



WHO FRAMEWORK CONVENTION  
ON TOBACCO CONTROL

# **Best practices in implementation of Article 9 of the WHO FCTC Case study: Brazil and Canada**

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## **1. Introduction**

The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) was adopted by the 56th World Health Assembly in May 2003, and includes demand and supply reduction measures including Articles 9&10 on the regulation of tobacco-product contents and disclosures. The Conference of the Parties has adopted Partial Guidelines on the implementation of Articles 9&10, and a working group is actively engaged in advancing the discussion and proposing new elements to the Partial Guidelines in order to support Parties' efforts in addressing tobacco-product regulation. This report is an example on how two Parties to the WHO FCTC have implemented Articles 9&10 of the treaty and provides case studies of Brazilian and Canadian best practice. It also responds to the recommendations made at the Regional Meeting for the Implementation of the WHO FCTC in the Americas, held in Bogotá, Colombia, from 3-6 September 2013, which highlighted noteworthy efforts by the Parties to implement treaty articles.

This report describes efforts made by the governments of Brazil and Canada to comply with the requirements of the WHO FCTC in regulating tobacco-product contents (Articles 9&10). Whereas Article 9 deals with the testing and measuring of the contents and emissions of tobacco products and their regulation, Article 10 deals with the disclosure of information on such contents and emissions. This report will focus primarily on Article 9, nevertheless some reference to measures towards implementation of Article 10 will also be briefly covered.

## **2. Methodology**

This report is the result of a desk review of literature related to tobacco-control measures taken by the governments of Brazil and Canada in regulating the content of tobacco products as well as the disclosure of such contents. The literature review includes Brazilian and Canadian tobacco-control legislation, the 2014 reports on the implementation of the WHO FCTC submitted by Brazil and Canada, scientific journal articles, and reports in the public domain.

## **3. Requirements under the WHO FCTC**

Article 9 of the WHO FCTC states that Parties «shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measures, and for such regulation [of contents and emissions of tobacco products]».

Article 10 of the WHO FCTC states that «[e]ach Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about the toxic constituents of the tobacco products and the emissions that they may produce.»

## 4. The case of Brazil

### *Tobacco Control in Brazil*

Brazil uses a multi-faceted approach to tobacco control, with the Brazilian Commission for the Implementation of the WHO FCTC [Comissão Nacional para a Implementação da Convenção-Quadro para o Controle do Tabaco (CONICQ)] responsible for coordinating WHO FCTC implementation. Brazilian tobacco control is led, in different areas, by the National Cancer Institute [Instituto Nacional do Câncer (INCA)], the Ministry of Health [Ministério da Saúde] and the National Agency for Health Surveillance [Agência Nacional de Vigilância Sanitária (Anvisa)].

Following the FCTC negotiations, the Brazilian government created CONICQ by Presidential Decree on 1 August 2003<sup>1</sup>. The Commission is responsible for building and implementing a multisectoral agenda to address FCTC obligations and guidelines, and is chaired by the Minister of Health and composed of representatives of 18 agencies and ministries. INCA occupies the Executive Secretariat of CONICQ, and is also responsible for coordinating the National Tobacco Control Program [Programa Nacional de Controle do Tabagismo (PNCT)].

Anvisa, the federal regulatory agency, was established by Federal Law 9.782 in 1999<sup>2</sup>. Its mission is to «protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance». Anvisa enjoys administrative and financial autonomy, as well as independently appointed directors. Anvisa's Collegiate Board issues regulatory resolutions with legal power (hereafter, RDC) usually after public consultations and/or hearings. Anvisa was mandated, by law, to regulate, control and inspect tobacco products in 1999. Since 2000, a number of resolutions have been issued to regulate tobacco products, mandating disclosure of contents and requiring Anvisa to establish and oversee a tobacco-testing laboratory. Anvisa resolutions have been amended from time to time and those referred to in this paper constitute the latest versions.

Since 1989, a series of tobacco-control measures have been implemented in Brazil. These measures have been concomitant with a considerable reduction in smoking prevalence. The National Surveys conducted in 1989, 2003, 2008 and 2013 show a decrease in smoking among adults of more than one half - from 34.8% in 1989, to 22.4% in 2003, to 18.2% in 2008, and to 15% in 2013<sup>3</sup>. The last telephone-based survey in Brazilian capitals (Vigitel) has suggested that this trend continues, with estimated adult prevalence rates of 10.8% in 2014<sup>4</sup>.

