



**FRAMEWORK CONVENTION ALLIANCE (FCA) FCTC BRIEFING  
PAPER FOR TOBREG KOBE MEETING**

**DEVELOPING EFFECTIVE PRODUCT REGULATION UNDER THE  
FCTC**

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## Summary

There are three Articles in the FCTC concerning tobacco product regulation: Article 9 concerns guidelines for testing, measuring and then regulating contents and emissions of tobacco products, Article 10 concerns the disclosure of information on contents and emissions from manufacturers and Article 11 packaging and labelling (see Annex 1).

At the first session of the Conference of the Parties (COP) in February 2006 a decision was adopted concerning the elaboration of guidelines for Articles 8 to 13. A template was adopted (see Annex 2) for the elaboration of a guideline on Article 9. The highest priority was accorded to the first phase of Article 9 and the Convention Secretariat was asked to initiate work on the basis of the template and to present either draft guidelines or a progress report to the second COP. The first phase of Article 9 involves the development of a guideline for the *testing* and *measuring* of the contents and emissions of tobacco products. Phases two and three were to address *regulations* and/or *disclosure* (Article 10) and the order of these next two phases was to be considered by the second session of the COP. A draft workplan on Article 11 was presented but not discussed. Ten criteria were adopted for prioritization of the work related to guidelines with respect to these and other Articles (see Annex 3).

The key facilitators for guidelines on Articles 9 and 10 were identified as Norway, Canada and the European Community and a first meeting of these key facilitators and WHO was held in Oslo in May 2006. A second meeting is being held in Kobe on 1 July following a WHO TobReg meeting, which is open to civil society and to which the FCA has been asked to present. A third meeting is planned for Ottawa 26-28 October. The likely outcome of these meetings appears to be that a progress report, rather than draft guidelines, will be presented to the second session of the COP.

This FCA briefing paper has been prepared for the second meeting in Kobe. It updates a previous FCA briefing paper on tobacco product regulation presented at the first COP session. It describes the FCA's position on guideline development for Article 9 and considers the other phases of work for Articles 9 to 11 where appropriate.

### ***Recommendations:***

**Prioritisation** Criteria set by the COP for prioritisation of work on guidelines for Articles 9 to 13 and 5.3 and 14 include the potential impact of the measure at reducing the impact of tobacco. Whilst a much greater understanding of tobacco products is critically important in tobacco control, it is not yet understood how tobacco products can best be regulated to reduce the harm. Work must continue in this important area but tobacco regulation policies should not be implemented at the expense of existing effective tobacco control strategies, such as smoke-free policies, tobacco advertising bans and health warnings. The FCA therefore believes that it is important to distinguish the priority given to the *development* of a guideline from the priority assigned to *implementation*, by all Parties, of that guideline or the Article under which it is made. Some Parties that have already implemented laws governing aspects of tobacco product regulation (such as the European Union Directive placing a ceiling on tar, nicotine and carbon monoxide yields on packs), may have a stronger need for an effective, internationally agreed strategy in this area which they can then adopt. It is likely that many Parties, particularly those without significant existing capacity in the

area of product regulation, will need to prioritise the implementation of other Articles, guidelines and protocols within the FCTC concerning other tobacco control issues. An approach that recognises the need to prioritise in the context of limited resources is necessary.

### **Article 9 Phase 1 – the development of a guideline for the testing and measuring of the contents and emissions of tobacco products**

The FCA recommends that draft guidelines for Article 9 phase 1 *not* be presented to the second session of the COP for the following reasons:

- **Emissions** Whilst validated standards do exist for testing and measuring the *content* (and *design*) of cigarette products, largely through work carried out by WHO TobReg, they do not yet exist for testing and measuring *emissions*. A number of emission regimes are currently under discussion but a consensus does not yet exist within the tobacco control movement as to which are the most appropriate regimes to use. Work should continue in this area with a view to developing standards when a consensus is reached and the implications of particular standards are better understood.
- **Capacity** Testing and measuring will require considerable resources from Parties. Each characteristic being assessed will need to be measured for all cigarette brands on the market and then analysed. In order to ensure that testing and measuring requirements do not overwhelm Parties, and to meet the “ease of implementation” criterion agreed by the COP, it is critical to develop a strategy for managing the process and data that is collected. The FCA therefore believes that there is a need for an international centralised data management system and repository, which should be independent of the tobacco industry, and could operate to minimise the burden on individual Parties as far as possible. Such a system would allow for consistency of the data collected under Article 9 phase 1 (and indeed under phases 2 and 3), and offer a structure for the appropriate oversight and use of the data. The FCA believes that the feasibility of an international data repository, or other suitable mechanisms, needs to be established as a precondition to implementing Article 9 phase 1. This work should proceed in parallel with the development of guidelines so that it does not stall the implementation process.
- **Communication** A further concern arises around controlling the communication of information gathered under Article 9, phase 1 (and phases 2 and 3). Article 11 addresses the packaging and labelling of constituent and emission information, and requires Parties to ensure that packaging and labelling are not false, misleading, deceptive or likely to create an erroneous impression about product characteristics, health effects, hazards or emissions. Guideline development for this Article has not yet been initiated. The FCA recommends action by the COP to ensure that numerical information on emissions not be communicated directly to consumers and that this be done as a precondition for implementing Article 9 phase 1 (This would also be a desired approach when implementing Article 11 although as Article 11 includes implementing package warnings it should not be a precondition for implementation of this Article). The FCA also recommends that Parties

