



Brazil **Tobacco Industry Interference** Index 2023

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The complete version of the Global Tobacco Industry Interference Index can be accessed at globaltobaccoindex.org.

Background and Introduction

Brazil has been considered an example of success in tobacco control for many years. In 2019, it was recognized by the World Health Organization (WHO) as the second country to implement MPOWER measures at the highest level. In the same year, the United Nations also awarded CONICQ, the Brazilian National Commission for the Implementation of WHO FCTC, which is responsible to articulate the activities and the Tobacco Control program from the federal government, in recognition for their work to reduce the smoking prevalence in the country, which went from 15.7% in 2006 - the year in which Brazil became a Party to the FCTC - to 9.1% in 2021 (according to Vigitel survey¹).

Policies adopted by the country include a comprehensive smokefree law, a ban on electronic smoking devices, free treatment for smoking cessation in the Brazilian Unified Health System (Sistema Único de Saúde – SUS), advertisements ban (except for package exhibition at points of sale) and the adoption of health warning labels. The country had also adopted a tax policy, but it hasn't been updated since 2016 - and, as a result, cigarettes are becoming considerably more affordable in Brazil. Considering the region of the Americas, Brazil is ranked second in the list of countries with the cheapest cigarettes.²

Unfortunately, the tax policy is not the only issue. In the last few years, the Brazilian tobacco control program has suffered setbacks in other areas too. This is reflected in the country's results in the Index: in the last edition, Brazil had a score of 58. Now, in 2023, the score is 66. This significant increase can be partially explained by the fact that ACT Health Promotion and the Observatory on Strategies of the Tobacco Industry from the Center for Studies on Tobacco and Health (CETAB) of the National School of Public Health (ENSP) of the Oswaldo Cruz Foundation (Fiocruz), the organizations responsible for the data collection for this report, have been constantly improving their monitoring work on industry's activities and strategies, but there are also clear evidence that tobacco companies have expanded their lobbying and corporate social responsibility (CSR) activities in the reporting period - a movement that happened both from inside the companies and from the outside, as the political context of the country seems to have favored the industry's interference strategies.

2022 marked the end of the Bolsonaro administration in Brazil. The federal government adopted a pro-industry approach in many economic sectors and a number of public programs and social policies were downgraded or terminated. Civil society organizations also found it more difficult to participate in decision-making processes. In previous editions of the Index, we had already mentioned that CONICQ had been officially disbanded, along with other national commissions, at the beginning of the government term. Later, investigative journalists from O Joio e o Trigo had access to a video register of a meeting in which congressman Marcelo Moraes admitted that he acted along with a government minister, Onyx Lorenzoni, to extinguish CONICQ. Even so, up to a certain point, CONICQ members maintained a regular meeting schedule nonetheless, as there were some legal arguments that put in doubt the legitimacy of the act that disbanded it. In the course of Bolsonaro's government term, however, Moraes, Lorenzoni and other congressmen linked to the industry worked to assure that it was not officially reestablished - and, as a result, CONICQ's activities ended up decreasing severely in the period, which negatively affected many Index indicators, as shall be seen - members of CONICQ's Executive Secretariat were even excluded from the COP9 delegation, for instance. The good news is that CONICQ and the other commissions were in fact reestablished in 2023 by an act of the new government headed by Lula, elected at the end of 2022 - but, up to the end of the preparation of this version of the Index, CONICQ was still undergoing a reorganization process and had not yet resumed many of its activities.

Another point of concern in Brazil is the use of flavour additives in tobacco products. Anvisa, Brazil's health regulatory agency, banned their use back in 2012, but the norm has never entered into force due to legal complaints from the industry and its allies. Now, over 10 years later, we are still struggling with a number of lawsuits that prevent the implementation of this essential public health policy.

During the reporting period, a great number of CSR activities and unnecessary interactions between government members and the industry and its allies were also registered, especially in cities and states that produce tobacco in the South of Brazil. Eduardo Leite, governor of Rio Grande do Sul, Brazil's southernmost state, for instance, took part in several events and meetings with the tobacco industry - and the same happened with members of the federal government, including congressmen, ministers and secretaries. CSR activities, many times endorsed by the municipal, state and/or federal government, include multiple donations, sponsorship of events, educational programs and campaigns on topics such as child labour, illicit trade, environmental protection, LGBTQ rights and others. For the tobacco industry, however, those seem to be easier said than done, as the reality is that issues of child labor³, depression⁴ and intoxication of tobacco growers, human rights violations⁵ and environmental problems⁶ remain in the production chain - not mentioning, of course, the multitude of diseases and health issues caused by tobacco products to their consumers.

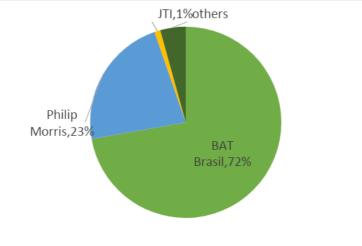
Meanwhile, on a positive note, a technical report from Anvisa recommended the maintenance of the ban on electronic cigarettes and heated tobacco products. The final decision is expected by the end of 2023, after a public consultation.⁷ This was a huge victory for public health, especially considering that the tobacco industry and its allies put a lot of pressure on the agency to try and revert the ban using many different strategies, including the installment of a process in the Chamber of Deputies to investigate Cristiane Jourdan Gomes, former director of Anvisa. The process was articulated by congressmen linked to the industry who claimed that she had possibly "politicized" her function as director. Even though the investigation was archived, it was certainly a demonstration of power by the industry, and seemingly an attempt to intimidate Anvisa's staff members.

Electronic smoking devices can still be found and bought illegally in the country, both on the internet and in stores, but Anvisa's recommendation is essential nevertheless, as it was based on robust scientific evidence showing the harms caused by these products and was heavily supported by civil society. Moreover, the fact that the country's main health agency has taken this stand, so aligned with the best tobacco control practices, shows that Brazil has potential to implement more policies to reduce smoking prevalence, prevent industry interference and continue to be recognized as an example - especially considering that the path is now clear for CONICQ to return at its best.

Tobacco industry and its allies in Brazil

Brazil is the third largest tobacco producing country in the world, following China and India.⁸ Tobacco used in cigarettes is mainly grown in small properties in the South region of the country (which includes the states of Rio Grande do Sul, Santa Catarina and Paraná). Another 5% of the tobacco crops are grown in the Northeast region, most of it being destined for cigars. Around 70% of the total national production is exported for other countries.

The three main tobacco companies that operate in Brazil are British American Tobacco Brasil (BAT Brasil, formerly known as Souza Cruz), Philip Morris and Japan Tobacco International (JTI). The most recent market share data available is from 2021 and is shown in **Graph I**:



Graph I. Market share of tobacco companies in Brazil (2021)

Source: Valor Econômico, 20219

Apart from the companies, the tobacco industry in Brazil also counts with front groups, associations, affiliated organizations and individuals - including a few that are members of the government in municipal, state and federal levels - that also work to further the industry's interests. The main groups and organizations mentioned in this edition of the Index are the following:

- Interstate Tobacco Industry Union (Sindicato Interestadual das Indústrias de Tabaco - SindiTabaco): union that includes 14 manufacturing, processing and import companies, including BAT Brasil, Philip Morris and JTI.
- Brazilian Tobacco Industry Association (Associação Brasileira da Indústria do Fumo - Abifumo)
- Association of Brazilian Tobacco Growers (Associação de Fumicultores do Brasil Afubra), which represents farmers who grow tobacco, but whose stand is in favor of tobacco industries. It is classified by academics as an entity with ties to SindiTabaco.¹⁰
- National Industrial Confederation (Confederação Nacional da Indústria CNI) an association of Industrial Federations. It has already taken a stand against tobacco control measures and proposals.

- National Forum Against Piracy and Illegality (Fórum Nacional Contra a Pirataria e Ilegalidade FNCP), which is financed by Philip Morris Brasil and BAT Brasil.^{11 12}
- Brazilian Institute of Ethics in Competition (Instituto Brasileiro de Ética Concorrencial – ETCO), an FNCP partner, also funded by BAT Brasil.¹³
- Tobacco Producing Municipality Association (Associação de Municípios Produtores de Tabaco Amprotabaco) an association of cities that produce tobacco.

Smoking prevalence¹⁴

Brazil has a number of national and regional surveys that collect data on smoking and other health related information in different periods and populational groups. The most comprehensive one is the National Health Survey (Pesquisa Nacional de Saúde - PNS), which includes samples from the entire country, but so far it has only been held twice, in 2013 and 2019. Thus, for the evaluation of the current smoking prevalence in the country, other surveys were also considered, according to the following list:

- **PNS** National Health Survey, held in 2013 and 2019;
- **Vigitel** Surveillance of Risk and Protective Factors for Chronic Diseases by Telephone Survey, held every year between 2006 and 2021 in the 26 Brazilian capitals and in the Federal District, with adults over 18 who live in a place with a telephone line;
- **Covitel** countrywide cross-sectional telephone-based survey held in 2022;
- Other surveys considered will be nominated as they appear.

Table I shows the evolution of smoking prevalence in Brazil according to PNS, Covitel and other surveys held previously. As there is yearly data for Vigitel, it will be included as a separate table (**Table 2**).

Table I. Percentage of smokers in the population over the age of 18 (PNS, Covitel
and other surveys)

Survey	Year	Total	Male	Female
National Health and Nutrition Survey	1989	34.8	43.3	27.0
World Health Survey	2003	22.4	27.1	18.4
Special Survey on Smoking	2008	18.2	22.9	13.9
PNS - National Health Survey	2013	14.7	18.9	11.0
PNS - National Health Survey	2019	12.6	15.9	9.6
Covitel	2022	12.2	14.5	9.9

Year Total Male Female 2006 15.7 19.5 12.4 2007 19.5 12.3 15.6 2008 14.8 18.0 12.0 2009 14.3 17.5 11.5 2010 14.1 16.8 11.7 2011 13.4 16.5 10.7 2012 12.1 9.2 15.5 2013 11.3 14.4 8.6 2014 10.8 12.8 9.0 2015 10.4 12.8 8.3 2016 10.2 12.7 8.0 2017 10.1 13.2 7.5 2018 9.3 12.1 6.9 2019 9.8 12.3 7.7 2020 9.5 11.7 7.6 2021 9.1 11.8 6.7

 Table 2. Percentage of smokers in the population over the age of 18 in Brazilian capitals and in the Federal District (Vigitel)

Data on smoking prevalence among adolescents is more scarce. The National Survey of School Health (PeNSE), held in 2015 and 2019, had the following results for students between 13 and 17 years of age (**Table 3**):

 Table 3. Percentage of smokers in the population of students between 13 and 17 years of age (PeNSE)

Year	Total	Male	Female
2015	6.6	7.1	6.0
2019	6.8	7.1	6.5

Deaths caused by smoking in Brazil

The Instituto de Efectividad Clínica y Sanitaria (IECS) has gathered data on deaths caused by smoking in many countries of Latin America, including Brazil. According to their latest report¹⁵, published in December of 2020, 161.853 deaths are caused by tobacco every year in Brazil. **Table 4** shows the yearly death estimates according to the main tobacco-related causes.

