

Policy Briefing: Adoption of guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and tobacco product disclosures)

Fourth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, 15-20 November 2010, Punta del Este, Uruguay

Recommendation

The Framework Convention Alliance endorses the draft guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and tobacco product disclosures) and recommends that the fourth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control adopt the proposed guidelines without change.

The FCA recommends that Parties at an earlier stage of FCTC implementation should consider prioritising implementation of other FCTC measures over implementation of the Articles 9 and 10 guidelines, and urges that the Conference of the Parties include advice to this effect in its decision adopting the guidelines.

Background

Article 9 of the WHO Framework Convention on Tobacco Control (FCTC) deals with the testing and measuring of tobacco product contents and emissions, and with the regulation of tobacco product contents and emissions. Article 10 deals with disclosure of information about tobacco product contents and emissions.

The Conference of the Parties, at its first session (COP-1), decided to initiate the elaboration of guidelines for implementation of Articles 9 and 10.¹ (The work of the working group was continued by the second session (COP-2)² and the third session (COP-3).³)

COP-2 requested the working group to include in its work 'product characteristics, such as design features, to the extent that they affect the objectives of the Convention'.⁴

COP-3 mandated the working group to continue its work 'elaborating guidelines in a step-by-step process, and to submit a first set of draft guidelines to the Conference of the Parties for consideration at its fourth session' (COP-4).⁵ This decision by COP-3 envisaged that these draft guidelines presented to COP-4 would be only partial, a step-by-step approach supported by the Framework Convention Alliance (FCA). The working group has presented draft guidelines (document FCTC/COP/4/6).

FCA continues to recommend, as in previous briefing papers, that while Articles 9 and 10 are important components of tobacco control policy, they should not be implemented at the expense of existing effective tobacco control policies required by other articles of the FCTC. Even if the tobacco industry is required to fund implementation of Articles 9 and 10 – a position FCA supports – there

¹ Decision FCTC/COP1(15).

² Decision FCTC/COP2(14).

³ Decision FCTC/COP3(9).

⁴ Decision FCTC/COP2(14).

⁵ Decision FCTC/COP3(9).

could remain resource and opportunity costs for regulators, notably associated with detailed reporting requirements. In a decision adopting guidelines for implementation of Articles 9 and 10, the COP should therefore include advice to the effect that Parties at an earlier stage of FCTC implementation should consider prioritising implementation of other provisions over implementation of Articles 9 and 10.

The draft guidelines

FCA congratulates the working group on Articles 9 and 10 for the excellent work that it has done in elaborating draft guidelines. FCA considers that the draft guidelines should be adopted by COP-4 without change.

The draft guidelines elaborated by the working group offer very useful guidance to Parties in implementing Articles 9 and 10. They draw upon research, country experience, and knowledge of industry practices. The draft guidelines provide advice and recommendations on the regulation of ingredients to reduce product attractiveness, as well as on the disclosure to governmental authorities of ingredients and design features.

These initial draft guidelines do not deal with regulation to reduce addictiveness or toxicity, with testing/disclosure of emissions, or with public disclosure of information related to contents and emissions – these aspects are left to future guideline development, consistent with the COP decision to develop guidelines for implementation of Articles 9 and 10 in a step-by-step process.

The guidelines will, if adopted, assist Parties in effectively implementing Articles 9 and 10.

FCA supports the draft guidelines and comments here on some of their particularly important features.

Regulation of flavours and other ingredients (section 3.1.2)

The draft guidelines recommend that Parties should either prohibit or restrict ingredients that may be used to increase palatability (attractiveness), such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products (section 3.1.2.2(i)).

A growing number of countries/jurisdictions have legislation to curb flavours, including Australia, Canada, France, Thailand and the United States, with new measures pending in Singapore following adoption of new enabling legislation in 2010. In a consultation document released on 24 September 2010, the European Commission identified curbs on flavours as part of potential changes to the Tobacco Product Directive that would apply across the 27-country European Union.⁶

Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. (FCA has prepared a compilation of photographs of packages of flavoured cigarettes from many countries, which can be viewed online at:

http://www.fctc.org/index.php?option=com_content&view=article&id=89&Itemid=92.)

