FCTC/COP4(10) **Partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control** (*Regulation of the contents of tobacco products and Regulation of tobacco product disclosures)*

The Conference of the Parties,

Taking into account Article 7 (*Non-price measures to reduce the demand for tobacco*), Article 9 (*Regulation of the contents of tobacco products*) and Article 10 (*Regulation of tobacco product disclosures*) of the WHO Framework Convention on Tobacco Control (WHO FCTC);

Recalling its decision FCTC/COP1(15) to establish a working group to elaborate guidelines for implementation of Article 9 (*Regulation of the contents of tobacco products*) and Article 10 (*Regulation of tobacco product disclosures*) of the WHO FCTC, and its decision FCTC/COP2(14) to extend the work of the working group to include product characteristics, such as design features, to the extent that they affect the objectives of the WHO FCTC;

Recalling its decision FCTC/COP3(9) mandating the working group to continue to monitor the areas set out in its first progress report (document A/FCTC/COP/2/8) which include dependence liability and toxicology, to continue to examine the challenges and potential approaches to setting up a global data repository, to continue its work elaborating guidelines in a step-by-step process, and to submit a first set of draft guidelines to the Conference of the Parties for consideration at its fourth session;

Emphasizing that the aim of the guidelines is to assist Parties in meeting their obligations under Articles 9 and 10 of the WHO FCTC and to provide guidance for implementation of these Articles;

Mindful of the provisional nature of the guidelines and the need for periodical reassessment in light of the scientific evidence and country experience,

1. ADOPTS the partial guidelines for implementation of Article 9 (*Regulation of the contents of tobacco products*) and Article 10 (*Regulation of tobacco product disclosures*) of the WHO FCTC contained in the Annex to this decision;

2. WELCOMES the report of WHO's Tobacco Free Initiative to the Conference of the Parties (document FCTC/COP/4/INF.DOC./2);

3. REQUESTS the Convention Secretariat:

(a) to invite WHO's Tobacco Free Initiative to continue the validation of the analytical chemical methods for testing and measuring cigarette contents and emissions in accordance with the progress report (document FCTC/COP/3/6) and to inform the Conference of the Parties through the Convention Secretariat on a regular basis of the progress made;

(b) to make accessible, via a web site, the studies, research and other reference material used in the development of the guidelines for implementation of Articles 9 and 10 of the WHO FCTC;

4. DECIDES to mandate the working group to:

(a) continue its work in elaborating guidelines in a step-by-step process, and to submit draft guidelines on addictiveness and toxicity to future sessions of the Conference of the Parties for consideration;

(b) continue to monitor areas such as dependence liability and toxicology;

(c) examine the regulation of cigarette ignition propensity, as a product characteristic;

5. INVITES Parties, by 31 January 2011, to confirm to the Convention Secretariat their intention to continue as members of the working group or their intention to join the working group;[1]

6. ALSO DECIDES, in accordance with decision FCTC/COP3(9):

(a) to request the Convention Secretariat to provide assistance and make the necessary arrangements including budgetary arrangements for the working group to continue its work, and to ensure, in consultation with the Bureau of the Conference of the Parties, that Parties have access to the draft text (for example, via a protected web site) and can provide comments before the circulation of the draft guidelines to the Conference of the Parties;

(b) to adopt the timeline set out below:

Draft report made available by the Secretariat for comments by the Parties	At least six months before the opening day of the fifth session of the Conference of the Parties
Submission of the final report by the working group to the Secretariat	At least three months before the opening day of the fifth session of the Conference of the Parties
Circulation to the Conference of the Parties	At least 60 days before the opening day of the fifth session of the Conference of the Parties in accordance with Rule 8 of the Rules of Procedure of the Conference of the Parties

[1] Current membership of the working group is as follows:
– Key Facilitators: Canada, European Union, Norway
– Partners: Algeria, Australia, Brazil, Bulgaria, China, Congo, Denmark, Finland, Ghana, Hungary, India, Jordan, Kenya, Mali, Mexico, Netherlands, Singapore, Thailand, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland.