## ***Towards fulfilling obligations under Article 9 of the WHO FCTC***

### **I) Regulation of tobacco ingredients**

Back in March 2001, Anvisa's RDC 46/2001 established maximum levels of tar, nicotine and carbon monoxide in cigarettes, and prohibited tobacco companies from using any descriptor on packaging or advertising materials that might induce the consumer to misinterpret the toxicity of cigarettes, such as «light, extra light, mild, low tar» and similar adjectives - making Brazil the first country in the world to implement this measure<sup>5</sup>. This regulation was revised and revoked by the publication, in March 2012, of RDC 14/2012<sup>6</sup>.

RDC 14/2012 also restricts the use of some additives in tobacco products. By adopting such measures, Brazil became the first country in the world to ban the use of additives including menthol in tobacco products. The resolution prohibits the use of «additives associated with alleged stimulating or invigorating properties, including taurine, guaraná, caffeine and glucuronolactone; pigments or colouring agents; fruits, vegetables or any product originating from the processing of fruits and vegetables, except charcoal and amides; sweeteners, honey, molasses or any other substance that can impart a sweet flavour, apart from sugars; seasoning, herbs and spices or any substance that can impart a flavour of seasoning, herbs and spices; ameliorants; and ammonia or any of its compounds and derivatives». An exception was made for sugar, allowing manufacturers to add it exclusively for the purpose of restoring the quantity lost during the tobacco-leaf curing process. Manufacturers and importers were granted a period of 18 months to comply with the resolution and another six months to withdraw all tobacco products containing any of those substances from the national market. In September 2013, this resolution was suspended by means of a federal injunction issued by the Federal Supreme Court following a lawsuit filed by the National Confederation of Industries on behalf of the tobacco industries. This will be discussed in more detail later.

## ***Related obligations under Article 10 of the WHO FCTC***

### **I) Disclosure of tobacco product ingredients<sup>1</sup>**

In accordance with the recommendations made in the Partial Guidelines for implementation of Articles 9&10, the Brazilian government has required the tobacco industry to disclose information on tobacco-product ingredients since 2001. The relevant directive is resolution RDC 90, of 27 December 2007<sup>7</sup>. This legislation requires the tobacco industry and importers to register all brands of tobacco products manufactured within the nation's borders, imported or exported, to use an Electronic Application System, and to renew it annually.

<sup>1</sup>“Ingredients” include tobacco, components (e.g. paper, filter), including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing), and substances that migrate from the packaging material into the product (contaminants are not part of the ingredients)

## II) Disclosure of emission levels in packaging

Brazil does not oblige manufacturers to disclose the level of tar, nicotine and carbon monoxide emissions on the packaging of tobacco products. Resolution RDC 335, from 2003, made the disclosure of such information by manufacturers optional<sup>8</sup>. In making this decision, Anvisa aimed to prevent smokers from erroneously interpreting the risks associated with the use of tobacco products, as recommended on the guidelines for implementation of Article 11. An indication of the contents might mislead consumers by giving the impression that cigarettes with lower levels are less harmful to health. This is untrue, as there are no safe levels of consumption.

## III) Disclosure information on product characteristics

Resolution RDC 90/2007 required manufacturers and importers to disclose analytical data concerning parameters and compounds in the mainstream, sidestream and the whole product<sup>11</sup>. According to Anvisa, the analyses must be performed by a laboratory using internationally accepted methods or based on an agreement or international convention ratified by Brazil. In 2012, Anvisa inaugurated the Laboratory of Tobacco and Derivatives [Laboratório de Tabaco e Derivados (LATAB)], the first laboratory in Latin American dedicated exclusively to the analysis of tobacco products. Its activity centres on research and validation of methodologies; furthermore LATAB will be able to develop new methods for determining compounds in tobacco products, analytical research on the composition of these products and advise on the development of new regulations for smoke compounds and additives<sup>9</sup>.

## IV) Disclosure of general company information

Anvisa requires the tobacco industry to register each brand, disclosing not only tobacco product contents and emissions but also general company information. National manufacturers and importers of tobacco products must submit to Anvisa an application to register the brand or provide information for each brand to be sold, imported or exported. After approval, tobacco companies are required to annually renew the registration for each brand, and to pay an annual fee, as mandated in Federal Act 9.782/99. Since the programme began in 1999, two major tobacco companies have filed lawsuits against the rate fee charged by Anvisa and have since deposited the disputed sums under court-sanctioned control<sup>10</sup>.