Tobacco-related cause	Deaths
Chronic obstructive pulmonary disease (COPD)	37.686
Cardiac diseases	33.179
Other types of cancer	25.683
Lung cancer	24.443
Passive smoking and other causes	18.620
Pneumonia	12.201
Cerebrovascular accident	10.041
Total	161.853

Table 4. Yearly amount of tobacco-related deaths by main causes

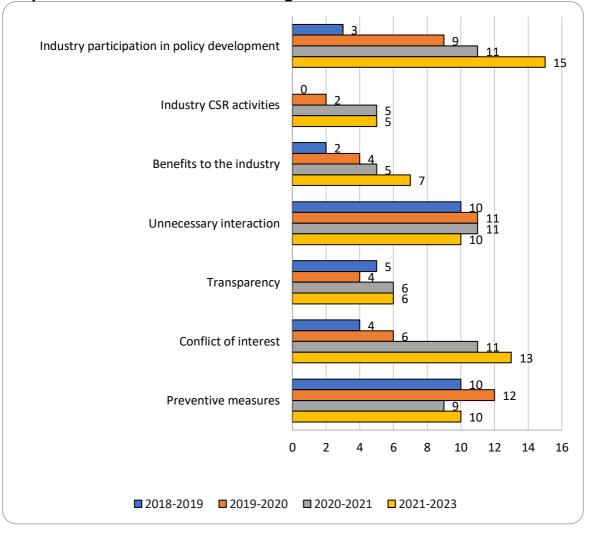
TII Index in Brazil

The report is based on a questionnaire developed by the Southeast Asia Tobacco Control Alliance. There are 20 questions based on the Article 5.3 guidelines. Information used in this report is obtained from the public domain only. A scoring system is applied to make the assessment. The score ranges from 0 - 5, where 5 indicates highest level of industry interference, and 1 is low or no interference. Hence the lower the score, the better for the country. The 0 score indicates absence of evidence or not applicable. Where multiple pieces of evidence are found, the score applied reflects an average. The report includes information on incidents from April 2021 to March 2023, but also includes incidents prior to 2021 that still have relevance today.

To contribute to the collection and analysis of the incidents, ACT Promoção da Saúde (ACT Health Promotion) counted on the collaboration of the Center for Studies on Tobacco and Health (CETAB) of the National School of Public Health (ENSP) of the Oswaldo Cruz Foundation (Fiocruz), which houses the Observatory on Strategies of the Tobacco Industry.

Overview of score changes since the previous version of the Index

As mentioned in the Introduction, the fact that CONICQ was unable to continue its regular activities affected many indicators of the Index. Brazil's score went from 58 (recorded in the 2021 edition of the Index) to 66 - a raise of 8 points. **Graph 2** shows the evolution of the country's indicators scores since the first edition of the Index.



Graph 2. Brazil's indicators scores throughout Index editions

In Indicator I, Industry participation in policy development, the score had a 36% raise, from 11 to 15. This was due to increased scores in questions I (as the industry had a clear interference in CONICQ, the country's main agency in regard to tobacco control), 3 (with the increased activities of the Tobacco Sectorial Chamber, among other findings) and 4 (as several interference actions regarding COP 9 were recorded). The score of question 2 went down from 4 to 3, as discussions on the tax reform dwindled in the reporting period.

Indicator 2 maintained the score 5, as tobacco companies and their allies kept their CSR activities in many areas, as recorded in the previous Index edition.

Indicator 3 was raised from 5 to 7 considering that the flavour additives ban has been delayed due to industry interference for a very long time now - more than 10 years. Question 7 kept the score 3, as the exemptions and incentives found were similar to the previous reporting period.

There was a slight decrease in Indicator 4, from 11 to 10. Question 8 and 9 maintained the score 4, but question 10 went from 3 to 2 as more incidents of partnerships between the government and the industry were found in the previous Index edition.

The Transparency indicator (#5) had the same score of 6, as the rules for disclosure of meetings and register of lobbyists from the industry have not changed in the reporting period.

Indicator 6, which includes questions on Conflicts of Interest, had its score raised from 11 to 13. The main difference was in question 14, as the industry and its allies have hired two former Anvisa directors and other former government members to actively work on their behalf, especially in the topic of electronic smoking devices - which is regulated by Anvisa. It is really worrisome that former members of the agency are now working against its own norms.

Lastly, Indicator 7, Preventive Measures, had a very significant increase - its score went up from 9 to 10. The raise was caused by the fact that many of the preventive measures implemented and proposed in the country were linked to CONICQ. With the commission being unable to operate properly in the reporting period, scores of this indicator were severely affected.

Recommendations overview

The most important recommendation is that the Brazilian government must ensure that CONICQ is promptly and fully reestablished and is able to resume its activities and structure. As mentioned, the commission is essential to help prevent industry interference, as well as advancing other tobacco control policies in the country.

Another step that must be taken is to forbid the industry and its allies to receive any kind of tax exemption or benefit, as well as not allowing them to take any part in social corporate responsibility or philanthropic activities. Lastly, it is necessary to increase awareness among government members about FCTC Article 5.3 and develop and implement more measures to improve transparency and prevent conflicts of interest.

Summary of Findings

I INDUSTRY PARTICIPATION IN POLICY DEVELOPMENT - 15 points

Investigative journalists found evidence that industry allies plotted to disband CONICQ, the Brazilian National Commission for the Implementation of WHO FCTC, and prevent its reestablishment. Other findings include the dwindlement of Brazil's diversification program by Fernando Schwanke, an industry ally that was a member of the government, attempts from tobacco companies at interfering with Anvisa's decision on electronic smoking devices, activities of the Tobacco Sectorial Chamber - an entity from the Ministry of Agriculture itself that holds regular meetings gathering industry representatives and/or allies, congressmen and government members to discuss topics of interest to the industry - and attempts of interference at Brazil's delegation and position at COP 9 - members of CONICQ's Executive Secretariat were in fact excluded from the delegation.

2 INDUSTRY CSR ACTIVITIES - 5 points

Tobacco companies and associated entities have organized, supported and financed a great number of CSR activities in the reporting period. A few examples of the findings include a reforestation project with the Brazilian Development Bank (BNDES), educational projects with the declared aim of fighting child labour, entrepreneurship trainings, sponsorship of several events and of a daily news program in the South of Brazil, campaigns on the recycling and disposal of cigarette butts and several donations.

3 BENEFITS TO THE INDUSTRY - 7 points

In 2012, Anivsa banned the use of flavour additives in tobacco products. Over ten years later, however, the norm has still not entered into force due to undue interference from the industry and its allies, that have filed a number of lawsuits against the agency. The industry also received tax exemptions through incentives to cultural activities - which means that the companies receive fiscal benefits and improve their images at the same time. Another finding was that in 2022 BAT Brasil was able to get a judicial decision that allowed the company to market and sell their products during Rock in Rio, one of the country's main music festivals, even though the points of sale were not in accordance with the current legislation. BAT also received another benefit from the federal government that allowed the company to access a security area to explore the genetic heritage of five microorganisms. Lastly, an article by O Joio e o Trigo found that part of a public funding for tobacco growers aimed at the purchase of machinery was reactivated.

4 UNNECESSARY INTERACTION - 10 points

Members of the government, notably Fernando Schwanke, National Secretary of Family Agriculture, and Eduardo Leite, governor of the state of Rio Grande do Sul, made declarations in favour of the industry and went to events organized by tobacco companies or their allies. The industry also established partnerships, made donations and supported government actions to fight illicit trade, prevent cargo theft and other topics.

5 TRANSPARENCY - 6 points

Even though government members usually have a public work schedule, details of the topics discussed in meetings are not always readily available. There were also records of unregistered meetings between government members and the Tobacco Sectorial Chamber. Moreover, Brazil has been discussing the regulation of lobbying activities for a few years now, but the project hasn't entered into effect yet, so there is no register of industry lobbyists.

6 CONFLICT OF INTEREST - 13 points

Financial contributions from private companies to political parties and candidates are now banned in Brazil, but it was possible to see that individuals linked to the tobacco industry are still making donations for political campaigns. Also, the industry and its allies have hired two former Anvisa directors and former members of the government to work on their behalf, especially on the matter of electronic smoking devices - which is a huge issue, aggravated by the fact that Anvisa is the agency that regulates these products. Finally, Brazil's current Minister of Defense (as of May, 2023), José Múcio Monteiro, was hired in 2021 as a consultant by Philip Morris - the same company where Gabriela Schwanke, daughter of Fernando Schwanke, National Secretary of Family Agriculture until July of 2021, works since 2014.

7 PREVENTIVE MEASURES - 10 points

Most preventive measures that are in effect in Brazil are not specific to the tobacco industry - civil servants of the Executive Branch, for example, must follow a code of conduct and there is a decree to regulate the interactions between public agents and companies in general. Regarding the availability of data about the tobacco industry activities, some of it can be found in the Internal Revenue Service and Anvisa's websites, but marketing expenditures and other information are not public. Lastly, CONICQ had a huge role in raising awareness about FCTC Article 5.3 and in the implementation of preventive measures, so the lack of activities from the commission has negatively affected this indicator.

Recommendations

RECOMMENDATION I

Fully re-establish CONICQ's activities and structure before COP 10

A complete return of CONICQ is essential to recover tobacco control advances and to articulate FCTC measures' implementation - not only those related to the national coordination of the national tobacco control policy, but also the ones referring to article 5.3, especially considering that COP 10 and MOP 3 will be taking place in 2023 and must be protected from tobacco industry interference.

RECOMMENDATION 2

Increase awareness of government officials of FCTC Article 5.3

It is urgent to increase awareness of FCTC Article 5.3 and how it is related to the advances in the national tobacco control policy. There is already some activity in this respect, but considering that the score related to the industry's participation in policy development has increased, this recommendation becomes necessary.

RECOMMENDATION 3

As described in FCTC, the government should not endorse, support, form partnerships with or participate in activities of the tobacco industry described as socially responsible

Tobacco companies and its allies should not be allowed to implement, organize, finance, support, take part nor in any way contribute to corporate social responsibility projects, actions and events along with any government entity or member. Donations from the tobacco industry and its allies should not be accepted.

RECOMMENDATION 4

Forbid tax exemptions and benefits to the tobacco industry

Tobacco companies should not be allowed to benefit from tax breaks, exemptions or benefits of any kind. The government should also resume the country's tobacco taxation policy and take measures to assure that industry arguments against taxes, such as allegations that they would raise illicit trade, are answered and not taken into account during policy development processes.

RECOMMENDATION 5

Develop and implement mechanisms to avoid conflicts of interest and to improve transparency

The Brazilian government must improve transparency and implement mechanisms to avoid conflict of interests and undue interference, especially in interactions between government representatives and congressmen with the tobacco industry.