ANNEX

PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (REGULATION OF THE CONTENTS OF TOBACCO PRODUCTS AND OF TOBACCO PRODUCT DISCLOSURES)

1. PURPOSE, OBJECTIVES AND USE OF TERMS

1.1 PURPOSE

The purpose of the guidelines is to assist Parties in meeting their obligations under Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC). The guidelines, drawing on the best available scientific evidence and the experience of Parties, propose measures that may assist Parties in strengthening their tobacco-control policies through regulation of the contents and emissions of tobacco products and through regulation of tobacco product disclosures. Parties are also encouraged to implement measures beyond those recommended by these guidelines.[2]

Whereas Article 9 deals with the testing and measuring of the contents and emissions of tobacco products, and their regulation, Article 10 deals with the disclosure of information on such contents and emissions to governmental authorities and the public. Owing to the close relationship between these two articles, guidance for their implementation has been consolidated into one set of guidelines.

1.2 OBJECTIVES

1.2.1 Regulation of the contents and emissions of tobacco products

One objective of the guidelines is to support Parties in developing effective tobacco product regulation. Tobacco product regulation has the potential to contribute to reducing tobacco-attributable disease and premature death by reducing the attractiveness of tobacco products, reducing their addictiveness (or dependence liability) or reducing their overall toxicity.

1.2.1.1 Attractiveness

Tobacco products are commonly made to be attractive in order to encourage their use. From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive. Other measures to reduce the attractiveness of tobacco products have been included in the guidelines on the implementation of Articles 11 and 13 of the WHO FCTC.[3]

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[2] Parties are directed to the WHO FCTC web site (http://www.who.int/fctc/) where further sources of information on topics covered by these guidelines are maintained.

[3] See *WHO Framework Convention on Tobacco Control: guidelines for implementation. Article 5.3; Article 8; Article 11; Article 13*. Geneva, World Health Organization, 2009.

The WHO FCTC, in its preamble, recognizes that tobacco products are harmful and create and maintain dependence. Any reduction of their attractiveness resulting from removing or reducing certain ingredients in no way suggests that those tobacco products are less dangerous for human health.

1.2.1.2 Addictiveness (dependence liability)

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.[4])

1.2.1.3 Toxicity

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

1.2.2 Disclosure to governmental authorities

Pursuant to Article 10, the primary objective of requiring disclosure to governmental authorities is to obtain from manufacturers and importers relevant information on the contents and emissions of tobacco products, as well as on their toxicity and addictiveness. This information is required for the development and implementation of relevant policies, activities and regulations, such as further analysis of tobacco product contents and emissions, monitoring of market trends, and assessment of tobacco industry claims.

1.2.3 Disclosure to the public

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

1.3 USE OF TERMS

"Attractiveness" refers to factors such as taste, smell and other sensory attributes, ease of use, flexibility of the dosing system, cost, reputation or image, assumed risks and benefits, and other characteristics of a product designed to stimulate use.[5]

"Contents" means "constituents" with respect to processed tobacco, and "ingredients" with respect to tobacco products. In addition:

- "Constituents":

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

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[4] The guidelines are partial and will be completed in phases as new country experience, and scientific, medical and other evidence become available. Further progress will also depend on the validation of the analytical chemical methods for testing and measuring cigarette contents and emissions and other work pursuant to the decision by the Conference of Parties at its third session (decision FCTC/COP3(9)).

[5] WHO. The scientific basis of tobacco product regulation: Report of a WHO Study Group. WHO Technical Report Series 945. Geneva, World Health Organization, 2007.

- "Ingredients" include tobacco, components (e.g. paper, filter), including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing), and substances that migrate from the packaging material into the product (contaminants are not part of the ingredients).

"Design feature" means a characteristic of the design of a tobacco product that has an immediate causal link with the testing and measuring of its contents and emissions. For example, ventilation holes around cigarette filters decrease machine-measured yields of nicotine by diluting mainstream smoke.

