FRAMEWORK CONVENTION ALLIANCE

POLICY BRIEFING

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Sixth Session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, 13-18 October 2014, Moscow

FCA Policy Briefing

Report of the Working Group on Articles 9 and 10 of the WHO FCTC (Regulation of the contents of tobacco products and tobacco product disclosures)

Key Recommendations

The Working Group on Articles 9 and 10 has provided the Conference of the Parties with a progress report. There are no proposed guidelines for consideration at COP6. Accordingly, the only decision for COP concerning Articles 9 and 10 is potential future work of the Working Group.

If the Conference of the Parties decides to extend the mandate of the Working Group on Articles 9 and 10, FCA recommends that the COP:

1a. Request the Convention Secretariat to invite WHO to prepare a report on design characteristics of cigarettes, including ventilation, slim and superslim cigarettes and specialised filters of cigarettes, to inform the work of the Working Group on product attractiveness and false, misleading or deceptive conduct and/or representations and product design characteristics.

1b. Mandate the Working Group to consider developing guidelines or a progress report on product design characteristics regarding ventilation, slim and superslim cigarettes and specialised filters, as well as related characteristics.

2. Decide not to develop guidelines for the testing and measuring of cigarette emissions at this time. In particular, the flawed ISO test method (or equivalent) for cigarette emissions should not be included in the Article 9 and 10 guidelines. Similarly, the modified ISO "intense" test method for cigarette emissions should not be included in the Article 9 and 10 guidelines.

3. Consider requesting the Convention Secretariat to invite WHO to monitor ongoing research and prepare a report on nicotine content in order to inform future Working Group discussions on this issue.

4. Continue to monitor and research dependence liability and toxicology. However, the drafting of guidelines in these areas would be premature at this time.

5. Request the Convention Secretariat to invite WHO to prepare a report on the definition of the term "constituents" in the context of the partial guidelines on Article 9 and 10, in order to inform future Working Group discussions on this issue.

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Introduction

The Working Group on Articles 9 and 10 has provided the Conference of the Parties with a progress report. The Working Group is not providing guidelines for adoption at COP6. Accordingly, the only decision for COP concerning Articles 9 and 10 is potential future work of the Working Group.

It should be noted that Annexes 1 and 2 to the progress report of the Working Group contain possible text regarding the testing of cigarette constituents (Annex 1) and cigarette emissions (Annex 2). The contents of these Annexes were not approved by the Working Group and they are not being submitted to COP for approval. In the case of Annex 2 – testing of cigarette emissions – there was not time for even limited discussion of this text at the Working Group meeting in January 2014.

Product Design Characteristics

FCA Recommendation

If the Conference of the Parties decides to extend the mandate of the Working Group on Articles 9 and 10, FCA recommends that the COP:

> **1a. Request the Convention Secretariat to invite WHO to prepare a report on design characteristics of cigarettes, including ventilation, slim and superslim cigarettes, and specialised filters of cigarettes, to inform the work of the Working Group on product attractiveness and false, misleading or deceptive conduct and/or representations and product design characteristics.**
> **1b. Mandate the Working Group to consider developing guidelines or a progress report on product design characteristics regarding ventilation, slim and superslim cigarettes and specialised filters, as well as related characteristics.**

There is an increasing understanding that product characteristics themselves can be deceptive and can increase the attractiveness of tobacco products. Examples include ventilation in cigarette filters and specialised filters. Another example is slim/superslim cigarette dimensions.

Given that slim/superslim cigarette dimensions is an issue that has received considerable recent attention in the European Union, this brief discusses this issue in greater detail to illustrate the importance of potential study by the Working Group of product characteristics that may be attractive and may be deceptive, notably slims and superslims cigarettes.

There is increasing recognition of the need to ban slims and superslims cigarettes. The tobacco industry is actively marketing slims and superslims worldwide, the result of which has been dramatic growth in global sales, from 221 billion cigarettes in 2008 to 347 billion in 2012, an increase of 57 percent. [1]

[1] Philip Morris International, Morgan Stanley Global Consumer Conference, New York, Nov. 20, 2013 http://investors.pmi.com/phoenix.zhtml?c=146476&p=irol-presentations. PMI indicates that the 347 billion slims cigarettes sold in 2012 is almost double the 192 billion menthol cigarettes sold in the same year Note that the PMI sales volumes exclude China, the United States and duty-free.

