

UCSF

UC San Francisco Previously Published Works

Title

The taste of smoke: tobacco industry strategies to prevent the prohibition of additives in tobacco products in Brazil

Permalink

<https://escholarship.org/uc/item/7190q4jb>

Journal

Tobacco Control, 28(e2)

ISSN

0964-4563

Authors

da Silva, Andre Luiz Oliveira
Bialous, Stella Aguinaga
Albertassi, Patrícia Gonçalves Duarte
et al.

Publication Date

2019-12-01

DOI

10.1136/tobaccocontrol-2018-054892

Peer reviewed

The taste of smoke: tobacco industry strategies to prevent the prohibition of additives in tobacco products in Brazil

Andre Luiz Oliveira da Silva,^{1,2} Stella Aguinaga Bialous,³
 Patrícia Gonçalves Duarte Albertassi,² Daniela Aparecida dos Reis Arquete,²
 Ana Marcia Messeder Sebrao Fernandes,² Josino Costa Moreira¹

¹CESTEH, Escola Nacional de Saude Publica Sergio Arouca, Rio de Janeiro, RJ, Brazil
²Agencia Nacional de Vigilancia Sanitaria - ANVISA, Rio de Janeiro, RJ, Brazil
³Center for Tobacco Control, UCSF, San Francisco, California, USA

Correspondence to

Dr Andre Luiz Oliveira da Silva, Laboratório de Toxicologia do Centro de Estudos de Saude do Trabalhador e Ecologia Humana, Escola Nacional de Saude Publica Sergio Arouca, Fundação Oswaldo Cruz (CESTEH/ENSP/FIOCRUZ), Rua Leopoldo Bulhões, 1480 - Manguinhos, Rio de Janeiro, RJ, Brazil; andre.sp.ensp@gmail.com

Received 15 December 2018
 Revised 10 April 2019
 Accepted 23 April 2019

ABSTRACT

Background The tobacco industry (TI) uses several strategies to attract new consumers, including using additives in tobacco products, which makes tobacco especially attractive to youth. Based on scientific evidence and the principles of the WHO Framework Convention on Tobacco Control, the Brazilian Health Regulatory Agency (ANVISA, for the name in Portuguese), published the Collegiate Board Resolution (RDC, for the name in Portuguese) 14/2012 in 2012, prohibiting the addition of substances that enhance the flavour and taste of tobacco products in order to make them more attractive. In response, the TI used various strategies to prevent RDC 14/2012 from entering into force. At the time, the Brazilian additive ban was the most comprehensive in the world as it included a ban on menthol.

Objectives This paper analyses the arguments and strategies used by the TI to prevent the implementation of the additives ban.

Methods Review of published articles, reports, legislation and legislative activity, internal TI documents, media stories and other documents to describe TI's reaction to the ban.

Results The results show that the TI used some well-known strategies to delay or cancel the entering into force of the resolution. For example, the TI attempted political interference, used litigation and commissioned studies with findings that questioned the resolution's rationale. The TI strategies used in Brazil are similar to those used at the global level to oppose other tobacco control measures.

Conclusions TI successfully delayed the most comprehensive additive ban in the world using its usual tactics, despite the fact that none of the arguments presented by the TI had an acceptable scientific basis or evidence.

Estimates indicate that, globally, 82 000 to 99 000 children start smoking every day.^{6–8} In Brazil, data indicate (2013–2014) that 18.5% of adolescents between 12 and 17 years of age have tried cigarettes in their lifetime.⁹ The national Special Tobacco Survey (PETab) conducted by the Brazilian Ministry of Health showed that 17.2% of the population aged 15 years or older used tobacco products in 2008.¹⁰ Other surveys showed that the majority of smokers in Brazil started to smoke before they were 20 years of age.^{10 11}

The tobacco industry (TI) uses a variety of strategies to attract new smokers, maintain dependency and prevent tobacco control regulations.^{1 12 13} These strategies lead to reduced cessation and target young people to start, as the industry needs to replace smokers who stop smoking or die.^{14–16} Among the strategies used by the TI to maintain addiction and profits, cigarette engineering is perhaps one of the most ingenious. Modern cigarettes are the result of innumerable technological developments where all aspects of their composition are controlled and built to, among other characteristics, optimise the delivery of nicotine to the smoker, facilitate the initiation of new smokers, make the product more palatable and less irritating, mask environmental tobacco smoke and reduce production costs.^{17–23}

One of the technologies used by the TI is the use of additives. The TI's own internal documents point to additives as an important technology for expanding its markets.^{16 17 19 23–28} The use of additives in tobacco products facilitates tobacco use, enhances the effects of nicotine and allows the TI to use false claims of properties associated with health and well-being.^{27 29–32}

Data from the TI³³ show that flavourings are added to cigarettes to improve their flavour and aroma.³⁴ Additionally, TI documents show that these additives are also used to reduce airway irritation caused by smoke.^{23 33–35} The TI recognises that irritation caused by smoke, unpleasant taste, astringency, dry mouth and other unpleasant tobacco characteristics are effective barriers to the initiation and perpetuation of smoking,¹⁶ this the TI considered additives pivotal to market success.

Aware of the TI's reasons to use additives, ANVISA, the Brazilian agency empowered, by legislation, to regulate tobacco products, considered the evidence on additives and its public health harms and published a resolution, RDC 14/2012, in 2012, which *inter alia* prohibited the use of additives that

INTRODUCTION

Tobacco use is the leading cause of preventable death and disease in the world.¹ Efforts to address this global epidemic need to include strategies to ensure that young people do not become addicted to tobacco products. Evidence shows that the younger the person starts smoking, the sooner he or she becomes a regular smoker, and the harder it is for them to quit.^{2 3} Even smoking chocolate cigarettes in childhood correlates with smoking in adulthood.^{4 5}



© Author(s) (or their employer(s)) 2019. No commercial re-use. See rights and permissions. Published by BMJ.

To cite: Oliveira da Silva AL, Bialous SA, Albertassi PGD, et al. *Tob Control* Epub ahead of print: [please include Day Month Year]. doi:10.1136/tobaccocontrol-2018-054892

altered the flavour and taste of tobacco products to make them more attractive.³⁶

This paper reviews the TI's strategies in response to the resolution and analyses the TI's arguments to prevent it from going into effect.

METHODS

This retrospective, qualitative analysis was conducted from January 2016 to June 2018. We conducted a literature review using the PubMed (MEDLINE), using the terms tobacco+additives and cigarettes+additives (heat not burn tobacco, JUUL and electronic cigarettes were not included). Tobacco+additive returned 147 papers. We selected papers published in English, Spanish or Portuguese and scanned them to determine relevance to this study, resulting in 56 papers included. Using the same criteria, and excluding the repeated papers, the search using cigarette+additive resulted an additional 14 papers for a total of 70 papers published from 1990 to 2018.

We searched SCIELO using the same strategy. The term tobacco+additives returned a total of eight papers. After excluding duplicates, one additional paper was found. The term cigarette+additives returned no new papers.

Additional systematic searches of internal TI documents were conducted using the Truth Tobacco Industry Documents library (TTID),³⁷ using the snowball searches³⁸ and combining qualitative content analysis with iterative strategies described for searching TTID.³⁹ We tried to identify additional documents on the TI strategies to stop the additives ban. No strategies were found that had not been previously described.

We searched the internet, including websites hosted by TI or its allies, websites of organisations that support tobacco control policies, federal government websites, the regional newspapers from south (the main tobacco producer region in the country) and the largest newspapers in Brazil, to identify additional sources of information related to the additive ban and the TI's response to it. Legislative activity was monitored through the

websites of the House of Representatives and the Federal Senate, as well as internet search engines.^{40 41}

Information regarding the public consultation process on the ban, lawsuits and other information related to the resolution was obtained through a request to ANVISA under the auspices of the Access to Information Law.⁴²

To ensure data reliability and reproducibility, information from all data sources, including the TI documents, has been triangulated with scientific papers, government reports, Framework Convention on Tobacco Control (FCTC) documents or other official document from governments or international organisations.

The findings are presented using the taxonomy on TI interference described in the article by Ulucanlar *et al.*⁴³

RESULTS

The process of banning additives in Brazil started as part of Brazil's engagement with the FCTC Working Group on articles 9 (Regulation of the contents of tobacco products) and 10 (Regulation of tobacco product disclosures) in 2010. Shortly after the fourth Conference of the Parties (COP4) of the FCTC (COP4) in 2010, ANVISA took procedural steps to call a public consultation on a proposed resolution to ban additives.⁴⁴ After the resolutions was issued, the TI continued its attacks, through litigation (see figure 1 for a timeline of events).