"Emissions" are substances that are released when the tobacco product is used as intended. For example, in the case of cigarettes and other combusted products, emissions are the substances found in the smoke. In the case of smokeless tobacco products for oral use, emissions are the substances released during the process of chewing or sucking, and in the case of nasal use, refer to substances released by particles during the process of snuffing.

"Expanded tobacco" is tobacco that has been expanded in volume by quick volatilization of a medium such as dry ice.

"Reconstituted tobacco" is a paper-like sheet material comprised mainly of tobacco.

"Tobacco industry" means, as defined in Article 1 of the WHO FCTC, "tobacco manufacturers, wholesale distributors and importers of tobacco products".

"Tobacco products", as defined in Article 1 of the WHO FCTC, are "products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing, or snuffing".

2. PRACTICAL CONSIDERATIONS

2.1 APPROVAL AND IMPLEMENTATION OF MEASURES PURSUANT TO ARTICLE 9

As stated in Article 9 of the WHO FCTC, each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures, for the testing and measuring of the contents and emissions of tobacco products and for the regulation of these contents and emissions.

Parties should consider giving the authority responsible for tobacco control matters the responsibility for, or at a minimum the power to provide input into, the approval, adoption and implementation of the above-mentioned measures.

2.2 APPROVAL AND IMPLEMENTATION OF MEASURES PURSUANT TO ARTICLE 10

As stated in Article 10 of the WHO FCTC, each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures for the disclosure by manufacturers and importers of tobacco products to governmental authorities of information about the contents and emissions of tobacco products, as well as for the public disclosure of information about the toxic constituents of tobacco products and their emissions.

Parties should consider giving the authority responsible for tobacco control matters the responsibility for, or at a minimum the power to provide input into, the adoption and implementation of the above-mentioned measures.

2.3 FINANCING

Implementing effective tobacco product regulations and operating a programme for their administration require the allocation of significant resources by Parties. In order to alleviate governmental budgetary pressure, Parties could consider placing these costs on the tobacco industry and retailers. There are various means of financing tobacco product regulation measures.

The list below sets out some options that Parties could consider using:

(a) designated tobacco taxes;

(b) tobacco manufacturing and/or importing licensing fees;

(c) tobacco product registration fees;

(d) licensing of tobacco distributors and/or retailers;

(e) non-compliance fees levied on the tobacco industry and retailers; and

(f) annual tobacco surveillance fees (tobacco industry and retailers).

See Appendix 1 for descriptive examples of means of financing tobacco product regulation measures.

2.4 LABORATORIES USED FOR PURPOSES OF DISCLOSURE

Laboratories used by manufacturers and importers of tobacco products for the purposes of disclosure to governmental authorities should be accredited in accordance with International Organization for Standardization (ISO) Standard 17025 (General requirements for the competence of testing and calibration laboratories), by a recognized accreditation body. The accreditation methods used should include, at a minimum, the methods set out in these guidelines.

2.5 LABORATORIES USED FOR COMPLIANCE PURPOSES

Laboratories used by Parties for compliance purposes should be either governmental laboratories or independent laboratories that are not owned or controlled, directly or indirectly, by the tobacco industry. In addition, such laboratories should be accredited as set out in the previous paragraph. Parties may consider making use of governmental or independent laboratories located in other countries.

2.6 CONFIDENTIALITY IN RELATION TO DISCLOSURE TO GOVERNMENTAL AUTHORITIES

Parties should not accept claims from the tobacco industry concerning the confidentiality of information that would prevent governmental authorities from receiving information about the contents and emissions of tobacco products. Governmental authorities should apply appropriate

rules in accordance with their national laws when collecting information claimed to be confidential by tobacco manufacturers and importers in order to prevent unauthorized use and/or dissemination of this information.[6]

2.7 CONFIDENTIALITY IN RELATION TO DISCLOSURE TO THE PUBLIC

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

2.8 CIVIL SOCIETY

Civil society has an important role to play in raising public awareness and building support for the regulation of the contents and emissions of tobacco products, and for the disclosure of information on these contents and emissions. Civil society should be involved as an active partner.