consider using researched messages giving qualitative information on tobacco constituents or quitting information. The COP may take action to this end either through a formal decision to this effect or the adoption of a guideline. However, Parties do not need to wait for such a decision to do this. In fact, Australia has already done so.

- **Design** The design of a cigarette has an important influence on the chemical profile of the smoke and the puffing behaviour of smokers. Articles 9 and 10 do not explicitly refer to the design of cigarettes but the need to study design features has been noted in the template for Article 9, phase 1. The FCA recommends that testing and measuring design features should also be included in the guidelines being developed for Article 9 phase 1.

### **Phases 2 and 3 – guidelines to address regulations and/or disclosure (Article 10)**

For Articles 9 and 10 phases 2 and 3, the FCA believes that, with the exception of reduced ignition propensity cigarettes, guidelines for setting *regulatory limits* for content, design or emission are premature and should not be developed at the present time. Change to the design of cigarettes to reduce ignition propensity is one area where there is an evidence base. The FCA believes that the introduction of reduced ignition propensity cigarettes can be considered if Parties have the required capacity at country level to monitor and enforce these regulations. A template for this could be developed based on current evidence.

**Table 1: Summary of FCA position on relevant parts of Articles 9 to 11**

Relevant Article	Do validated standards exist?	Comments in relation to COP criteria for prioritisation ? (see Annex 3)	Is there sufficient <i>capacity</i> at Party level?	Are there controls over how the information would be <i>communicated</i> ?	Should guidelines be developed?	Should Parties be required to perform the obligation set out in the Article?
<b>9 (phase 1)</b> <i>Testing &amp; measuring</i> the <i>contents</i> of tobacco products	Yes (TobReg standards)	Concerns around 4 and 5	No	No	Yes	Subject to capacity.
<b>9 (phase 1)</b> <i>Testing &amp; measuring</i> the <i>emissions</i> of tobacco products	No – several regimes under discussion	Concerns around 2, 4 and 5	No	No	No, until a consensus is reached on which regime is best	Not yet
<b>Not specified</b> <i>Testing &amp; measuring</i> the <i>design</i> of tobacco products	Yes (TobReg standards)	Concerns around 4 and 5	No	No	Yes	Not yet
<b>9 (phase 2/3)</b> <i>Regulating</i> the <i>content &amp; emissions</i> of tobacco products	No	Concerns around 2, 4 and 5	No	No	Not yet	Not yet
<b>Not specified</b> <i>Regulating</i> the <i>design</i> of tobacco products	No	Concerns around 2, 4 and 5	No	No	Not yet	Not yet
<b>10 (phase 2/3)</b> Governmental and public <i>disclosure</i> of <i>contents and emissions</i>	No, but will follow from Art 9 (phase 1)	Concerns around 2, 4 and 5	No	No	Not yet	Not yet
<b>11 (under point 2)</b> Packaging and labelling of constituent & emission information	Yes	No concerns	Yes	No	Yes – urgently needed – to remove numerical information for consumers	Yes

### ***Background: What needs to be regulated and why?***

Most of this briefing paper focuses on cigarettes, the most dominant tobacco product internationally. However, in some countries, other forms of tobacco, such as smokeless tobacco or waterpipe are prevalent, so it is important that over time the FCTC Articles on product regulation encompass these products, in addition to novel tobacco products which are being introduced in several countries.

Cigarettes kill about half those who regularly smoke them, but they are virtually unregulated. Unlike other consumer products, there are hardly any regulations governing what goes into and comes out of cigarettes, despite the fact that they are highly engineered and sophisticated devices designed to deliver nicotine efficiently to the human body. Although there are considerable scientific and practical challenges to be overcome, this regulatory vacuum needs to be filled.