We did not identify any TI strategy that had not been previously described. The following TI's strategies were used to interfere with the implementation of additive ban: litigation,^{45 46} mechanisms to prevent regulations,⁴⁷ front groups,⁴⁸ use of bad science,⁴⁹ lobby,^{47 50 51} allegations about the increase of illicit trade,⁵² fake news and false arguments.^{47 50 51 53}

TI and COP 4

The discussion on the regulation of additives in Brazil began before ANVISA called for a public consultation on the topic.

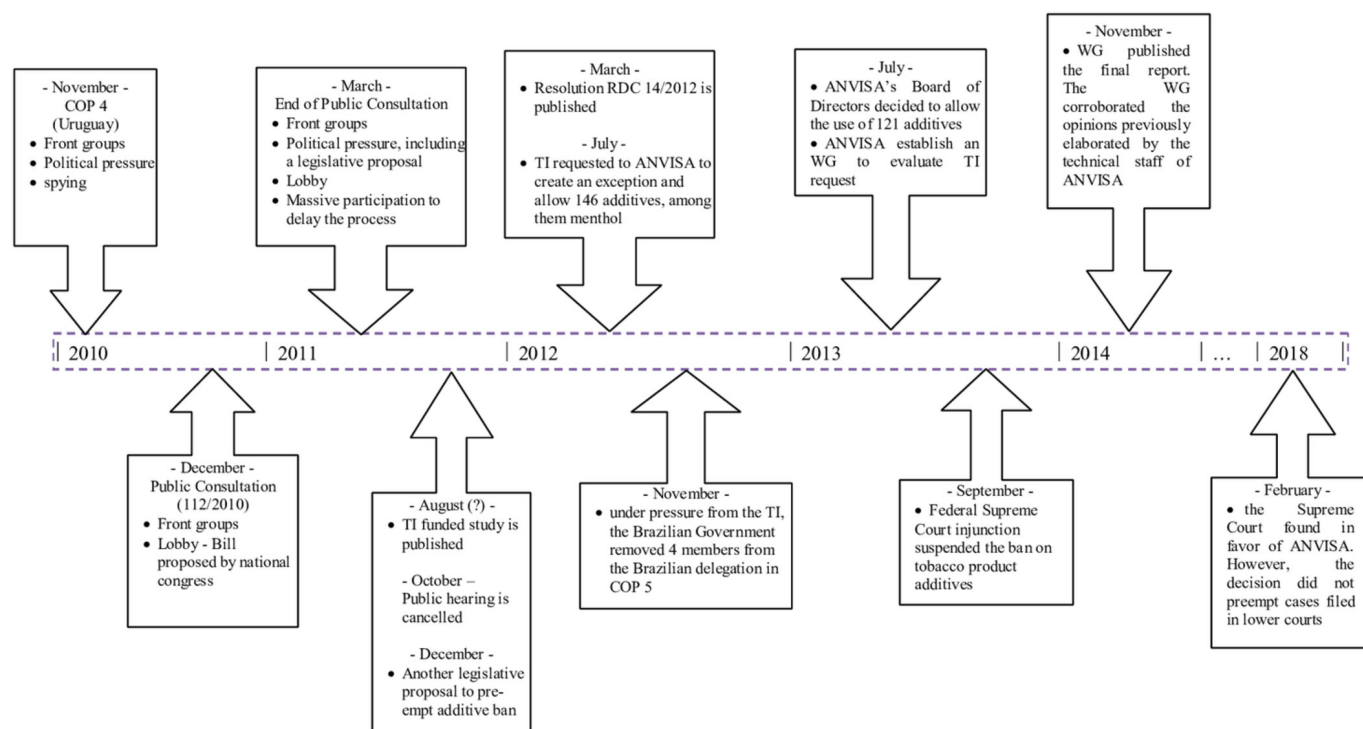


Figure 1 Timeline of process of additive ban and TI strategies in Brazil. COP, Conference of the Parties; TI, tobacco industry; WG, working group.

In November 2010, at COP4, the TI (and related groups), noting that restrictions on using additives in tobacco products was part of the discussions on the development of guidelines for the implementation of articles 9 and 10 of the FCTC, moved to prevent the adoption of such restrictions, mostly through the International Tobacco Growers Association (ITGA), a TI lobbying tool.^{54 55} In Brazil, ITGA's opposition effort⁵⁶ was represented by the Brazilian Association of Tobacco Growers (AFUBRA).⁴⁸ Brazilian farmers, backed by the TI, demonstrated at the door of COP4,⁵⁷ and congressmen linked to the TI's interests exerted political pressure to change the members of the Brazilian delegation to COP4.^{53 58} At the time, news reports surfaced alleging that a civil servant, who was a member of the Brazilian delegation, was providing information to the TI directly from COP4.^{59 60} The Brazilian Government initiated an administrative process to investigate this allegation, but found that the statute of limitation was reached and there were no known consequences from the investigation.⁶¹

The main argument used by the TI to prevent the adoption of the guidelines was that the prohibition of additives would make the production of burley-type tobacco unfeasible. The TI claimed that as burley require the addition of sugars to become palatable, a ban would lead to the loss of income for thousands of workers. Further, the TI claimed that there was no scientific evidence to support an additives ban.^{64 62 63}

Despite the TI pressure, FCTC Parties at COP four decided, by consensus, to adopt the recommendation to restrict the use of additives in tobacco products.^{64 65}

Using Ulucanlar's taxonomy⁴³ to TI's response, the discursive strategies of unanticipated costs to economy and society and intended public health benefits were the strategies identified. The instrumental strategies were the use of coalition management, information management and direct involvement and influence in policy (table 1).

TI and public consultation to discuss the additives ban

After COP4, on 29 November 2010, ANVISA published a public consultation, CP112/2010, making available for comments a draft update of Resolution 46/2001⁶⁶ and a proposed prohibition of additives.⁶⁷ The consultation lasted from November 2010 to March 2011, the longest public consultation process of ANVISA's entire history to date (the usual public consultation duration at the time was 30 days).⁶⁸ The draft text banned the addition to tobacco products of all substances used to alter flavour, aroma, colour or suggest any therapeutic/beneficial association with tobacco products, including all sugars except starch. Exceptions were also applied to components that were considered essential for manufacturing or did not enhance the attractiveness of tobacco products, such as adhesives and pigments to make the cork colour pattern in filters.⁶⁷ The TI and its allies reacted to the public consultation on several fronts, using arguments similar to those used to interfere with the Partial Guidelines for Implementation of articles 9 and 10 of the FCTC at COP4.⁵⁴

Contributions to the public consultation were sent electronically, by post and hand-delivered.⁶⁹ ANVISA considered as actual contributions those that objectively brought arguments against or in favour of the proposed draft. Contributions that simply stated that they were against or in favour of the text⁶⁹ were counted but not addressed. Additionally, statements that omitted the participant's name, address, position (in favour or against) or lacked a reference to the public consultation were disqualified.⁶⁹ Of the 127 905 documents received, only 10 were, in effect, a contribution. (To date, this public consultation

remains the one with the highest number of comments received by ANVISA.) While in itself this was not a concern, a story by newspaper *Folha de São Paulo*⁵⁰ suggested that such a large number of comments aimed to delay the process of analysis of public comments and, consequently, the release and implementation of the proposed resolution. Analysis of documents obtained through access of information law⁶⁹ revealed that:

1. The TI printed its own form for submitting contributions, containing filling instructions, to protest against the proposed regulation. Two thousand of these forms were blank when delivered.
2. Thousands of forms were mailed from Rio de Janeiro, according to the postmark, however the addresses on the forms were from other states.
3. Five hundred forms were sent without any identification and only contained a statement against the proposed draft.
4. In some cases, ANVISA contacted the signatory to seek clarification on the comment submitted, and was told by the supposed signatory that they had never participated in the process.
5. In one case, the person indicated that they were at an event, was requested to sign the public comment form, but indicated that he was led to believe that the form was some type of survey research.
6. Some of the addresses submitted on the forms were non-existent.

These findings indicate that these comments, and the massive participation in the public consultation, were likely coordinated by TI as a strategy to delay the conclusion of the process.