### ***The experience of Brazil in banning additives***

As stated in the Partial Guidelines for the implementation of Articles 9&10, the effects of tobacco products can be reduced in a variety of ways including adding ingredients, eliminating substances with known irritant properties, balancing irritation alongside with other significant sensory effect, or altering the chemical properties of tobacco product emissions by adding or removing substances.

Knowing that additives or other substances may impart, modify, improve or intensify the taste and aroma of tobacco products, thereby making tobacco products more palatable for

<sup>11</sup> Requested parameters and compounds are specified in Annex I of the RDC 90/2007, available at: [http://portal.anvisa.gov.br/wps/wcm/connect/5d1f1e804745973d9f98df3fbc4c6735/2008-03-28\\_RDC+090\\_Republicada\\_28Mar08\\_OK\\_PDF.pdf?MOD=AJPERES](http://portal.anvisa.gov.br/wps/wcm/connect/5d1f1e804745973d9f98df3fbc4c6735/2008-03-28_RDC+090_Republicada_28Mar08_OK_PDF.pdf?MOD=AJPERES)

first-time users, Anvisa issued Resolution RDC 14/2012 prohibiting the commercialization of tobacco products that contain any synthetic and/or natural additive with aromatizing and flavouring properties<sup>6</sup>. Anvisa's resolution is currently the strongest anti-additive legislation in the world. However, prior and subsequent to the publication of this resolution, Anvisa faced an arduous public debate and hostile campaigning from the tobacco industry and its allies against the proposal<sup>11</sup>. As we will discuss below in more detail, the tobacco industry articulated several strategies to block Anvisa's resolution, including political manoeuvres within the Brazilian Congress.

Prior to the publication of the RDC 14/2012, Brazil, along with 25 other Parties, was a member of the working group for the development of guidelines for implementation of Articles 9&10. In 2010, before COP4, there was disagreement within the Brazilian government over adoption of the guidelines. On the one hand, the Ministry of Health and the Ministry of Agrarian Development supported Brazil's position during COP4 favouring the guidelines. On the other hand, the Ministry of Agriculture supported arguments made by the tobacco industry, which argued that adoption would have damaging economic consequences<sup>12</sup>. This campaign against restrictions on tobacco additives was denounced by the Alliance for Tobacco Control [Aliança de Controle do Tabagismo (ACT)], a Brazilian NGO<sup>13</sup>. It declared that Afubra [Associação dos Fumicultores do Brasil], the Brazilian member of the International Tobacco Growers Association (ITGA), and the Tobacco Industries Syndicate [Sindicato Interestadual da Indústria do Tabaco (SindiTabaco)], had falsely claimed that restrictions on tobacco additives would pose a threat to more than 50,000 tobacco growers, especially those producing Burley tobacco<sup>13</sup>, and cause job losses. The dispute within the government resulted in an agreement brokered by the Casa Civil (the Chief of Staff to the Presidency). It was decided that Brazil would remain neutral at COP4, and that Anvisa would not regulate additives unless the partial guidelines were adopted<sup>14</sup>.

Following the adoption of the partial guidelines at COP4, Anvisa's Office of Tobacco Products [Gerência de Produtos Derivados do Tabaco (GPDTA)], presented the Agency's Collegiate Board of Directors [Diretoria Colegiada (DICOL)], with a proposal to ban additives in tobacco products. Anvisa submitted the proposal for public consultation (CP 112/2010), seeking suggestions on permissible levels of tar, nicotine and carbon monoxide in cigarettes, and on the prohibition of additives or any flavourings, such as menthol, clove, fruits, aromatic spices and the like, in tobacco products<sup>15</sup>. Anvisa received public support from international health organizations as well as from Brazilian civil society and tobacco-control advocates<sup>IV</sup>. It also received scientific support from Canadian experts, which suggests that the agency sought support from other governments that had already partially banned additives, such as Canada and United States<sup>15</sup>. Support for Anvisa's move was also proffered by governments such as those of Canada and US, which expressed their support during the public hearings.

The public consultation generated a series of strong responses from the tobacco industry and its allies, against both Anvisa and the proposed additive ban. First, the Brazilian Congress proposed suspension of the effects of Anvisa's public consultation. Second, a

<sup>III</sup> Burley tobacco is air-cured and tends to be bitter so that it requires additives in order to make it palatable.