The primary harm caused by cigarette smoking is the result of nicotine addiction that causes smokers to repeatedly expose themselves to the toxins found in the smoke. The emissions generated from combusted tobacco also pose a risk to non-smokers who breathe in the toxins in the polluted air. The level of toxins generated by cigarette smoke is the result of a complex interaction between the cigarette (contents), how it is designed, how it is smoked, what comes out of the cigarette (emissions), what fraction of the emissions are actually absorbed by the user (exposure), and how the product is marketed (labelling, promotion and advertising, which can all impact on usage). It therefore follows that regulations to reduce the harmfulness of cigarettes will need to focus on a number of these different dimensions. The FCTC contains three Articles focusing on tobacco product regulation: Article 9 concerns testing, measuring and then regulating contents and emissions of tobacco products, Article 10 concerns the disclosure of information on contents and emissions from the manufacturers and Article 11 packaging and labelling (Annex 1). The first phase of Article 9 was prioritised as a matter on which a guideline should be developed at the first session of the COP and a template for a guideline for the elaboration of Article 9 was adopted (Annex 2). Ten criteria were also adopted for prioritization of the work related to guidelines with respect to Articles 9 to 11 among others (see Annex 3).

The WHO Study Group on Tobacco Product Regulation (formerly known as SACTOB, now referred to as WHOTobReg) has done much important work for Articles 9 to 11 by setting out guiding principles for the development of tobacco product research and testing capacity, and what content, design features and emissions should be tested. In particular, WHOTobReg began the process of developing guidelines for standardized reporting protocols for the industry to disclose details of the content and design of their products, building upon comprehensive reporting guidelines that already exist in countries such as Canada.

This briefing paper describes some of the issues involved in measuring and regulating cigarettes in relation to the Articles of the FCTC, the conclusions of the first session of the COP and WHO TobReg's work.

## Contents

The content of tobacco influences what the smoker absorbs. For example nitrate content is thought to affect the amount of toxins in cigarette smoke, and the proportion of nicotine in the blend will affect how deeply smokers inhale. Health Canada requires the tobacco industry to disclose on a brand by brand basis the name and quantity of every ingredient found in the tobacco, paper, and filter portions of cigarettes. Although Health Canada has the authority to regulate content of tobacco products, it does not yet do so<sup>1</sup>. Other jurisdictions such as the European Union have attempted to control the presence of toxic ingredients<sup>2</sup>, but there are concerns about the comprehensiveness of the definition of ingredient that has been used, and how toxicity of ingredients is evaluated (currently relative to the overall toxicity of tobacco products, rather than the absolute toxicity of the individual ingredient concerned).

Few additives were used in cigarettes before 1970 but today, additives may constitute more than 15% of weight of cigarettes in the EU. Many additives were introduced to improve the acceptability of low tar cigarettes but others were introduced ostensibly for technological reasons such as to prevent the fall of ash or inhibit mould formation. However, additives are used sparingly in other countries such as Canada and certain types of cigarettes claim to be free of additives. So it appears that the vast majority of ingredients do not seem to be necessary for the manufacture of cigarettes or their acceptance by consumers.

### ***FCTC and WHO Tob Reg recommendation re content***

The first phase of Article 9 - development of a guideline for the *testing and measuring* of the contents (and emissions) of tobacco products - was established as a priority at the first session of the COP. The template suggested that the focus should be on a selected set of especially harmful substances (or smoke emissions).

WHO TobReg has previously recommended that as a minimum the following contents (in the un-burnt tobacco) be disclosed on an annual basis:

- Nicotine/free nicotine (smokeless products)
- Ammonia/ammonium ion
- Metals (arsenic, cadmium, chromium, lead, mercury, nickel, selenium)
- Nitrosamines [N-nitrosornicotine (NNN), 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK), N-nitrosoanatabine (NAT), and N-nitrosoanabasine (NAB)]
- Menthol

Others (e.g. Fowles) have recommending expanding this list to include a more complete list of “additives,” including various flavourings, sugars, etc. WHO Tob Reg has also developed a more comprehensive definition of ingredients: *‘ingredients*

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<sup>1</sup> WHOTobReg (2005). Best Practices in Tobacco Control. Regulation of Tobacco Products Canada Report. WHO Tobacco Free Initiative. Available at:

[http://www.who.int/tobacco/global\\_interaction/tobreg/canadian\\_bp/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/canadian_bp/en/index.html)

<sup>2</sup> The term ingredients often encompasses the commonly used term ‘additive’ (eg in the EU). However, in Canada these two terms have different meanings see

[http://ec.europa.eu/health/ph\\_determinants/life\\_style/Tobacco/Documents/tobacco\\_fr\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_fr_en.pdf) . pp176-7.

*include all product components, materials used to manufacture those components, residual substances from agricultural practices, storage and processing, and substances that can migrate from packaging into the product’.*

To our knowledge, WHO TobReg has not proposed developing regulatory limits based upon product characteristics at the current time.

### ***FCA position re contents***

The FCA welcomes the development of guidelines for the testing and measurement of the *contents* of cigarettes. The FCA recommends that the WHO TobReg definition of ingredients is adopted by all Parties. The technical standards for determining the above characteristics are well established and accepted by public health scientists. However, while tobacco manufacturers would be responsible for the substantial costs associated with testing and reporting product characteristics, the FCA has concerns about the capacity of Parties to conduct the testing and measuring and a lack of clarity about how the findings would be communicated (see below for a discussion on these issues). Disclosure of such contents by industry will be important but we do not believe that regulatory limits for contents can be proposed at this stage without further research being undertaken into the impact of such a strategy.

