FRAMEWORK CONVENTION ALLIANCE

POLICY BRIEFING

Briefing 3:
Elaboration of guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and of tobacco product disclosures)

Third session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control
17-22 November 2008, Durban, South Africa

Recommendation

The Framework Convention Alliance supports the recommendations of the working group on Articles 9 and 10 (Regulation of the contents of tobacco products and of tobacco product disclosures) in relation to its future work (as presented in paragraphs 34-40 of its progress report (Document FCTC/COP/3/7)) and recommends that the third session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control mandate the working group to continue its work on the development of guidelines 'step-by-step', and request it to elaborate, if possible, a first set of draft guidelines, dealing with the disclosure to governmental authorities of the product characteristics identified in paragraphs 31-32 of the progress report, for presentation to the fourth session of the Conference of the Parties.

Background

The Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (FCTC) decided at its first session (COP-1) to commence the elaboration of guidelines on Article 9 of the Convention, with highest priority to be accorded to the 'first phase of Article 9' – the testing and measuring of the contents and emissions of tobacco products.[1] A working group was established and requested to submit either draft guidelines or a progress report to the second session of the COP (COP-2). COP-2, having considered the progress report submitted by the working group, decided that the working group should continue its work, 'extending its mandate to Article 10 and including product characteristics, such as design features, to the extent that they affect the objectives of the Convention'.[2] The working group, having continued its work and met twice since COP-2, has prepared a progress report (Document FCTC/COP/3/7) to be considered by the COP at its third session (COP-3).

[1] 'Elaboration of guidelines for implementation of the Convention' (World Health Organization, Conference of the Parties to the WHO Framework Convention on Tobacco Control, first session, decision FCTC/COP1(15)).
[2] 'Elaboration of guidelines for implementation of Articles 5.3, 9 and 10, 11, 12 and 14' (World Health Organization, Conference of the Parties to the WHO Framework Convention on Tobacco Control, second session, decision FCTC/COP2(14)).

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The Framework Convention Alliance (FCA) considers that the working group has made significant progress in addressing the very complex issues relating to the testing and measuring of tobacco product contents, emissions and product characteristics, and the disclosure of contents, emissions and product characteristics to both governmental authorities and the public. As the progress report makes clear, the working group considers that it will take a number of years before guidelines on all aspects of Articles 9 and 10 can be proposed to, and adopted by, the COP. In these circumstances, the working group has reached the conclusion that guidelines should be developed 'step-by-step' (para 34). It has made recommendations to COP-3 with respect to future work on Articles 9 and 10. The recommendations recognize the important role to be played by WHO's Tobacco Free Initiative (TFI) and WHO's Tobacco Laboratory Network (TobLabNet) in performing technical work to assist in the elaboration of guidelines.

FCA supports the continuation of work towards the development of guidelines on Articles 9 and 10. As FCA has previously argued, however, neither work by the COP with respect to the elaboration of guidelines on Articles 9 and 10, nor action by Parties domestically to implement Articles 9 and 10, should take place at the expense of work on other Articles of the FCTC, for which the urgency of action is greater – such as Articles 5.3 (protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry), 6 (price and tax measures to reduce the demand for tobacco), 8 (protection from exposure to tobacco smoke), 11 (packaging and labelling of tobacco products), 12 (education, communication, training and public awareness), 13 (tobacco advertising, promotion and sponsorship), 14 (demand reduction measures concerning tobacco dependence and cessation) and 15 (illicit trade in tobacco products).

The purpose of this briefing paper is to articulate, for consideration by Parties at COP-3, FCA's position with respect to the future work of the working group on Articles 9 and 10. This briefing paper will not make detailed recommendations with respect to the content of guidelines on Articles 9 and 10. FCA will make such recommendations to the working group, and the COP, at the appropriate times, as work on Articles 9 and 10 continues.

Regulation of tobacco product disclosures (Article 10)

Background

Article 10 of the FCTC deals with two kinds of disclosure of the contents, emissions and product characteristics of tobacco products: disclosure *to governmental authorities* by manufacturers and importers of tobacco products and *public disclosure*.

Disclosure to governmental authorities

FCA agrees with the objectives and purposes of disclosure to governmental authorities set out in the progress report (paras 21-22), namely: to provide governmental authorities with 'relevant, precise information on the contents and emissions of tobacco products, the toxicological effects and dependence liability of the contents and emissions, and their composition and design'; to enable government authorities 'to take action and to inform the public about the harmful effects of tobacco use'; and to inform 'the elaboration and implementation of relevant policy, regulations and litigation and for countering tobacco industry arguments'.

In order to achieve these objectives and purposes, FCA considers that manufacturers and importers of all tobacco products in a market should be required to provide comprehensive data to governmental authorities on *all* aspects of their products. FCA agrees with the list of types of information that should be collected from the tobacco industry set out in para 25 of the progress report, namely:

(a) contents and emissions;
(b) a list of all ingredients, and quantities thereof, used in the manufacture of tobacco products, per brand and type;
(c) all toxicological information;
(d) factors influencing attractiveness and addictiveness;
(e) product characteristics, including design features;
(f) market data.