3. MEASURES

3.1 CONTENTS

3.1.1 Ingredients (Disclosure)

This section outlines measures that Parties could introduce to require the disclosure by manufacturers and importers of tobacco products of information about ingredients.

3.1.1.1 Background

By requiring manufacturers and importers to disclose information about ingredients to governmental authorities, valuable insight will be gained on the composition of tobacco products, which in turn will assist authorities in developing effective, product-appropriate measures.

3.1.1.2 Recommendations

(i) Parties should require that manufacturers and importers of tobacco products disclose to governmental authorities information on the ingredients used in the manufacture of their tobacco products at specified intervals, by product type and for each brand within a brand family. Contrary to disclosing ingredients as part of a combined list, disclosing on a brand-by-brand basis and in a standardized format will provide opportunities to governmental authorities to analyse trends in product composition and keep track of subtle changes in the market.

(ii) Parties should ensure that manufacturers and importers disclose to governmental authorities the ingredients used in the manufacture of each of their tobacco products and the quantities thereof per unit of each tobacco product, including those ingredients present in the product's components (e.g. filter, papers, glue), for each brand within a brand family. Parties should not accept disclosure only of maximum quantities by category of ingredient,

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[6] Guidance regarding public disclosure of this information is left to future guidelines.

or only of the total quantity. To do so would seriously limit the kind of analysis that could be performed.

(iii) Parties should require that manufacturers and importers disclose further information on the characteristics of the tobacco leaves they used, for example:

(i) type(s) of tobacco leaves (e.g. Virginia, Burley, Oriental), and percentage of each type used in the tobacco product;

(ii) percentage of reconstituted tobacco used;

(iii) percentage of expanded tobacco used;

(iv) Parties should require that manufacturers and importers notify governmental authorities of any changes to tobacco product ingredients when the change is made;

(v) Parties should require that manufacturers and importers provide governmental authorities with a statement setting out the purpose[7] of the inclusion of an ingredient in the tobacco product and other relevant information;

(vi) Parties should require that manufacturers disclose the name, address and other contact information of each ingredient's supplier to facilitate direct disclosure to the Party by the supplier, where appropriate, and for compliance monitoring purposes.

3.1.2 Ingredients (Regulation)

This section outlines measures that Parties could introduce to regulate ingredients.

Parties should introduce the measures outlined in this section, in accordance with their national laws, taking into account their national circumstances and priorities.

Parties should consider scientific evidence, other evidence and experience of others countries when determining new measures on ingredients of tobacco products and they should aim to implement the most effective measures that they can achieve.

3.1.2.1 Background

Regulating ingredients aimed at reducing tobacco product attractiveness can contribute to reducing the prevalence of tobacco use and dependence among new and continuing users. The preamble to the WHO FCTC states that Parties recognize "that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence".

Attractiveness and its impact on dependence should be taken into account when considering regulatory measures. The guidelines on implementation of Article 13 of the WHO FCTC, on

[7] Examples include substances that are used as adhesives, binders, combustion modifiers, addictiveness enhancers, flavours, humectants, plasticizers, casings, smoke enhancers and colourings.

tobacco product advertising, promotion and sponsorship, recommend that restrictions apply to as many as possible of the features that make tobacco products more attractive to consumers. Such features include coloured cigarette papers and attractive smells. Similarly, this section presents measures that will help limit inducements to use tobacco.

3.1.2.2 Tobacco products

(i) Ingredients used to increase palatability

The harsh and irritating character of tobacco smoke provides a significant barrier to experimentation and initial use. Tobacco industry documents have shown that significant effort has been put into mitigating these unfavourable characteristics. Harshness can be reduced in a variety of ways including: adding various ingredients, eliminating substances with known irritant properties, balancing irritation alongside other significant sensory effects, or altering the chemical properties of tobacco product emissions by adding or removing specific substances.