### **Design**

The design of a cigarette has an important influence on the chemical profile of the smoke and the puffing behaviour of smokers. The design of the cigarette includes the following factors:

- type of tobacco used (different blends of tobacco influence smoke yields and constituents)
- percentage of reconstituted tobacco
- percentage of expanded tobacco
- type of filter (eg cellulose acetate or charcoal)
- amount of filter ventilation
- length of the filter
- pressure drop (otherwise known as ‘resistance to draw’)
- pH of the cigarette smoke which is believed to affect the proportion of nicotine that is absorbed into the blood stream
- aerosol particle size
- moisture content
- type of cigarette paper used and its porosity (cigarette paper is highly engineered and factors such as permeability, weight, thickness, strength can all play a role in influencing how the cigarette is smoked)
- dimensions of the cigarette and the tobacco rod (factors such as circumference, weight and density can all play a role).

To our knowledge, no country has regulated any aspect of design other than the propensity of cigarettes to cause fires.

### *Reduced ignition propensity cigarettes*

Cigarette-related fires are the leading cause of unintentional fire deaths in many parts of the world. Industry documents indicate that tobacco companies have long had the capability to manufacture reduced ignition propensity cigarettes by changing several design features, such as reduced tobacco density, reduced paper porosity, decreased circumference, and the removal or reduction of burn additives.

In 2004, New York State became the first jurisdiction in the world to implement ignition propensity standards, while Canada became the first country to do so in 2005. The New York State and Canadian laws stipulate that at least 75 percent of cigarettes must self-extinguish before burning the full length of their tobacco columns, utilizing the American Society for Testing and Materials (ASTM) method for measuring ignition propensity. Extensive testing and preliminary evaluations of the New York state regulations suggest that the ignition propensity standards are achieving their goal of reducing cigarette-related fires<sup>3</sup>.

### ***FCTC and WHO Tob Reg recommendation re design***

Article 9 of the FCTC does not explicitly mention design characteristics but the need to study design features was noted in the template for Article 9.

WHO TobReg has recommended that 11 of the above design-related features should be reported and that manufacturers should be required to report these parameters for each of their products on an annual basis.

WHO TobReg has not proposed developing regulatory limits based upon product characteristics at the current time.

### ***FCA position re design***

The FCA recommends that testing, measuring, disclosure of (and ultimately regulation of) the *design* of tobacco products should also be included in the guidelines being developed for Articles 9 and 10. The technical standards for determining these characteristics are well established and without controversy. As with content, tobacco manufacturers would be responsible for the substantial costs associated with testing and reporting design characteristics, but there are concerns about the capacity of Parties to conduct or regulate the testing, measuring and disclosure and a lack of clarity about how the findings would be communicated (see below for a discussion on these issues). The FCA believes that reduced ignition propensity regulations could be introduced for all manufactured cigarettes if there is sufficient regulatory capacity at country level to monitor and enforce these regulations.

### **Smoke Emissions**

To date, most tobacco product regulation has focused on machine based emissions of cigarettes. The term emissions covers all the substances produced when the cigarette

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<sup>3</sup> Connolly GN, Alpert HR, Rees V, et al (2005). Effect of the New York State cigarette fire safety standard on ignition propensity, smoke constituents and the consumer market. *Tobacco Control*, 14: 321-7.

is smoked. Machine based emissions refer to the substances collected on the filter pad when a machine smokes a cigarette. Only smoke drawn through the filter is captured (ie not sidestream smoke which arises from the lit end of the cigarette) and not all particles in the smoke are captured. Most commonly, measurements and regulations of machine based emissions have focused on tar (what is left on the filter in the machine minus nicotine and water) and nicotine.

Machines smoke the cigarette in a particular manner, with a set volume and duration for each puff and a fixed inter-puff interval and continue to smoke the cigarette until a particular butt length is reached. The most common parameters used are referred to as the ISO method<sup>4</sup>. With this method, ventilation holes are not covered.

The European Union has introduced maximum yields for tar, nicotine (and more recently carbon monoxide) when measured using the ISO method<sup>4</sup>. Manufacturers achieved the reduction in machine-measured yields using several techniques but the main method used was to dilute the smoke by placing ventilation holes in the cigarette filters<sup>5</sup>. This resulted in air also being drawn in through the filter causing a reduction in the machine-registered yields.