<sup>IV</sup> Campaign for Tobacco-Free Kids, the Pan American Health Organization, the Tobacco Free Initiative of the World Health Organization, the International Union Against Tuberculosis and Lung Disease, Johns Hopkins University, ACTBR, CONICQ, Department of Socio-Economic Rural Studies (DESER), Brazilian Federal Council of Medicine.

study commissioned by the tobacco industry was released concerning the socioeconomic risks that the proposal could pose, which was later deemed inaccurate by national and international entities<sup>16</sup>. Third, a total of 128,386 responses (481 emails and 127,905 letters) to the public consultation were sent to Anvisa, of which only 10 had contained considered contributions, inevitably delaying the process<sup>14</sup>. Fourth, the industry requested a concession allowing the industry to add sugar lost from tobacco leaves in the curing process, which was accepted by Anvisa. Fifth, another proposal from the Brazilian Congress suggested the omission of menthol from the list of banned additives. Finally, a proposal to allow the use of clove and menthol in tobacco products was made during a discussion at Brazil's presidential cabinet by means of a Provisional Measure (MP 540/11<sup>17</sup>). This proposal, backed by the tobacco industry, was made during a debate on the taxation of industrialized products, rather than tobacco additives<sup>11</sup>.

Civil society, tobacco-control advocates and international health organizations worked closely to counteract the tobacco industry's strategy to foil Anvisa's proposals: ACT lobbied legislators to support tobacco-control measures, as well as Anvisa's right to regulate tobacco, by distributing factsheets and briefing materials to members of congress; ACT launched a media campaign listing reasons for banning additives in tobacco products (see Picture 1); the NGO also sent a letter to Brazil's President and to the Minister of Health requesting support from the Casa Civil for on the public consultation<sup>18, 19</sup>.

A study undertaken by the National School of Public Health (ENSP), in partnership with the Federal University of Rio de Janeiro (UFRJ) and INCA has analyzed data from school-based surveys conducted between 2005-2009 in the capitals of 13 Brazilian states. The study result showed that out of the 5,700 students listed as smokers, 54% preferred flavoured cigarettes, with 38% preferring menthol and 16% other flavours such as chocolate, strawberry, clove etc<sup>20</sup>. Using scientific data such as this, as well as other research conducted by the technical department at Anvisa, and despite continuing tobacco industry lobbying, Anvisa successfully published RDC 14/2012 restricting the use of additives in tobacco products. Its implementation and enforcement were scheduled for September 2013.

Brazil's participation as a member of the working group to develop the partial guidelines for Articles 9&10 allowed Anvisa to exchange lessons and experience with other Parties. Even though the regulation was published after the adoption of the Partial Guidelines at COP4, its drafting began beforehand and was heavily influenced by the technical knowledge acquired by Anvisa during the working group meetings. Canada's experience in partially banning additives provided Anvisa with useful information, allowing Anvisa, unlike Canada, to propose a full ban on additives including menthol<sup>14</sup>.

As expected, resolution RDC 14/2012 was contested in a series of legal actions. Sindi-Tabaco brought a suit to stop Anvisa from implementing the resolution in the Federal District and Bahia State Courts. In both cases, courts granted a preliminary injunction halting implementation of the rule. Anvisa successfully appealed the preliminary injunctions, with the support of Brazil's Attorney General Office (AGU) and the Brazilian Federal Prosecution Office. In November 2012, the National Confederation of Industry (CNI) challenged the constitutionality of part of the law that established Anvisa (Law 9.782), through a lawsuit at the Supreme Federal Court (STF), entitled Direct Unconstitutionality Action (AID) 4874/2012, arguing against Anvisa's right to regulate tobacco products and, therefore, the legitimacy of the RDC 14/2012<sup>21</sup>. In September 2013, when the additive regulation was due to take effect, the Supreme Court granted an injunction to suspend it.



Escondemos este cigarro aqui para chamar a sua atenção. A indústria do tabaco faz o mesmo com crianças e jovens.

Embalagens coloridas, sabores, aromas e exposição próxima a doces. Parece coisa de criança, mas é estratégia da indústria de tabaco. Nós lutamos contra tudo isso. A indústria do tabaco está de olho nas crianças e jovens. Fique de olho nela.

29 de agosto. Dia nacional de combate ao fumo. **#LIMITETABACO**

**ACTbr**  
Aliança de Controle do Tabagismo

Picture 1

The Brazilian Association of Tobacco Industry [Associação Brasileira da Indústria do Fumo (Abifumo)], then submitted a petition asking Anvisa to allow 145 substances to be used as additives in tobacco products. Anvisa's Collegiate Board of Directors decided to partially accept the appeal, and through the Normative Instruction IN 06/2013, authorized the preliminary use of 121 additives for a period of one year<sup>22</sup>. The ban on menthol, clove and other additives imparting flavours to tobacco products was maintained.