In 2010, a bill was proposed in congress (PDL 3034/2010)⁷⁰ to stop the results of the Public Consultation 112/2010, claiming that the proposed resolution usurped the mandate of the national congress. (In 2012, this legislative proposal was modified to counteract the effects of the actual resolution, RDC 14/2012.) According to public references, the bill proponent had received campaign donations from Alliance One (R\$100 000) and five cars from Souza Cruz (British and American Tobacco in Brazil) to donate to charities.^{60 71–73} As of March 2019, this bill proposal is listed as archived.⁷⁰

Another legislative proposal, in 2011 (PL 2901/2011)⁷⁴ aimed to amend Tobacco Control Law 9294/1996⁷⁵ of 15 July 1996, by banning additives except for menthol and tobacco flavours. The justification used in PL 2901/2011 was the same as that used by the TI, that the prohibition of additives would prevent the production of burley-type tobacco, while preserving the use of menthol and tobacco-flavouring additives. The proposed bill would also remove ANVISA's authority to regulate additives. In 2015, this bill proposal was removed by its author.⁷⁴

At the municipal level, the Municipal Councils of Paraíso-RS, Santa Cruz do Sul-RS, Cruz das Almas-BA, Mato Leitão-RS, São Miguel do Oeste-SC and Canguçu-RS,^{76–81} requested the cancellation of the call for public comments. The City Council of Rio Pardo-RS also submitted a request to ANVISA for the revocation of articles 9 and 10 of the FCTC.⁸² At the state level, the states of Rio Grande do Sul, Santa Catarina and Paraná^{83–85} sent declarations opposing CP112/2010. These municipalities, and states, are the largest tobacco growing regions in Brazil.

Additional opposition to the Public Consultation CP112/2010 came from Congressional Agriculture Committee⁸⁶ which made a motion to repudiate the consultation. Additionally, ANVISA received a request for clarification from the Cabinet of the President (Civil House)⁸⁷ and a request for cancellation from a Charter⁸⁸ of the Tobacco Production Chain Sectoral Chamber (part of the Ministry of Agriculture, Livestock and Supply).

Table 1 Discursive and instrumental strategies used by the tobacco industry to try to stop additive ban in Brazil, based on Ulucanlar *et al*⁴³

During COP4–2010		
Discursive strategy	Domain	Argument
Unanticipated costs to economy and society	The economy	Loss of jobs (specially farmers) and sales; impossibility to grow burley tobacco.
	Law enforcement	Rise of illicit trade: adults who smoke flavoured cigarettes will purchase them in illicit market.
	The law	WHO/FCTC is acting beyond its mandate.
Unintended benefits to undeserving groups	Smugglers will profit	Rise of illicit trade.
Public health benefits	There is not enough evidence of positive impact on public health	There is no scientific evidence about the relation between the use of additives in tobacco use and the attractiveness of tobacco products.
COP, Conference of the Parties; FCTC, Framework Convention on Tobacco Control.		
Instrumental strategy	Technique	Description
Coalition management	Constituency recruitment	TI reached out to allies and affiliates requesting support to its complaints in the media and with policy makers, in an attempt to change Brazil's position about additives ban at COP4.
	Constituency fabrication	Tobacco growers associations demonstrated at COP4, supported by TI.
Information management	Amplification	Dissemination of TI arguments in newspapers and other media.
Direct involvement and influence in policy	Access	Allegation that a member of the Brazilian at COP4 was passing information to the TI.
	Incentives and threats	A congressman supported by TI tried to influence Brazil's positions about additives at COP4.
COP, Conference of the Parties; TI, tobacco industry.		
During public consultation: 2010–2011		
Discursive strategy	Domain	Argument
Unanticipated costs to economy and society	The economy	Loss of jobs (specially farmers) and sales, impossibility to grow burley tobacco.
	Law enforcement	Loss of tax revenue due to increase in illicit trade.
	The law	Rise of illicit trade as adults who smoke flavoured cigarettes will purchase them in illicit market, thus increasing contraband.
		ANVISA has no mandate to ban additives.
Intended public health benefits	There is not enough evidence of public health benefits from additive bans	There is no scientific evidence about the relation between the use of additives in tobacco products and attractiveness of tobacco products, particularly to youth.
	Policy (ban) will not work	The additive ban will be ineffective to prevent youth uptake of tobacco use.
Unintended benefits to undeserving groups	Smugglers will profit	The additive ban will rise illicit trade and will only benefit smugglers and crime.
Expected tobacco industry costs	Additives ban will reduce sales and jobs	The additive ban will increase illicit trade, and it will prevent the growing of burley tobacco, generating poverty, job losses and loss of tax revenues.
		Impossibility to manufacture cigarettes without additives, thus the ban will lead to job losses in the industry and rise in unemployment.
Instrumental strategy	Technique	Description
Coalition management	Constituency recruitment	TI associations' complaints and arguments to try to cancel the public consultation.
	Constituency fabrication	Growers associations' demonstrations and complaints about the public consultations. ⁴
Information management	Amplification	Dissemination of TI arguments in newspapers and other media.
		Dissemination of misleading information.
		Massive participation in the public consultation, opposing the ban but mostly, overwhelming the process.
	Suppression	'Scientific studies' funded by TI contesting the additive ban positive impact.
Direct involvement and influence in policy	Incentives and threats	Political campaign funding of politicians that protect TI interests.
	Actor in legislative processes	Congressman supported by TI tried to cancel the public consultation through legislative measures.
	Actor in government decision-making	Ministry of Agriculture hosted a tobacco sector meeting chaired by TI.
Litigation	Legal action to contest/ obstruct regulations	Injunction to cancel the public hearing results.
TI, tobacco industry.		

Continued

Table 1 Continued

After the resolution (RDC 14/2012) was issued

Discursive strategy	Domain	Argument
Unanticipated costs to economy and society	The economy	Loss of jobs (specially farmers) and sales, impossibility to grow burley tobacco. Loss of tax revenue due to increase in illicit trade.
	Law enforcement	Rise of illicit trade as adults who smoke flavoured cigarettes will purchase them in illicit market, thus increasing contraband.
	The law	ANVISA has no mandate to ban additives in tobacco products
	Politics/governance	The resolution is a typical example of the nanny state, the government is over reaching in its regulatory mandate.
Intended public health benefits	There is not enough evidence	There is no scientific evidence about the relation between additives use and attractiveness of tobacco products.
	Policy will not work	The additive ban will be ineffective to avoid kids start to smoke.
Unintended benefits to undeserving groups	Smugglers will profit	The additive ban will rise illicit trade.
Expected tobacco industry costs	Additives ban will reduce sales and jobs	The additive ban will increase illicit trade and not allow grow burley tobacco generating poverty and loss of jobs.
Instrumental strategy	Technique	Description
Information management	Amplification	Dissemination of TI arguments in newspapers and other media. Dissemination of misleading information.
	Suppression	Brazilian Delegates casted out during COP5 due TI pressure.
Direct involvement and influence in policy	Incentives and threats	Political campaign funding of political party who defend TI interests.
	Actor in legislative processes	Congressman supported by TI trying to cancel the additive ban through legislative measures.
	Actor in government decision-making	Ministry of agriculture hosts a sectoral group of tobacco chaired by TI.
Litigation	Legal action to contest/ obstruct regulations	Injunction to cancel the ANVISA's resolution to ban additives.

COP, Conference of the Parties; TI, tobacco industry.

ANVISA also received a joint letter from a congressman and a Senator, copying the Minister of Health, requesting the cancellation of the public consultation. According to public references, this congressman received contributions from TI to his campaign.^{71 89} We were unable to determine if the Senator has received financial or other contributions from TI.

After the public consultation ended, a public hearing on the additives ban was scheduled for October 2011 at the National Cancer Institute (INCa). The hearing was suspended following a preliminary court injunction from the Federal Court of Rio Grande do Sul, filed by the Interstate Tobacco Industry Union (SINDITABACO).⁴⁵ The injunction alleged that INCa's space would be insufficient to accommodate those interested in participating in the public hearing. Two months later, a public hearing was held at a sports centre in Brasília (capacity 24 000 people), with approximately 100 people participating.

In 2011, the Getúlio Vargas Foundation (FGV for the name in Portuguese) published a study,⁴⁹ funded by TI and groups linked to the TI⁹⁰ (according to the publication—SINDITABACO—Interstate Tobacco Industry Union, FETAG—Federation of Agricultural Workers in Rio Grande do Sul; FETAESC—Federation of Agricultural Workers of the State of Santa Catarina; STIFA—Union of Workers in the Tobacco and Food Industries of Santa Cruz do Sul and Region; CNTUR—National Confederation of Tourism; ABRASEL—Brazilian Association of Bars and Restaurants), concluding that the prohibition of additives would bring no public health benefits while it would negatively affect the production of burley-type tobacco and increase illicit trade.⁴⁹ FGV is a respectable and traditional research institute and university, which until the publication of this study had never positioned itself contrary to public health policies, especially tobacco control. In fact, in the past, it has contributed to research and data supporting tobacco control policies.