Some tobacco products contain added sugars and sweeteners. High sugar content improves the palatability of tobacco products to tobacco users. Examples of sugars and sweeteners used in these products include glucose, molasses, honey and sorbitol.

Masking tobacco smoke harshness with flavours contributes to promoting and sustaining tobacco use. Examples of flavouring substances include benzaldehyde, maltol, menthol and vanillin.

Spices and herbs can also be used to improve the palatability of tobacco products. Examples include cinnamon, ginger and mint.

Recommendation:

Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products.

Ingredients indispensable for the manufacturing of tobacco products and not linked to attractiveness should be subject to regulation according to national law.

(ii) Ingredients that have colouring properties

Colouring agents are added to various components of tobacco products to make the resulting product more appealing. Attractively-coloured cigarettes (e.g. pink, black, denim blue) have been marketed in some countries. Examples of colouring agents include inks (e.g. imitation cork pattern on tipping paper) and pigments (e.g. titanium dioxide in filter material).

Recommendation:

Parties should prohibit or restrict ingredients that have colouring properties in tobacco products. However, Parties should consider allowing the use of colouring agents for tax-related markings or for health warnings and messages.

(iii) Ingredients used to create the impression that products have health benefits

Various ingredients have been used in tobacco products to help create the impression that such products have health benefits, or to create the impression that they present reduced health hazards. Examples include vitamins, such as vitamin C and vitamin E, fruit and vegetables (and products resulting from their processing such as fruit juices), amino acids, such as cysteine and tryptophan, and essential fatty acids such as omega-3 and omega-6.

Recommendation:

Parties should prohibit ingredients in tobacco products that may create the impression that they have a health benefit.

(iv) Ingredients associated with energy and vitality

Energy drinks, popular with young people in some parts of the world, are perceived to increase mental alertness and physical performance. Examples of stimulant compounds contained in such drinks include caffeine, guarana, taurine and glucuronolactone. Tobacco industry documents and patent applications show that some of these (caffeine and taurine) have also been considered for use in tobacco products.

Recommendation:

Parties should prohibit ingredients associated with energy and vitality, such as stimulant compounds, in tobacco products.

3.1.3 Constituents (Disclosure)

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

3.1.4 Constituents (Regulation)

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

3.2 EMISSIONS

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

3.3 PRODUCT CHARACTERISTICS

3.3.1 Disclosure

This section outlines measures that Parties could introduce to require the disclosure by manufacturers and importers of tobacco products of information about product characteristics, such as design features.

3.3.1.1 Background

Collecting data on product characteristics, such as design features, will help Parties improve their understanding of the impact these characteristics have on smoke emission levels, properly interpret measurements obtained and, more importantly, keep abreast of any changes to cigarette design features.

3.3.1.2 Recommendations

(i) Parties should require that manufacturers and importers of tobacco products disclose information on design features to governmental authorities at specified intervals, and as appropriate, including the results of tests conducted by the tobacco industry.

(ii) In order to establish and maintain the consistency of the data reported to them by the tobacco industry, Parties should specify the recommended methods, where applicable, for the reporting of design features as set out in Appendix 2.

(iii) Parties should ensure that every manufacturer and importer provides to governmental authorities a copy of the laboratory report where a laboratory test was performed for the measurement of a particular design feature, as well as the proof of accreditation of the laboratory that performed the analysis.

(iv) Should there be any change to the design features of a particular brand of tobacco product, Parties should require that manufacturers notify governmental authorities of the change and provide the updated information when the change is made.

3.3.2 Regulation

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

3.4 DISCLOSURE TO GOVERNMENTAL AUTHORITIES – OTHER INFORMATION

3.4.1 Background

In order to put effective product regulation in place, including regulation of ingredients, it is essential that governmental authorities have accurate market information. Governmental authorities need to know the importance of a particular tobacco product compared to others to help determine regulatory needs and priorities. Furthermore, consistent with Article 20.2 of the WHO FCTC, information on tobacco companies and on their sales will help assess the magnitude and patterns of tobacco consumption.

