



## The World Health Organization's Framework Convention on Tobacco Control (WHO FCTC)

### Introduction

One of the major issues raised about tobacco control within the public policy circle is the employment effect of tobacco control policies, and the significance of the structural costs associated with exit of growers from farming. While the loss of jobs in the tobacco industry (tobacco farming, manufacturing and distribution) is evident, advocates of tobacco control argue that it can be countered by a gain in employment in another industry so that there would be no net loss. This argument is in fact based on the premise that consumers of tobacco products would switch their spending on tobacco products to other products and services in the non-tobacco sector, thereby allowing the creation of new or additional demand in the non-tobacco sector. However, when exports account for a larger share of the local production such as in the United States where the tobacco industry is employing hundreds of thousands of people, the plausibility of the above premise tends not to be tenable. The adoption and implementation of tobacco control measures by countries that import U.S. tobacco and tobacco products, particularly members of EU, Russian Federation, Japan, South Korea and Middle Eastern countries could have important implications for U.S. tobacco growers.

This issue of *FDA Issue Briefs* presents the set of tobacco control measures that U.S. tobacco and cigarette importing countries have agreed to adopt and implement as part of the WHO FCTC, and compares them with that of the Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA) which became public law on June 22, 2009, granting the Food and Drug Administration (FDA) a regulatory authority over tobacco products.

The WHO FCTC is a global tobacco control treaty that was formally initiated at the 48<sup>th</sup> World Health Assembly in 1995. After years of negotiations it was adopted at the 56<sup>th</sup> World Health Assembly on May 21, 2003, and entered into force on February 27, 2005.

The institutional arrangement of the WHO FCTC is that the Conference of Parties (COP), which is comprised of all the member countries and/or States who have signed and ratified the treaty (called Parties), is the governing body of WHO FCTC. Note that

Parties are bound under international law to comply with the provisions of the treaty. As of November 2009, the WHO FCTC had 171 Parties. Countries such as the United States that are signatories but have not yet become Parties to the Framework Convention are under no obligations to comply with the provisions of the treaty.

The WHO FCTC has a permanent secretariat designated by the COP who is housed in the WHO's Headquarters in Geneva. The head of the Convention Secretariat is accountable to the COP, and also to the Director-general of WHO. The COP also has an administrative unit called the Bureau of COP, consisting of a President and five Vice-Presidents, each representing a WHO region (Africa, the Americas, south-east Asia, Europe, eastern Mediterranean and western pacific). The six officers are elected at each regular session of the COP to serve only one term, which lasts between the end of the regular session in which they were elected and the end of the next regular session at which point another similar group of officers is elected.

### **Provisions of the WHO FCTC**

The WHO FCTC has 38 Articles of which 12 are dedicated to outlining a set of provisions relating to the reduction of the demand and supply of tobacco products. The demand reduction provisions ranging from prevention to cessation of the use of tobacco are organized into Article 6 (price/tax measures), and Articles 7-14 (non-price measures). Those relating to the reduction of the supply of tobacco products are organized into Articles 15-17 (illicit trade in tobacco products, sales to and by minors, and provision of support for economically viable alternative activities). Table 1 compares the provisions of the WHO FCTC and FSPTCA of 2009. Full text of the Framework Convention is available at <http://whqlibdoc.who.int/publications/2003/9241591013.pdf> and that of the Act is available at <http://tobaccogrowerresearch.com/fda/TobaccoControlAct.pdf>.

It is important to note that the WHO FCTC does not spell out specific rules for countries or States to adopt legislatively or administratively. Rather, it lays down general obligations and guidelines to assist them in meeting their obligations under the different articles that could reduce demand and supply of tobacco products.

### **Review of COP Activities**

The COP meets for regular sessions to review the implementation of the provisions of the different articles of the Convention and make decisions necessary to promote an effective implementation. Thus far, the COP has met four times from 2006 to 2010.

- At the first session held in Geneva in February of 2006 the Rules of Procedure and Financial Rules for the COP were adopted by consensus.
- At its second session held in July of 2007, the COP adopted guidelines and recommendations for the implementation of Article 8 (protection from tobacco smoke).

- Similarly, at its third session held in November of 2008, the COP adopted guidelines and recommendations for the implementation of Article 5.3 (protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry), Article 11 (packaging and labeling of tobacco products) and Article 13 (tobacco advertising, promotion and sponsorship).
- At the fourth session held on November 15-20, 2010, the COP deliberated on a host of issues, including the guidelines on the regulation of the contents of tobacco products and of tobacco product disclosures (Articles 9 and 10).

Emphasizing that the aim of the guidelines is to assist Parties in meeting their obligations and to provide guidance for implementation of these articles, the COP has adopted partial guidelines for implementation of both articles, which are available at [http://apps.who.int/gb/fctc/PDF/cop4/FCTC\\_COP4\\_28draft-en.pdf](http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_28draft-en.pdf).

One of the recommendations in the adopted partial guidelines is: “Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products.” The emphasis being on ingredients which have coloring properties, and help create the impression that such products have health benefits, or create the impression that they present reduced health hazards. Emphasis is also on ingredients (e.g. such as caffeine) associated with energy and vitality.