It is now widely accepted that the ISO method does not accurately reflect human smoking behaviour because its rigidity does not reflect human smoking behaviour. Most people smoke because they are addicted to nicotine and smokers, unlike machines, alter the way they smoke to achieve their preferred nicotine levels, a process known as compensation. The machines therefore fail to take account of cigarette smoking as predominantly nicotine-seeking behaviour. Smokers can alter 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, and are therefore easy to block.

Actual nicotine intakes of smokers therefore differ greatly from the machine-measured nicotine yields. Indeed, actual nicotine intakes are broadly similar across the range of machine-delivered nicotine yields. The ISO method cannot therefore be used to measure what smokers are actually taking in from their cigarettes and does not accurately reflect exposure of smokers to carcinogens and other toxins, largely underestimating exposure particularly with 'lower tar' cigarettes. In addition, the ISO method introduces misleading differences between brand designs that are not reflective of human smoking.

Some countries have introduced more intense standards for machine cigarette testing to try to overcome the limitations. British Columbia and subsequently Canada required manufacturers to measure cigarette smoke using the standard ISO method as well as a modified ISO or more intense puffing test. Commonly known as the Canadian intense method, the main changes involve fully blocking the ventilation holes and increasing the machine puff volume. The Massachusetts Department of health proposed reporting requirements for smoke constituents using a further

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<sup>4</sup> ISO means International Standards Organisation. The methodology used in the ISO test was introduced first by the US Federal Trade Commission and then adopted by ISO.

<sup>5</sup> O'Connor RJ, McNeill A, Cummings KM, Kozłowski LT, Giovino GA (in press). How did UK cigarette makers get their brands to 10mg 'Tar' or less? British Medical Journal.

modification of the ISO method which reduced the puff volume slightly compared to the Canadian system and blocked only 50% of the ventilation holes.

In addition, some countries have started to measure a greater variety of smoke constituents. When tobacco is burned during smoking, more than 4,000 chemical constituents are produced. Tar has markedly different compositions across different products and across different countries. Given it is misleading to view tar as a consistent homogeneous toxic substance, Canada measures a greater variety of smoke constituents such as nitrosamines and polynuclear aromatic hydrocarbons, believed to be some of the more dangerous constituents of tobacco smoke<sup>6</sup>.

### ***FCTC and WHO Tob Reg recommendation re emissions***

Development of a guideline for the *testing* and *measuring* of the emissions (and content, as described above) of tobacco products was established as a priority at the first session of the COP. The template suggested that the focus should be on a selected set of especially (harmful substances or) smoke emissions.

TobReg has recommended that manufacturers disclose a range of emissions in mainstream tobacco smoke, including:

- Nicotine/free nicotine
- Tar
- Carbon monoxide
- Ratio of nicotine-free dry particulate matter to nicotine yield
- Polynuclear aromatic hydrocarbons: benzo[a]pyrene
- Volatiles: benzene, 1,3-butadiene, formaldehyde, acetaldehyde
- Nitrosamines: NNN, NNK, NAT, NAB
- Metals: arsenic, cadmium, chromium, lead, mercury, nickel,
- Gas-phase compounds: nitrogen oxide, hydrogen cyanide

TobReg has recommended that the emissions be tested and reported according to two machine smoking regimes: the ISO and the “Canadian Intense” methods. There is considerable debate surrounding these testing methods. [It should be noted however, that neither regime is being proposed as a basis for communicating emission yields to consumers or for the purposes of modelling human exposure. TobReg has published clear statements to this effect. Rather, these regimes are solely for the purpose of generating information for scientists and regulators].

Over the last year, the relevant ISO committee (ISO/TC 126, the committee responsible for the ISO standards related to smoking<sup>7</sup>) set up a working group (WG9) mandated to modify the current ISO smoking machine standard. Broadly speaking, the committee recognised that no machine smoking regime could represent all human

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<sup>6</sup> WHOTobReg (2005). Best Practices in Tobacco Control. Regulation of Tobacco Products Canada Report. WHO Tobacco Free Initiative. Available at: [http://www.who.int/tobacco/global\\_interaction/tobreg/canadian\\_bp/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/canadian_bp/en/index.html)

<sup>7</sup> It should be noted that there have been numerous indications that ISO does not take public health concerns seriously. The current Chair of TC/126 is Peter Adams, from British American Tobacco (BAT). WHO became aware that he was soon to retire and found that a new Chair, Dr Henning Lutz was being appointed who was also from the tobacco industry and is shortly to take up a consultancy role with the UK Tobacco Manufacturers Association.

smoking behaviours and recommended that machines which test the product under conditions of different intensities of machine smoking testing were needed. Four options for intensifying the machine smoke testing were originally proposed and two were forwarded to the main ISO TC/126 meeting in May. However, at the May meeting a decision was delayed as was subsequent work on a new regime until after the FCTC guidelines were established.

TobReg and IARC are also proposing to use these emissions as the basis for setting regulatory limits on toxic constituents, such as the amount of TSNAs per mg of nicotine. It would appear that the recommended methods for measuring the emissions are the ISO regime in combination with the Canadian intense method, although this has yet to be established.

