securing individuals against health risks and global health emergencies[25].

In this context, health surveillance policies face the dilemma of responding to market demands in opposition to social and public needs. State institutions are therefore often called upon to act as arbiters that must balance the diverse interests of individuals or groups, a situation in which mobilizing social participation mechanisms is recommended.

Valente[10] points out that social participation in the definition of regulatory policies has been historically limited to the holding of public hearings and public consultations. Since the implementation of regulatory agencies in Brazil in 1996, the mere mention of these mechanisms was already enough to confer on them a status of legitimacy, transparency, and accountability.

According to the document 'Menu of Social Participation in Regulation'[1], social participation mechanisms are intended to consult affected and interested parties in order to gather information and receive contributions that improve the quality of the analysis supporting the decision-making process. It also aims to understand the positions and interests of groups in order to verify the relevance of the proposals under consultation. Furthermore, the document emphasizes the contribution of social participation mechanisms to building legitimacy, acceptance, and adjustments in the policy at issue.

From this perspective, the selection of the stakeholders to be involved is presented as the first prerequisite for achieving the aforementioned objectives. In the case of ENDS, public hearings, public consultations, and the Public Acceptance of Subsidies promoted greater diversity of stakeholders, functioning

as mechanisms open to any interested party without defining a specific target audience. By contrast, ANVISA's selection of stakeholders for public hearings – invited for specific presentation stages – signaled a combination of direct regulatory-body guidance with the opening of debates to public participation. In this regard, Picciotto[19(39)] draws attention to the importance of going beyond the version of an inclusive process in which only debate is informed and "promotes knowledge by those who have the right to know, the duty to advise, the obligation to provide, or the power to stipulate".

We also observed that most of the social participation mechanisms mobilized in the electronic cigarette case exhibited only superficial degrees of stakeholder involvement in the regulatory process, representing significant limitations in the degree of participation. Stakeholder adherence is also an important point to consider within this dimension. For example, the small number of contributions received through targeted consultations is noteworthy regarding the scope that this mechanism was supposed to cover. In the public consultation, we should underscore that, despite the significant number of participants, only 2% contributed specifically to the consultation's normative text. Most participants merely chose to express their opinion on the regulatory topic[23].

Thus, the analysis based on the adapted model of Cousins and Whitmore[14] and Cousins and Chouinard[15] suggests that the regulatory body retained control over decision-making regarding value in the process under study. A brief example within this dimension is that the guidance documents for the public hearings listed the questions to be answered by interested parties[22], that is, the questions directed the process on the basis of ANVISA's public health premises.

A recognized limitation of this study is that parties who did not formally appear in the regulatory arena may have exerted greater influence on the regulatory process and were not considered. Lima[26] notes that, in general, most mechanisms are more useful for capturing information that serves as input for the process of formulating regulation. Thus, the author states that the most common participation mechanisms are geared more toward collecting information about parties' demands and perspectives on the issue than toward supporting an in-depth debate on regulatory claims and the construction of 'solutions' that address social concerns through legal adequacy and technical certainty.

As a general rule, the RIA Report[22] reinforces the role of public hearings, targeted consultations, and the Public Acceptance of Subsidies in collecting evidence and contributions from stakeholders, followed by analysis and final disclosure of the reasons why contributions were accepted or rejected by the regulatory body.

In this context of regulatory policies, therefore, in addition to ensuring the participation of multiple parties in the process, we underscore the importance of mediation techniques for the consensual 'resolution' of controversies, precisely through what has come to be called the consensus-building procedure[26,27]. In the Brazilian case of electronic cigarettes, these techniques take on some specific features because of multiple and diverse stakeholders involved.

From this perspective, it becomes essential to reflect on what is in conflict, to clarify the controversies, and to consider how to build and negotiate the 'solution', even if only provisionally. When a regulatory alternative is chosen, one assumes that criteria have been applied; in other words, the core of valuation lies in the criteria, not in the alternative itself. Therefore, the criterion is understood as a synthetic unit of valuation.

Multiple evaluative approaches or theories of evaluation may affect how valuation presents itself[28]. Patton[29] states that added value is appreciated for its effectiveness in satisfying the needs of interested and affected parties. The author argues that the descriptive

approach based on stakeholder valuation holds that no particular value should be prioritized; that is, different values should be considered without favoring any. Patton[17,18,30] believes that this approach lies within a pluralistic and democratic sphere of valuation; nevertheless, it may also be evidence-based.

The author[31] further states that a democratic and participatory evaluation should not be restricted to meeting absolute standards of technical quality in the investigation, but should ensure that its methods are appropriate to the validity and credibility requirements of its specific objectives and uses. Cousins, Whitmore, and Shulha[32] and Shulha et al.[33] emphasize the importance of interaction and interface mechanisms among the stakeholders involved, considering their different perspectives and positions in society.

Picciotto[19] considers that the basic concept of democracy is so universally popular that all governments claim to be democratic. From this perspective, participatory evaluation emerges as an 'art of the possible', requiring rapid adaptations to varying governance contexts, including the most complex ones, in light of the unprecedented challenges currently faced by open society and democracy.