The FGV report had no scientific merit, as it misrepresented references used in its analysis, used references from authors with conflicts of interest and concluded that the resolution would stimulate the illicit trade without any justification.⁹¹ In addition, the report did not provide any information of authorship; thus, it is impossible to verify possible conflicts of interest or the credentials of those who wrote it, a pivotal concern given previous research showing TI's use of junk science as a strategy to oppose tobacco control policies. The FGV report was analysed by Lencucha and Pontes,⁹² and the authors concluded: "FGV document either drew from unreliable sources (ie, those directly or indirectly supported by the tobacco industry) or misrepresented information presented in credible sources."

The discursive and instrumental strategies used during the public comments' process are detailed in [table 1](#).

TI and the ANVISA's resolution banning additives—RDC 14/2012

Despite all the pressure to cancel it, the public comments process was finalised, and resolution RDC14/2012 was published on 15 March 2012.³⁶ It prohibited the use of substances with flavouring or aromatising properties that could impart, intensify, modify or enhance flavour or aroma of all tobacco products. The group of prohibited substances included adjuvants of technology for aromatisation and flavouring agents; additives with nutritional properties, such as amino acids and vitamins; additives associated with alleged stimulating or invigorating properties (eg, guarana and caffeine); pigments; fruit and other vegetables; sweeteners or any substance capable of giving sweet aroma or flavour, other than sugars; seasonings, herbs and spices or any substance that may give aroma or flavour of spices and herbs; ameliorants; and ammonia and all its compounds and derivatives.

The resolution included a few exceptions allowing the use of some humectants, sugars and some other components considered essential to the manufacture of cigarettes. The resolution also allowed the use of certain additives, provided that they were not used to change the taste of cigarettes (and other tobacco products), and that TI could offer a justification for their use. In the case of sugars, ANVISA was sensitive to TI's economic arguments. Sugars are known to be used to improve the organoleptic aspects of tobacco smoke, in addition to being suspected of potentiating the effects of nicotine.^{35 93–95} However, the resolution allowed sugar to be added, although only to the extent necessary to replace the naturally occurring loss of sugar during the curing process.

After the publication of the resolution, the TI continued to pressure ANVISA to review its position and to allow the use of additives. In July 2012, the TI requested ANVISA's Board of Directors to create an exception and allow the industry to use 146 additives, among them menthol. The TI argued that these were necessary to maintain the original flavour of the tobacco, lost during the curing and manufacturing process, and that they would occur naturally in tobacco.^{52 96 97} ANVISA's technical staff opposed this exception.^{52 96 97} ANVISA's Board of Directors decided to temporarily allow the use of 121 of the 146 additives, during which time a working group (WG) of experts would evaluate the possibility of permanently creating an exception for these 121 additives.⁹⁸ In August 2014, the WG⁹⁹ published its final report.¹⁰⁰ It corroborated the opinion of the technical staff of ANVISA, reinforcing the importance of prohibiting the use of all flavouring substances in tobacco products, and recommending the full implementation of RDC 14/2012.^{28 100} The WG report also recommended the ban of sugars. After the WG's report, ANVISA's Board of Directors revoked the Normative Instruction that had temporarily allowed the use of 121 additives in tobacco products.⁹⁹

In 2012, under pressure from the TI, the Brazilian Government removed four members from the Brazilian delegation (from ANVISA and INCA) that were attending the fifth Conference of the Parties (COP5) of the FCTC in Seoul, South Korea. These delegates had less than 12 hours' notice to return to Brazil.^{101 102}

At the same time, according the non-governmental organisation (NGO) ACTBr, a Brazilian delegation member, despite the scientific literature to the contrary, advocated TI friendly positions during COP5.^{101–104} The NGO accused part of the Brazilian delegation of working in line with TI's interests and providing false information to the press.¹⁰²

In September 2013, a Federal Supreme Court injunction suspended the ban on tobacco product additives. The court filing by Brazil's National Confederation of Industries did not question any technical aspects of the resolution. It questioned, instead, the competence of ANVISA to regulate tobacco products' additives. In March 2018, the Supreme Court found in favour of ANVISA.⁴⁶ However, the decision did not preempt cases filed in lower courts halting the implementation. These cases are being judged one by one and, as of March 2019, there are 18 court cases pending and the resolution remains without implementation. According ANVISA, TI more than doubled the number of flavoured cigarettes in the Brazilian market between 2008 and 2018 (23 brands in 2008 to 58 brands in 2018).¹⁰⁵

The discursive strategies and instrumental strategies are listed in [table 1](#).

TI key arguments to deter the additive ban

[Table 2](#) lists the key arguments used by TI and its allies.^{27 29–32 63 106–114}

DISCUSSION

The TI strategies used to interfere in the implementation of Brazil's additive ban are the same described in the literature.^{115–128} We found no difference between the arguments used to deter new regulations worldwide and arguments used in Brazil, with adaptations to the Brazilian context. A similar pattern of strategies was found in the Canadian additive ban in 2009, the first additive regulation in the world.^{129 130}

Casting doubt on the public health impact, misusing science, using public relations, funding political campaigns, lobbying, intimidating, using economic power and litigation, corruption, using front groups and establishing alliances are TI strategies

Table 2 The key arguments used by TI against the additive ban in Brazil

TI arguments	Comments/counter-arguments
Additives do not increase toxicity of tobacco products	ANVISA, following FCTC partial guidelines to implement articles 9 and 10, did not use the issue of the toxicity of additives in its proposed ban—it focuses on how additives increase attractiveness and palatability of tobacco products. Despite research published by TI ^{106–108} showing no increased toxicity associated with additives, independent research indicates that there could be an increased toxicity, or at a minimum, that additives are not innocuous, ^{110 111} thus making this TI argument controversial. Increased attractiveness of tobacco products facilitates initiation and deep inhalation of smoke, ²⁷ thus it is currently undeniable that additives negatively affect public health.
The additives ban would make it impossible to grow Burley tobacco	The TI already produces cigarettes using Burley tobacco without using any of the additives prohibited by ANVISA's resolution. In Brazil, these "additive-free" cigarettes emerged in 2012. ¹¹² Internal TI documents show a patent application from the 1990s to recompose Burley tobacco's sugars (lost during the curing process) without the use of additives. ¹¹³ According to data from the TI, over 80% of the tobacco leaf production in Brazil is exported. ¹¹⁴ The resolution has no impact on tobacco that is grown for export, as it only applies to tobacco products manufactured for sales and distribution in Brazil.
It is not possible to manufacture 'American blend' cigarettes without additives, as this blend requires the use of Burley tobacco	As described above, the argument that the resolution would ban the growth and use of Burley tobacco was not supported by evidence.
ANVISA has no mandate to ban additives	The Supreme Court found in favour of ANVISA's mandate to regulate tobacco products, including the ban of additives.
The resolution banning additives will lead to an increase illicit trade	There is no evidence to support this statement.
Additives are not used to attract teenagers to use tobacco products	The use of additives in tobacco products facilitates tobacco use, enhances the effects of nicotine and uses false claims of properties associated with health and well-being. ^{27–32} Data from the TI ³³ show that flavourings are added to cigarettes to improve their flavour and aroma. ³⁴ TI documents show that additives are used to reduce airway irritation caused by smoke. ^{23 33–35}

TI, tobacco industry.

that have been previously described.¹¹⁵ In Brazil, the TI used very similar strategies, suggesting a high degree of coordination and organisation of these actions globally. This is not surprising, since the TI in Brazil, as in many other countries, is mostly composed of few multinational companies.

The main arguments of the TI and its allies against the prohibition of additives had no scientific basis. The main reference used by the TI and its allies to indicate the negative impact of the RDC 14/2012 was the report produced by the FGV and financed by the TI.⁴⁹ The TI claims about the impossibility to use burley tobacco and the economic damage to tobacco growers were not true, as TI can produce cigarettes with no additives. The use of front groups allegedly representing tobacco growers, has similarly been previously described.^{54 55 115}

The litigation and the mechanisms to prevent regulation are also well described by previous research,^{115 121 125–128 131–133} as is the use of public consultation as a strategy to prevent, or at least delay, the regulation (in other areas of tobacco control policy), although the massive amount of submissions in Brazil is unique. It highlights the need for transparency and disclosure of conflicts in public's participation in policy making.

CONCLUSION

The prohibition of additives in tobacco products is essential to contain the tobacco epidemic and its benefits to public health are unquestionable. Its rationale is largely supported by the scientific literature, internal TI documents and by the TI's own statements during the Brazilian additive ban process. None of the arguments used by the TI was evidence-based.

Brazil was the first country in the world to prohibit all additives that change smell and taste (Canada's ban has exceptions), even those ones that not direct impart a characteristic flavour, in all tobacco products. The case of Brazil is a lesson on how countries considering a comprehensive additive ban should prepare to face fierce opposition from the TI. Mechanisms used to guarantee transparency and stakeholders' participation can be used by the TI to prevent new tobacco control regulations. Governments, therefore, be prepared to prevent TI from abusing the system and dedicate appropriate resources to respond. Governments must adopt mechanisms that prevent undue pressure in its public health policies. In addition, the judiciary should be encouraged to reflect on its important role in preserving the health of the population.