In order to evaluate use of the 121 additives temporarily sanctioned, Anvisa established a Working Group of independent experts. In August 2014, the Working Group concluded, inter alia, that there was sufficient evidence to support a ban on additives, and «that the RDC 14/2012, when fully implemented, [would have] the potential for significant reductions in tobacco consumption and therefore significant reduction in tobacco-related diseases and death». Furthermore, the group recommended that RDC 14/2012 should be amended so that sugars would no longer be excluded from the additives ban<sup>23</sup>. As of June 2015, the Supreme Court injunction allowing the use of additives remains in force, with a final decision still awaited.

### ***The way forward: Opportunities for further strengthening***

Measures that could strengthen Brazilian efforts to regulate the contents of tobacco products:

- Brazil's Supreme Federal Court should be urged to give a final verdict to the injunction presented by CNI, and Brazil should strongly promote the enforcement of Anvisa's resolution RDC 14/2012;
- Legislative and enforcement action should support Anvisa's legal right to regulate tobacco products;
- Anvisa should adopt the conclusions of the Working Group established by the decision of its Collegiate Board of Directors on additives and prohibit the use of all additives, including sugar.

## **5. The case of Canada**

### ***Tobacco Control in Canada***

Canada started its tobacco control efforts in 1963 and since 1988 the country has been successfully implementing increasingly tough tobacco-control legislation. In 2010, Canada was the first country in the world to ban the use of selected additives, including most flavours, in little cigars, cigarettes and blunt wraps.

Strict measures taken by the Government of Canada on tobacco control, as well as provincial and territorial efforts, have played a role in lowering the prevalence of tobacco use. Surveys have shown that the percentage of current smokers dropped to 15% in 2013 from 25% in 1999 - with 15% representing the lowest national smoking rate ever recorded<sup>27</sup>.

The Canadian Department of Health, known as Health Canada, is responsible for the administration and enforcement of the federal Tobacco Act passed in 1997, which regulates the manufacture, sale, labeling and promotion of tobacco products. Health Canada inspectors

monitor compliance with the federal Tobacco Act across all levels of the supply chain, from manufacturers, distributors and importers to retailers. Health Canada inspectors have the power to issue warnings, seize non-compliant products, and/or refer cases for prosecution. Since health in Canada is a shared jurisdiction between federal, provincial and territorial governments, tobacco control measures have also been adopted at provincial and territorial levels.

Health Canada also leads the implementation of the Federal Tobacco Control Strategy (FTCS) of the Canadian Government, which is a collaborative effort, intended to reduce tobacco use in Canada<sup>25</sup>. It is composed of numerous federal agencies, including Canada Revenue Agency, Canada Border Services Agency, Public Safety Canada and the Royal Canadian Mounted Police.

In 2000, two important regulations were adopted pursuant to the Tobacco Act: the Tobacco Reporting Regulations and the Tobacco Product Information Regulations<sup>26, 27</sup>. In 2011, the Tobacco Product Labelling Regulations were adopted to strengthen the labelling of cigarettes and little cigars<sup>28</sup>.

### ***Towards fulfilling obligations under Articles 9 and 10 of the WHO FCTC***

#### **I) Regulation of tobacco ingredients**

The Canadian government recognizes the importance of regulating tobacco additives<sup>v</sup> in order to decrease tobacco products' attractiveness and help prevent tobacco use among youth. In 2009, with the enactment of the Cracking Down on Tobacco Marketing Aimed at Youth Act, also known as Bill C-32, Parliament amended the Tobacco Act to address the marketing of flavoured tobacco products to young people<sup>29</sup>.

The 2009 amendment also prohibits the use of selected additives in the manufacture of cigarettes, little cigars and blunt wraps. Among the banned additives are most flavourings, as well as sugars, sweeteners, vitamins, mineral nutrients, fruits and vegetables and essential fatty acids<sup>vi</sup>. Nevertheless, the legislation does not cover all tobacco products. Cigarillos weighing over 1.4g, regular cigars<sup>vii</sup>, pipe tobacco, smokeless tobacco and sheesha (waterpipe tobacco) were not included. Nor does the ban include all additives, allowing for instance, the continued use of menthol.