Relations among the parties are revealed, albeit only partially, during the ENDS regulatory process, essentially in the public hearings. As stakeholders interact, they negotiate meanings and interests, forming dynamics of persuasion, coalition, perception, and action. Even so, one should recognize that debates have a front stage and a backstage, where disputes occur, consensus techniques are conducted, and groupings are formed in the State's absence.

In this respect, we identified that the adapted model of Cousins and Whitmore[14] and Cousins and Chouinard[15] needs to consider the level and types of relationships and organization among the parties involved. These interactions may hierarchically define the level of power in controlling decision-making. The diagram does not suggest a multidialogical representation, thereby prompting further studies and reflections to address these participatory processes.

In the case of ENDS, the repositioning of the various parties around prohibition movements is notable. Interaction among peers stands out as a possible alignment in the search for a shared evaluation, consolidated in dispositives such as administrative rules, resolutions, and normative instructions that are always provisional, for example, RDC Nº 46/2009 and RDC Nº 855/2024, with the indication that they may remain flexible on the basis of new evidence.

In sum, the movements of representing controversies and mobilizing toward the intentionality of their possible 'solution', advanced by social participation mechanisms, may require a theorization of regulatory processes as a network of dispositives. In the case of the participatory process, we should underscore that the negotiation of 'consensus' and the resignification of values – that is, a transvaluation – may or may not occur depending on the forces at play[34].

The concept of evaluation consists fundamentally of making a value judgment about a given intervention and its components. One of its important objectives is to produce knowledge about the evaluation itself and legitimize decision-making by providing valid and legitimate information about the intervention, so that the different parties involved – whose fields of judgment are sometimes multiple and diverse – can position themselves and build, individually or collectively, a judgment that may be translated into action[35].

In this regard, Verhine[36] highlights that evaluation and regulation both involve decision-making and require precise, reliable, and contextualized information about the problem in focus. The author emphasizes decision-making regarding added value as an intersection between evaluation and governmental regulation. Although in some situations, disagreement in their purposes underscores central tensions, it also opens

pathways for identifying possible complementarities. In such cases, evaluation is a learning process, a formative and constructive practice that contrasts with the role of regulation as a predominantly bureaucratic and legalistic function.

Final considerations

The Brazilian political-institutional context was marked by deteriorated democratic instability and exacerbated denialist and anti-scientific discourse, which affected regulatory processes through narratives and actions directed against institutional integrity, exposing ANVISA to political pressure, media scrutiny, and attacks on its legitimacy[37]. This setting placed strain on the Agency's social participation mechanisms, with potential impacts on public trust and the effectiveness of regulatory decisions[38].

This article specifically aimed to identify approaches that would allow an analysis of the role of social participation mechanisms in the regulatory process concerning electronic cigarettes in Brazil, in light of the model adapted from Cousins and Whitmore[14] and Cousins and Chouinard[15]. We should stress that the 'Menu of Social Participation in Regulation' emerged at a stage marked by the induction and implementation of minimal-state policies and may be seen both as a strategy of hegemonic construction and as potentially containing movements toward strengthening the shared management of public policies.

The 1988 Federal Constitution[39] highlighted the relevance of user participation in direct and indirect public administration, signaling a State that allows the participation of individuals and groups in political, economic, social, and cultural processes. Therefore, it is evident that, in addition to regulatory 'good practices' or guidelines for social participation, it is crucial to implement innovative initiatives that improve the understanding of the regulatory system, emphasizing the achievement of the objectives of its participatory mechanisms.

This article, therefore, reinforces the relevance of discussing the relationship between regulation and evaluation. First, Dill and Berkens[40] state that regulation may take different forms, such as the definition of quality standards, evaluation methods, performance criteria, and the implementation of legal, financial, and monitoring instruments. Second, regulatory norms constitute a reference for oversight and inspection purposes, with clear implications for legal, technical, and civil responsibility. Thus, this perspective differs from approaches that view them as generative dispositives, that is, provisional solutions to strategic crises grounded in movements of social participation.

This work assumes that evaluation and regulation are technical-political processes. It is therefore crucial to address the need to understand and manage the tensions between their technical aspects, such as the collection and analysis of evidence, and political factors, such as interests, power, and values. This reinforces the importance of considering, in evaluation and regulation, the quality of methods and the political dynamics that shape their influence on decision-making. Moreover, in the context of replacing disciplinary societies by globally and virtually controlled societies[41], the emergence of new dispositives[42] intended to support democratic values needs to be closely examined, especially the new modes of state 'command and control'.

Understanding the social participation mechanisms envisioned by ANVISA as a network of dispositives reinforces new perspectives for exploring the relationships among the evaluation team, the stakeholders, and the context, which is critical for understanding contemporary evaluation practices.

In this regard, the model discussed in this article should be expanded so as to explore in depth the interactions and alliances among stakeholders and their different positions of power throughout disputes, controversies, and solutions, something that seems particularly

important for making negotiation interactions more transparent and for inducing more inclusive alternatives of transvaluation in evaluation and in regulatory initiatives.

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Authorship contributions

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