Of particular interest is that slims cigarettes are misleading because they are perceived by many consumers as less harmful to health than regular cigarettes. This is supported by evidence.[2] It is also supported by the new Tobacco Products Directive[3] in the European Union, which states in the Preamble:

> (27) Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours' or 'slim', or certain names, pictures, and figurative or other signs. Other misleading elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. Neither the unit packets of tobacco products nor their outside packaging should include printed vouchers, discount offers, reference to free distribution, two-for- one or other similar offers that could suggest economic advantages to consumers thereby inciting them to buy those tobacco products. *(emphasis added)*

Several countries have already prohibited "slim" as a misleading descriptor so there is existing regulatory experience to build on.[4]

[2] Eg Mutti S, Hammond D, Borland R, Cummings KM, O'Connor RJ, Fong GT. "Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey" *Addiction* 2011 April 12; doi: 10.1111/j.1360-0443.2011.03402; Doxey J, Hammond D. "Deadly in pink: The impact of female-oriented cigarette packaging among young women" *Tobacco Control* 2011; 20: 353-360. doi: 10.1136/tc.2010.038315.

[3] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

[4] E.g. Malaysia, Control of Tobacco Product (Amendment) Regulations 2008, section 16A(2) http://www.tobaccocontrollaws.org/files/live/Malaysia/Malaysia%20-20Tobacco%20Control%20Amendment.pdf

In the draft EU Tobacco Products Directive released in December 2012,[5] there was a provision to prohibit cigarettes with a diameter of 7.5mm or less because such cigarettes are misleading:[6]

> Prohibited elements and features may include but are not limited to texts, symbols, names, trade marks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading. *(emphasis added)*

Though this provision is not in the final Directive, subsequent to tobacco industry lobbying, the final version of the new Directive allows EU member states to prohibit categories of tobacco products.[7]

Slims cigarettes are not only misleading regarding health effects, slim cigarettes also create perceptions regarding body image and weight loss. Slims cigarettes may be associated with sophistication, stylishness and fashionability, and packages of slims themselves may be associated with stylishness. Moreover, slim packages often distort the appearance of health warnings.

The EU draft Directive does include a provision setting minimum sizes for warnings, which in effect prohibits slim "purse packs", though slim cigarettes per se are not prohibited.[8] In Australia, plain packaging requirements include standardised pack dimensions, which also prohibit slim "purse packs", though not slim cigarettes per se.[9]

Finally, FCA recommendations in this brief regarding slim cigarettes and other deceptive product design characteristics should be considered as part of the much broader context for Articles 9 and 10. Articles 9 and 10 relate to many aspects regarding tobacco products themselves. Some areas are already subject to guidelines (e.g. ingredient disclosure; ignition propensity; regulation of flavours; colour of cigarette paper). Other areas have been identified for potential future guidelines and have been left blank in the current partial guidelines for Articles 9 and 10.

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[5] European Commission, Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, 19 December 2012. http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf

[6] Ibid, Article 12(2)

[7] Directive 2014/40/EU Article 24(3).

[8] Pursuant to Article 10(1)(g) of the draft EU Directive, for cigarette packages there is a minimum height for health warnings of 44 mm and a minimum width of 52 mm. Also, pursuant to Article 9(3), there is a minimum width of 16 mm for the lateral sides.

[9] Australia regulations specify that cigarette packs are to have a minimum height of 85mm, a minimum width of 55mm, and a minimum depth of 20mm. See Tobacco Plain Packaging Regulations 2011, SLI 2011 No. 263, section 2.1.1. http://www.tobaccocontrollaws.org/files/live/Australia/Australia%20-%20PP%20Regs%20-%20national.pdf

Testing and measuring of cigarette emissions

FCA Recommendation

If the Conference of the Parties decides to extend the mandate of the Working Group on Articles 9 and 10, FCA recommends that the COP:

> **2. Decide not to develop guidelines for the testing and measuring of cigarette emissions at this time. In particular, the flawed ISO test method (or equivalent) for cigarette emissions should not be included in the Article 9 and 10 guidelines. Similarly, the modified ISO "intense" test method for cigarette emissions should not be included in the Article 9 and 10 guidelines.**

There is extensive rationale for *not* including cigarette emission test methods in Articles 9 and 10 guidelines at this time, as outlined below.

Need for a clear goal
The work of the FCTC Conference of the Parties is guided by the overall objective of the Convention, i.e. the reduction of death and disease from tobacco use.[10] Guidelines provide details on how individual articles of the Convention can be implemented so as to maximise public health impact.

Article 9 foresees guidelines for measuring, testing *and regulation* of tobacco product emissions and contents. While this can be done in steps (as the Articles 9 and 10 Working Group has already done in the past by proposing partial guidelines e.g. on attractiveness), clearly any measuring or testing methods the Working Group recommends must have a reasonable prospect of leading to sound regulation.

Regulations based on data from machine testing have been tried in a number of jurisdictions, in particular via limits on "tar" and nicotine levels. However, there is no evidence that such regulations have yielded population-level reductions in harm, whether by directly reducing the health risks of inhaling cigarette smoke or cigarette addictiveness.

The FCA is of the view that no testing regime that relies on smoking machines provides an accurate indication of the relative harm of different products/brands. We therefore believe that enshrining any such test methods in FCTC guidelines cannot be justified at this time.