#### **II) Disclosure of tobacco product ingredients**

In line with the Partial Guidelines for implementation of Articles 9 and 10, Canada requires manufacturers and importers to provide information on tobacco-product ingredients as set out in the Tobacco Reporting Regulations<sup>26</sup>. Manufacturers of the different tobacco products are obliged to compile a quarterly report including information and analytical data for each ingredient and their components by brand and type of product. Among the information required are the common, chemical and commercial names of the ingredient; the biological

<sup>v</sup>Pursuant to the Tobacco Act, « additive » means an ingredient other than tobacco leaves.

<sup>vi</sup>See Annex 1 for the list of prohibited additives.

<sup>vii</sup>Through an amendment taking effect in December 2015 more types of cigars and cigarillos are being covered.

origin, if applicable; the registry number in accordance with the Chemical Abstracts Service of the American Chemical Society; the amount in milligrams per gram of the consumer tobacco product, paper, tube or filter (and in the case of bidi, cigarette, cigar, tobacco stick or kretek, per unit of product). Manufacturers must also provide information such as name, address and contact information of each ingredient's supplier and country of origin.

### III) Disclosure of emission levels in packaging

As part of the Tobacco Product Labelling Regulations (Cigarette and Little Cigars)<sup>28</sup> adopted in 2011, Canadian manufacturers and importers are no longer obliged to disclose the emission levels of nicotine, tar, carbon monoxide, benzene, hydrogen cyanide and formaldehyde on cigarette packages. Instead, qualitative statements about various emissions must be displayed on the package.

### IV) Disclosure of information on product characteristics

Canada was the first country to amend the smoking conditions set out in the International Organization for Standardization standard ISO 3308, entitled Routine analytical cigarette-smoking machine — Definitions and standard conditions, to test and measure cigarette smoke emissions more intensely (known as the Canadian Intense Method<sup>VIII</sup>).

Since 2001, manufacturers and importers are required to disclose to Health Canada the levels of selected chemicals in the mainstream and sidestream smoke of cigarettes and other combustible tobacco products and as contents in the unburned tobacco. The regulations also stipulate the method to be used to test and measure each analyte. Canadian regulations oblige laboratories that perform analytical tests to be accredited under International Organization for Standardization standard ISO/IEC 17025, and to disclose the analytical methods used. In addition to these measures, Canada was the first country to require that cigarettes meet a reduced ignition propensity standard, to reduce fire risks from lit cigarettes.

### V) Disclosure of general company information

The Canadian Tobacco Act requires manufacturers to disclose general company information, including the name, address of tobacco-manufacturing establishments, a list of every consumer tobacco product manufactured, and related sales volumes by province, by brand and by each type of package and carton, including duty-free sales.

### ***Canada's experience in implementing the ban on additives***

Starting in the early 2000s, small flavoured cigars became increasingly popular among Canadian youth, making up the majority of the threefold increase (from 200 million units in 2001 to approximately 649 million units in 2009) in cigar. Whereas the sale of flavoured cigars increased rapidly, the sale of traditional cigars remained steady during the same pe-

<sup>VIII</sup>The Canada Intense Method consists of increasing the puff volume from 35ml to 55ml; decreasing puff interval from 60 to 30 seconds; and blocking all ventilation holes using tape. It was designed to generate emissions under a more intensive set of smoking parameters that would provide a "maximum" exposure limit that could be exceeded only by very few smokers

riod<sup>30</sup>. As mentioned above, in 2009, the Canadian Government responded to the increased popularity of flavoured tobacco products by introducing an amendment to the Tobacco Act to include a ban on the use of additives in the manufacture of cigarettes, little cigars, and blunt wraps.

During review of the Bill before Parliament (both the House of Commons and the Senate) in 2009, concerns were raised by interested parties, mainly related to: the exemption of menthol from the additives ban; the legislation's anticipated impact on trade between the U.S. and Canada; and the possible impact on contraband tobacco<sup>34</sup>.

Health Canada representatives testified before the House of Commons that the 2009 proposed amendment did not include a ban on menthol because its focus was on targeting products that have a greater impact on tobacco consumption among young people, such as fruit and candy flavours<sup>32</sup>. Because research indicated that sales of menthol-flavoured cigarettes had been declining and was used by only about 2% of smokers in Canada, Health Canada did not see that banning menthol would help prevent young people from trying tobacco at the time<sup>31</sup>.