RECOMMENDATION 6

Demand more comprehensive information from the tobacco industry

The government should demand more comprehensive information from the tobacco industry, including data regarding marketing expenses, lobbying, corporate social responsibility activities and political contributions.

Brazil Tobacco Industry Interference Index 2023 Results and Findings

	0		2	3 4	5
INDICATOR I: Level of Industry Participation in Policy-Develop	ment				
 The government accepts, supports or endorses any offer for assistance by or in collaboration with the tobacco industry or any entity or person working to further its interests. in setting or implementing public health policies in relation to tobacco control (Rec 3.4) 					5
I. Congressmen that are known industry allies plotted to disband Brazilian National Commission for the Implementation of the FO			Q (t	he	
CONICQ, the Brazilian National Commission for the Implementation of policies in the country, including measures to prevent industry inte- editions of the Index, we had already mentioned that CONICQ had disbanded, along with other national commissions, at the beginning government term. Later, investigative journalists from O Joio e of video register of a meeting from the Tobacco Sectorial Chamber of Question 3) in which congressman Marcelo Moraes, a known indu- vice-leader of the government in the Chamber of Deputies in 202 acted along with a government minister, Onyx Lorenzoni, to extir was still acting to prevent its reestablishment. Up to a certain poir maintained a regular meeting schedule nonetheless, as there were that put in doubt the legitimacy of the act that disbanded it. In the government term, however, Moraes and other industry allies wor was not officially reestablished - and, as a result, CONICQ's activi decreasing severely in the period, which negatively affected many a control policies in Brazil. Before the Elections in 2022, Moraes also CONICQ's disbandment was determined by the government to b asked his followers to vote for Bolsonaro and Lorenzoni (which w President and Governor of Rio Grande do Sul, respectively - both	tobac rferer d bee g of the rigo h more stry al , adm guish o t, CO some cours ced to cies en spects o reaffi enefit ere ru endec	co co nce. n of e Bc nad a deta lly ¹⁷ itteo COI NIC lega cOI NIC lega s of irme the unnin d up	in pr ficiall olsona access ails in who d that NICC Q m l arge Bols ure t up tobaced that indus ng for defe	ol reviou y aro s to a was t he Q and embe umen onarc hat it cco at stry a ated)	nd
More details about the politicians' activities and the effects of COI are described in other questions.	11CŐ,	s dis	sbanc	Iment	t

Screenshot of the meeting in which industry representatives and members of the Parliament and government discussed CONICQ's disbandment and other topics of interest to the tobacco industry

0 1 2 3 4 5

2. Other matters of interest to the tobacco industry were also defended by congressmen

Among others, congressmen Marcelo Moraes, Heitor Schuch and Luis Carlos Heinze were involved in the following incidents:

- a. Congressman Marcelo Moraes declared that he would act to include representatives from the tobacco industry in CONICQ.¹⁹
- b. Congressman Heitor Schuch made a declaration attacking CONICQ and suggesting that tobacco producers should be heard at COP.²⁰
- c. Congressman Luis Carlos Heinze declared that Brazil's position at COP 10 should not be harmful to tobacco production.²¹
- d. Congressman Marcelo Moraes nominated Afubra for an award.²²

3. Philip Morris sent a letter and so-called "scientific evidences" regarding new tobacco products to Anvisa

During Anvisa's process of reviewing the legislation that bans electronic cigarettes and heated tobacco products, Philip Morris has tried to influence the agency's decisions. There are records of a letter sent by Manuel Chinchilla, CEO of Philip Morris Brazil, claiming that the process had failures. The company also declared that they sent "scientific evidence" to the agency.²³



PHILIP MORRIS BRASIL

Brasilia, 21 de junho de 2022

Exmo Sr. Dr. Antonio Barra Torres Diretor-Presidente da Agência Nacional de Vigilância Sanitária – Ar

Ref. Inclusão em pauta do Processo nº 25351.911221/2019-74

Excelentíssimo Senhor Diretor-Presidente,

Diante da recente publicação da pauta da 11º Reunião Ordinária Pública da Diretoria Colegiada, com a inclusão dos tiens 2.2.2 e 2.3.3, que versam sobre a votação do Relatório Final de Análise de Impacto Regulatório sobre os Dispositivos Eletrônicos para Fumar (DEF) e a abertura de consulta pública com minuta para regulamentação do tema, a Philip Morris Brasil Indústria e Comércio Ltda. (PMB) vem, respeitosamente e através da presente missiva, chamar a atenção para alguns pontos de preocupação com relação à condução do citado processo regulatório.

Em que pese reconheça a ampla experiência e capacidade da Anvisa na condução de análises de impacto regulatório, a PMB entende que o **Relatório Parcial de Análise de Impacto Regulatório sobre** DEF, o qual foi objeto da Tomada Pública de Subsidios (TPS) η ^σ6/2022 e veio a dar origem ao Relatório Final ora pautado para votação, está elvado de vicios que, enquanto não forem sanados, tornam-no inapto a embasar processo decisório de tamanha releváncia e complexidade.

Tais vícios, processuais e de mérito, abordados em detalhe na contribuição da PMB à referenciada TPS (protocolada em 09/06/2022), certamente subsistem no Relatório Final pautado para votação, em que pese o teor de tal documento não tenha sido tornado público. Não haveria como ser diferente, afinal, o prazo para o envio de contribuições pela sociedade à referida TPS se encerrou em 10/06/2022. Dois dias úteis depois, em 14/06, o tema foi colocado em pauta.

Não é crivel que em 48h a equipe técnica responsável pelo Relatório Parcial tenha analisado todas as contribuições recebidas – possivelmente milhares de laudas e incontáveis referências bibliográficas – e, com a criticidade e isenção necessária, as tenha refletido no Relatório Final e na minuta de regulamentação, ou, ao menos, justificado com dados e tecnicidade o seu afastamento.

Entre os graves vícios identificados pela PMB no Relatório Parcial, seguramente mantidos no Relatório Final, pois não houve tempo hábil para análise dos apontados descumprimentos às Leis nº 13.874/19 (Lei de Liberdade Econômica) e nº 13.848/19 (Lei das Agências Reguladoras), bem como ao Decreto 10.411/2020 (que regulamenta a AIR), destacamos os seguintes pontos de atenção:

- Erro na identificação do problema regulatório ao se desconsiderar a realidade corrente, na qual os DEF já estão amplamente disponíveis à população no mercado ilícito, apesar da política proibicionista vigente (art. 6ª, II e VII, do Decreto 10.411/2020);
- Inexatidão na identificação dos agentes afetados pela regulação, com a desconsideração do impacto sobre o sator regulado, o comércio ilegal, produtores rurais e adultos fumantes (art. 6º, III, do Decreto 10.411/2020);

Philip Morris Brasil – Assuntos Corporativos e Regulatórios SCN Quadra 04, bloco B, centro Empresarial Varig, sala 1201 CEP 70.714-900, Brasilio, DF Tet + 65 (61) 2102 – 11.08 / e-mail: <u>sauntos regulatorios@pmi.com</u>

Letter sent to Anvisa by the CEO of Philip Morris Brazil. It can be seen in full in Annex B.

4. In Rio Grande do Sul, industry representatives present demands to the state's Industry Parliamentary Front

Congressmen from Rio Grande do Sul Industry Parliamentary Front have met with representatives from SindiTabaco and other industries to hear their demands.²⁴



Meeting between the Industry Parliamentary Front and representatives of SindiTabaco and other industries

2.	The government accepts, supports or endorses policies or			
	legislation drafted by or in collaboration with the tobacco industry.		3	
	(Rec 3.4)			

1. Brazil's diversification program is dwindled by Fernando Schwanke, an industry ally²⁵

Schwanke had already been mentioned in previous editions of the Index due to its connections to the tobacco industry - his daughter works for Philip Morris, for instance, as described in Question 15 - and the fact that he often makes statements and acts in a way that is favorable to the tobacco industry. While he was Secretary of Family Agriculture, Schwanke blocked or redirected resources from Brazil's diversification program, which used to be a reference. As a result, the program has dwindled severely.

2. Chamber of Deputies investigates former director of Anvisa²⁶

The process was articulated by congressmen linked to the industry who claimed that director Cristiane Jourdan had possibly "politicized" her function in the process of reviewing the ban on electronic cigarettes and heated tobacco products (that ended up with a unanimous decision to approve the technical report which recommended the maintenance of the ban). The investigation has been archived²⁷, but nevertheless it was certainly a demonstration of power by the industry, and seemingly an attempt to intimidate Anvisa's staff members.

3. Local legislations to the benefit of the industry or its allies have been approved in the period

The bills listed below were clearly created to further the industry's interests:

- a. Expoagro Afubra, an event organized by Afubra, was included in Rio Grande do Sul official calendar.²⁸
- b. Rio de Janeiro approved a law to celebrate Anti-Tobacco Illicit Trade Week.²⁹

c. Iro Schunke, president of SindiTabaco, receives a title of distinguished citizen in the city of Candelária, Rio Grande do Sul.³⁰

3.	The government allows/invites the tobacco industry to sit in				
	government interagency/ multi-sectoral committee/ advisory				
	group body that sets public health policy. (Rec 4.8) 1 Never 5			4	
	Yes				

I. Tobacco Sectorial Chamber

The Ministry of Agriculture houses a Sectorial Chamber for tobacco producers, which holds regular meetings gathering industry representatives and/or allies, congressmen and government members³¹ to discuss topics of interest to the industry. Even though it is a government entity by nature, as it is part of the Ministry of Agriculture, the Chamber is clearly a group created to defend the interests of the industry. It has already declared that it acted to try to avoid the ratification of FCTC by Brazil, for example.³² Some of the Chamber activities registered in the data collection period are the following:

- a. In a meeting, Chamber members and the Ministry of Agriculture discussed COP and tobacco taxes in a favorable way to the industry.³³
- b. Members of the Ministry of Agriculture, ETCO (the Brazilian Institute of Ethics in Competition, a known industry ally) and FNCP (National Forum Against Piracy and Illegality, also an industry ally, especially in the matter of taxation, as they constantly affirm that raising tobacco taxes would increase illicit trade) participate in a meeting from the Tobacco Sectorial Chamber.³⁴
- c. Afubra and the Chamber talked about electronic cigarettes and heated tobacco products, defending that their sales should be allowed in the country.³⁵

2. National Council to Combat Piracy and Crimes against Intellectual Property includes FNCP, an ally of the industry³⁶

The National Forum Against Piracy and Illegality (FNCP) is a known industry ally. They have already promoted a media campaign claiming that tobacco taxes increase illicit trade, for instance³⁷. The Council studies and suggests measures to fight illicit trade and piracy, promote training of public agents and supports awareness campaigns, among other attributions. The tobacco industry is clearly benefited to have an ally in such a relevant council to the matter of illicit tobacco trade and taxation.