What this paper adds

What is already known on this subject

- The tobacco industry uses a range of additives, including flavours, to make tobacco products more palatable, to increase nicotine absorption and to make products more attractive to population groups such as youth and certain minority groups.

What important gaps in knowledge exist on this topic

- Very few countries have attempted to pass comprehensive bans on tobacco products' additives, thus the tobacco industry's range of responses to these policies have not yet been documented.

What this study adds

- This is the first study to describe the tobacco industry's reaction to an additive ban policy. The lessons from Brazil could assist countries considering additives ban to prepare for, and counter, the tobacco industry opposition.

Acknowledgements The authors would like to thank ANVISA, FIOCRUZ and the Brazilian National Council for Scientific and Technological Development (CNPq, *Conselho Nacional de Desenvolvimento Científico e Tecnológico*).

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Disclaimer This paper represents solely and exclusively the opinion and thinking of the authors, based on the evidence available at the time. It does not represent ANVISA, FIOCRUZ, Ministry of Health and the Brazilian Government's institutional views, policies or opinions.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

- 1 U.S. Department of Health and Human Services. The health consequences of smoking: 50 years of progress. A report of the surgeon General. Atlanta (GA): U.S. department of health and Human services, centers for disease control and prevention, National center for chronic disease prevention and health promotion, 2014. Available: www.cdc.gov/tobacco [Accessed 15 May 2016].
- 2 Chen J, Millar WJ. Age of smoking initiation: implications for quitting. *Health Rep* 1998;9:39–46.
- 3 Khuder SA, Dayal HH, Mutgi AB. Age at smoking onset and its effect on smoking cessation. *Addict Behav* 1999;24:673–7.
- 4 Ferriman A. Chocolate cigarettes “recruit” children to smoking. *BMJ* 2003;326.
- 5 Klein JD, Thomas RK, Sutter EJ. History of childhood candy cigarette use is associated with tobacco smoking by adults. *Prev Med* 2007;45:26–30.
- 6 Tanski SE, Prokhorov AV, Klein JD. Youth and tobacco. *Minerva Pediatr* 2004;56:553–65.
- 7 Prokhorov AV, Winickoff JP, Ahluwalia JS, et al. Youth tobacco use: a global perspective for child health care clinicians. *Pediatrics* 2006;118:e890–903.
- 8 Lando HA, Hipple BJ, Muramoto M, et al. Tobacco is a global paediatric concern. *Bull World Health Organ* 2010;88.
- 9 Figueiredo VC, Szklo AS, Costa LC, et al. Erica: smoking prevalence in Brazilian adolescents. *Rev Saúde Pública* 2016;50.
- 10 Instituto Nacional de Câncer José de Alencar Gomes da Silva, Pan American Health Organization. *Pesquisa especial de tabagismo - PETab: relatório Brasil*. Rio de Janeiro, RJ: Brasília, DF, Brasil: Instituto Nacional do Câncer, Ministério da Saúde; Organização Pan-Americana da Saúde - Representação Brasil, 2011.
- 11 Ministério da Saúde. Tabagismo. In: *Inquérito Domiciliar sobre Comportamentos de Risco e Morbidade Referida de Doenças e Agravos não Transmissíveis. Brasil, 15 capitais e Distrito Federal 2002–2003*. Rio de Janeiro: Instituto Nacional do Câncer, Ministério da Saúde, 2004.
- 12 U.S. Department of Health and Human Services. Preventing tobacco use among youth and young adults: a report of the surgeon General. Atlanta, GA: U.S. department of health and Human services, centers for disease control and prevention, National center for chronic disease prevention and health promotion, 2012. Available: <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html> [Accessed 15 May 2016].
- 13 U.S. Department of Health and Human Services. E-cigarette use among youth and young adults: a report of the surgeon General. Atlanta, GA: U.S. Department of health and Human services, centers for disease control and prevention and health promotion, office on smoking and health, 2016. Available: http://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/ [Accessed 27 Sep 2017].
- 14 World Health Organization. WHO Report on the Global Tobacco Epidemic, 2008 - The MPOWER package. Available: <http://www.who.int/tobacco/mpower/2008/en/> [Accessed 16 May 2016].
- 15 Unknown, RJ Reynolds. I. The importance of younger adults. truth tobacco industry documents, 1984. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/ktmk0084>
- 16 Teague CE, Reynolds RJ. Research planning memorandum on some thoughts about new brands of cigarettes for the youth market. truth tobacco industry documents: RJ Reynolds records, 1973. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/pspp0094>
- 17 Marketing Innovations Inc. Youth Cigarette - New Concepts. Brown and Williamson Tobacco Corp. Truth Tobacco Industry Documents, 1972. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/hjfi0045>
- 18 Hoffmann I. The changing cigarette, 1950–1995. *J Toxicol Environ Health A* 1997;50:307–64.
- 19 Bates C, Jarvis M, Connolly GN. Tobacco additives: Cigarette engineering and nicotine addiction. London, 1999. Available: http://www.ash.org.uk/files/documents/ASH_623.pdf
- 20 Connolly GN, Wayne GD, Lymperis D, et al. How cigarette additives are used to mask environmental tobacco smoke. *Tob Control* 2000;9:283–91.
- 21 Anderson SJ. Menthol cigarettes and smoking cessation behaviour: a review of tobacco industry documents. *Tob Control* 2011;20(Suppl 2):ii49–56.