In a 6 July 2010 draft opinion prepared for the European Commission, the Scientific Committee on Emerging and Newly Identified Health Risks cited numerous studies and concluded that: “Attractiveness can similarly be improved in a number of ways, such as by adding flavours”.⁷ A series of studies and other items of evidence is included in the Annex to this briefing paper, including a statement of the U.S. Food and Drug Administration and references to internal industry documents. The rationale exists for governments to take action – and more and more governments are doing exactly that.

The recommendation in the draft guidelines to “either prohibit or restrict” flavouring substances has received considerable opposition from Philip Morris International, British American Tobacco and other

⁶ European Commission, Health and Consumers Directorate-General, Possible Revision of the Tobacco Products Directive 2001/37/EC, Public Consultation Document, DG SANCO, 2010.

http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm

⁷ Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), “Addictiveness and Attractiveness of Tobacco Additives”, pre-consultation opinion prepared for the European Commission, Directorate-General for Health and Consumers, approved July 6, 2010., released July 9, 2010, p.38.

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_cons_12_en.htm

tobacco interests. These tobacco industry lobbying efforts are aimed at discrediting a recommendation which is entirely reasonable, necessary and worthy of support. Although the tobacco industry may wish to have the unregulated freedom to use chocolate, fruit, sugar, candy, ice cream flavours (e.g. vanilla) and other flavourings to improve product attractiveness, this is incompatible with public health.

Philip Morris International, British American Tobacco and other tobacco companies have been orchestrating an international misinformation campaign in opposition to the draft guidelines for implementation of Articles 9 and 10. Contrary to tobacco industry claims, the draft guidelines do not recommend a ban on burley tobacco or any other type of tobacco. Also, cigarettes containing burley continue to be sold in jurisdictions where strong restrictions on flavourings are in place. In Canada, U.S.-style cigarettes that include burley tobacco continue to be sold but without flavours; examples include Camel, Winston, Gauloises and Marlboro.⁸

The draft guidelines also recommend that Parties should either prohibit or restrict ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) in cigarettes and cigarette-like tobacco products (section 3.1.2.2(ii), (iii) and (iv)).

The draft guidelines note that the existing guidelines for implementation of Article 13 (Tobacco advertising, promotion and sponsorship) recommend that Parties apply restrictions to as many as possible of the features that make tobacco products more attractive to consumers, such as coloured cigarette papers and attractive smells (section 3.1.2.1).

The draft guidelines recommend that Parties should consider collecting information on the ingredients found in non-cigarette-like tobacco products, and review this information to assess whether to regulate these ingredients (section 3.1.2.3).

The draft guidelines recommend that Parties should consider imposing a ban on the sale of tobacco products the packaging of which suggests the presence of an ingredient that is not permitted (section 7). This would greatly assist with enforcement. Thus if packaging described the product as mango-flavoured or cinnamon-flavoured cigarettes, and such flavours were banned, then it would be easy for inspectors to seize the product based on the packaging alone.

Disclosure of ingredients

The draft guidelines recommend that Parties require tobacco manufacturers and importers to disclose the additives and other ingredients (and their quantities) in tobacco products on a brand-by-brand basis, at specified intervals, in a standardised reporting format (section 3.1.1.2).

The draft guidelines recognise that the purpose of disclosure to governmental authorities is to obtain relevant information to assist in the development and implementation of relevant policies, activities and regulations; analysis of tobacco product contents and emissions; monitoring of market trends; and assessment of tobacco industry claims (section 1.2.2).

The recommendation for reporting of ingredients to governments is based on international best practice. Various countries have ingredient disclosure requirements, but the nature of these requirements varies considerably. Where a company submits a long list of additives used in all its brands, there is no way to tell which additives are used in which specific brands. In terms of the reporting format, a standardised format, perhaps electronic, would facilitate government administration as well as study and analysis.

The draft guidelines also state that Parties should not accept claims from the tobacco industry concerning the confidentiality of information that would prevent governmental authorities from receiving information about contents and emissions of tobacco products (section 2.6). In some countries, tobacco companies have opposed legislation requiring ingredient disclosure to government on the grounds that this would be an infringement of trade secrets. The disclosure to the public of

⁸ In Canada, Marlboro is sold in packages with Marlboro logos, colours and slogans, but without the word mark “Marlboro” for trademark reasons.

ingredient information reported to governments is an issue which has been left to future guideline development.

