



**FCTC**

WHO FRAMEWORK CONVENTION  
ON TOBACCO CONTROL

## **Partial guidelines for implementation of Articles 9 and 10**

Regulation of the contents of tobacco products and regulation of tobacco product disclosures

Adopted by the Conference of the Parties at its fourth session (decision FCTC/COP4(10)) with amendments adopted at the fifth session (decision FCTC/COP5(6)) and at the seventh session (decision FCTC/COP7(14))

Online version available at

[http://www.who.int/fctc/treaty\\_instruments/guidelines\\_articles\\_9\\_10\\_2017\\_english.pdf](http://www.who.int/fctc/treaty_instruments/guidelines_articles_9_10_2017_english.pdf)

# **PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL<sup>1</sup>**

## **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.<sup>2</sup>

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

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<sup>1</sup> As adopted by the COP at its fourth session in 2010, with amendments adopted at its fifth session in 2012.

<sup>2</sup> 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.

attractiveness of tobacco products have been included in the guidelines on the implementation of Articles 11 and 13 of the WHO FCTC.<sup>3</sup>

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.<sup>4</sup>)

#### *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

Pursuant to Article 10, the primary objective of public disclosure of information about the toxic constituents and emissions of tobacco products is to inform the public of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke. This information may also assist the public in contributing to the development and implementation of relevant policies, activities and regulations.

## **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.<sup>5</sup>

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

<sup>4</sup> 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)).

“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.)

- “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.

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

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:

- designated tobacco taxes;
- tobacco manufacturing and/or importing licensing fees;
- tobacco product registration fees;
- licensing of tobacco distributors and/or retailers;
- non-compliance fees levied on the tobacco industry and retailers; and
- 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 purpose 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.<sup>6</sup>

## **2.7 Confidentiality in relation to disclosure to the public**

Parties should disclose information about the toxic constituents and emissions of tobacco products to the public in a meaningful way. Parties may determine in accordance with their national laws the information about the toxic constituents and emissions of tobacco products that should not be disclosed to the public.

## **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 Content**

### **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.

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<sup>6</sup> Guidance regarding public disclosure of this information is left to future guidelines.

### 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, 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<sup>7</sup> 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.

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<sup>7</sup> Examples include substances that are used as adhesives, binders, combustion modifiers, addictiveness enhancers, flavours, humectants, plasticizers, casings, smoke enhancers and colourings.

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 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 Contents (Disclosure to governmental authorities)

This section outlines requirements which Parties could introduce for the disclosure by manufacturers and importers of tobacco products of information on the contents of these products to governmental authorities

#### *3.1.3.1. Background*

Given the numerous toxic and addictive substances contained in tobacco products, governmental authorities with access to information on tobacco contents are in a better position to understand the nature of their tobacco product market. Such information can then be used by governmental authorities to inform the development of policies and regulations respecting the attractiveness, addictiveness or toxicity of tobacco products. For example, given that nicotine is

the main substance in tobacco involved in the addictive process, Parties may wish to obtain information on the amount of nicotine present in the various tobacco products available in their domestic market.

To help collect such information, governmental authorities can mandate the use of analytical laboratory methods for the testing and measuring of contents of tobacco products developed under the auspices of WHO<sup>8</sup>. The WHO Study Group on Tobacco Product Regulation identified a non-exhaustive list of priority toxic contents and emissions of tobacco products for regulation under Articles 9 and 10 of the WHO FCTC<sup>9</sup>. These methods can be easily performed by a wide spectrum of laboratories. Methods have also been developed by various governmental authorities and international organizations.

### *3.1.3.2 Recommendations*

(i) Parties should consider requiring manufacturers and importers of tobacco products to disclose to governmental authorities at specified intervals, information about the contents of their tobacco products by product type, and for each brand within a brand family.

(ii) When requiring the testing and measuring of contents, Parties should consider where it is appropriate specifying that standards agreed by the Parties to the Convention or recommendations by the WHO Tobacco Laboratory Network could be used by the laboratories performing the test on behalf of the manufacturers and importers of tobacco products. On nicotine, Parties should consider specifying that the Tobacco Laboratory Network Official Method SOP 04, entitled Standard operating procedure for determination of nicotine in cigarette tobacco filler, World Health Organization<sup>10</sup>, be used by the laboratories performing the test on behalf of the manufacturers and importers of tobacco products.

(iii) Parties should consider requiring that every manufacturer and importer provides to governmental authorities a copy of the laboratory report that shows the product tested and the results of the testing and measuring conducted on that product. Parties should also consider asking for proof of accreditation or membership in the WHO Tobacco Laboratory Network or be approved by competent authorities of the Parties in question of the laboratory that performed the testing and measuring.