3.4.2 Recommendations

Parties should require that manufacturers and importers of tobacco products disclose general company information, including the name, street address and contact information of the principal place of business and of each manufacturing and importing facility. This information may prove useful for compliance monitoring purposes.

Parties should consider requiring that tobacco manufacturers and importers disclose, at specified intervals, for each brand within a brand family, sales volume information in units (e.g. number of cigarettes or cigars, or weight of roll-your-own tobacco). These disclosures should be on a national basis, and where appropriate on a sub-national basis as well.

3.5 DISCLOSURE TO THE PUBLIC

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

4. COMPLIANCE AND ENFORCEMENT

4.1 COMPREHENSIVE APPROACH

Effective legislative, executive, administrative or other measures should impose legal responsibilities for compliance on manufacturers and importers of tobacco products and should provide penalties for violations. Legislative, executive, administrative or other measures should identify the authority or authorities responsible for enforcement, and should include a system both for monitoring compliance and for prosecuting violators.

4.2 INFRASTRUCTURE AND BUDGET

Parties should consider ensuring that the infrastructure necessary for compliance monitoring and enforcement activities exists. Parties should also consider providing a budget for such activities.

4.3 STRATEGIES

To enhance compliance, Parties should inform stakeholders of the requirements of the law before it comes into force.

Parties should consider using inspectors or enforcement agents to conduct regular visits to manufacturing and importing facilities, as well as at points of sale, to ensure compliance. It may not be necessary to create a new inspection system if mechanisms are already in place that could be extended to inspect business premises as required.

4.4 DEADLINE – PROHIBITED OR RESTRICTED INGREDIENTS

Parties should specify a deadline following which tobacco industry and retailers must only supply tobacco products that comply with requirements.

4.5 INSPECTIONS – PROHIBITED OR RESTRICTED INGREDIENTS

Parties should consider conducting visits to manufacturing facilities to verify whether any prohibited or restricted ingredient is being used. Inspection should include direct access to the raw supplies storage area and to the finished products storage area, as well as direct observation of the manufacturing process. Inspections should not constitute an approval or certification of the tobacco products, nor recognition of their manufacturing procedures.

4.6 SAMPLING AND TESTING – PROHIBITED OR RESTRICTED INGREDIENTS

Parties should consider having samples of tobacco products collected from importers' facilities, from retail outlets and, where needed, from manufacturers' facilities. These samples should then be tested for the presence of prohibited or restricted ingredients in laboratories used for compliance purposes (see Appendix 3).

4.7 AUDITS FOLLOWING DISCLOSURE TO GOVERNMENTAL AUTHORITIES

Parties should consider conducting audits at manufacturers' facilities to ensure that information received concerning tobacco products is complete and accurate. Audits should not constitute an approval or certification of the tobacco products, nor recognition of their manufacturing procedures.

4.8 RESPONSE TO NON-COMPLIANCE

Parties should ensure that their enforcement authorities are prepared to respond quickly and decisively to instances of non-compliance. Strong, timely responses to early cases will make it clear that compliance is expected and will facilitate future enforcement. Parties should consider making the results of enforcement action public in order to send a strong message that non-compliance will be investigated and that appropriate action will be taken.

4.9 SANCTIONS

In order to deter non-compliance with the law, Parties should specify appropriate sanctions, such as criminal sanctions, monetary amounts, corrective actions, and the suspension, limitation or cancellation of business and import licences.

4.10 SEIZURE, FORFEITURE AND DESTRUCTION

Parties should ensure that they have authority to have non-compliant tobacco products seized**,** forfeited and destroyed, under supervision in accordance with national law.