According to the guidelines, ingredients necessary for the manufacturing of tobacco products and not linked to attractiveness should be subject to regulation according to national law. No recommendation has been made regarding regulation of ingredients that contribute to addictiveness and toxicity. It is indicated that guidance will be proposed in phases in the future as new scientific and medical evidences become available.

At this point, the focus has been on assisting Parties in implementing measures that would reduce or prohibit attractiveness of tobacco products. Even so, the recommendations are open-ended, encouraging national governments to implement measures beyond those recommended in the partial guidelines. The fact that the regulation of ingredients is at the discretion of national governments means that the potential is always there for some countries to prohibit or restrict all ingredients used in tobacco products. A good example is the Canadian tobacco control legislation (referred to as the Cracking Down on Tobacco Marketing Aimed at Youth Act) that became law on October 8, 2009, banning the sale of cigarettes, little cigars and blunt wraps that contain specified additives, including most flavoring agents.

With respect to Article 10 (regulation of tobacco product disclosures), recommendations included:

- Parties should ensure that manufacturers and importers disclose to government authorities the types and quantities of ingredients used in the manufacture of tobacco products.
- Parties should require manufacturers and importers of tobacco products to disclose information on design features and provide a copy of results of laboratory tests performed for measurement of a particular design feature to governmental authorities.
- Parties should require manufacturers and importers of tobacco products to disclose further information on the characteristics of the tobacco leaves used, including the type (s) of tobacco leaves (e.g., Virginia, Burley, Oriental), and the percentage of each type used in the product type.

No recommendation was made on disclosure and regulation of constituents. It was suggested that guidance would be provided in the future.

The COP has also deliberated on Article 17 and 18 (provision of economically sustainable alternatives to tobacco growing and protection of the environment). The COP's decision on these articles was to request the assigned working group to continue its work and to submit a working report to the COP at its fifth session in 2012 that may include, inter alia, policy options and recommendations for implementation of both articles.

Other articles deliberated at the fourth session include Article 12 (education, communication, training and public awareness), and Article 14 (demand reduction measures concerning tobacco dependence and cessation) of the WHO FCTC. The decision of the COP with respect to both these articles was adoption of the proposed guidelines for implementation of the respective articles.

In addition, the COP hosted presentations on comprehensive technical report relating to Article 6 (price/tax policies), and decided to establish a working group composed of fiscal and health experts for the elaboration of guidelines for implementation of the article. The working group shall present a progress report or, if possible, draft guidelines for consideration by the COP at its fifth session (2012). Furthermore, the COP deliberated on a set of measures that would contribute to the elimination of cross-border advertising, promotion and sponsorship (in relation to recommendations on Article 13 of the Convention), protocol to eliminate illicit trade in tobacco products, control and prevention of smokeless tobacco products and electronic cigarettes (proposed by a Party) as well as implementation of Article 19 of the Convention, that is "Liability" (proposed by a Party). For detailed information, please visit [http://apps.who.int/gb/fctc/E/E\\_cop4.htm](http://apps.who.int/gb/fctc/E/E_cop4.htm).

Table 1: Provisions of the WHO FCTC and FSPTCA of 2009

WHO FCTC	FSPTCA of 2009
Key provisions of tobacco demand and supply reduction Articles	Provisions of the Act
<p><b>Article 6: Price and Tax measures to reduce the demand for tobacco</b></p> <p>Each Party should implement tax policies, where appropriate, price policies on tobacco products</p> <p>Each Party should prohibit or restrict, as appropriate, sales to and/or importation by international travelers of tax-and duty-free tobacco products</p> <p>Each Party shall provide tax rates and trends of consumption of tobacco products in periodic reports to the COP</p>	<p>The FSPTCA does not include excise tax measure. However, the State Children’s Health Insurance Program Reauthorization Act of 2009 (SCHIP) that was signed into law on February 4, 2009, raised the Federal excite tax on cigarettes from \$0.39 per pack to 1.01 per pack, effective on April 1, 2009.</p>
<p><b>Article 7: Non-price measures to reduce the demand for tobacco</b></p> <p>Each Party shall adopt non-price measures necessary to implement its obligations pursuant to Articles 8 to 13</p>	<p>The Act includes a set of specific demand reduction provisions.</p>
<p><b>Article 8: Protection from exposure to tobacco smoke</b></p> <p>Each Party shall adopt and implement measures providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places.</p>	<p>Protection from exposure to smoke was not part of the Act. However, several states and local governments have implemented a ban on smoking in public and work places.</p>
<p><b>Article 9: Regulation of the contents of tobacco products</b></p> <p>The COP shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions.</p> <p>Each Party shall, where approved by competent national authorities, adopt and implement effective measures for such testing and measuring, and for such regulation</p>	<p>The Act require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and sub-brand</p> <p>The Act prohibits use of candy, fruit, and spice flavors as characterizing flavors</p>
<p><b>Article 10: Regulation of tobacco product disclosures</b></p>	<p>The Act requires the provision of information to FDA about ingredients; smoke constituents, additives, and other relevant industry</p>