### 3.1.4 Constituents (Regulation)

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

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<sup>8</sup> See the list of available WHO methods at [http://who.int/tobacco/publications/prod\\_regulation/en/](http://who.int/tobacco/publications/prod_regulation/en/)

<sup>9</sup> For the full list, see WHO Technical Report Series, n. 989, WHO Study Group on Tobacco Product Regulation: report on the scientific basis of tobacco product regulation, available at: <http://apps.who.int/iris/bitstream/10665/161512/1/9789241209892.pdf?ua=1&ua=1>

<sup>10</sup> See <http://apps.who.int/fctc/implementation/database/article/article-10/resources>

## **3.2 Emission**

(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.

Furthermore, when combined with sales figures, such data will help Parties analyse market trends.

#### *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**

#### *3.3.2.1 Cigarettes – Regulation in relation to fire-risk (reduced ignition propensity)*

##### **(i) Background**

Lit cigarettes that are laid down and left unattended smoulder and can ignite upholstery, other furniture, bedding and other textiles, or other material. This has been observed most often in cases

of smoking in bed or smoking while under the influence of alcohol, illicit drugs or medication. Every year a considerable number of people around the world are injured or die (e.g. from burns or smoke gas poisonings) as a result of fires caused by cigarettes.

In order to prevent a significant number of such injuries and deaths, cigarettes can be designed in a way that the cigarette self extinguishes when not puffed or left unattended and thereby has a reduced risk of starting fires. These cigarettes are known as reduced ignition propensity cigarettes (RIP cigarettes).

Reductions in the number of cigarette fires and related victims have been observed in some jurisdictions that have mandated the replacement of conventional cigarettes with RIP cigarettes. Although RIP cigarettes do not self-extinguish in every case, they are expected to reduce the risk of a fire being ignited, and thus the risk of injuries and deaths. It is important to note that mandating an RIP standard is aimed at reducing the number of fires caused by lit cigarettes; it will not eliminate them.

There have been claims that RIP cigarettes may have a different toxicity than conventional cigarettes. Research suggests that RIP cigarettes are just as toxic as conventional cigarettes and equally dangerous to human health.

(ii) Regulating the ignition propensity of cigarettes

In regulating the ignition propensity of cigarettes, governmental authorities usually take a performance-based approach by adopting provisions that prescribe the test method to be used, and then provisions that set the pass/fail criteria (performance standard) applicable to the results obtained after conduct of the test (see Appendix 4).

In a number of cases, governmental authorities have also laid down requirements related to a specific technique for achieving RIP, namely banded paper technology, and requirements related to certification (see Appendix 5).

(iii) Recommendations

(i) Parties should require that cigarettes comply with an RIP standard, taking into account their national circumstances and priorities.

(ii) When implementing recommendation (i) of this paragraph, Parties should consider setting a performance standard that corresponds at a minimum to the current international practice, regarding the percentage of cigarettes that may not burn their full length when tested according to the method described in Appendix 4.

(iii) Parties should not allow any claims to be made suggesting that RIP cigarettes would be unable to ignite fires.

*3.3.2.2 Tobacco Products – Regulation in relation to attractiveness*

(i). Background

The tobacco industry is continuously aiming at making tobacco products more attractive by modifying existing product design features or introducing new ones. An example is the industry's

manufacture of cigarettes with an ever-smaller circumference (slim, superslim, ultraslim). Another example is the placement of capsules in cigarette filters that release flavour when crushed.

Product design features are used by the tobacco industry to develop strategies making products more attractive to different segments of society, an approach known as market segmentation. These segments can be based for example on age, gender, ethnic or cultural background, socioeconomic status and health concerns. The tobacco industry then targets these segments by developing product design features that meet their expectations and interests with regard to health, glamour, novelty, self-image, weight loss, convenience/ease of use, sensory experience and others.

Regulating product design characteristics to decrease tobacco product attractiveness can contribute to reducing the prevalence of tobacco use.

(ii). Recommendations

Consistent with 3.1.2.2., Parties should regulate all tobacco product design features that increase the attractiveness of tobacco products, in order to decrease the attractiveness of tobacco products.

### **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**

#### **3.5.1 Background**

Many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality attributable to tobacco use and exposure to tobacco smoke. Complementing other measures relating to the reduction of demand for tobacco, Article 10 of the WHO FCTC requires that each Party shall adopt and implement effective measures for public disclosure of

information about the toxic constituents of tobacco products and the emissions that they may produce. As stated in Article 4.1 of the WHO FCTC, Parties shall be guided by the principle that every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke.

### 3.5.2 Scope and means of public disclosure

#### *3.5.2.1 Public access to information disclosed to governmental authorities*

Detailed information about the toxic constituents and emissions of tobacco products is difficult to comprehend, and public disclosure of such information might not directly promote or protect public health. However, such information may assist other members of civil society, particularly academic institutions and nongovernmental organizations, in contributing to tobacco control policy.