The proposed amendment also raised concerns among U.S. congressmen who feared that banning the use of additives such as sugars and flavours would hurt the sale of U.S. Burley tobacco in Canada, and that this could be discriminatory and a possible violation of international trade agreements, including the North American Free Trade Agreement (NAFTA)<sup>33</sup>. Senate members also suggested the ban on legitimate American-blend cigarettes might actually result in a bigger market for illegal cigarettes manufactured in the U.S. and smuggled into Canada<sup>34</sup>.

Phillip Morris International (PMI) attacked the proposed amendment, claiming that the Bill would prohibit the manufacture in Canada, for export, of American-blend cigarettes, costing jobs at its Canadian manufacturing plant (see picture 2). PMI managed to mobilize workers from its Canadian operations at Rothmans, Benson & Hedges to protest against the ban on additives and threatened to close a Quebec factory that employs more than 300 people<sup>35, 36</sup>.

Despite the concerns expressed by the tobacco industry and the campaign against it, the proposed amendment received support from a majority of Canadian parliamentarians. It also received support from the Canadian Cancer Society, the Canadian Lung Association, and the Heart and Stroke Foundation. American-blend cigarettes continue to be sold in Canada, but now without the additives prohibited by the Canadian legislation.

In 2011, two years after adoption of the amendment, the Secretariat of the Technical Barriers to Trade Committee, part of the World Trade Organization (WTO), reported that 29 members states, including some that are also Parties to the WHO FCTC, had raised special trade concerns regarding the new Canadian legislation. Some of the member states, which claimed to support Canada's objective to reduce tobacco consumption and protect the health of young people, declared that Canada's legislation was discriminatory. They asserted that the measure was more trade restrictive than necessary to achieve Canada's objective. They also noted that Canada had not complied with its transparency obligations under the TBT Agreements, since it did not notify other WTO Members about its measure at an early appropriate stage. In response, Canada's representative at the WTO «emphasized that the Act prohibited the use of certain additives which contributed to making products more attractive to youth regardless of their origin and did not ban any type of tobacco or tobacco product»<sup>37</sup>. In the end, the measure was not formally disputed.

# Banned in Canada?



Politicians in Canada are rushing through a new law that would ban the manufacture or import of American blend cigarettes while not banning the more popular Canadian tobacco. This discriminatory bill, that targets American growers of burley tobacco and American cigarettes, will endanger thousands of jobs and further damage trade relations between the United States and Canada.

The legislation, C-32, is on the fast track in Canada. If Democrats and Republicans don't speak out now, other countries may follow Canada's protectionist lead. Canada's path could destroy an entire segment of the American tobacco farming community.

**Tell the Canadian Parliament to stop and think before they destroy  
American jobs and increase trade tensions.**

**Fix C-32 before it is enacted.**

Burley Stabilization Corporation • Burley Tobacco Growers Cooperative Association • Council for Burley Tobacco Inc. • Fair Products Inc.  
International Tobacco Growers Association • North Carolina Agribusiness Council • North Carolina Farm Bureau • North Carolina Growers Association  
Palmetto Agribusiness Council • Philip Morris International Inc. • Tobacco Growers Association of North Carolina • Virginia Farm Bureau

Picture 2

## ***Challenges in implementing the ban on selected additives***

After adoption of the 2009 amendment, the tobacco industry exploited a loophole in the legislation<sup>38</sup>. As mentioned above, the new legislation covered little cigars which were defined as cigars weighing no more than 1.4g or with a cigarette filter. It also covered cigarettes and blunt wraps, but left out other tobacco products.

To avoid the new restrictions, some manufacturers of candy-flavoured cigarillos increased the size of their cigarillos by replacing filters with additional tobacco<sup>39</sup>. Since cigars other than little cigars were not subject to the ban on additives, Health Canada's efforts were undermined by the industry. Indeed, the tobacco industry continued to sell flavoured cigars, albeit larger than little cigars, which were attractive to some young people, in defiance of the intent of the legislative amendment.

In order to address this loophole, an amendment to the Schedule to the Tobacco Act was adopted in 2015<sup>IX</sup>. The amendment extended the ban on selected additives to cigars weighing more than 1.4g but not more than 6g and on cigars having physical characteristics similar to those of cigarettes or little cigars, such as tipping paper or a wrapper with a straight seam<sup>30</sup>. However, the use of certain additives that impart aroma associated to port, wine, rum or whisky, which are generally appealing to adults, is allowed, as is the continued use of menthol<sup>40</sup>.

## ***Impact of the legislation***

While it may not currently be possible to fully evaluate the impact of the 2009 legislative amendment on youth smoking of cigarillos/little cigars, data from Canadian surveys suggest a reduction in the use of cigarillos/little cigars after the enactment of the legislation.