### ***FCA position re emissions***

The FCA supports the development of guidelines for the testing and measurement of *emissions* from cigarettes once a consensus has been reached among relevant experts as to the most appropriate testing regime to use.

The FCA believes that none of the more intensive smoking machine tests proposed provided an adequate means of characterising brands for the purposes of public health regulation. All suffer from the same fundamental limitations as the current ISO method. If machine yields are to be used in any regulatory capacity, they must reflect the range of human smoking behaviour, and to do so must also reflect compensatory human smoking. This will require multiple testing regimes. No testing regime currently in operation achieves these aims and some FCA members are currently in the process of developing a model for such a testing regime<sup>8</sup>. These will be considered in the context of biomarkers of human behaviour, in other words the test regime will be compared with measures of actual exposure to cigarette smoke in smokers. The FCA believes that there needs to be more discussion about the potential role of machine testing regimes and the broader scope of product regulation under the FCTC before any alternative testing regimes can be endorsed. Further, the FCA believes that ISO is not the appropriate forum for this debate, because it is industry dominated. This debate needs to be undertaken by independent public health bodies, since the tobacco industry has an inherent conflict of interest in the outcome of establishment of regulatory standards for their products.

As with other characteristics, even when a consensus is reached about measuring emissions, there are similar concerns about capacity and communication (see below). If these concerns are satisfied, disclosure will be important. However, the FCA believes that it is premature for COP to adopt guidelines for regulatory limits on toxins at this stage. Although in principle the FCA believes that it is appropriate to invoke the precautionary principle to setting toxin limits, concerns about how the emissions are measured, as well as concerns about capacity and communication (see below), need to be addressed as a precondition to implementing such a strategy.

### **Areas for concern**

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<sup>8</sup> Hammond D, Wiebel F, Kozlowski LT, Borland R, Cummings KM, O'Connor RJ, McNeill A, Arnott DA, Fong GT (submitted for publication) Revising the ISO machine smoking regime for cigarette emissions: Implications for tobacco control policy.

### ***(1) Capacity issues***

A key area of concern is one of capacity. Most Parties do not yet have the capacity to deal with the vast amounts of data that will be produced in implementing testing and measuring of cigarette characteristics. Implementing a strategy for disclosure (Article 10) will add further complexity. In addition to managing the vast amounts of data generated, previous experiences in Canada and elsewhere suggest that many Parties will need to adopt compliance measures to ensure accurate and timely reporting. Parties may also face legal challenges from manufacturers, particularly concerning public disclosure of data. Implementing and enforcing regulations will require much greater resources. The little capacity that does exist must not be devoted to implementing product regulatory measures in Articles 9 to 10 at the expense of implementing other proven tobacco policies.

#### ***FCTC and WHO Tob Reg recommendation re capacity***

The WHO, following the advice of WHOTobreg, also recognised the need for capacity building and set up the WHO Tobacco Laboratory Network (TobLabNet), a global laboratory network set up to strengthen national and regional capacity for tobacco product testing and research<sup>9</sup>.

#### ***FCA position re capacity***

The FCA supports the WHO TobLabNet initiative although it has concerns that laboratories in the network should be independent from the tobacco industry, as had been originally proposed by WHOTobReg. However, the FCA also remains concerned that the capacity of regulators to oversee, understand and act on the data being produced through the laboratories remains extremely limited in most countries around the world.

The FCA therefore believes that there is a need for an international centralised data management system and repository, independent of the industry, to facilitate and analyse the implementation of guidelines when they are agreed. Developing such a framework and body will be key to meaningful product regulation. A licensing system might be the best means of funding such a body, but it would be critical to maintain absolute independence from the tobacco industry and ensure that industry engagement is not allowed in any aspect of the organisation or management of the body, or in any of the data analysis or interpretation. Setting up a centralised data repository would allow for consistency of the data collected under Articles 9 and 10 and analysis of the data in a meaningful way without consuming the limited capacity for tobacco regulation at Party level. The FCA believes that the feasibility of such a repository needs to be explored as a precondition to implementing guidelines. There are a number of organisations that have the data management capacity to develop such a repository so this should not stall progress greatly.

### ***(2) Potential impact of guideline under Articles 9 and 10 and prioritisation***

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<sup>9</sup> See [http://www.who.int/tobacco/global\\_interaction/tobreg/laboratory/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/laboratory/en/index.html) for more information.

Whilst a much greater understanding of tobacco products is critically important in tobacco control, it is not yet understood how they can best be regulated to reduce the harm. Work must continue in this important area but not at the expense of implementing existing effective tobacco control strategies of proven benefit to public health.