Lack of inclusion in FCTC guidelines should not prevent ongoing research in this area at country level.

[10] FCTC Article 3: "to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke..."

Machine smoking has been discredited as a measure of harm to humans
At the time of the FCTC's adoption, it was already clear to many experts that the ISO test method developed and promoted by the tobacco industry was severely flawed for the purpose of understanding human exposure or regulating products to reduce toxic exposure. (Indeed, that was one reason for the language in Article 11 on banning deceptive labelling.) Tobacco companies developed filter ventilation – tiny holes around the filter – to reduce tar and nicotine numbers, in full knowledge that human smokers would continue to extract their habitual dose of nicotine (and with it, high levels of tar).

This is because most people who smoke are addicted to nicotine – and smokers, unlike machines, alter the way they smoke to achieve their preferred nicotine levels, a process known as compensation. They can change the way they smoke by taking more or deeper puffs or covering the ventilation holes. These holes are positioned in the filter where smokers place the fingers or lips, and are therefore easy to block.

As a result, data using the ISO test method shows large differences between brands and brand variants that are not reflected in actual levels of human exposure to the carcinogens and toxic gases in cigarette smoke.[11]

Various adjustments have been tried to the ISO test method, of which the so-called Canadian intense method is probably the best known. (It involves blocking ventilation holes and adjusting puffing parameters.) However, analyses have shown that such alternative smoking regimes are not more representative of human smoking behaviour and none provide better predictions of human exposure.[12] Yields from machine tests are not representative of human exposure.[13]

In short, experience has shown that smoking machine-based methods cannot be "fixed" simply by modifying parameters, as they are unable to simulate the nicotine-seeking behaviour of human smokers.

Emission test methods not needed for cigarette package labelling
Articles 9 and 10 of the FCTC were finalised in 2003, after which the Working Group on Articles 9 and 10 was established by COP1 in February 2006.

[11] Jarvis MJ, Boreham R, Primatesta P, et al. "Nicotine yield from machine smoked cigarettes and nicotine intakes in smokers: evidence from a representative population survey". Journal of the National Cancer Institute, 2001;93:134–8; Hecht SS. Murphy SE, Carmella SG, et al. Similar Uptake of Lung Carcinogens by Smokers of Regular, Light, and Ultralight Cigarettes, *Cancer Epidemiology, Biomarkers and Prevention*, *2005:*14; *693*-698, doi: 10.1158/1055-9965.EPI-04-0542.

[12] Hammond D, Wiebel F, Kozlowski L, Borland R, Cummings M, O'Connor R, McNeill A, Connolly G, Arnott D, Fong G. Revising the machine smoking regime for cigarette emissions: implications for tobacco control policy**.** Tob Control. 2007;16(1): 8–14.

[13] US Department of Health and Human Services. Risks associated with smoking cigarettes with low machine measured yields of tar and nicotine. Bethesda, MD, USA: US Department of Health and Human Services, Public Health Services, National Institutes of Health; National Cancer Institute, 2001; Jarvis MJ, Boreham R, Primatesta P, Feyerabend C, Bryant A. Nicotine yield from machine-smoked cigarettes and nicotine intakes in smokers: evidence from a representative population survey. J Natl Cancer Inst 2001; 93(2):134-8.

One of the reasons originally prompting the work on cigarette emission test methods in 2006 was the perceived need to find a replacement for the ISO method in order to place emission yield numbers on the side of cigarette packages. But since 2006, because of a recognition that such emission numbers are highly misleading to smokers, a practice has emerged whereby countries are placing qualitative text messages about emissions on the side of packages, without yield numbers.[14] This approach was included as a recommendation in the Article 11 guidelines, adopted in 2008.[15] Thus, there is no longer a need for a replacement cigarette test method (e.g. "Canadian" intense method) for the purposes of package labelling.

Not only do the Article 11 guidelines recommend that Parties should not require emission yield numbers on packages, they also recommend that Parties should go further and prohibit tobacco companies from doing so on their own initiative. The Article 11 guidelines state that:

> 33. […], Parties should require that relevant qualitative statements be displayed on each unit packet or package about the emissions of the tobacco product. Examples of such statements include "Smoke from these cigarettes contains benzene, a known cancer-causing substance." and "Smoking exposes you to more than 60 cancer-causing chemicals." […]
> 34. Parties should not require quantitative or qualitative statements on tobacco product packaging and labelling about tobacco constituents and emissions that might imply that one brand is less harmful than another, such as the tar, nicotine and carbon monoxide figures […]
> 44. Parties should prohibit the display of figures for emission yields (such as tar, nicotine and carbon monoxide) on packaging and labelling, including when used as part of a brand name or trademark. Tar, nicotine and other smoke emission yields derived from smoking-machine testing do not provide valid estimates of human exposure. In addition, there is no conclusive epidemiological or scientific evidence that cigarettes with lower machine-generated smoke yields are less harmful than cigarettes with higher smoke emission yields. The marketing of cigarettes with stated tar and nicotine yields has resulted in the mistaken belief that those cigarettes are less harmful.