- 22 Ling PM, Glantz SA. Tobacco industry research on smoking cessation. Recapturing young adults and other recent quitters. *J Gen Intern Med* 2004;19:419–26.
- 23 Wayne G, Connolly G. How cigarette design can affect youth initiation into smoking: camel cigarettes 1983–93. *Tob Control* 2002;11:i32–9.
- 24 Denoble VJ. Declaration of victor john denoble, ph.d.; [handwritten comments of philip morris outside litigation counsel, sent from same counsel to philip morris senior executive in connection with rendering of legal advice on denoble declaration submitted in waxman hearing (redacted: pp. 2050806151, 2050806152, 2050806153, 2050806155, 2050806157)]. Truth Tobacco Industry Documents, 1995. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/gfjk0005>
- 25 Keithly L, Ferris Wayne G, Cullen DM, et al. Industry research on the use and effects of levulinic acid: a case study in cigarette additives. *Nicotine Tob Res Off J Soc Res Nicotine Tob* 2005;7:761–71.
- 26 RIVM. (National Institute for public health and the environment). additives in tobacco products, 2012. Available: http://www.rivm.nl/Documenten_en_publicaties/Algemeen_Actueel/Brochures/Leefstijl_Voeding/Additives_in_tobacco_products [Accessed 18 May 2016].
- 27 German Cancer Research Center. Additives in tobacco products contribution of Carob bean extract, cellulose fibre, guar gum, liquorice, menthol, prune juice concentrate and vanillin to attractiveness, Addictiveness and toxicity of tobacco smoking. Heidelberg: German Cancer research center, 2012. Available: http://www.dkfz.de/de/tabakkontrolle/download/PITOC/PITOC_Additives_in_Tobacco_Products_Report.pdf [Accessed 18 May 2016].
- 28 Ferreira CGM, Silveira D, Hatsukami DK, et al. The effect of tobacco additives on smoking initiation and maintenance. *Cad Saude Publica* 2015;31:223–5.
- 29 Rabinoff M, Caskey N, Rissling A, et al. Pharmacological and chemical effects of cigarette additives. *Am J Public Health* 2007;97:1981–91.
- 30 Truth Tobacco Industry Documents. Product design MSA collection [A Cigarette that Enhances Positive Feelings], 1982. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=tjwk0037>
- 31 Wackowski OA, Evans KR, Harrell MB, et al. In Their Own Words: Young Adults' Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives. *Nicotine Tob Res Off J Soc Res Nicotine Tob*.
- 32 Stevenson T, Proctor RN. The secret and soul of Marlboro. *Am J Public Health* 2008;98:1184–94.
- 33 Reynolds RJ. Cigarette ingredients: a complete list and background. truth tobacco industry documents: product design MSA collection, 1994. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=zzbj0037> [Accessed 9 Jul 2017].
- 34 ———, Leffingwell JC, Young HJ, et al. *Tobacco flavorings for smoking products*. RJ Reynolds Records: Truth Tobacco Industry Documents; 1972.
- 35 Talhout R, Opperhuizen A, van Amsterdam JGC. Sugars as tobacco ingredient: effects on mainstream smoke composition. *Food Chem Toxicol Int J Publ Br Ind Biol Res Assoc* 2006;44:1789–98.
- 36 BRASIL. Agência Nacional de Vigilância Sanitária. Resolução de Diretoria Colegiada - RDC no 14 de 15 março de 2012. Dispõe sobre os limites máximos de alcatrão, nicotina e monóxido de carbono nos cigarros e a restrição do uso de aditivos nos produtos fumígenos derivados do tabaco, e dá outras providências, 2012. Available: http://portal.anvisa.gov.br/wps/wcm/connect/d50d8f804d44b146bcecf4031a95fac/Resolucao_RDC_14_Teores_e_Aditivos_16Mar12.pdf?MOD=AJPERES
- 37 Roper Org Inc. A Study of Smokers' Habits and Attitudes with Special Emphasis on Low Tar and Menthol Cigarettes Volume II. Truth Tobacco Industry Documents: Philip Morris Records, 1979. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=mzyw0189> [Accessed 26 Jun 2018].
- 38 Anderson SJ, McCandless PM, Klausner K, et al. Tobacco documents research methodology. *Tob Control* 2011;20:i8–11.
- 39 Bero L. Implications of the tobacco industry documents for public health and policy. *Annu Rev Public Health* 2003;24:267–88.
- 40 Portal da Câmara dos Deputados. Portal da Câmara DOS Deputados. Available: <http://www2.camara.leg.br/> [Accessed 9 Jul 2017].
- 41 Senado Federal. Rádio Senado no YouTube: acompanhe o 'Conexão Senado' ao vivo, direto do estúdio. Available: <http://www12.senado.leg.br/hpsenado> [Accessed 9 Jul 2017].
- 42 BRASIL. Lei no 12.527, de 18 de novembro de 2011 Regula O acesso a informações previsto no inciso XXXIII do art. 5o, no inciso II do § 3o do art. 37 E no § 2o do art. 216 da Constituição federal; altera a Lei no 8.112, de 11 de dezembro de 1990; revoga a Lei no 11.111, de 5 de maio de 2005, E dispositivos da Lei no 8.159, de 8 de Janeiro de 1991; E dá outras providências, 2011. Available: http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei12527.htm [Accessed 9 Jul 2017].
- 43 Ulucanlar S, Fooks GJ, Gilmore AB. The policy Dystopia model: an interpretive analysis of tobacco industry political activity. *PLOS Med* 2016;13:e1002125.
- 44 Agência Nacional de Vigilância Sanitária. *Processo Administrativo 25351.609367/2010-21 - Revisão da RDC 46/2001 e Consulta Pública CP 112/2010 (obtido através da Lei no 12.527/2011, lei de acesso a informação)*, 2010.
- 45 Justiça Federal 4a região. Processo nº 5050264-41.2011.4.04.7100. Ofício 7340966. Parte Autora: Sindicato interestadual da indústria do tabaco/ parte ré: agência nacional de vigilância sanitária - anvisa. Portal Justiça Fed. 4a Reg. Available: <https://www2.jfirs.jus.br/resultado-da-consulta-processual/> [Accessed 20 Nov 2017].
- 46 Supremo Tribunal Federal. Ação direta de inconstitucionalidade - ADI 4874, 2013. Available: <http://www.stf.jus.br/portal/processo/verProcessoAndamento.asp?numero=4874&classe=ADI&origem=AP&recurso=0&tipoJulgamento=M> [Accessed 23 Mar 2018].
- 47 Formentti L. Indústria do tabaco reforça Lobby para manter aditivo. Estadão, 2012. Available: <https://www.estadao.com.br/noticias/geral,industria-do-tabaco-reforca-lobby-para-manter-aditivo,845902> [Accessed 11 Feb 2019].
- 48 Canguçu Line - Notícias. COP 4: Produtores de tabaco do RS desembarcam no Uruguai, 2017. Available: <http://www.cangucuonline.com.br/noticia/cop-4-produtores-de-tabaco-do-rs-desembarcam-no-uruguai> [Accessed 16 Nov 2017].
- 49 Fundação Getúlio Vargas. Estudo de Efeitos Socioeconômicos da Regulamentação DOS Assuntos das Consultas Públicas no 112 E 117, 2011. Available: http://fgvprojetos.fgv.br/sites/fgvprojetos.fgv.br/files/estudo_13.pdf [Accessed 21 Nov 2017].
- 50 Folha.com. Lobby retarda veto aos aditivos no tabaco, 2011. Available: <http://www1.folha.uol.com.br/eqilibrio/903937-lobby-retarda-veto-aos-aditivos-no-tabaco.shtml> [Accessed 9 Jul 2017].
- 51 Formentti L. *Indústria do fumo apela Casa Civil*. 18. Estado São Paulo, 2012.
- 52 Agência Nacional de Vigilância Sanitária. *Parecer Técnico no 003/2013 – GGTAB/ANVISA. Lista de ingredientes necessários fabricação de cigarros apresentada Anvisa pela Associação Brasileira do Fumo – Abifumo, com base no §2o do art. 7o da RDC N. 14/2012*. Agência Nacional de Vigilância Sanitária, 2013.
- 53 Corr. Estado. Parlamentares a favor da indústria de fumo E Contra aditivos em cigarros. Available: <http://www.correiodeestado.com.br/noticias/parlamentares-a-favor-da-industria-de-fumo-e-contra-aditivos-em-cigarr/83761/> [Accessed 16 Nov 2017].
- 54 Assunta M. Tobacco industry's ITGA fights FCTC implementation in the Uruguay negotiations. *Tob Control* 2012;21:563–8.
- 55 Must E. *International Tobacco Growers' Association (ITGA). ITGA uncovered: Unraveling the spin - the truth behind the claims*. Canada: HealthBridge, 2001.
- 56 Afubra - Assoc. Fumicultores Bras. Tanzani³ sedi³ 26^a Assembleia³ d³ ITGA^A - 22/10/2011, 2011. Available: <https://afubra.com.br/noticias/779/tanzania-sedia-26-assembleia-da-itga.html> [Accessed 16 Nov 2017].
- 57 Corr. Povo. Fumicultores gaúchos protestam Na COP 4, 2010. Available: <http://www.correiopovo.com.br/Impresso/?Ano=116&Numero=49&Caderno=0&Noticia=223461> [Accessed 16 Nov 2017].
- 58 Câmara Deputados. Indústria Quer manter aditivos que tornam fumo MAIS atrativo, 2017. Available: <http://www2.camara.leg.br/camara/noticias/noticias/INDUSTRIA-E-COMERCIO/150977-INDUSTRIA-QUER-MANTER-ADITIVOS-QUE-TORNAM-FUMO-MAIS-ATRATIVO.html> [Accessed 16 Nov 2017].
- 59 Carvalho MC. Servidora da União é acusada de espionar para a Souza cruz. Folha São Paulo, 2011. Available: <http://www1.folha.uol.com.br/fsp/cotidian/ff1407201111.htm> [Accessed 13 Jul 2016].
- 60 Folha de São Paulo. Suspeita será investigada, diz ministério, 2011. Available: <http://www1.folha.uol.com.br/fsp/cotidian/ff1407201112.htm> [Accessed 9 Jul 2017].
- 61 Acesso Informação. Brasil. Resultado de apuração sobre conduta irregular de funcionária - Pedido 52750000505201661, 2016. Available: <http://www.consultaetic.cgu.gov.br/busca/dados/Lists/Pedido/Item/display.aspx?List=0c839f31%2D47d7%2D4485%2Dab65%2Dab0cee9cf8fe&ID=506137&Web=88cc5f44%2D8cfe%2D4964%2D8ff4%2D376b5ebb3bef> [Accessed 6 Mar 2019].
- 62 Tesche O. Fumo tipo Burley Na corda bamba. Corr. Povo, 2010. Available: <http://www.correiopovo.com.br/Impresso/?Ano=115&Numero=263&Caderno=11&Noticia=156329> [Accessed 16 Nov 2017].
- 63 Freitas T. OMS Quer proibir aditivos no cigarro; medida atingirá produtores. Folha São Paulo, 2010. Available: <http://www1.folha.uol.com.br/mercado/830478-oms-quer-proibir-aditivos-no-cigarro-medida-atingira-produtores.shtml> [Accessed 16 Nov 2017].
- 64 World Health Organization. Partial guidelines for implementation of articles 9 and 10 of the WHO framework convention on tobacco control (regulation of the contents of tobacco products and regulation of tobacco product disclosures), 2016. Available: http://www.who.int/tobacco/publications/prod_regulation/who_fctc_decisions9and10.pdf?ua=1
- 65 World Health Organization. Who | fourth session of the Conference of the parties to the WHO FCTC. Who, 2010. Available: http://www.who.int/fctc/cop/sessions/fourth_session_cop/en/ [Accessed 13 Nov 2017].
- 66 BRASIL. Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada - RDC no 46, de 28 de março de 2001 - Estabelecer os teores máximos permitidos de alcatrão, nicotina e monóxido de carbono presentes na corrente primária da fumaça, para os cigarros comercializados no Brasil. Available: <http://portal.anvisa.gov.br/legislacao/visualizar/26704> [Accessed 22 Oct 2018].
- 67 Agência Nacional de Vigilância Sanitária. Consulta Pública no 112 de 29/11/2010 - Proposta de Revisão da RDC 46/2001 que trata sobre os teores de alcatrão, nicotina e monóxido de carbono nos cigarros, e a proibição de aditivos nos produtos derivados do tabaco e dá outras providências. Available: <http://portal.anvisa.gov.br/consultas-publicas/visualizar/25611> [Accessed 13 Nov 2017].