### ***FCA position re prioritisation***

The FCA therefore believes that it is important to distinguish the priority given to the development of a guideline from the priority assigned to implementation of that guideline or the Article under which it is made. Some Parties who have already implemented laws governing aspects of tobacco product regulation (such as the European Union Directive placing a ceiling on tar, nicotine and carbon monoxide yields on packs), may have a stronger need for an effective, internationally agreed strategy in this area which they can then adopt. It is likely that many or most other Parties, particularly those without significant existing capacity in the area of product regulation, will need to prioritise the implementation of other Articles, guidelines and protocols within the FCTC concerning other tobacco control issues (for example, protection from exposure to tobacco smoke, banning tobacco advertising, introducing appropriate health warnings). An approach that recognises the need to prioritise in the context of limited resources is necessary.

### ***(3) Communication of information***

Tobacco manufacturers have labelled lower ISO tar yield cigarettes as 'light' and 'mild' but many smokers see these terms not as technical descriptors but implying health benefit. Some jurisdictions including Brazil and the European Union have therefore instituted bans on these terms. In addition, in Australia, the Australian Competition and Consumer Commission (ACCC) accepted court-enforceable undertakings from the three major Australian tobacco manufacturers in which they agreed that they would no longer use these terms. This was after the ACCC had reached the conclusion that the industry had engaged in misleading and deceptive conduct, in breach of Australian consumer protection law, in the marketing of 'light' and 'mild' products. In addition, the ISO tar yields themselves are also misleading as they imply that some brands are less harmful than others. Australia has eliminated its regulatory requirement to place ISO yields on cigarette packages and instead now requires the display of qualitative information about chemicals in tobacco smoke.

### ***FCTC and WHO Tob Reg recommendation re communication***

Part of Article 11 stipulates that product packaging and labelling must not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions.

As the ISO tar yields themselves are misleading as they imply that some brands are less harmful than others, WHO TobReg has called for their removal and indeed the ISO WG9 referred to above appears to have recognized this. One resolution from the ISO WG9 meeting in December 2005 noted that '*communication of machine*

*measurements to smokers can result in misunderstanding about differences in exposure and risk across brands’.*

***FCA Position re communication***

The long history of deceptive marketing of lower ISO tar yield cigarettes as ‘light’ and ‘mild’, and smokers’ perceptions of these labels as meaning that the cigarettes are ‘safer’ alternatives to traditional brands, means that these terms should be banned as is the case in other jurisdictions such as Brazil and the European Union.

Regarding Article 11.2, which deals with emissions information on the package, the FCA strongly recommends that countries avoid using the ISO numbers. For example, Brazil and Australia have removed their previous requirement for ISO numbers to appear on packages. It is unlikely that in the foreseeable future any new emission testing regime will result in meaningful data. The FCA therefore recommends action by the COP to ensure that numerical information on emissions not be communicated directly to consumers and that this be made a precondition for implementing Articles 9 to 10. This would also be a desired approach when implementing Article 11 although as Article 11 includes implementing package warnings it should not be a precondition for this. The FCA also recommends that Parties consider replacing the numerical information with researched messages giving qualitative information on tobacco constituents or quitting information. Some countries may choose not to ‘define’ any emissions/constituents and thus not require additional information regarding emissions/constituents elsewhere on the packaging. The COP may take action to ensure numerical information on emissions is not communicated either through a formal decision to this effect or the adoption of a guideline.

## **Annex 1 Articles 9 to 11 of the FCTC**

### ***Article 9***

#### *Regulation of the contents of tobacco products*

The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.

### ***Article 10***

#### *Regulation of tobacco product disclosures*

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

### ***Article 11***

#### *Packaging and labelling of tobacco products*

1. 1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:
  - a. tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and
  - b. each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:
    - i. shall be approved by the competent national authority,
    - ii. shall be rotating,
    - iii. shall be large, clear, visible and legible,
    - iv. should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,
    - v. may be in the form of or include pictures or pictograms.
2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.
3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.
4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

**Annex 2 Template guideline for Article 9 given in Committee Report 3 of the COP1**

**ANNEX 2: ARTICLE 9: PRODUCT REGULATION**

<b>Subject</b>	<b>Guidelines for the implementation of Articles 9 and 10 on the regulation of the contents of tobacco products and of tobacco product disclosures</b>
<b>Introduction</b>	<p>The overall purpose of guidelines for the implementation of the provisions in Articles 9 and 10 is to assist Parties in strengthening the regulation of the content of tobacco products.</p> <p>The elaboration of these guidelines involves three phases: first phase – the development of a guideline for the testing and measuring of the contents and emissions of tobacco products; phases two and three – to address regulations and/or disclosure (Article 10). The order of the second and third phases shall be considered by the COP at its second session.</p>
<b>CONTENTS:</b>	
Rationale	<ul style="list-style-type: none"> <li>• The testing and measuring of the contents and emissions of tobacco products serve as the basis for the regulation</li> </ul>
Objective	<ul style="list-style-type: none"> <li>• To provide guidelines for testing and measuring the contents and emissions of tobacco products</li> </ul>