In addition, other information disclosed to governmental authorities in accordance with these guidelines, such as information on ingredients, product characteristics and the market, may also contribute to raising public awareness and advancing tobacco control policy.

#### *Recommendation:*

Parties should consider, in accordance with their national laws, making information about the toxic constituents and emissions of tobacco products and other information disclosed to governmental authorities in accordance with these guidelines publicly accessible (e.g. via the Internet, or by request to a governmental authority) in a meaningful way.

#### *3.5.2.2 Public disclosure of constituents and emissions in the context of Articles 11 and 12 of the WHO FCTC*

Information on how public disclosure is linked to Articles 11 and 12 of the WHO FCTC can be found in section 7, “LINKS TO OTHER ARTICLES OF THE WHO FCTC”.

## **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 Deadlines**

##### 4.4.1 Prohibited or restricted ingredients

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

##### 4.4.2 Reduced ignition propensity

Parties should specify a deadline following which the tobacco industry and retailers must only supply cigarettes that comply with the required RIP standard.

#### **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**

##### 4.6.1 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).

##### 4.6.2 Reduced ignition propensity

Parties should consider having samples of cigarettes collected from manufacturers, importers or retailers. These samples should then be tested to ascertain whether they comply with the required RIP performance standard. Both sampling and testing should be carried out according to the method described in Appendix 4.

#### **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**

### **7.1 Packaging suggesting the presence of a prohibited ingredient**

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.

### **7.2 Information on relevant constituents and emissions on tobacco packaging**

Tobacco product packaging and labelling are an effective means of public communication about constituents and emissions of tobacco products, as recognized in Article 11 of the WHO FCTC. Parties should refer to Article 11 and the guidelines for its implementation.

### **7.3 Information on relevant constituents and emissions in education, communication, training and other public awareness programmes**

Parties should consider including messages about constituents and emissions of tobacco products in education, communication, training and other public awareness programmes. Such messages may reinforce efforts to inform the public of the health consequences, addictive nature and mortal threat posed by tobacco use and exposure to tobacco smoke in programmes established in accordance with Article 12 of the WHO FCTC and the guidelines for its implementation.

## **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<sup>11</sup>**

- (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)
- (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)<sup>12</sup>
- (m) Type of filter (for example, cellulose acetate) and other characteristics, where applicable (for example, charcoal content)

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<sup>11</sup> See ISO 9512 (Cigarettes – Determination of ventilation – Definitions and measurement principles) for an explanation of the terms used here.

<sup>12</sup> See Horwitz W, Latimer G, eds. *Official methods of analysis*, 18th ed., Revision 3. Gaithersburg, MD, AOAC International, 2010.

(n) Description and explanation of function of all innovative components added to the cigarette, such as capsules.

### 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)*.<sup>13</sup> 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.

(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”.<sup>14</sup> It is very similar to headspace analysis, but differs in that the headspace is concentrated.

### APPENDIX 4

#### Performance standard for reduced ignition propensity (RIP) cigarettes and related standard test methods

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<sup>13</sup> 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).

<sup>14</sup> 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).

The performance standard for RIP cigarettes has been expressed as the percentage of cigarettes that, when ignited and laid down on a pre-determined substrate, do not burn through their whole length.

As of 2012, international practice is to require a not-burn-through rate of no less than 75%.

As of 2012, available standard test methods for sampling and verifying the conformity of cigarettes with the required not-burn-through rate include: ISO 12863:2010 “Standard test method for assessing the ignition propensity of cigarettes”; EN ISO 12863:2010 “Standard test method for assessing the ignition propensity of cigarettes”; AS 4830-2007 “Determination of the extinction propensity of cigarettes”; NZS/AS 4830:2007 “Determination of the extinction propensity of cigarettes”; and ASTM E2187-09 “Standard Test Method for Measuring the Ignition Strength of Cigarettes”.

## APPENDIX 5

### **Reduced ignition propensity cigarettes – additional information**

#### (a) Design of the cigarette paper

Where Parties have required banded paper technology, one of the practices with respect to both filter and non-filter cigarettes is for one band surrounding the tobacco column to be located not less than 15 mm from the lighting end of the cigarette, and for a second such band to be located not less than 10 mm from the filter end or, in the case of non-filter cigarettes, not less than 10 mm from the labelled end of the tobacco column.

#### (b) Certification approach

Where a self-certification approach has been adopted, the practice is to require the tobacco industry to file with the appropriate governmental authority a statement of conformity and/or declaration of truth, with the required RIP standard. An alternative approach would be to mandate third-party certification.