- 68 Agência Nacional de Vigilância Sanitária. Consultas Públicas - Anvisa. Available: <http://portal.anvisa.gov.br/consultas-publicas> [Accessed 17 Nov 2017].
- 69 Agência Nacional de Vigilância Sanitária. *Parecer Técnico no 001/2012 - GPDTA/DIAGE/ANVISA. Análise das contribuições da Consulta Pública e da Audiência Pública - CP112/2010 que versa sobre a revisão da Resolução de Diretoria Colegiada 46/2001*. Agência Nacional de Vigilância Sanitária, 2017.
- 70 Deputado Luis Carlos Heinze. PDL 3034/2010 - Projeto de Decreto Legislativo de Sustação de Atos Normativos do Poder Executivo. Susta os efeitos da Consulta Pública da Agência Nacional de Vigilância Sanitária - Anvisa - número 112, de 29 de novembro de 2010, 2010. Available: <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=489609> [Accessed 9 Jul 2017].
- 71 Peres J, Neto M. *Roucos E Sufocados. A Indústria do Cigarro Está Viva E Matando*. São Paulo: Elefante, 2018.
- 72 Tribunal Superior Eleitoral. SPCE 2014 - Consulta Financiamento Eleitoral e Gastos de Campanha - v.: 1.6.5. Available: <http://inter01.tse.jus.br/spceweb.consulta.receitasdespesas2014/abrirTelaReceitasCandidato.action> [Accessed 9 Jul 2017].
- 73 Congr. Em Foco. Luis Carlos Heinze (PP). Available: <http://congressoemfoco.uol.com.br/noticias/luis-carlos-heinze-pp/> [Accessed 17 Nov 2017].
- 74 Deputado Jerônimo Goergen (PP-RS). Projeto de Lei n. 2901/2011 'Dispõe sobre a restrição de inclusão de aditivos em produtos fumíferos em geral, derivados ou não do tabaco, comercializados em território nacional', 2011. Available: <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=530864> [Accessed 20 Nov 2017].
- 75 BRASIL. Lei no 9.294, de 15 de julho de 1996. Dispõe sobre as restrições AO uso E propaganda de produtos fumíferos, bebidas alcoólicas, medicamentos, terapias E defensivos agrícolas, NOS termos do § 4º do art. 220 da Constituição federal, 1996. Available: http://www.planalto.gov.br/ccivil_03/leis/L9294.htm [Accessed 16 May 2017].
- 76 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 005/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. Sipar 25000.061095/2011-20*. Agência Nacional de Vigilância Sanitária, 2011.
- 77 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 006/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. Sipar 25000.051291/2011, MEM 729/2011 - GADIP/ANVISA, of. 20/2011 - camara municipal de Vereadores de SANTA cruz do Sul*. Agência Nacional de Vigilância Sanitária, 2011.
- 78 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 018/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. Requerimento 12/2011 do Vereador Osvaldo da PAZ, camara municipal de cruz das Almas - Ba, de 11 de março de 2011, REQ122011, 2011*.
- 79 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 016/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. of. 058/2011 - camara de Vereadores do Município de Mato Leitão de 16 de março de 2011, Moção de Apoio AO Ofício circular 004/2011 da camara municipal de SANTA cruz do Sul, 2011*.
- 80 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 015/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010 Referências: Moção de Apelo N. 6/2011 da camara de Vereadores de São Miguel do Oeste de 17/03/2011, 2011*.
- 81 Prefeitura Municipal de Canguçu - SC. *Ofício 688/11/GP - Prefeitura de Canguçu de 16 de dezembro de 2011*.
- 82 Vereador Rafael Reis Barros - PTB. *Moção de Apoio n.o 012, de 2011. Dispõe sobre apoio aos fumicultores da região e sugere a REVOGAÇÃO de alguns itens e resoluções da Convenção Quadro para que não venham em prejuízo total dos produtores de fumo, especialmente da variedade 'burley', 2011*.
- 83 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 007/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. Ofício 0294 SAJ, SIPAR 25000.051976/2011-32, of. Circ 004/2011 - CAPC Comissão de Agricultura, Pecuária E Cooperativismo*. Agência Nacional de Vigilância Sanitária, 2011.
- 84 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 009/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. Proposições OFV 232011 E OFV92011, Ofício 23/11 de 27 de março de 2011, Ofício 09/11 de 27 de março de 2011, manifesto da Audiência Pública realizada no Dia 14 de março de 2011*. Agência Nacional de Vigilância Sanitária, 2011.
- 85 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 017/2011/GPDTA/ANVISA. Consultas Públicas 112 E 117/2010. Referências: Ofício Gab 55/11 da Assembleia Legislativa do Estado do Paraná de 30 de março de 2011, Moção de Repúdio da Assembleia Legislativa do Estado do Paraná às Consultas Públicas 112 E 117/2010 de 28 de março de 2011, Proposição OFV5511, 2011*.
- 86 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 008/2010/GPDTA/ANVISA. Moção da Comissão de Agricultura, Pecuária, Abastecimento e Desenvolvimento Rural. Moção de apoio continuidade de produção de fumo da variedade Burley pelos agricultores brasileiros*.
- 87 Agência Nacional de Vigilância Sanitária. *Nota Técnica n.º 001/2011/GPDTA/ANVISA. Solicitação da Comissão de Agricultura, Pecuária, Abastecimento e Desenvolvimento Rural da Câmara dos Deputados para revogação da Consulta Pública 112/2010. Referência: Nota Técnica no 1073/2010/SAG - C. Civil - PR*. Agência Nacional de Vigilância Sanitária, 2011.
- 88 Câmara Setorial do Tabaco do Ministério da Agricultura, abastecimento e Pecuária. *Carta da Câmara Setorial do Tabaco de 06 de março de 2012*.
- 89 Carvalho I. Livro sobre fumo descreve ANA Amélia, vice de Alckmin, como articuladora importante do setor. Olho NOS rural, 2018. Available: <https://deolhonosruralistas.com.br/2018/09/03/livro-sobre-fumo-descreve-ana-amelia-vice-de-alkmin-como-articuladora-importante-do-setor/> [Accessed 15 Dec 2018].
- 90 Centro de Estudos do Tabaco (CETAB). Organizações ligadas AO tabaco. Obs.Sobre Estratégias Indústria TAB. No Bras, 2016. Available: http://cetab.ensp.fiocruz.br/index.php/Categoria:Organiza%C3%A7%C3%B5es_ligadas_ao_tabaco [Accessed 24 Mar 2019].
- 91 Blanco A, Oliveira G, Cohen J, et al. Análise do "Estudo dos Efeitos Socioeconômicos da Regulamentação, pela ANVISA, dos Assuntos de que tratam as Consultas Públicas no. 112 e 117, de 2010", assinado pela Fundação Getúlio Vargas. Organização Pan Americana de Saúde; Johns Hopkins Bloomberg School of Public Health; Campaign for Tobacco-Free Kids; Aliança de Controle do Tabagismo, 2011. Available: http://www.actbr.org.br/uploads/conteudo/664_RESPOSTA_FGV.pdf [Accessed 22 Nov 2017].
- 92 Lencucha R, de Lima Pontes C, Pontes C de L. The context and quality of evidence used by tobacco interests to oppose ANVISA's 2012 regulations in Brazil. *Glob Public Health* 2018;13:1204-15.
- 93 SCENIHR. (Scientific Committee on emerging and newly identified health risks). *Addictiveness and attractiveness of tobacco additives*. Brussels: European Commission DG Health & Consumers, 2010.
- 94 Talhout R, Opperhuizen A, van Amsterdam JGC. Role of acetaldehyde in tobacco smoke addiction. *Eur Neuropsychopharmacol J Eur Coll Neuropsychopharmacol* 2007;17:627-36.
- 95 van Amsterdam J, Talhout R, Vleeming W, et al. Contribution of monoamine oxidase (MAO) inhibition to tobacco and alcohol addiction. *Life Sci* 2006;79:1969-73.
- 96 Agência Nacional de Vigilância Sanitária. *Parecer Técnico no 008/2013 - GG TAB/ANVISA. Complementação do Parecer 003/2013-GGTAB/ANVISA sobre a lista de ingredientes necessários fabricação de cigarros apresentada ANVISA pela Associação Brasileira do Fumo - Abifumo, com base no §2o do Art. 7o da RDC n. 14/2012*. Agência Nacional de Vigilância Sanitária, 2013.
- 97 Agência Nacional de Vigilância Sanitária. *Parecer Técnico no 009/2013 - GG TAB/ANVISA. Resposta carta da Abifumo SE 00713 de 08 de maio de 2013, sobre a lista de ingredientes necessários fabricação de cigarros apresentada Anvisa pela Associação Brasileira do Fumo - Abifumo, com base no §2o do Art. 7o da RDC n. 14/2012*. Agência Nacional de Vigilância Sanitária, 2013.
- 98 Agência Nacional de Vigilância Sanitária. Instrução Normativa n.º 06, de 26 de agosto de 2013. Diário Oficial da União no 165, sessão 1, 2013. Available: <http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=27/08/2013&jornal=1&pagina=81&totalArquivos=128> [Accessed 20 Nov 2017].
- 99 Agência Nacional de Vigilância Sanitária. Aditivos em Produtos Derivados do Tabaco - Anvisa. Available: http://portal.anvisa.gov.br/aditivos-em-produtos-derivados-do-tabaco?p_p_id=56_INSTANCE_q25sQrhOIL9T&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1 [Accessed 21 Nov 2017].
- 100 et alSilveira D, Hatsukami DK. Report of the Working Group on tobacco additives. Agência Nacional de Vigilância Sanitária, 2014. Available: <http://portal.anvisa.gov.br/documents/106510/106594/Report+Working+Group+Tobacco+Additives/b99ad2e7-23d9-4e88-81cd-d82c28512199>
- 101 Formenti L. Governo é acusado de recuar ante tabagistas. Estadão, 2012. Available: <http://www.estadao.com.br/noticias/geral/governo-e-acusado-de-recuar-ante-tabagistas,961453> [Accessed 26 Nov 2017].
- 102 Aliança de Controle do Tabagismo - ACTbr. Brasil manda delegados da saúde de volta para casa durante COP5, 2012. Available: http://actbr.org.br/uploads/conteudo/774_COP5_nota.pdf [Accessed 25 Nov 2017].
- 103 de OPPV, Sihler CB, de ML, et al. First reported outbreak of green tobacco sickness in Brazil. *Cad Saude Publica* 2010;26:2263-9.
- 104 Fassa AG, Faria NM, Meucci RD, et al. Green tobacco sickness among tobacco farmers in southern Brazil. *Am J Ind Med* 2014;57:726-35.
- 105 Agência Nacional de Vigilância Sanitária. Anvisa - Resposta ao Protocolo 2018348661, 2018. Available: atendimento.central@anvisa.gov.br
- 106 Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part I: Flavourings and additives. *Food Chem Toxicol Int J Publ Br Ind Biol Res Assoc* 2004;42(Suppl):3-37.
- 107 Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part II: casing ingredients. *Food Chem Toxicol Int J Publ Br Ind Biol Res Assoc* 2004;42(Suppl):S39-S52.
- 108 Roemer E, Schorp MK, Peadar J-J, et al. Scientific assessment of the use of sugars as cigarette tobacco ingredients: a review of published and other publicly available studies. *Crit Rev Toxicol* 2012;42:244-78.
- 109 SCENIHR. (Scientific Committee on emerging and newly identified health risks). *additives used in tobacco products*. Luxembourg: European Commission Health & Food Safety, 2016.
- 110 Wertz MS, Kyriak T, Paranjape S, et al. The toxic effects of cigarette additives. Philip Morris' project mix reconsidered: an analysis of documents released through litigation. *PLoS Med* 2011;8.