3. Amprotabaco³⁸

Amprotabaco is an association of cities that produce tobacco. According to Rodrigo Solda, mayor of Rio Azul - a tobacco producing city - and President of the association between 2020-2021, the association was created to act as a political representation of the industry, to complement the work done by SindiTabaco, which represents the companies, and Afubra, which represents the producers. The association claims to have over 500 associated cities, but the actual number is unclear, according to investigations by the news website O Joio e o Trigo. It is likely that it is not even close to that, but the sole existence of an association of cities created to act on behalf of the tobacco industry is extremely worrisome. It is also very difficult to track Amprotabaco's actions, as they do not have an official website, but there are records of recent activities, such as a new board assuming in April of 2021³⁹ and claiming that the fight on illicit trade and the matter of new tobacco products should receive more attention from the entity. There were also

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records of an entity meeting in March, 2022, and the fact that the city Vale do Sol advanced a bill to join Amprotabaco⁴⁰.

4. City Council in Santa Cruz do Sul elects an Afubra representative as president⁴¹

In August of 2021, the Municipal Development Council of Santa Cruz do Sul elected Marco Antonio Donelles, Afubra's representative, as their new president until 2023.



Election of Marco Antonio Donelles as President of the Municipal Development Council of Santa Cruz do Sul

-		_	 	
4.	The government nominates or allows representatives from the tobacco industry (including State-owned) in the delegation to the			
	COP or other subsidiary bodies or accepts their sponsorship for		3	
	delegates. (i.e. COP 4 & 5, INB 4 5, WG) (Rec 4.9 & 8.3)			
	For non-COP year, follow the previous score of COP year. For			
	non-Parties, apply a score of '0'			

I. Members of CONICQ's Executive Secretariat were excluded from the COP 9 and MOP 2 Brazilian delegation while members of the government made declarations in favor of tobacco production

Following CONICQ's disbandment, and to the interest of the tobacco industry, the government excluded members of CONICQ's Executive Secretariat from the Brazilian delegation who took part in COP 9 and MOP 2. This happened along with the register of many incidents of industry allies in the Congress and in the federal government trying to influence Brazil's position in the event. Moreover, congressman Marcelo Moraes joined a meeting hosted by CONICQ to discuss COP (before their members were excluded from the delegation) and tried to single-handedly end it, affirming that it could not be happening, as CONICQ was disbanded (even though there were still discussions about it). Considering these facts, and the other incidents listed below, it is clear that, even though official tobacco industry representatives were not included in Brazil's delegation, the industry and its allies were able to influence the definition of delegation members. In the end, Brazil's position during the event was not so inclined to tobacco production as the declarations of members of the government had suggested, but the fact that CONICQ members were excluded is a clear and worrisome sign of industry interference.

a. CONICQ's Executive Secretariat members were excluded from the COP 9 and MOP 2 delegation⁴²

		0		2	3	4	5
c. d. e. f.	After a meeting in which members of the Tobacco Sectorial strategies and decided to try to talk about COP to Carlos A Ministry of Foreign Affairs, França actually met shortly after the Heinze, a known industry ally which was mentioned in the C Tobacco Sectorial Chamber also requested all documents ret the Foreign Affairs Ministry and that the country's position s afterwards, to "avoid divergent positionings" ⁴⁴ Minister Onyx Lorenzoni declared that the government wou producers during COP 9 ⁴⁵ , as also declared César Halum, the of Family Agriculture that replaced Schwanke ⁴⁶ . There are registers of congressmen and government member Brazil's position during COP 9, and Marcelo Moraes tried to COP meeting to hear civil society regarding the position that take during COP. ⁴⁷ Entities that represent the tobacco sector delivered a docum of Agriculture, Labor and Foreign Affairs to ask the governme COP 9 decisions would not harm tobacco production ⁴⁸ and should remain neutral on the matter of electronic cigarettes products. ⁴⁹	lbern with cham garc houl ild su ers av ers av ers av ers av end t the hent that and	to Fr Luis ber 1 ling (d onl uppo ation cting a Co to the to as the c heat	ança Cai mee COF ly bo rt to al S to i ON ntry ne M suro coui ed t	a, rlos eting 9 fl e de ecre influ ICC 7 sh 1 inis e th ntry toba	g. ⁴³ fron efine cco etar uenc 2 Pr oulc strie at	n ed y ee- d ss
	2: Industry CSR activities	1	· · · · · ·				
partnershi industry de example, d B. The gov contributio contributio further its <i>NOTE: ex</i>	ment agencies or their officials endorse, support, form ps with or participates in activities of the tobacco escribed as "socially responsible" or "sustainable". For environmental programs. (Rec 6.2) wernment (its agencies and officials) receives CSR ons (monetary or otherwise, including CSR ons) from the tobacco industry or those working to interests during the pandemic. (Rec 6.4) clude enforcement activities as this is covered in uestion						5
another question Image: CETAB/Fiocruz, in partnership with STOP/The UNION and Vital Strategies, developed a research project to identify tobacco industry's corporate social responsibility strategies to inform decision makers and engage the population in generating responses in favour of public health and tobacco control. ⁵¹							

I. Tobacco industry supports projects with the Brazilian Development Bank (BNDES)

BNDES is accepting contributions from tobacco companies for environmental programs:

- a. Floresta Viva (Living Forest)⁵²: BNDES created a 500 million BRL fund to be used in the reforestation of the Amazon rainforest, the Cerrado and the Atlantic Forest. Philip Morris, along with Heineken and other companies, is part of the project.
- b. Conexão Araucária (Araucaria Connection)⁵³: a project by the Society for Wildlife Research and Environmental Education (SPVS), in Paraná, that aims to help producers of rural properties in permanent preservation areas of Araucaria forests to comply with the Environmental Regularization Program and the Forest

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Code. It is funded by BNDES and Japan Tobacco International (JTI) and it is supported by Chico Mendes Institute for Biodiversity Conservation (ICMBio), a government entity linked to the Ministry of the Environment.



Conexão Araucária project is funded by JTI

2. Instituto Crescer Legal / Growing Up Right Institute⁵⁴

The Growing Up Right Institute is a project by Sinditabaco and their associated companies (which include BAT Brasil, Philip Morris, JTI, Alliance One and many more) with the declared aim of promoting education and fighting child labour, so that young people stay and thrive in rural areas. In Sinditabaco's website, the Institute affirms that it has benefited over 500 young people.⁵⁵ An article⁵⁶ published in April of 2021 noted that the participants took part in Entrepreneurship and Rural Management courses after their regular school hours. Since 2017, the Institute also had a program that discussed gender issues aimed at young women.

The Institute partners with schools, cities and states to execute their activities. The city of Novo Cabrais, for example, announced in September of 2022, that it had partnered with the Institute to promote an educational program in the city in 2023.⁵⁷ Canguçu is another city that partners with Crescer Legal, and announced that 18 students took part in the program in 2022.⁵⁸

In July of 2021, the Institute promoted a seminar for their teachers and other members of the staff to talk about education during the pandemic and common issues that arise during adolescence.⁵⁹



Crescer Legal promotes a seminar for teachers

In July of 2022, the Institute organized a seminar about child labour⁶⁰, where it was mentioned that the project is supported by the Ministry of Labour. Among the speakers were professors such as Ana Paula Motta Costa, a consultant of the Institute and also the vice-director of the Law School of the Federal University of Rio Grande do Sul (UFRGS).



Seminar about child labour organized by Crescer Legal

3. Decola Jovem project / Upwardly Mobile Youths61

BAT Brasil has continued to implement the Decola Jovem program, which is aimed at providing incentives for youths in socially vulnerable positions through entrepreneurship training. According to BAT Brasil's website,⁶² the project is aimed at people between 18 and 35 years of age who want to start a business. The Secretary of Culture and Creative Economy of Rio de Janeiro is listed on the project's website as an institutional supporter, and it also includes partnerships with cities, as listed below:

- a. In 2021, the training was provided in partnership with the city of Porto Alegre⁶³, in Rio Grande do Sul.
- b. The city of Araxá, in Minas Gerais, also partnered with BAT Brasil to offer the training in 2021.⁶⁴
- c. Santa Cruz do Capibaribe, in Pernambuco, partnered with BAT Brasil in August of 2022.65

4. Verde é Vida project / Green Means Life

Afubra continued to work on the project, which was created in 1991 with the declared goal of developing socio-environmental awareness, promoting the preservation of the environment, rural education, diversification and sustainability and to value farmers. The project partners with cities and public schools.

a. In 2021, the project celebrated 30 years of existence with many activities. They included a campaign (MuDáAlimento) that exchanged non-perishable foods for seedlings in an action with students from public schools - the food collected, that amounted to over 270 kg,⁶⁶ was donated to assistance entities. A virtual event with students and teachers and a science fair also took place.⁶⁷ On the occasion, Mayor Ronaldo Moraes praised the partnership between Afubra and the city.

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Food collected and donated by Afubra to assistance entities

- b. In 2022, the project Bolsa de Sementes ("Bag of Seeds"), which is part of Verde É Vida, celebrated 20 years of existence and highlighted the partnership with schools, teachers, parents, and with the public university UFSM (Universidade Federal de Santa Maria). In the project, public schools collect seeds and send them to the university.⁶⁸
- c. In 2021, Afubra and the city of Camaqua renewed the partnership.69
- d. The city of Treze Tílias also renewed the partnership to implement the project in a public school with the theme "Sustainable Planet: act locally and think globally".⁷⁰



The city of Treze Tílias renewed the partnership to implement Verde É Vida in a public school

- e. Also in 2022, Afubra promoted an award among schools that are part of the project. The winners were awarded 1.200 BRL that could be exchanged for products.⁷¹
- f. In the city of Braço do Norte, representatives from Afubra planted a tree along with the city mayor, Beto Kuerten Marcelino, to celebrate 20 years of partnership between the city and Afubra in 2022. Braço do Norte is part of the project Bag of Seeds.⁷²

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A yellow ipe is planted to celebrate the partnership between the city and Afubra

g. In 2022, the project partnered with the city of Candelária in activities for World Environment Day. Electronic trash was collected and exchanged for seedlings.⁷³

5. ARISE - JTI program to fight child labour

ARISE is a global program by Japan Tobacco International (JTI) that claims to prevent and help eliminate child labour. It is active in Brazil and has partnered with local governments. In 2021, JTI expanded the program in Brazil from six to ten cities in Rio Grande do Sul. It claims to have benefited over 4,000 children and adolescents through courses given in schools, support for protection networks and implementation and monitoring of municipal plans for the Child Labor Eradication Program, among other actions.⁷⁴ 500 students took part in the program in 2022 in the states of Rio Grande do Sul and Paraná.⁷⁵

6. Events sponsored or supported by the tobacco industry

a. SindiTabaco and Afubra promoted an event in the city of Cerro Branco, Rio Grande do Sul, to discuss health and safety of the producer and protection of children and adolescents. Over 300 people, including farmers, health agents, public school principals, guardianship counselors and other authorities were present in the event, which happened in June of 2022.⁷⁶