Disclosure of design features

The draft guidelines recommend that Parties require tobacco manufacturers and importers to disclose information on design features in cigarettes and cigarette-like tobacco products at specified intervals (section 3.3 and Appendix 2). Examples of design features include dimensions, diameter and weight; filter characteristics including location of ventilation holes; degree of paper ventilation; type of cigarette paper; and moisture content.

The draft guidelines recognise that collecting data on product characteristics, such as design features, will help Parties improve their understanding of the impact these characteristics have on smoke emission levels, properly interpret measurements obtained and, more importantly, keep abreast of any changes to cigarette design features (section 3.3.1.1).

Further, design features can increase the attractiveness of products. For example, filter ventilation holes around the tipping paper of cigarettes reduces the harshness of smoke inhalation, which promotes stronger inhalation, as well as false perceptions of lower risk.

Disclosure of market data

The draft guidelines recommend that Parties should require that tobacco manufacturers and importers disclose, on a brand-by-brand basis and at specified intervals, sales volume information in units (e.g. number of cigarettes or weight of roll-your-own tobacco) (section 3.4.2).

The draft guidelines also recognise that it is essential that governmental authorities have accurate market information in order to put effective product regulation in place; that governmental authorities need to know the importance of a particular tobacco product compared to others to help determine regulatory needs and priorities; and that information on tobacco companies and their sales will help assess the magnitude and patterns of tobacco consumption (section 3.4.1). Various countries (e.g. New Zealand) already have laws requiring reporting of sales data on a brand-by-brand basis. Also, various governmental excise/tax authorities require reporting of sales volume information, but often there are impediments to sharing this information with health ministries.

Financing

The draft guidelines provide a helpful list of potential financing options that Parties could consider using to recover costs associated with tobacco product regulation and disclosure (section 2.3 and Appendix 1). The listed options are: (a) designated tobacco taxes; (b) tobacco manufacturing and/or importing licensing fees; (c) tobacco product registration fees; (d) licensing of tobacco distributors and/or retailers; (e) non-compliance fees levied on the tobacco industry and retailers, and (f) annual tobacco surveillance fees (tobacco industry and retailers).

Collecting extensive product data from the tobacco industry can result in significant costs to Parties. That is why it may be beneficial for Parties to consider recovering those costs to avoid resources being diverted from other areas of tobacco control. Brazil is an example where government recovers costs through annual fees on the tobacco industry.

Civil Society

The draft guidelines recognise that civil society has an active role to play, and should be involved as an active partner (section 2.8). Existing FCTC guidelines also recognise the important role of civil society.

Compliance and Enforcement

The draft guidelines contain a series of recommendations on compliance and enforcement (section 4). Many of the recommendations are similar to the provisions in existing FCTC guidelines.

International cooperation

The draft guidelines recognise that international cooperation is essential for progress in tobacco product regulation and disclosure (section 5). Other existing FCTC guidelines also recognise the importance of international cooperation.

Annex - Flavours

There are numerous studies and other materials^{9, 10, 11, 12, 13,14,15,16,17,18}, some of which are cited below, providing evidence that flavouring of cigarettes and similar products makes the products more attractive and increases overall consumption, as well as new examples of the tobacco industry using flavouring.

If the flavouring of cigarettes has no impact on overall sales, then why is the tobacco industry objecting to measures to restrict or prohibit flavours?

Here is an excerpt (including references) from a U.S. Food and Drug Administration (FDA) fact sheet,¹⁹ which describes how smoking of flavoured cigarettes is far more popular among younger people than among older people:

- “In 2004, 22.8% of 17-year-old smokers reported using flavoured cigarettes over the past month, as compared to 6.7% of smokers over the age of 25.”²⁰
- A poll conducted in March 2008 found that one in five youngsters between the ages of 12 and 17 had seen flavoured tobacco products or ads, while only one in 10 adults reported having seen them.²¹
- According to one study of youth smokers between the ages of 13 and 18, 52% of smokers who had heard of flavoured cigarettes reported interest in trying them, and nearly 60% thought that flavoured cigarettes would taste better than regular cigarettes.²²”

The FDA fact sheet also cites tobacco industry internal documents, as indicated by this excerpt (including references):

- Industry documents reveal clear patterns of designing flavoured cigarettes to target youth.
- Advisors to one company developed concepts for a “youth cigarette,” including cola and apple flavours, and a “sweet flavour cigarette,” stating, “It’s a well-known fact that teenagers like sweet products. Honey might be considered.”²³
- A memo from another company instructed workers to “make a cigarette which is obviously youth oriented. This could involve cigarette name, blend, flavour and marketing

⁹ Manning KC, Kelly KJ, Comello ML., (2009), “Flavoured cigarettes, sensation seeking and adolescents’ perceptions of cigarette brands,” *Tobacco Control*, 18: 459-465.