Capacity concerns

A key area of further concern is one of capacity. Most Parties do not yet have the capacity to deal with the vast amounts of data that would be produced when implementing cigarette emission test method guidelines.

The need for flexibility

Once a test method is entrenched in FCTC guidelines, it may be hard to change. It would be better to leave the cigarette emission test method outside the guidelines (at least at this time), in part because test methods can change, and because more appropriate test methods may emerge. The area of cigarette emissions is complex and requires the need for flexibility.

[14] For example, the new Tobacco Products Directive of the European Union includes the following qualitative text message to appear on a lateral side of cigarette packages: "Tobacco smoke contains over 70 substances known to cause cancer".

[15] Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products), paragraphs 32-35.

There is no regulatory experience with TSNAs
Regarding tobacco-specific nitrosamines (TSNAs), there is no experience anywhere regarding regulating TSNA emissions in cigarette smoke. This provides an added reason why it would not be appropriate to include in the guidelines at this time ISO and intense smoking methods to measure TSNAs.

Testing and measuring of nicotine content in tobacco in cigarettes

FCA Recommendation:

If the Conference of the Parties decides to extend the mandate of the Working Group on Articles 9 and 10, FCA recommends that the COP:

> **3. Consider requesting the Convention Secretariat to invite WHO to monitor ongoing research and prepare a report on nicotine content in order to inform future Working Group discussions on this issue.**

FCA notes that in June 2014, TobLabNet published a standard for measuring nicotine content in cigarettes,[16] and FCA believes that it would be useful to assess whether these methods are applicable for other products, such as smokeless tobacco.

Parties may wish to conduct research and consider other related initiatives at the national level. Parties that wish to do so have the option of using the TobLabNet standard for nicotine content in cigarettes for research, analysis or other purposes. It is recognised that nicotine content is an area where research is currently ongoing. Parties may wish to consider requesting that the Convention Secretariat invite WHO to monitor ongoing research into nicotine content and prepare a report for consideration by the Article 9 and 10 Working Group.

Monitoring of dependence liability and toxicology

FCA Recommendation:

If the Conference of the Parties decides to extend the mandate of the Working Group on Articles 9 and 10, FCA recommends that the COP:

> **4. Continue to monitor and research dependence liability and toxicology. However, the drafting of guidelines in these areas would be premature at this time.**

[16] World Health Organization Tobacco Laboratory Network, Standard operating procedure for method Determination of nicotine in cigarette tobacco filler, WHO TobLabNet Official Method SOP 04, June 2014 http://apps.who.int/iris/bitstream/10665/102318/1/9789241503907_eng.pdf

Regarding addictiveness, FCA reiterates its recommendation made in 2012 to the Working Group on Articles 9 and 10:

> *Recommendation:*
> Given the complexity of addiction and the fact that no nation has positive practical regulatory experience regulating tobacco products for addictiveness, efforts to reduce addictiveness through regulation of product contents and characteristics will require further research as well as practical regulatory experience before it will be possible to identify best practices sufficient to support a guideline in this area. FCA believes that research in this area should be encouraged, but that the drafting of guidelines on addictiveness would be premature at this stage. The FCA recommends that the Working Group should not consider developing guidelines on addictiveness until there is significant national regulatory experience which can be drawn upon. The adoption of proven tobacco control measures should be the priority for Parties.

This recommendation on addictiveness continues to be valid. Among other considerations, FCA believes that it is premature at this time for there to be FCTC guidelines on nicotine reduction in cigarettes (as discussed in document FCTC/COP/6/14). Moreover, the principles in this recommendation are also applicable to the area of toxicology and tobacco products, specifically that guidelines would be premature.

Definition of "constituents"

FCA Recommendation:

If the Conference of the Parties decides to extend the mandate of the Working Group on Articles 9 and 10, FCA recommends that the COP:

> **5. Request the Convention Secretariat to invite WHO to prepare a report on the definition of the term "constituents" in the context of the partial guidelines on Article 9 and 10, in order to inform future Working Group discussions on this issue.**

Despite having examined this issue a number of times since COP5, the Working Group has not as yet been able to agree a definition for the term 'constituents'. The Working Group has defined 'contents', a term used in Article 9 of the FCTC, as follows: *'"Contents" means "constituents" with respect to processed tobacco, and "ingredients" with respect to tobacco products.'* FCA believes that it would be helpful to gain advice from experts on this issue, taking into account the concerns of Parties about the definitions that have been thus far proposed.