SindiTabaco and Afubra promote event in the city of Cerro Branco

- b. Afubra and tobacco companies sponsor Oktoberfest, the traditional German party, along with the city, state, and federal governments in 2021⁷⁷ and 2022⁷⁸.
- c. Christmas festival in Santa Cruz do Sul is announced, with support from SindiTabaco.⁷⁹
- d. "Tobacco Festival" (Festa do Fumo)⁸⁰ took place in April of 2022 in the city of Chuvisca. The event included popular concerts, exhibitions, local cuisine, colonial products, money raffles and agricultural machinery. Moreover, a forum to discuss the perspectives of the tobacco production chain was held during the festival.
- e. In August of 2022, Afubra promoted a meeting for tobacco producers in the city of Jaguari (Rio Grande do Sul). The event was supported by the city hall and the Chamber of city councilors.⁸¹
- f. Afubra named, sponsored and promoted a sports event, Copa Santa Auta Afubra, with soccer, volleyball and boules championships. The games included categories for adolescents and prizes.⁸²



Afubra's logo in an outdoor from the event

g. Afubra promoted an award for technological innovations in agricultural machinery for family farming in October, 2022. This was actually the 8th time that the award was promoted. It happened in partnership with a public university (UFPEL -Universidade Federal de Pelotas) and a private university (Unisc).⁸³

7. Educational programs sponsored or supported by the tobacco industry

 Alliance One and China Brasil Tabacos sponsored a project that provided leadership and management training for 17 students from public schools in Santa Cruz do Sul. The amount of 40,000 BRL was provided through the Municipal Council of Children and Adolescent Rights.⁸⁴



Students that took part on the training

 b. The Municipal Department of Water and Sewage of Uberlândia, Minas Gerais,took students from public schools to play educational games in Souza Cruz/BAT Brasil in 2022.⁸⁵

8. Gazeta: tobacco industry sponsors a daily news program

Along with the city of Santa Cruz do Sul and Unisc, a university from the same city, SindiTabaco sponsors a daily news program (Gazeta Notícias) on YouTube.⁸⁶ The program and the vehicle's website constantly publish articles and news with a favorable view to the industry activities. Moreover, they publish the Brazilian Tobacco Yearbook, which praises the production in Brazil.

In 2021, Afubra and the city of Santa Cruz do Sul sponsored a soccer championship organized by Gazeta.⁸⁷

9. CSR activities specific to the COVID-19 pandemic

- a. Philip Morris partnered with a news vehicle (Gazeta, which is also sponsored by the industry, as seen above) and an association of cities from the Vale do Rio Pardo region in an awareness campaign about COVID prevention.⁸⁸
- In 2021, in Uberlândia, Minas Gerais, Souza Cruz/BAT Brasil donated 40 multiparameter monitors to the City Hall. The investment made by the company was of 700,000 BRL.⁸⁹
- c. Also in 2021, BAT Brasil donated 4 respirators and 40,000 masks to the region of Vale do Rio Pardo.⁹⁰

10. CSR activities on the recycling and disposal of cigarette butts and other environmental matters

a. In 2022, the city of Santa Cruz do Sul partnered with JTI and the company Poiato Recicla to collect and recycle cigarette butts, turning them into materials for artisans.⁹¹ The city of Florianópolis (Santa Catarina) also partnered with JTI and Poiato to install butt collectors in 10 beaches and neighborhoods of the city.⁹²



Cigarette butt collector in Florianópolis, Santa Catarina. The logos of JTI, the city of Florianópolis and Poiato are displayed.

- b. Since 2000, SindiTabaco and Afubra have maintained a project to receive and dispose of empty pesticide packages. According to the organizations, over 18 million packages have been collected by the program since it was launched.⁹³
- c. Philip Morris has expanded a program on water resources management. It includes partnerships with cities and universities⁹⁴.
- d. Souza Cruz/BAT Brasil partnered with the Municipal Department of Water and Sewage and the Municipal Secretary of Environment of Uberlândia, Minas Gerais, to collect over 100kg of recyclable materials and 160 liters of oil during World Cleanup Day in 2021.⁹⁵



World Cleanup Day event with Souza Cruz/BAT Brasil in Uberlândia

e. BAT Brasil and Unisc, the university of Santa Cruz do Sul, partnered in 2022 in a water management program that will provide a water security diagnosis in 40 properties.⁹⁶

11. General donations by tobacco companies

a. Universal Leaf donates blankets to a social project: in a winter campaign, the company donated over 500 blankets to municipal institutions that do social work.⁹⁷



The Municipal Secretary of Housing, Social Development and Sports received the blankets from Universal Leaf

- b. Universal Leaf and Premium Tabacos donate computers for public schools⁹⁸: 49 computers and 2 projectors were delivered to public schools in the city of Santa Cruz do Sul.
- c. Through SindiTabaco, tobacco companies made donations to renovate a section of a highway⁹⁹.
- d. BAT Brasil donated an industrial kitchen to the city of Recife, claiming that it would help the preparation of meals for people in social vulnerability conditions.¹⁰⁰

12. Sponsorship of activities regarding LGBTQ rights

Philip Morris has sponsored the Citizenship in Respect for LGBT Diversity Award¹⁰¹ in 2022 and supported the Gay Parade¹⁰², the largest event that celebrates LGBTQ diversity in Brazil.

13. Valeef¹⁰³

Valeef is an association created to promote the use of bioactive plants. Among its members are included tobacco companies and associations, government institutions and ministries, and even the Food and Agriculture Organization of the United Nations.

INDICATOR 3: Benefits to the Tobacco Industry				
 The government accommodates requests from the tobacco industry for a longer time frame for implementation or postponement of tobacco control law. (e.g. 180 days is common for PHW, Tax increase can be implemented within 1 month) (Rec 7.1) 			4	

1. Over 10 years later, the additives ban is still not active

As mentioned in the previous version of the Index, lawsuits filed by the industry and their allies prevent the ban on flavor additives, determined by Anvisa in 2012, from entering into force. In the period of data collection for this Index, the lawsuits remained on hold, and as a result the measure was not implemented.

2. BAT Brasil challenge and receives permission to sell their products in a music festival

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In 2022, during Rock in Rio, one of Brazil's largest music festivals, BAT Brasil was previously warned by Rio de Janeiro's Health Surveillance Agency that their points of sale inside the event were not in accordance with the legislation. Two days later, BAT was able to get a judicial decision that prevented the agency from closing the company's points of sale at the event, claiming that the auditor that had inspected the points of sale had been "arbitrary". The decision stated that, even if the company was breaking the law, the agency would have to notify them first and start an administrative process. Meanwhile, the event continued, and BAT Brasil ended up being able to promote and sell their products for all of it without further disturbance - even though they had not followed the current legislation.

7. The government gives privileges, incentives, tax exemptions or benefits to the tobacco industry (Rec 7.3)

1. **PRONAMP** - public funding for the purchase of machinery for medium-sized rural properties

According to an article by O Joio e o Trigo, Fernando Schwanke, Secretary of Family Agriculture between 2019 and 2021, was able to reactivate part of a public funding for tobacco growers aimed at the purchase of machinery.¹⁰⁴

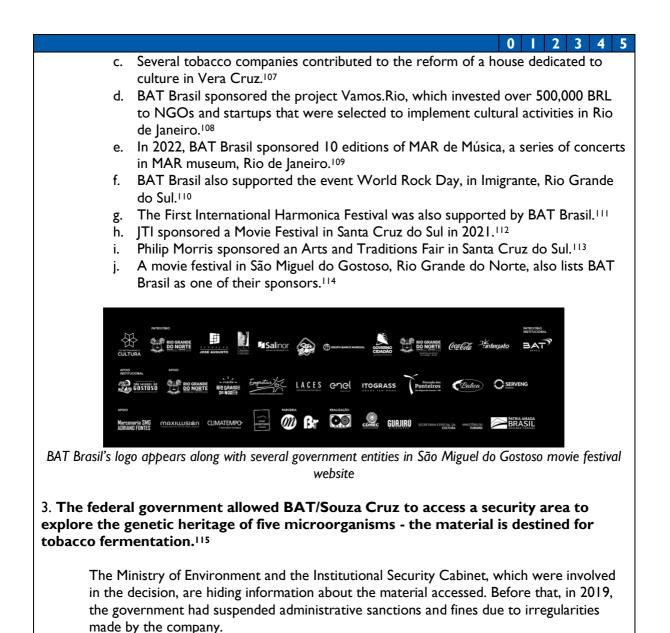
2. Tax exemptions through incentives to cultural activities

As mentioned in previous versions of the Index, in Brazil there are mechanisms that provide tax exemptions based on contributions made by the companies to cultural and social projects approved by government entities (through the Rouanet/Incentive to Culture Law). The tobacco industry continued to use this mechanism to receive tax exemptions and also to link their images to the projects supported and away from their harmful products in many occasions, such as the ones listed below:

- a. Festival dos Festivais: held in Rio Grande do Sul in 2021, the event included the Chula Festival, the Rio Grande do Sul Traditional Dancing Festival and the Rio Grande do Sul Art and Tradition Meeting. Philip Morris and the city of Santa Cruz do Sul sponsored the event.¹⁰⁵
- b. Universal Leaf sponsored a play that was exhibited for free for children and their families in Rio Pardo, Rio Grande do Sul.¹⁰⁶



Children play is sponsored by Universal Leaf through the Incentive to Culture Law



4. Amprotabaco

Amprotabaco claims to be funded by the associated city governments. However, data on the matter is not easily found - as mentioned in a previous item, it was not possible to find the exact amount of associated cities, and neither if they do indeed pay the association fee. Amprotabaco's statute allows contributions from companies and associations, but it was not possible to find if this actually happened, as they did not answer to inquiries made by O Joio e o Trigo.¹¹⁶

5. Exemptions for travelers

International travelers are allowed to bring 200 cigarettes, 25 cigars and 250 grams of tobacco into Brazil as well as purchase further 400 cigarettes, 25 cigars and 250 grams of tobacco at duty-free stores.¹¹⁷

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INDICATOR 4: Forms of Unnecessary Interaction					
8. Top level government officials (such as President/ Prime Minister or Minister) meet with/ foster relations with the tobacco companies such as attending social functions and other events sponsored or organized by the tobacco companies or those furthering its interests. (Rec 2.1)				4	

1. Fernando Schwanke, Secretary of Family Agriculture of the Brazilian Ministry of Agriculture between 2019 and 2021

Schwanke left the Secretariat of Family Agriculture in July, 2021, few months after the start of the period of data collection for this edition of the Index, but it was still possible to find incidents of unnecessary interactions in which he was involved, besides being responsible for the dwindling of Brazil's diversification program and for an increase in incentives for tobacco producers, as mentioned in previous questions.