¹⁰ World Health Organization Study Group on Tobacco Product Regulation. Candy-Flavoured Tobacco Products: Research Needs and Regulatory Recommendations, The Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series 945, 2007, pp. 25-42. Available at: http://www.who.int/tobacco/global_interaction/tobreg/tsr/en/index.html

¹¹ Connolly GN (2004), “Sweet and spicy flavours: new brands for minorities and youth,” *Tobacco Control*, 13(3): 211-212.

¹² Lewis, M.J., Wackowski, O., “Dealing with an innovative industry: a look at flavored cigarettes promoted by mainstream brands” *American Journal of Public Health*, 2006;96(2):244-251.

¹³ Carpenter CM, Ferris Wayne G, Connolly GN, Pauly J, Koh H (2005b), “New cigarette brands with flavors that appeal to youth,” *Health Affairs*, 24(6): 1601-10.

¹⁴ Carter SM, Chapman S (2006), “Smokers and Non-smokers Talk About Regulatory Options in Tobacco Control,” *Tobacco Control* 2006;15:398-204.

¹⁵ Danish Cancer Society (2008), “Tobacco Additives – A Study of the Available Literature” 2008 [English summary of full report].

¹⁶ Talhout R, Opperhuizen A, van Amsterdam J (2006), “Sugars as tobacco ingredient: Effects on mainstream smoke composition,” *Food and Chemical Toxicology*, Nov 2006;44(11):1789-98.

¹⁷ Connolly GN, Ferris Wayne G, Lymperis D, Doherty M. (2000), “How cigarette additives are used to mask environmental tobacco smoke,” *Tobacco Control*, 9: 283-291.

¹⁸ Ashare, RL, Hawk LW Jr., Cummings KM, O’Connor RJ, Fix BV, Schmidt WC, “Smoking expectancies for flavored and non-flavored cigarettes among college students” *Addictive Behaviours*, 2007;17:537-544.

¹⁹ U.S. Food and Drug Administration, “Flavored Tobacco Product Fact Sheet” updated April 19, 2010, accessed June 14, 2010. <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183198.htm>

²⁰ Klein SM, Giovino GA, Barker DC, Tworek C, Cummings KM, O’Connor RJ. Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005. *Nicotine and Tobacco Research*, 2008;10(7):1209-14.

²¹ National telephone survey of teens aged 12 to 17 and adults conducted by International Communications Research (ICR), March 2008.

²² American Legacy Foundation, First Look Report 17: Cigarette Preferences Among Youth--Results from the 2006 Legacy Media Tracking Online (LMTO), June 5, 2007, http://americanlegacy.org/PDFPublications/fl_17.pdf.

²³ Marketing Innovations, “Youth Cigarette - New Concepts,” Memo to Brown & Williamson, September 1972, Bates No. 170042014.

technique...for example, a flavour which would be candy-like but give the satisfaction of a cigarette.”²⁴

- Other internal documents describe sweetened products as “...for younger people, beginner cigarette smokers, teenagers . . . when you feel like a light smoke, want to be reminded of bubblegum.”²⁵

The following are government statements from the E.U., Australia, the U.S. and Canada, and other information:

Scientific Committee – European Commission

In a 6 July 2010 draft opinion prepared for the European Commission, the Scientific Committee on Emerging and Newly Identified Health Risks concluded that “Attractiveness can similarly be improved in a number of ways, such as by adding flavours” (p.38). The Committee also stated that “A number of additives favour attractiveness of tobacco products, and may thus promote smoking initiation” (p.14-15).²⁶

State of Victoria, Australia²⁷

On 31 May 2010, the Minister of Health in the Australian State of Victoria announced that the state government would ban fruit and candy flavoured cigarettes. In making the announcement, the Minister recognised that such cigarettes were appealing to children, stating: “Research by Cancer Council Victoria shows that 40 per cent of 16-17 year olds females agree that lolly or fruit flavoured cigarettes made them curious to try them, and one-third of males indicated the products would tempt them to try cigarettes. This new ban will come into force to ensure teenagers do not start smoking through the lure of fruit and lolly flavoured cigarettes.”