Clear definition of elements of guidelines	<ul style="list-style-type: none"> <li>• Address testing and measuring of tobacco contents and smoke emissions from a public health perspective</li> <li>• Start with cigarettes (because most commonly used tobacco product)</li> <li>• Focus on a selected set of especially harmful substances or smoke emissions</li> <li>• Include criteria to assess the toxicity, addictiveness and attractiveness of these substances and/or products</li> <li>• Study the design features of these products</li> <li>• A recommendation on further work in order to continue to inform Contracting Parties on how best to adopt new strategies of tobacco product regulation as new scientific evidence is obtained and as new or modified products are introduced into the market</li> </ul>
Needs/value-added	<ul style="list-style-type: none"> <li>• Guidelines assist national authorities in implementing this article and thus facilitate regulatory control over tobacco</li> <li>• Leads to the establishment of an independent set of data and testing and measurement methods on tobacco products and their emissions from a public health angle in the medium and long term</li> <li>• International cooperation in this area leads to sharing of costs and expertise (value added of international cooperation)</li> </ul>
Existing work to build on	Base guidelines on the work already done by the WHO Study Group on Tobacco Product Regulation and WHO's Tobacco Free Initiative (the latter shall specify in a paper what they can already deliver and continue to work on this subject).
<b>PROCESS:</b>	
Implementing entity (mandated by the Conference of the Parties)	Convention Secretariat to initiate its work with WHO's Tobacco Free Initiative and Study Group on Tobacco Product Regulation in consultation with competent international bodies, as necessary – under the guidance of Contracting Parties identified as key facilitator(s) and with the assistance of the Parties willing to ensure regional representation.
Parties who offer to act as key facilitators	Canada, the European Community, Norway
Other Parties who offer to partner in the development of guidelines	Brazil, China, Denmark, Finland, Hungary, Jordan, Mexico, Netherlands,
Parties who offer to act as reviewers (in addition to the usual peer experts)	Australia, France, Jamaica, United Kingdom of Great Britain and Northern Ireland
Resource implications	Convention Secretariat in consultation with WHO will consider the workplan and budget implications.

<b>Time frame:</b>	
<i>for guideline development</i>	For the second session of the COP a draft of guidelines or a progress report should be presented on the work undertaken so far.
<i>for review</i>	At least sixty days prior to submission to the Bureau
<i>for submission to the Bureau</i>	At least ninety days prior to the first day of the second session of the COP
<i>for circulation to the Conference of the Parties</i>	Minimum of thirty days prior to the first day of the second session of the COP

### Annex 3 Extract from decisions from COP1 taken from Committee Report 3

#### DECIDED:

(1) to adopt the templates for the elaboration of guidelines on Articles 8 and 9, as they appear in Annexes 1 and 2 to this Decision;

(2) to take note of the templates for the elaboration of guidelines on Article 9 phases 2 and 3, and Articles 10 to 13 as examples for the elaboration of guidelines for these articles, as they appear in Annexes 3 to 5 of this Decision;

(3) to accord the highest priority to guidelines on Article 8 and the first phase of Article 9, and to request the Convention Secretariat to initiate work on these guidelines, on the basis of the templates, and to present draft guidelines to the second Conference of the Parties, if possible, or progress reports;

(4) to adopt the following criteria for prioritization of the work related to the guidelines with respect to Articles 9 to 13 which are mandated specifically by the Framework Convention and Articles 5.3 and 14, which have been requested by several Parties:

1. **Request from Parties:** there is an expressed need for the guidelines to assist Parties in implementing the Framework Convention.
2. **Existing work on the topic:** there is relevant existing work, e.g. Tobacco Free Initiative guidelines, so guidelines can be developed more quickly and efficiently.
3. **International value added:** international guidelines may be of particular assistance to Parties to implement some obligations, while involving a number of Parties allows expertise and costs to be shared.
4. **Potential impact of the measure covered by the guidelines:** measures are known to be effective at reducing the impact of tobacco.
5. **Ease of implementation:** this includes cost of implementation.
6. **Willingness of Parties to lead:** Parties have volunteered as key facilitators, partners or reviewers.
7. **Outcome measurability:** this is relevant to reporting (Article 21) and the potential to measure and analyse data.
8. **Contribution to maintaining momentum in implementing the Framework Convention:** this is particularly important in the early stages of implementation.
9. **Cost of guidelines development:** guidelines should be developed efficiently.
10. **International cooperation and cost sharing** are essential to effectively implement the elements of the guidelines.

(5) to request the Convention Secretariat to utilize these criteria in preparing a workplan for the elaboration of guidelines on the relevant articles, for consideration by the COP at its second session.