- a. In an interview for the Brazilian Tobacco Yearbook, when asked about FCTC, Schwanke declared that the Ministry of Agriculture was a defender of tobacco production and that the sector needed to be "respected".¹¹⁸
- b. In March of 2021, Schwanke was a speaker in an online event from Afubra (Conecta Expoagro Afubra), talking about family agriculture.¹¹⁹

2. Eduardo Leite, governor of Rio Grande do Sul

Leite was elected governor of Rio Grande do Sul in 2018 and reelected for a new term in 2022. The state is the main tobacco producer in the country. Leite had already been mentioned in the previous version of the Index due to a visit in a Philip Morris' plant. As can be seen in the list below, the amount of unnecessary interactions between the governor and the tobacco industry has increased:

a. Eduardo Leite visited JTI in July of 2021, when he complimented the company for investments in Rio Grande do Sul.¹²⁰ In the same day, Leite went to an event of *Tá na Hora*, program sponsored by the TI¹²¹. On the occasion, ACT, CETAB and The Union sent Leite a letter speaking about the importance of not associating his image as governor to the tobacco industry.¹²²

Tá na Hora also had mayors¹²³ and secretaries¹²⁴ as participants in other editions.



Eduardo Leite in a visit to JTI's plant in 2021

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b. In a visit to Santa Cruz do Sul, Leite visited Philip Morris again and gave a statement saying that the state government supported the production and sales of electronic cigarettes and heated tobacco products¹²⁵ - even though they are forbidden in the country.



Leite visits Philip Morris and supports the production and sales of electronic cigarettes and heated tobacco products

c. Leite visited and made a speech in Expoagro (an event organized by Afubra) in 2022¹²⁶.



Leite gives a speech in Expoagro, event organized by Afubra

3. Acting governor Ranolfo Vieira Júnior visits BAT Brasil¹²⁷

Ranolfo Vieira Júnior was vice-governor to Eduardo Leite between 2018 and 2022. In March of 2022, Leite left the office to start campaigning for the elections that would be held in October, and Vieira Júnior assumed as governor until January of 2023. In May, two months after he assumed the government, Vieira Júnior visited a tobacco processing unit from BAT Brasil and said that the visit would help to integrate the work done to fight illicit trade.



Vieira Júnior visits a BAT Brasil tobacco processing unit

4. Event about illicit trade with government authorities and BAT Brasil¹²⁸

Government authorities participated in an online event about illicit trade with BAT Brasil. The event was organized by a public university, UEMS (State University of Mato Grosso do Sul) and included speeches from representatives of the tobacco company, the National Secretariat for Public Security, the Ministry of Justice, the Public Security of the State of Mato Grosso do Sul and Paraná and the Department of Border Operations.

5. BAT Brasil receives an award with the presence of representatives of the Ministry of Agriculture and other authorities¹²⁹

BAT Brasil was awarded a 100% Integrated Production certificate in September, 2021. To celebrate, the company organized an event in the city of Santa Cruz do Sul (Rio Grande do Sul). Representatives from the Ministry of Agriculture, the Brazilian Agricultural Research Corporation (Embrapa), the Federal University of Pelotas (UFPEL), SindiTabaco and Afubra, among others, were present.

6. Afubra personally delivered an invitation to Expoagro to the President of a City Council¹³⁰

Expoagro, one of the main events related to the tobacco production chain in Brazil, and which is organized by Afubra, included invitations to many politicians, especially from the South region of the country. In some cases, the invitations were made in person, such as for Nelson Azevedo Junior, President of the City Council of Cachoeira do Sul, Rio Grande do Sul. Azevedo received representatives from Afubra in March, 2022.



Representatives from Afubra invite City Council members to Expoagro

7. Philip Morris visits the Mayor of Santa Cruz do Sul¹³¹

Helena Hermany, Mayor of Santa Cruz do Sul, met with a Philip Morris representative, Cleber Silveira, in May, 2022. Hermany defended the importance of maintaining a good relationship between the government and the private sector and praised Philip Morris' contribution to the economy of the region. According to Silveira, who was Head of Government and Institutional Relations at the company, the visit reaffirmed the good relationship that Philip Morris has with the city government and renewed the partnership between them.



Hermany and Silveira met in May of 2022

8. The Secretary of Agriculture, Livestock and Rural Development and other congressmen from Rio Grande do Sul give declaration in favor of the industry in an event organized by government entities and industry representatives¹³²

During an event that marked the beginning of the tobacco harvest season in December of 2022, Domingos Antonio Velho Lopes, Secretary of Agriculture, Livestock and Rural Development from Rio Grande do Sul, highlighted the representativeness of the tobacco production chain. Elton Weber, state deputy, declared that the sector must be "defended". Rudinei Härter, Mayor of São Lourenço do Sul, said that the tobacco sector also stands out for its social activities (meaning corporate social responsibility activities). The event had been organized by a partnership between the state Secretary of Agriculture, Livestock and Rural Development, SindiTabaco, Afubra and the city of São Lourenço do Sul. The event is actually part of the state calendar and takes place annually in different cities. In 2021, it happened in the city of Vale do Sol.

4

9. Tobacco industry representatives meet with the Federal Revenue¹

Between February and June of 2022, the Federal Revenue had 4 meetings with representatives from the tobacco industry, and they all happened in-person. Even though the government cannot necessarily refuse these meetings, they are worrisome because the tobacco industry has already used opportunities such as these to mark their position against the raising of tobacco taxes, claiming that it would increase illicit trade. In a previous edition of the Index, it was already mentioned an incident in which the Ministry of Justice created a work group to evaluate the possibility of lowering tobacco taxes, and this happened after representatives from the tobacco industry and their allies had made visits such as these.

10. Requests from SindiTabaco are delivered to the Chinese embassy through a state secretary¹³³

In July, 2021, Edson Brum, Secretary of Economic Development of Rio Grande do Sul, participated in a remote meeting with representatives of the Chinese embassy. During the meeting, Brum actually delivered messages and requests from SindiTabaco: he thanked the country for the support given to tobacco production in Brazil and made a very specific request, asking the representatives to contact GACC (General Administration of Customs China) to ask for "efforts and agility" to clear for boarding tobacco batches that would be inspected in the following week. The fact that a government member actually acted as an intermediary between tobacco companies and a foreign embassy demonstrates the influence that the industry has in the Rio Grande do Sul government.



Online meeting between the Secretariat of Economic Development of Rio Grande do Sul and the Chinese embassy

9. The government accepts assistance/ offers of assistance from the tobacco industry on enforcement such as conducting raids on

¹ Brazilian legislation allows information to be requested in addition to that available on the websites. Thus, ACT periodically asks certain federal government agencies about meetings that their representatives had with the tobacco industry and their respective minutes. Access to this document is restricted to a specific platform, so we do not have a link available for reference. However, the document is saved.

I. PMI Impact

PMI Impact is a global project from Philip Morris that claims to help implement solutions for illicit trade. In Brazil, the program has partnered with University of São Paulo (USP), the country's largest public university¹³⁴. In 2021, over 5,000 policemen were trained by the program, in a partnership between USP and the Ministry of Justice financed by Philip Morris.¹³⁵ In 2022, the project was expanded¹³⁶ - initially, it focused on the triple border between Brazil, Paraguay and Argentina, but it now intends to include the Americas as a whole. A new edition of an online course on Illicit Markets and Organized Crime in the Americas is planned to happen in 2023.

2. Donations made by the tobacco industry

- a. The Federal Revenue received a shredding machine donated by Souza Cruz/BAT Brasil. The total donation value was estimated to be around 1.3 million BRL. The donation was given through a public call for potential donors that was open to any kind of company.¹³⁷
- b. JTI donated 30,000 BRL to the Municipal Commission for the Eradication of Child Labor of Santa Cruz do Sul, Rio Grande do Sul. The donation was destined to the purchase of musical instruments for an orchestra for students from public schools.¹³⁸

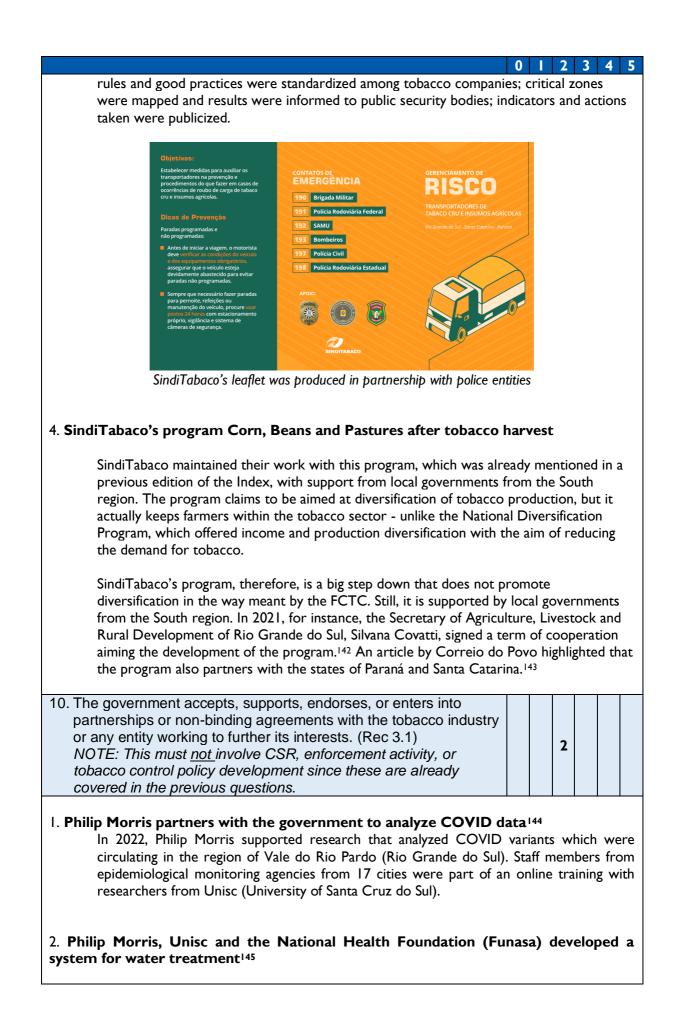


JTI representatives met with Mayor Helena Hermany and municipal secretaries, including the Health Secretary, Daniela Dumke

c. In 2022, BAT Brasil was one of the companies that contributed financially to the creation of a Police Station Specialized in the Investigation and Repression of Rural Crimes and Cargo Theft in Belo Horizonte, Minas Gerais.¹³⁹

3. Security Commission from SindiTabaco working along public security bodies to prevent cargo theft¹⁴⁰

According to SindiTabaco's website, cargo theft was reduced by 65% between 2019 and 2020. The article claims that actions from SindiTabaco's Security Commission contributed to the result. Among them, the organization published and distributed a leaflet¹⁴¹, with the support from civil, military and highway policies, with security tips for tobacco transporters from the states of Rio Grande do Sul, Santa Catarina and Paraná. Besides that, SindiTabaco's commission also promoted other actions, such as the following: safety



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Unisc and Funasa developed two systems for water defluoridation. One of them was supported by Philip Morris. The company declared that the goal of the project was diagnosing the quality of water used for human consumption in the region.

3. Embrapa and Philip Morris continue project that promotes organic gardens¹⁴⁶

Embrapa (the Brazilian Agricultural Research Corporation, that is a public company linked to the Ministry of Agriculture) and Philip Morris still partners (since 2017) in Projeto Quintais, a project with the declared aim of introducing technologies to implement organic fruit gardens in urban and rural areas. Other public entities support the project, such as FINEP, a public agency from the Ministry of Science and Technology that finances studies and projects.