U.S. Food and Drug Administration:²⁸

The following is an excerpt from the U.S. FDA:

“What is the significance of today’s announcement on flavoured cigarettes?

Smoking is the leading cause of preventable death in the United States, claiming over 400,000 lives each year. An important way to reduce the death and disease caused by smoking is to prevent children and adolescents from starting to smoke. Studies have shown that 17 year old smokers are three times as likely to use flavoured cigarettes as are smokers over the age of 25. In addition to being more attractive to young people, flavoured products make it easier for new smokers to start smoking by masking the unpleasant flavour of tobacco. Studies have also demonstrated that young people believe that flavoured tobacco products are safer than unflavoured tobacco products.

Flavoured cigarettes are just as addictive and have the same types of harmful effects as regular cigarettes. Removing these flavoured products from the market is important because it removes an avenue that young people can use to begin regular tobacco use. Congress specifically enacted the ban on sale of cigarettes and their component parts, such as filters and papers, which contain certain characterising flavours. The removal from the market of cigarettes that contain certain characterising flavours is an important step in the nation’s efforts to reduce the burden of illness and death caused by tobacco products as authorised by the FSPTCA, signed by President Obama on June 22, 2009.”

²⁴ R.J. Reynolds Inter-office Memorandum, May 9, 1974, Bates No. 511244297-4298.

²⁵ Report from R.M. Manko Assoc. to Lorillard Tobacco Co. (Aug. 1978), available at <http://tobaccodocuments.org/lor/85093450-3480.html?pattern=85093450-3480#images>.

²⁶ Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), “Addictiveness and Attractiveness of Tobacco Additives”, pre-consultation opinion prepared for the European Commission, Directorate-General for Health and Consumers, approved July 6, 2010., released July 9, 2010.

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_cons_12_en.htm

²⁷ State Government of Victoria, Australia, Department of Human Services, “Government to butt out fruit flavoured cigarettes” May 31, 2010.

<http://hnb.dhs.vic.gov.au/web/pubaff/medrel.nsf/LinkView/2F57704743D9983FCA257734002238A5?OpenDocument>

²⁸ U.S. Food and Drug Administration, “Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)” December 23, 2009.

<http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183228.htm>

Canadian Department of Health²⁹

The Canadian Department of Health has stated: “On October 8, 2009, Parliament passed an *Act to amend the Tobacco Act*. The amendments aim to protect children and youth from tobacco industry marketing practices that encourage them to use tobacco products. These marketing practices include the use of additives, such as flavourings, that contribute to making cigarettes, little cigars and blunt wraps more appealing to children and youth.”

In Canada, almost all little cigars have been flavoured. The little cigar category was barely in existence 10 years ago, with little cigar unit sales increasing from 53 million in 2001 to 469 million in 2008. A national survey in 2008 found that these little cigars were far more popular among younger people, with 9% of 15-19 year olds having smoked in the previous 30 days, and 12% of 20-24 year olds having done so, compared with only 3% of people aged 25 and over. Also, 31% of 15-19 year olds and 48% of 20-24 year olds had at least experimented with little cigars.^{30, 31}

²⁹ Canadian Department of Health, “An Act to amend the Tobacco Act” Fact sheet, accessed June 14, 2010 http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/federal/2009_fact-renseignements-eng.php

See also: Canadian Department of Health, “Government of Canada Delivers on Promise to Protect Kids from Tobacco” April 20, 2010, http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2010/2010_55-eng.php

³⁰ Cunningham, R. “Canada: ban on flavours” *Tobacco Control*, 2010;19(1):4-5.

<http://tobaccocontrol.bmj.com/content/19/1/3.full?sid=8a7adc9b-1bda-4c36-bed8-308add53127f>

³¹ Health Canada, Canadian Tobacco Use Monitoring Survey (CTUMS) 2008 http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/ctums-esutc_2008/ann_summary-sommaire-eng.php