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<p>Each Party shall 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.</p> <p>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.</p>	<p>documents (health-related and marketing-related studies).</p> <p>The Act also may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives.</p>
<p><b>Article 11: Packaging and labeling of tobacco products</b></p> <p>Each Party shall adopt and implement effective packaging and labeling measures that ensures that tobacco product packaging and labeling do not promote a tobacco product by any means. Each unit packet and package of tobacco products and any outside packaging and labeling of such products should carry health warnings describing the harmful effects of tobacco use. In addition to health warnings, they should contain information on relevant constituents and emissions of tobacco products as defined by national authorities.</p>	<p>The Act requires the display of nine new cigarette package warning labels (e.g. Cigarettes are addictive; tobacco smoke can harm your children, etc) on manufactured packages on a random basis. Each label statement shall comprise the top 50 percent of the front and rear panels of the package</p> <p>The Act directs the Secretary of HHS to issue regulations that require the display of color graphic warning labels depicting the health consequences of smoking to accompany the label statements indicated above.</p> <p>The Act allows the Secretary of HHS to alter label requirements to promote greater public understanding of the risks associated with the use of tobacco products</p> <p>The Act allows no use of terms "light," "low" and "mild" on tobacco products without an FDA order in effect.</p> <p>The Act also allows states or localities to impose specific bans or restrictions on the time, place, and manner, but not the content, of the advertising or promotion of any cigarettes.</p> <p>The Act amends the Comprehensive Smokeless Tobacco Health Education Act of 1986 to apply the same restrictions on labeling and advertising to smokeless tobacco products.</p>

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	<p>The Act requires the Secretary of HHS to determine whether manufacturers should be required to include on the label and advertisements the tar and nicotine yields of the product and allows the Secretary to require disclosure of the level of constituents in a tobacco product.</p>
<p><b>Article 12: Education, communication, training and public awareness</b></p> <p>Each Party shall promote and strengthen public awareness of tobacco control issues, using all available communication tools, as appropriate.</p> <p>Towards this end, each Party shall adopt and implement effective legislative, executive, administrative or other measures to promote the health risks of tobacco consumption and exposure to tobacco smoke</p>	<p>The provisions associated with labeling and disclosure of contents provides information to the public regarding the content of tobacco products and associated health risks.</p>
<p><b>Article 13: Tobacco product advertising. Promotion and sponsorship</b></p> <p>Each Party shall undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship.</p> <p>Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising</p>	<p>The Act has several provisions restricting tobacco marketing and sales to youth.</p> <p>It bans free giveaways of any non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase. It bans all remaining tobacco-brand sponsorships of sports and entertainment events It limits advertising in publications with significant teen readership as well as outdoor and point-of-sale advertising, except in adult-only facilities, to black-and-white text only. It restricts vending machines and self-service displays to adult-only facilities, and it requires retailers to verify age for all over-the-counter sales and provide for federal enforcement and penalties against retailers who sell to minors.</p> <p>Also, it grants an authority to the Secretary of HHS to develop regulations that impose restrictions on the advertising and promotion of tobacco products consistent with and to the full extent permitted by the First Amendment to the Constitution.</p>

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<p><b>Article 14: Demand reduction measures concerning dependence and cessation</b></p> <p>Each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence.</p>	<p>The Act requires the Secretary of HHS to consider designating products for smoking cessation as fast track research and approval products and approving the extended use of nicotine replacement products for the treatment of tobacco dependence and reviewing the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.</p> <p>It also directs the Secretary to report to Congress on how best to regulate, promote, and encourage the development of innovative products and treatments for smoking cessation.</p>
<p><b>Article 15: Illicit trade on tobacco products</b></p> <p>Each Party shall adopt and implement effective measures to ensure that all unit packets and packages of tobacco products and any outside packaging of such products are marked to assist Parties in determining the origin of tobacco products, the point of diversion and monitor, document and control the movement of tobacco products and their legal status.</p>	<p>The Act sets forth labeling, inspection, and record keeping requirements to prevent the illicit trade, smuggling, or counterfeiting of tobacco products.</p> <p>Requires the Comptroller General to conduct a study to collect data on cross border trades and advertising in tobacco products and the health effects resulting from such trades and to make recommendations on monitoring such trades and preventing or eliminating such advertising.</p>
<p><b>Article 16: Sales to and by minors</b></p> <p>Each Party shall adopt and implement effective measures at the appropriate government level to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or eighteen.</p> <p>Each Party shall prohibit or promote the prohibition of the distribution of free tobacco products to the public and especially minors</p> <p>Each Party shall endeavor to prohibit the sale of cigarettes individually or in small packets</p>	<p>The Act allows the reissuance of the 1996 regulation, restricting the sale and distribution of cigarettes and smokeless tobacco products. The rule contains provisions designed to limit youth access to tobacco products, as well as restrictions on marketing to curb the appeal of these products to youth.</p>

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<b>Article 17: Provision of support of economically viable alternative activities</b> Parties shall promote, as appropriate, economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers.	The FSPTCA does not apply to tobacco leaf
<b>Article 18: Protection of the environment and health of persons</b> Parties agree to have due regard to the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories.	The FSPTCA does not apply to protection of the environment

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