4.11 PENALTIES

Parties should specify a range of fines or other penalties commensurate with the severity of the violation and whether it is a repeat violation.

5. INTERNATIONAL COOPERATION

International cooperation is essential if progress in tobacco product regulation and disclosure is to be made. Several articles of the WHO FCTC provide for the exchange of knowledge and experience to promote implementation. As stated in Article 22 of the WHO FCTC, such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed. It would result in the effective implementation of these guidelines and facilitate development of the best possible measures for regulating the contents of tobacco products.

6. MONITORING AND EVALUATION

(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)

7. LINKS TO OTHER ARTICLES OF THE WHO FCTC

In the spirit of Articles 11 and 13 of the WHO FCTC, unless Parties have already adopted measures to ban any type of promotion on tobacco product packages (as outlined in the guidelines on Articles 11 and 13), Parties should consider imposing a ban on the sale of tobacco products whose packaging suggests the presence of an ingredient that has been prohibited or, where appropriate, restricted as per the above recommendations.

Appendix 1

Descriptive examples of means of financing tobacco product regulation measures

(a) Designated tobacco taxes

Designated tobacco taxes require a proportion of tobacco tax revenue to be allocated to a specified purpose or purposes, such as a tobacco-control programme or a health promotion fund. The proportion of tobacco tax revenue might be expressed as a percentage of revenue (e.g. 1%) or as a fixed monetary amount per unit (e.g. 25 cents per package of 20 cigarettes). Designated tobacco taxes are sometimes referred to as "earmarked tobacco taxes" or "hypothecated tobacco taxes".

(b) Tobacco manufacturing and/or importing licensing fees

A licensing fee on tobacco manufacturers and/or importers could be implemented in a number of ways. The fee could be a specified monetary amount per company, regardless of company size. (A separate fee might be required for each manufacturing and/or importing facility.) The fee could be a fixed monetary amount per unit sold (e.g. a certain amount per cigarette or package of cigarettes, or per gram for certain types of tobacco products). The fee could be based on a total amount for all companies, and determined on the basis of a company's market share (e.g. if the total amount to be paid by all companies was US$ 100 million and a company's market share was 20%, and the company's license fee would be US$ 20 million). The required fee might have to be paid at specified intervals, such as prior to the beginning of an annual period. Where a fee is based on a monetary amount per unit sold, the payment interval might be more frequent, e.g. monthly.

(c) Tobacco product registration fees

Tobacco product registration fees involve requiring the manufacturer and/or importer, or potentially a wholesale distributor, to register each tobacco product sold by the company and to pay an accompanying fee. The amount of the fee might be set at a level such that government costs (or average costs) associated with the product, such as testing, measuring and enforcement, are fully or partially recovered. The required fee might have to be paid at specified intervals, e.g. prior to the beginning of an annual period.

(d) Licensing of tobacco distributors and/or retailers

A licensing fee could be placed on distributors or retailers, or both. The fee could be a specified monetary amount per outlet, regardless of company size. (A separate fee might be required for each manufacturing and/or importing facility.) The fee could vary based on the size of the distributor and/or retailer, e.g. based on sales volume. The fee might be set at varying amounts depending on sales volume (either units or total monetary amount), e.g. a fee if sales are not higher than amount A, a higher fee if sales are between amount A and amount B, and a further increased fee if sales are higher than amount B. The required fee might have to be paid at specified intervals, e.g. prior to the beginning of an annual period.

(e) Non-compliance fees levied on the tobacco industry and retailers

Revenue could be collected from administrative monetary penalties. Administrative monetary penalties are a form of civil penalty in which an administrative body seeks monetary relief against an individual or corporate body as restitution for unlawful activity. Revenue could also be collected from fines imposed by a court.

(f) Annual tobacco surveillance fees (tobacco industry and retailers)

Annual tobacco surveillance fees involve assessing the amount to be paid by the tobacco industry and/or retailers for monitoring and enforcement. For tobacco manufacturers/importers/distributors, this could be a fixed amount per company, a fixed amount for each brand variation sold, a fixed amount per unit sold, or an amount based on market share. For tobacco retailers (or others), a separate licence and fee might be required for each retail outlet.