FCA also agrees with the working group's view that tobacco manufacturers and importers should not be permitted to use alleged trade secrets to resist disclosure of information to governmental authorities – that 'Parties should not accept claims from the tobacco industry concerning the confidentiality of information' (para 27). It further agrees with the working group that '[d]isclosure requirements should not allow the industry to discharge itself from litigation claims' (para 20).

In addition to recommendations with respect to the types of information that should be required to be provided to governmental authorities, FCA considers that guidelines on Article 10 should cover the format in which information should be provided (in a standardized, consistent, electronic format) and the frequency with which it should be provided.

FCA agrees with the concerns expressed by the working group (paras 24 and 26) about the capacity challenges of collecting, storing, evaluating and disseminating data. In recognition of these challenges, the working group invites Parties to consider the development of a 'global data repository'. FCA supports the establishment of such a repository. FCA considers that the primary functions of such a repository should be:

- to assist Parties to collect data in a consistent and meaningful form;
- to provide a repository for storing such data over time;

- to analyse and assess such data and provide reports to Parties to enable them to better understand the products on their market;
- to provide comparative assessments regionally and internationally;
- to perform a quality check on the data provided to it by Parties; and
- where appropriate, to check the accuracy of data provided to Parties by the tobacco industry in comparison with data provided to Parties by independent laboratories.

In order to be able to perform its functions effectively, and in accordance with Article 5.3 of the Convention, a global data repository would need to be entirely independent of the tobacco industry and funded adequately.

Disclosure to the public

FCA agrees with the view of the working group that, '[r]ecognizing the consumer's right to know', the 'main objective of disclosure to the public is to inform and educate them on the harmful effects of tobacco', with the expectation that '[b]y improving public knowledge about tobacco products, consumers' attitudes and behaviour could be influenced, with the final goal of reducing tobacco use' (para 23).

Working towards this objective, guidelines on Article 10 should make recommendations with respect to how best to inform and educate the public on the harmful effects of tobacco. It is now well understood that the communication of technical information to the public on emissions, contents and product characteristics can be misunderstood as implying significant differences between the harmfulness of different products. For example, disclosure of machine-based tar and nicotine yields to consumers by governments and the tobacco industry has been shown to promote the mistaken belief that some cigarette brands are less harmful than others.[3] (For this reason, FCA strongly supports the recommendations in the Draft guidelines for implementation of Article 11 (Packaging and labelling of tobacco products) (Document FCTC/COP/3/7) that: 'Parties 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' (para 33) and that Parties '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' (para 44).)

Risks of public misunderstanding of technical information necessitate that disclosure of information by the tobacco industry to the public about emissions, contents and product characteristics of tobacco products be regulated by governments rather than by the tobacco industry. '[*E*]*ffective*

[3] See: LT Koslowski, ME Goldberg, BA Yost, EL White, CT Sweeney, JL Pillitteri, 'Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking' (1998) 15 *Am J Prev Med* 9-16; US Department of Health and Human Services, 'Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine' (Bethesda, MD: US Department of Health and Human Services, Public Health Services, National Institutes of Health, National Cancer Institute, 2001).

measures for public disclosure of information', as required by Article 10, must deal both with what governmental authorities decide should be communicated to the public – which, if any, data relating to tobacco products should be publicly disclosed and the mechanisms for that disclosure – and with preventing the tobacco industry from communicating with the public in a way that undermines the effectiveness of government measures.

FCA considers that guidelines on Article 10 should provide advice on what information (whether quantitative or qualitative) should be publicly disclosed and appropriate channels for communication of this information (such as websites, packaging etc). As quantitative information can be easily misinterpreted, with differences in quantity erroneously understood as implying differences in harm, the communication of quantitative information requires considerable care. Further research should be undertaken to inform what information should be disclosed and how it may best be disclosed, as well as what information should not be disclosed. It can be noted at this stage that it may be preferable to require (and allow) the provision of only qualitative information to the public. Information that is potentially misleading should not be communicated.

FCA considers that guidelines on the public disclosure of information under Article 10 should be informed by the development of guidelines on: Article 11 (Packaging and labelling of tobacco products), which deals with information that should be required and information that should be prohibited on tobacco product packaging and labelling; Article 12 (Education, communication, training and public awareness), which covers promotion of public awareness of the health risks including the addictive characteristics of tobacco; and Article 13 (Tobacco advertising, promotion and sponsorship), which requires the prohibition of tobacco advertising, promotion or sponsorship that promote a tobacco product 'by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions': Article 13.4(a).

<u>FCA recommendations for future work of the working group with respect to Article 10</u>

FCA agrees with the recommendation made by the working group to COP-3 in para 40 of its report that the COP mandate the programme of work set out in paras 34 to 36, namely:

- continuation of work on the development of a first set of guidelines for possible adoption at the fourth session of the COP (COP-4), with guidelines to be developed 'step-by-step';
- continuation of the monitoring of areas set out in its progress report to COP-2, including dependence liability and toxicology;
- continuation of its work in examining the challenges and potential approaches for the development of a global data repository.