In 2009, prior to the adoption of the legislation, the use of cigarillos/little cigars, among 15-19 year-olds was 8%, and among the 20-24 year-olds it was 11%. In 2011, after the adoption of the legislation, the use of cigarillos/little cigars declined to 5% among 15-19 year-olds and to 7% among 20-24 year-olds. With regards to the use of cigarillos/little cigars among secondary school students in grades 10-12, consumption declined from 14% in 2008/9 to 9% in 2010/11<sup>41</sup>.

Finally, with respect to the concern raised regarding the potential impact on the new measure on the illicit trade of tobacco, which could constitute a serious threat to public safety and health, there is no evidence to demonstrate that the adoption of the legislative amendment has increased the contraband market.

## ***Recommendations***

Measures that could strengthen Canadian efforts in regulating tobacco contents include an implementation of a ban on menthol and other flavourings in tobacco products that are not yet covered in the regulations.

## **6. Recent advanced practice - The case of European Union**

Tobacco consumption is the single largest avoidable health risk in the European Union (EU), responsible for approximately 700,000 deaths every year. Most smokers in the EU began at a very young age, with approximately 70% starting before the age of 18 and 94% before the age of 25<sup>42</sup>.

Driven by other Parties of the WHO FCTC that have developed regulatory approaches in order to prevent young people from smoking initiation, and aware of new scientific evidence on tobacco flavourings, the EU recently adopted an updated Tobacco Product Directive (TPD) prohibiting cigarettes and roll-your-own tobacco with characterizing flavours.

Directive 2014/40/EU of 3 April, 2014 entered into force in May 2014 and the new rules will be applied in the first half of 2016<sup>43</sup>. The Directive recognizes the need to implement legal action at Union level regarding, inter alia, the regulation of tobacco product contents, aiming to reduce differences between the approaches to tobacco regulation among the 28 EU Member States<sup>42</sup>. In Article 7 of the Directive, it is established that Member States shall prohibit the sale of tobacco products containing additives, such as: vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks; caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality; additives having colouring properties for emissions; additives that facilitate inhalation or nicotine uptake, such as menthol; and additives that have carcinogenic, mutagenic or reprotoxic properties in unburnt form. Cigars, cigarillos and smokeless tobacco are still exempt from the ban on characterizing flavours originally, but will be considered if use and/or sale among young people increases significantly. The Directive also requires the tobacco industry to submit detailed reports to the Member States on the ingredients used in tobacco products, in particular cigarettes and roll-your-own tobacco.

Intensive lobbying from the tobacco industry and associated groups marked the development and adoption of the Directive. It was referred as the «most lobbied dossier in the history of the EU institutions»<sup>44</sup>. The tobacco Industry strongly lobbied Members of the European Parliament with pro-tobacco arguments, interfering with the process. Efforts to amend and delay the proposal were partially effective, which raised concerns about compliance with Article 5.3 during the process<sup>45</sup>. Poland took the lead against the TPD and was one of the four countries that voted against it. Influenced by Polish tobacco growers and cigarette manufacturers, the Polish government opposed the TPD alleging that the ban on additives, more specifically menthol, would unfairly affect Poland, since it is one of the region's biggest consumers and producers of menthol cigarettes<sup>46, 47</sup>.

While the TPD does not ban all additives, it is a step forward for reducing consumption among young people, and represents a significant public health advance. Since the Directive was only recently adopted, there are no studies showing the impact of the measure, but the European Commission expects to see a 2% drop in consumption of tobacco over a period of five years after legislation is implemented.

<sup>IX</sup> Recent developments with respect to restrictions on flavouring additives have also taken place at the provincial level. Starting May 31, 2015 the province of Nova Scotia, through the recent adoption of the Tobacco Access Act (Amended), has banned the sale of flavoured tobacco. Regulations, however, exempt «Port, rum, wine and whiskey flavoured cigars that are 5g or more and \$4 or more.» Starting June 1, 2015 flavoured tobacco products are banned in the province of Alberta, with some exceptions (cigars that cost more than \$4 each and weigh five grams or more, as well as pipe tobacco). Products that impart a clearly noticeable smell or taste of menthol and do not also impart another characterizing flavour are also exempted, but only until September 30, 2015; after that, date they will be banned as well. A third Canadian province, New Brunswick, has just passed legislation to ban flavoured tobacco products, including those containing menthol, effective January 1, 2016.

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