Appendix 2

Design features of cigarettes[8]

(a) Dimensions, diameter and weight

(b) Length of filter, shape of the cross-section of the filter

(c) Length of tipping paper

(d) Dimensions and shape of the cross-section of the tobacco rod

(e) Distance of ventilation holes from butt mark in millimetres

(f) Draw resistance of cigarette as determined in accordance with ISO 6565 (Tobacco and tobacco products – Draw resistance of cigarettes and pressure drop of filter rods – Standard conditions and measurement)

[8] See ISO 9512 (Cigarettes – Determination of ventilation – Definitions and measurement principles) for an explanation of the terms used here.

(g) Degree of filter ventilation as determined in accordance with ISO 9512 (Cigarettes –Determination of ventilation – Definitions and measurement principles)

(h) Degree of paper ventilation as determined in accordance with ISO 9512 (Cigarettes – Determination of ventilation – Definitions and measurement principles)

(i) Type of cigarette paper used and its air permeability or porosity determined in accordance with ISO 2965 (Materials used as cigarette papers, filter plug wrap and filter joining paper, including materials having an oriented permeable zone – Determination of air permeability)

(j) Product firmness (nominally a measure of packing density)

(k) Pressure drop of the filter as determined in accordance with ISO 6565 (Tobacco and tobacco products – Draw resistance of cigarettes and pressure drop of filter rods – Standard conditions and measurement)

(l) Moisture content as determined in accordance with Association of Official Analytical Chemists Official Method 966.02 (Loss on drying (moisture) in tobacco)[9]

(m) Type of filter (for example, cellulose acetate) and other characteristics, where applicable (for example, charcoal content)

Appendix 3

Analytical methods for ingredients

(a) For the purposes of compliance monitoring and enforcement, there may be cases in which analytical methods would be required to confirm the presence of prohibited or restricted ingredients. Such methods typically consist of several distinct steps: sampling, sample preparation, separation, identification, quantification and data analysis.

(b) Analytical procedures should be carried out by properly trained personnel in a suitably equipped laboratory. Such procedures frequently involve the use of hazardous materials. To ensure the correct and safe execution of these procedures, it is essential that laboratory personnel follow standard safety procedures for the handling of hazardous materials.

(c) For ingredients that are also food additives, suitable analytical methods may be found in the *Combined compendium of food additive specifications (volume 4)*.[10] This document provides a reference for the analytical methods mentioned in the specifications for the identity of additives used in foods or in food production.

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[9] See Horwitz W, Latimer G, eds. *Official methods of analysis*, 18th ed., Revision 3. Gaithersburg, MD, AOAC International, 2010.

[10] Joint FAO/WHO Expert Committee on Food Additives. *Combined compendium of food additive specifications. Volume 4: analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications*. Rome, Food and Agriculture Organization of the United Nations, 2006 (FAO JECFA Monograph No. 1) (http://www.fao.org/docrep/009/a0691e/A0691E00.htm, accessed 1 April 2010).

(d) For ingredients such as flavouring agents which have a low-boiling point (that is, which vaporize easily at low temperatures), a technique called "headspace-gas chromatography" may be used. A description of this method may be found in the *Combined compendium of food additive specifications (volume 4)*.

(e) Another laboratory technique for sampling ingredients with a low boiling point, which can be combined for separation, identification and quantification with gas chromatography/mass spectrometry, is called "solid-phase microextraction".[11] It is very similar to headspace analysis, but differs in that the headspace is concentrated.

(Tenth plenary meeting, 20 November 2010)

[11] Pawliszyn J et al. Solid-phase microextraction (SPME). *The chemical educator*, 1997, 2(4):1–7 (http://www.springerlink.com/content/h72xx3624q122085/fulltext.pdf, accessed 1 April 2010).