FCA recommends that COP-3 request that the first set of guidelines to be developed by the working group deal with the disclosure to governmental authorities of product characteristics identified in paras 31 and 32 of the

progress report. As explained in paras 30 to 32, these characteristics and design features either do not require any testing and measuring in order to be disclosed or may be tested or measured with existing standardized methods or readily available equipment. As stated above, guidelines should make recommendations with respect to what information should be disclosed, the format in which it should be disclosed and the frequency with which it should be disclosed.

FCA supports the recommendation of the working group (para 38) that the COP, through the Secretariat, request WHO: to identify best practices in reporting to regulators as regards contents, emissions and product characteristics, including electronic systems; to identify best practices in informing the public; and to collect information on legal cases and analyze the legal issues related to tobacco product disclosures. FCA considers that such work will be of significant assistance to the working group in the development of guidelines on Article 10. While the progress report recommends that WHO be requested to inform COP-4 of progress made in this work, it should be clear that, while a formal report should be submitted to COP-4, work undertaken by WHO should be provided to the working group as it becomes available through the inter-sessional period in order to inform the inter-sessional work of the working group.

Testing and measuring the contents and emissions of tobacco products (Article 9)

Article 9 of the FCTC deals with the testing and measuring of the contents, emissions and product characteristics of tobacco products, and the regulation of these contents, emissions and product characteristics. As set out above, COP-1 decided that the working group should commence with work on testing and measuring of contents, emissions and product characteristics. No mandate has yet been given to the working group with respect to product regulation.

FCA considers that the working group has made good progress in identifying and prioritising the list of contents and emissions of tobacco products that should be tested and measured. FCA agrees with the list set out by the working group at paras 10-12 of its progress report, but considers that a process should be established to regularly review and update the list based on the available science. FCA notes the working group's estimate that validation of the testing and measuring methods for the identified contents and emissions, which is proposed to be undertaken by TobLabNet, will take five and a half years (para 14).

FCA notes that the working group proposes that validation be performed using the two smoking regimens set out in para 18 of the progress report (known as the ISO regime and the Canadian intense regime). FCA also notes, and agrees with, the observation by the working group that 'data on cigarette emissions from machine-generated smoke are not intended to be, nor are they, valid measures of human exposure. All machine-smoking regimens have

limitations; none can generally represent human smoking patterns, exposure or risk' (para 16). FCA agrees with the working group that '[m]ethods to test and measure emissions should provide for machine smoking of cigarettes to help characterize the smoke and to monitor any change over time' (para 17). FCA agrees that the ISO regime and the Canadian intense regime are, in light of the current state of knowledge, appropriate regimens to use for these two purposes, but considers that a process should be established to review and re-evaluate these and other testing methodologies based on newly available information.

In FCA's view, the limitations of machine-generated smoking regimens support the use of two (or more) testing regimens. The purpose of using more than one testing regimen is to examine emissions under different smoking intensities – a critical aspect of 'product characterization', given the wide range of smoking patterns among humans. The use of two (or more) machine testing regimens may also help to prevent the misconception that products deliver a single, fixed amount of 'tar', nicotine, and other constituents. Multiple regimens may also help to avoid the false perception that more intensive regimens 'fix' the problems of the existing ISO method and generate better estimates of human exposure.

<u>FCA recommendations for the future work of the working group with respect to Article 9</u>

FCA supports the recommendations made by the working group in paras 37 and 39 of its progress report with respect to further work on testing and measuring of contents, emissions and product characteristics, namely that the COP, through the Secretariat, request WHO to:

- validate the analytical chemical methods for testing and measuring the priority cigarette contents and emissions identified in the progress report, using the ISO regimen and the Canadian intense regimen, and inform the COP through the Secretariat on a regular basis of the progress made;
- monitor scientific progress, and, when appropriate, develop and validate methods for the testing and measuring of the product characteristics identified in the progress report for which no standardized methods yet exist, no equipment is readily available or more research is needed (aerosol particle size and filter fibre residues), and inform the COP through the Secretariat on a regular basis of the progress made.

As stated above, FCA considers that work towards the development of guidelines on regulation of contents, emissions and product characteristics should not take precedence over or interfere with the development, adoption and implementation of guidelines on other Articles of the FCTC.

Principles for financing tobacco product regulation programmes

FCA agrees with the concern expressed by the working group that the implementation and operation of effective programmes for regulating tobacco products require the allocation of significant resources 'which may have the undesirable consequence of drawing funding and capacity away from other important tobacco control interventions of high priority' (para 6).

It is for this reason that FCA agrees with the working group's view that 'all costs related to tobacco product regulation should be borne by the tobacco industry' (para 6) and supports its intention to 'look further at means that Parties have at their disposal to finance tobacco product regulation programmes, in conjunction with a monitoring plan and in accordance with Article 5.3 of the WHO Framework Convention', including the examples set out in para 8, i.e. designated tobacco taxes, manufacturing and/or importing licencing fees, product registration fees, tobacco selling licences, and non-compliance fees.