4. Philip Morris and Afubra support a water protection program in Vera Cruz¹⁴⁷

Since 2017, and for the entire period of data collection for this edition of the Index, Philip Morris has financially supported a project in the city of Vera Cruz, Rio Grande do Sul. Afubra is also listed as a partner of the project, but there is no evidence of financial support. Besides them, the project also includes as partners the city of Vera Cruz, Unisc (University of Santa Cruz do Sul) and the National Water and Sanitation Agency (ANA), from the federal government.

By the end of 2022, 91 producers were part of the program. They received an annual remuneration considering the amount of preserved areas in their properties, good practices in soil management and waste disposal. Besides that, they were also exempted from water fees.

INDICATOR 5: Transparency			
11. The government does not publicly disclose meetings/ interactions			
with the tobacco industry in cases where such interactions are		3	
strictly necessary for regulation. (Rec 2.2)			

I. General rules for members of the government and of the parliament

In Brazil, government members usually have a public work schedule. However, details and the topics discussed are not always readily available. There is a legislation (Access to Information Law - LAI) that allows anyone to request more information about the meetings. Also, meetings with members of parliament are not public, but they usually post pictures on their social media profiles.

2. Unregistered meetings between government members and the Tobacco Sectorial Chamber

Even though government members usually publish their work schedule and meetings, O Joio e o Trigo found two incidents in August of 2021 in which members of the Tobacco Sectorial Chamber had unregistered meetings with Onyx Lorenzoni, who was Minister of Labor at the time, and João Lucas Quental Novaes de Almeida, who was a director of the Human Rights and Citizenship department of the Ministry of Foreign Affairs. In both times, the meeting was not included in their official work schedule.

Both times, the topic was COP 9, which would take place shortly after. In the meeting with Almeida, Chamber representatives - including congressman Marcelo Moraes -

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delivered a document asking the government to assure that COP 9 would not be harmful to the tobacco production chain. Lorenzoni, who is known for his favorable views to the tobacco industry, received the group on the same day. Even though the meeting was not in Lorenzoni's official work schedule, Moraes published a photo of it on his Instagram page:



Lorenzoni meets with members of the Tobacco Sectorial Chamber to discuss COP 9

12. The government requires rules for the disclosure or registration of		
tobacco industry entities, affiliated organizations, and individuals		
acting on their behalf including lobbyists (Rec 5.3)		

Brazil has been discussing the regulation of lobbying activities in the last few years. The project was approved at the House of Representatives and is being discussed at the Senate, so there is still no register of lobbyists.

INDICATOR 6: Conflict of Interest
 13. The government does not prohibit contributions from the tobacco industry or any entity working to further its interests to political parties, candidates, or campaigns or to require full disclosure of

such contributions. (Rec 4.11) 1 Never 5 Yes

In 2015, an electoral reform banned campaign donations from private companies. Since then, only individual supporters and the political parties themselves can contribute to electoral campaigns.

Before the reform, it was possible to consult donors to each candidate, and the tobacco industry used to make many contributions in all levels. Now, it is not possible to run a comprehensive monitoring, but there is evidence that contributions still occur through individual donations from people linked to the tobacco industry. An article from Joio showed that Carlos Eduardo Genehr, president of UTC Brasil, for instance, made donations to candidates in 2022. The article also found donations given between 2016 and 2020.¹⁴⁸

 Retired senior government officials form part of the tobacco industry (former Prime Minister, Minister, Attorney General) (Rec 4.4)

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I. Alessandra Bastos: former Anvisa director is now a consultant for BAT Brasil

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Alessandra Bastos was a director in Anvisa, Brazil's health regulatory agency responsible for several tobacco control policies, between 2017 and 2020. In 2021, she started to publish articles and take part in events as a consultant for BAT Brasil - and she even included her new affiliation in her LinkedIn profile.¹⁴⁹ The main topic that Bastos works with is the ban on electronic cigarettes determined by Anvisa: she constantly positions herself against the rule of her former agency. She published an article¹⁵⁰ in Exame magazine claiming that electronic cigarettes and heated tobacco products could reduce tobacco's harms by up to 95%. In an interview to CNN Brazil,¹⁵¹ she once again defended that the sales of these devices should be allowed, arguing that they are already consumed illegally in the country. This same argument was used by her in an interview to Gazeta (the same news vehicle that is sponsored by the tobacco industry, as seen in Question 5).¹⁵² Bastos also defended the release of electronic cigarettes in an article published in Folha de S. Paulo, one of Brazil's largest newspapers.¹⁵³

2. Direta (Tobacco Harm Reduction Information Directory) also hires former director of Anvisa

Direta, the Portuguese acronym for *Tobacco Harm Reduction Information Directory*, is a group led by Alexandro Lucian, a digital influencer known on the internet as "Hazard". He is also the founder of Vapor Aqui, a website aimed at promoting electronic cigarettes. At first sight, this may seem like an individual project by Lucian, but an article¹⁵⁴ by O Joio e o Trigo showed that Dirceu Barbano, another former director of Anvisa, is a member of Direta's consulting board. Moreover, Direta is linked to World Vaper's Alliance, which, in turn, is linked to the Consumer Choice Center (CCC). CCC is partially sponsored by BAT, Philip Morris and JTI. This shows that Barbano has indeed a link with the tobacco industry, as does Alessandra Bastos.

3. Former government member is hired as a lobbyist for Philip Morris¹⁵⁵

Cássio Cunha Lima (former Senator and Governor of Paraíba) was hired by Philip Morris in 2019, the same year he left the Senate. Cunha Lima has met at least once with a director from Anvisa to discuss the matter of electronic cigarettes in March, 2021.

4. Former government members act as legal consultants to the tobacco industry¹⁵⁶

The Brazilian Attorney General's Office (AGU) is currently suing the tobacco industry in a cost recovery lawsuit that aims to get financial compensation from the companies to the National Health System (SUS). Two former members of the government worked as legal consultants for the tobacco industry in this lawsuit: Tércio Sampaio Ferraz Junior, former Attorney General of the National Treasury and former Executive Secretary of the Ministry of Justice, and Everardo Maciel, former secretary of the Federal Revenue and from the Ministries of Finance, Education, Interior and Civil House.

 <u>Current government officials</u> and relatives hold positions in the tobacco business including consultancy positions. (Rec 4.5, 4.8, 4.10)

I. José Múcio Monteiro, Minister of Defense

0 1 2 3 4 Likewise Cássio Cunha Lima, José Múcio Monteiro was also hired by Philip Morris to act as a lobbyist.¹⁵⁷ When he was hired, in 2021, he was retired, but in January of 2023 Múcio assumed the Ministry of Defense. As of December, 2022, Philip Morris confirmed that Múcio was still a consultant and no records were found afterwards, so we cannot confirm if he has left the position.¹⁵⁸ 2. Gabriela Schwanke, daughter of Fernando Schwanke The daughter of Fernando Schwanke, Secretary of Agriculture until July of 2021, works for Philip Morris since 2014.159 **INDICATOR 7: Preventive Measures** 16. The government has put in place a procedure for disclosing the records of the interaction (such as agenda, attendees, minutes 2 and outcome) with the tobacco industry and its representatives. (Rec 5.1) Yes, but partial only: as mentioned in Question 11, government members usually have a public work schedule, but minutes are not usually public and the procedure is not specific to interactions with the tobacco industry. Minutes can be requested through the Access to Information Law. 17. The government has formulated, adopted or implemented a code of conduct for public officials, prescribing the standards with which they should comply in their dealings with the tobacco industry. (Rec 4.2); 1 for whole of government code; 2 for Yes but partial if only MOH Yes, but partial only: civil servants of the Executive Branch must follow a code of conduct and there is a decree to regulate the interactions between public agents and companies (Decree n° 4.334 of 12th August 2002). Once again, however, the codes are not specific to the tobacco industry. CONICQ members had two other normative instruments, CONICQ's Ethic Guidelines and the commission's statute. However, as discussed in previous questions, CONICQ's activities were suspended for most of the period in which data was collected. 18. The government requires the tobacco industry to periodically submit information on tobacco production, manufacture, market share, marketing expenditures, revenues and any other activity, including 2 lobbying, philanthropy, political contributions and all other activities. (5.2)Yes, but partial only: some of the mentioned data is available (production, manufacture, revenue, market share data) in the Internal Revenue Service and Anvisa's websites, but marketing expenditures and other activities are not public. 19. The government has a program / system/ plan to consistently 3 raise awareness within its departments on policies relating to FCTC Article 5.3 Guidelines. (Rec 1.1, 1.2)

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As mentioned in the previous edition of the Index, CONICQ was partially responsible for this, but the commission work was interrupted. Once again, it is possible to see that the absence of CONICQ created problems in many sectors and activities.						
20. The government has put in place a policy to disallow the acceptance of all forms of contributions/ gifts from the tobacco industry (monetary or otherwise) including offers of assistance, policy drafts, or study visit invitations given or offered to the government, its agencies, officials and their relatives. (3.4)			2			
Yes, but partial only: as mentioned in Q17, civil servants of the Executive Branch must follow a code of conduct and there is a decree to regulate the interactions between public agents and companies (Decree n° 4.334 of 12th August 2002).						
TOTAL SCORE			6	6		

Annex A: Sources of Information

	TOP TOBACCO COMPANIES/ DISTRIBUTORS	MARKET SHARE ²	BRANDS	SOURCE
I	BAT Brasil (former Souza Cruz)	72%	Dunhill, Kent, Lucky Strike, Rothmans	https://www.gov.br/anvisa/pt- br/assuntos/tabaco/consulta-a- registro/arquivos/marcas-de- cigarros 2023 05 15 am.pdf
2	Philip Morris Brasil	23%	Marlboro, L&M, Chesterfield	https://www.gov.br/anvisa/pt- br/assuntos/tabaco/consulta-a- registro/arquivos/marcas-de- cigarros 2023 05 15 am.pdf
3	JTI	1%	Camel, Winston, American Spirit	https://www.gov.br/anvisa/pt- br/assuntos/tabaco/consulta-a- registro/arquivos/marcas-de- cigarros_2023_05_15_am.pdf

	TOP MEDIA/ NEWSPAPERS	URL	
Ι	Observatório de	Online	http://tabaco.ensp.fiocruz.br/
	Monitoramento das		
	Estratégias da Indústria		
	do Tabaco		
2	Gazeta do Sul	Online	http://www.gaz.com.br/
3	Agrolink	Online	https://www.agrolink.com.br/
4	Folha do mate	Online	https://folhadomate.com
5	O Joio e o Trigo	Online	https://ojoioeotrigo.com.br/

	MAIN TOBACCO INDUSTRY ALLIES/ FRONT GROUPS	TYPE (FRONT GROUP, LOBBY GROUP, INDIVIDUAL)	SOURCE
Ι	Sindicato Interestadual da das Indústrias de Tabaco (SindiTabaco)/ Union Interstate Tobacco Industry	Affiliated	http://www.sinditabaco.co m.br/
2	Associação de Fumicultores do Brasil	Allies	https://afubra.com.br/
3	Confederação Nacional da Indústria	Affiliated	http://www.portaldaindus tria.com.br/cni/
4	Instituto Brasileiro de Ética Concorrencial (ETCO)	Front group	https://www.etco.org.br/t ag/contrabando/
5	Fórum Nacional de Combate à Pirataria e Ilegalidade (FNCP)	Front group	http://www.fncp.org.br/

² The data available is from 2021.