- 111 Paumgarten FJR, Gomes-Carneiro MR, de OA. The impact of tobacco additives on cigarette smoke toxicity: a critical appraisal of tobacco industry studies. *Cad Saude Publica* 2017;33(Suppl 3):e00132415.
- 112 Folha de São Paulo. Johanna Nublat. Nova linha de cigarro sem aditivos anuncia 'puro tabaco', 2013. Available: <http://www1.folha.uol.com.br/eqilibrioesaude/2013/09/1338487-nova-linha-sem-aditivos-anuncia-puro-tabaco.shtml> [Accessed 16 Nov 2017].
- 113 Brown & Williamson Tobacco. B&W Invention Disclosure. Additive-Free Cigarette and Process for Making Same. Truth Tobacco Industry Documents Unknow. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=gtgd0146> [Accessed 16 Nov 2017].
- 114 Sinditabaco. Dimensão do Setor. Available: <http://www.sinditabaco.com.br/sobre-o-setor/dimensoes-do-setor/> [Accessed 23 Nov 2017].
- 115 Saloojee Y, Dagli E. Tobacco industry tactics for resisting public policy on health. *Bull World Health Organ* 2000;78:902–10.
- 116 Assunta Met al. "Care and feeding": the Asian environmental tobacco smoke consultants programme. *Tob Control* 2004;13(suppl_2):ii4–12.
- 117 MacKenzie R, Collin J, Sriwongcharoen K, et al. "If we can just 'stall' new unfriendly legislations, the scoreboard is already in our favour": transnational tobacco companies and ingredients disclosure in Thailand. *Tob Control* 2004;13(suppl_2):ii79–87.
- 118 Stella Aguinaga Bialous, Stan Shatenstein. Profits over people: tobacco industry activities to market cigarettes and undermine public health in Latin America and the Caribbean. Washington, D.C: pan American health organization, 2002. Available: <https://escholarship.org/uc/item/82r4v193#main> [Accessed 23 Mar 2018].
- 119 Muggli ME, Hurt RD, Repace J. The tobacco industry's political efforts to derail the EPA report on Ets. *Am J Prev Med* 2004;26:167–77.
- 120 Lee S, Ling PM, Glantz SA. The vector of the tobacco epidemic: tobacco industry practices in low and middle-income countries. *Cancer Causes Control* 2012;23(Suppl 1):117–29.
- 121 Landman A, Glantz SA. Tobacco industry efforts to undermine Policy-Relevant research. *Am J Public Health* 2009;99:45–58.
- 122 Aguinaga Bialous S, Peeters S. A brief overview of the tobacco industry in the last 20 years. *Tob Control* 2012;21:92–4.
- 123 Allen M. Confronting the vector of tobacco-related disease. *Am J Law Med* 2013;39:308–31.
- 124 Yach D, Bialous SA. Junking science to promote tobacco. *Am J Public Health* 2001;91:1745–8.
- 125 Barnoya J, Glantz S. Tobacco industry success in preventing regulation of secondhand smoke in Latin America: the "Latin Project". *Tob Control* 2002;11:305–14.
- 126 Sebríe EM, Barnoya J, Pérez-Stable EJ, et al. Tobacco industry successfully prevented tobacco control legislation in Argentina. *Tob Control* 2005;14:e2.
- 127 Ibrahim JK, Glantz SA. Tobacco industry litigation strategies to oppose tobacco control media campaigns. *Tob Control* 2006;15:50–8.
- 128 Ł B, Stokłosa M, Balwicka-Szczyrba M, et al. Tobacco industry interference with tobacco control policies in Poland: legal aspects and industry practices. *Tob Control* 2016;25:521–6.
- 129 Lencucha R, Ruckert A, Labonte R, et al. Opening windows and closing gaps: a case analysis of Canada's 2009 tobacco additives ban and its policy lessons. *BMC Public Health* 2018;18.
- 130 World Trade Organization (WTO). Committee on technical barriers to trade (TBT). Minutes of the Meeting of 5-6 November 2009. truth tobacco industry documents: Dutch tobacco industry collection, 2009. Available: <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=zhxb0191> [Accessed 7 Mar 2019].
- 131 Tobacco Tactics. TPD: Delaying the Process of Consultation - TobaccoTactics, 2017. Available: http://www.tobaccotactics.org/index.php/TPD:_Delaying_the_Process_of_Consultation [Accessed 15 Dec 2018].
- 132 Hiilamo H, Glantz SA. Old wine in new bottles: tobacco industry's submission to European Commission tobacco product Directive public consultation. *Health Policy* 2015;119:57–65.
- 133 Smith J, Lee K. Protecting the plain packaging consultation from tobacco industry interference. *CMAJ* 2016;188:E340–1.