Annex B: Philip Morris' letter to Anvisa (in full)



PHILIP MORRIS BRASIL

Brasília, 21 de junho de 2022.

Exmo Sr. Dr. Antonio Barra Torres Diretor-Presidente da Agência Nacional de Vigilância Sanitária – Anvisa

Ref. Inclusão em pauta do Processo nº 25351.911221/2019-74

Excelentíssimo Senhor Diretor-Presidente,

Diante da recente publicação da pauta da 11ª Reunião Ordinária Pública da Diretoria Colegiada, com a inclusão dos itens 2.2.2 e 2.3.3, que versam sobre a votação do Relatório Final de Análise de Impacto Regulatório sobre os Dispositivos Eletrônicos para Fumar (DEF) e a abertura de consulta pública com minuta para regulamentação do tema, a Philip Morris Brasil Indústria e Comércio Ltda. (PMB) vem, respeitosamente e através da presente missiva, chamar a atenção para alguns pontos de preocupação com relação à condução do citado processo regulatório.

Em que pese reconheça a ampla experiência e capacidade da Anvisa na condução de análises de impacto regulatório, a PMB entende que o **Relatório Parcial de Análise de Impacto Regulatório sobre DEF**, o qual foi objeto da Tomada Pública de Subsídios (TPS) nº 6/2022 e veio a dar origem ao Relatório Final ora pautado para votação, **está eivado de vícios que, enquanto não forem sanados, tornam-no inapto a embasar processo decisório de tamanha relevância e complexidade**.

Tais vícios, processuais e de mérito, abordados em detalhe na contribuição da PMB à referenciada TPS (protocolada em 09/06/2022), certamente subsistem no Relatório Final pautado para votação, em que pese o teor de tal documento não tenha sido tornado público. Não haveria como ser diferente, afinal, o prazo para o envio de contribuições pela sociedade à referida TPS se encerrou em 10/06/2022. Dois dias úteis depois, em 14/06, o tema foi colocado em pauta.

Não é crível que em 48h a equipe técnica responsável pelo Relatório Parcial tenha analisado todas as contribuições recebidas – possivelmente milhares de laudas e incontáveis referências bibliográficas – e, com a criticidade e isenção necessárias, as tenha refletido no Relatório Final e na minuta de regulamentação, ou, ao menos, justificado com dados e tecnicidade o seu afastamento.

Entre os graves vícios identificados pela PMB no Relatório Parcial, seguramente mantidos no Relatório Final, pois não houve tempo hábil para análise dos apontados descumprimentos às Leis nº 13.874/19 (Lei de Liberdade Econômica) e nº 13.848/19 (Lei das Agências Reguladoras), bem como ao Decreto 10.411/2020 (que regulamenta a AIR), destacamos os seguintes pontos de atenção:

- Erro na identificação do problema regulatório ao se desconsiderar a realidade corrente, na qual os DEF já estão amplamente disponíveis à população no mercado ilícito, apesar da política proibicionista vigente (art. 6º, II e VII, do Decreto 10.411/2020);
- Inexatidão na identificação dos agentes afetados pela regulação, com a desconsideração do impacto sobre o setor regulado, o comércio ilegal, produtores rurais e adultos fumantes (art. 6º, III, do Decreto 10.411/2020);

Philip Morris Brasil – Assuntos Corporativos e Regulatórios SCN Quadra 04, bloco B, Centro Empresarial Varig, sala 1201 CEP 70.714-900, Brasília, DF Tel: +55 (61) 2102 – 1108 / e-mail: <u>assuntos.regulatorios@pmi.com</u>

- Falha na descrição das alternativas apresentadas para enfrentamento do problema regulatório, com a ocorrência de diversas confusões conceituais e de premissa como, a título de exemplo, uma errônea suposição de que regular significa permitir indiscriminadamente a venda de qualquer produto no mercado (art. 6º, VI, do Decreto 10.411/2020);
- Parcialidade dos subsídios adotados, tendo em vista que o Relatório privilegia informações e dados compartilhados por instituições que já haviam se manifestado contrariamente à regulação dos DEF durante a fase preliminar de audiências públicas sobre o tema, ao mesmo tempo em que desconsidera um robusto corpo de evidências científicas independentes, ou que adotam metodologias internacionalmente reconhecidas, por não suportarem as conclusões endossadas pelo Relatório (art. 6º, XI, do decreto 10.411/2020);
- Avaliação genérica dos riscos inerentes aos DEF, sem considerar as diferentes classes e gerações de produto (tais como cigarros eletrônicos de sistema aberto ou fechado, e produtos de tabaco aquecido), e a possibilidade de regulá-los de forma distinta (art. 6º, X, do Decreto 10.411/2020);
- Ausência de coerência quanto à Alternativa recomendada em relação à regulamentação vigente para cigarros convencionais com combustão (art. 3º, IV, e 4ª-A da Lei 13.874/19 e 4º da Lei 13.848/19); e
- Ausência de uma efetiva análise de impacto regulatório e das externalidades positivas e negativas incidentes sobre cada uma das três Alternativas identificadas (art. 6º, XII do Decreto 10.411/2020).

A dizer, o Relatório parece ter sido elaborado por um caminho inverso do que o esperado de um processo supostamente orientado por uma metodologia científica, mediante o qual haveria a exploração e investigação do objeto (as Alternativas) de forma aberta, isenta e cientificamente embasada, culminando com uma conclusão.

Ao invés disso, os vícios identificados no Relatório levam a crer que, sob as vestes de um processo formal, o que se tem é uma conclusão apriorística, com uma posterior seleção de elementos para embasá-la e lhe conferir legitimidade aparente.

Neste contexto, é digno de nota que a PMB levantou como ponto de preocupação em sua contribuição uma aparente suspeição na condução do processo de AIR, uma vez que um dos colaboradores do corpo técnico da Anvisa responsável pelo Relatório já publicou, previamente à condução do atual processo de revisão da norma, estudos se manifestando de forma contrária a qualquer forma de regulamentação dos DEF¹. Soma-se a isso a ocorrência recente de uma aparente antecipação do voto da diretora designada para a relatoria da presente discussão, a qual externou sua posição a respeito do tema em entrevistas concedidas ao UOL em 27/04/2022 (ainda durante a fase de TPS, portanto) e ao editorial Joio e Trigo em 15/06/2022. Tal vocalização de voto antes da referida reunião para votação do tema – e até mesmo antes da conclusão da etapa de TPS - pode acabar por influenciar na condução do processo como um todo e, como tal, prejudicar seu curso regular e isento.

Novamente, embora respeitemos possíveis discordâncias técnicas por parte dos condutores do processo, nos causa espanto que todas as contribuições recebidas tenham sido analisadas, endereçadas, e, no que diz respeito a eventuais vícios apontados, o Relatório tenha sido corrigido em menos de 02 dias úteis. O tema é sabidamente complexo e, novamente, espera-se que as contribuições recebidas pela

¹ SILVA, Andre Luiz Oliveira da. MOREIRA, Josino Costa. A proibição dos cigarros eletrônicos no Brasil: sucesso ou fracasso? Disponível em https://doi.org/10.1590/1413-81232018248.24282017.

Agência tenham sido vultuosas, o que é compatível com o Relatório Parcial de mais de 265 páginas – sem contar anexos – submetido à TPS.

Considerando o açodamento da inclusão do tema em pauta, difícil concluir algo diverso do que a ocorrência de uma desconsideração das contribuições apresentadas pelos agentes afetados. Além disso, nos causa similar estranheza que, além do Relatório, conste na agenda da 11ª Reunião a aprovação de uma minuta normativa que, igualmente, parece ter sido elaborada antes mesmo do fim da referida etapa de TPS, sem considerar as manifestações tempestivas e válidas apresentadas pela sociedade, segundo critérios definidos pela Agência em edital. Ou seja, o TPS parece ser reputado como uma etapa irrelevante do processo de coleta de evidências científicas e participação social, antes o cumprimento de uma formalidade do que um exercício democrático legítimo.

A desproporcionalidade temporal com que o Relatório Final relativo aos DEFs foi produzido e pautado para votação após a conclusão da etapa de TPS, aliás, não encontra respaldo em nenhum outro precedente recente desta Agência. Pelo contrário, hoje há diversos outros processos administrativos de revisão de norma cuja etapa de TPS está encerrada há semanas ou meses, sem que o Relatório Final tenha sido concluído e pautado, o que é normal e esperado em um cenário no qual as contribuições recebidas estejam sendo efetivamente consideradas e analisadas.

Entendemos que a decisão final sobre o processo regulatório em curso cabe aos membros da Diretoria Colegiada. Tal decisão, contudo, deve estar embasada por subsídios técnico-científicos robustos, reunidos e avaliados de forma isenta e crítica, sempre tendo como horizonte a proteção da saúde pública. Fornecer tais subsídios seria o papel do Relatório, não fosse a existência dos já referenciados vícios nele identificados.

Submeter o Relatório à votação em sua atual formatação, portanto, empobrece o debate, dificulta a tomada de uma decisão informada pela Diretoria Colegiada e suscita questões acerca da conformidade legal do processo de revisão da regulamentação em curso, o qual, nos termos do art. 5º da Lei nº. 13.874/2019, dependeria da realização de uma efetiva – e não meramente formal – etapa anterior de AIR. Há uma clara violação não só do já referenciado Decreto 10.411/2020, mas também do próprio regramento da Anvisa acerca da realização de AIR, notadamente os arts. 10, 14, III, e 16 da Portaria 1741/2018 e art. 24 da Orientação de Serviço 56/2018. Adicionalmente, a condução do processo em curso deveria ter sido realizada conforme as melhores práticas indicadas pelo Guia para Elaboração de Análise de Impacto Regulatório da SEAE e pelo Guia de Análise de Impacto Regulatório da própria Anvisa (Guia nº 17/2021) – mas não é o que se verificou na prática.

Diante do exposto, solicitamos a vossa atenção para que, caso entenda pertinente, adote as providências necessárias para corrigir os vícios apontado, possibilitando que a Diretoria Colegiada tenha condições de tomar uma decisão isenta e técnica sobre o tema, considerando todos os riscos e benefícios envolvidos em cada um dos cenários avaliados, e, assim, evite a formação de um precedente negativo de condução de análise de impacto regulatório, incompatível com a tradição da Agência.

Cordialmente, Manuel Chinchilla Presidente

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