



WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

**Conference of the Parties to the
WHO Framework Convention
on Tobacco Control**

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Agenda item 5.2

**FCTC/COP/4/6 Rev.1
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**Draft guidelines for the implementation of
Articles 9 and 10 of the WHO Framework
Convention on Tobacco Control**

**Including amendments received from Parties during
the first meeting of Committee A**

Bold indicates proposed new text, strikethrough indicates proposed deletions.

1. At its first session (Geneva, Switzerland, 6–17 February 2006), the Conference of the Parties to the WHO Framework Convention on Tobacco Control decided¹ to set up a working group to draft guidelines on the implementation of Articles 9 and 10 of the Convention. Draft guidelines or a progress report were to be presented by the working group at the second session of the Conference of the Parties.
2. At its second session (Bangkok, Thailand, 30 June – 6 July 2007), the Conference of the Parties reviewed a progress report by the working group. The report gave an overview of the work accomplished to that point, including details of meetings of the working group, and proposed an outline for future work. The Conference of the Parties requested the working group to continue its work, as proposed, and to provide a progress report to the Conference of the Parties at its third session.² The Conference of the Parties also requested the working group to extend its work to include product characteristics, such as design features, to the extent that they affect the objectives of the Convention.
3. At its third session (Durban, South Africa, 17–22 November 2008), the Conference of the Parties received a progress report³ from the working group, which summarized progress, proposed

¹ See decision FCTC/COP1(15).

² See decision FCTC/COP2(14).

³ Document FCTC/COP/3/6.

future work and made recommendations to the Conference of the Parties on related topics. The areas covered by the working group to that point were: principles for financing tobacco product regulation programmes; testing and measuring the contents and emissions of tobacco products; regulation of tobacco product disclosures; and investigating the elaboration of guidelines for product characteristics, including design features. The Conference of the Parties decided¹ to mandate the working group to:

- continue its work, elaborating the 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;
- continue to monitor the areas set out in its previous progress report, including dependence liability and toxicology; and
- continue to examine the challenges and potential approaches to setting up a global data repository.

4. The sixth meeting of the working group (Amman, Jordan, 20–22 October 2009) was attended by the Key Facilitators and Partners of the working group. The participants also included representatives of civil society, the Convention Secretariat and WHO’s Tobacco Free Initiative. At the meeting, the working group discussed and amended the draft guidelines proposed by the Key Facilitators. The draft was then further elaborated, in order that it be submitted to Parties to the Convention for their comments, in accordance with decision FCTC/COP3(9).

5. The timeline established by decision FCTC/COP3(9) required the draft guidelines to be made available for comments by Parties at least six months before the fourth session of the Conference of the Parties. Consistent with this request, the draft guidelines were submitted to Parties for their comments in May 2010. On the basis of the comments received, the Key Facilitators of the working group amended the draft guidelines. The resulting draft guidelines are attached at Annex.

CONSIDERATIONS IN THE DEVELOPMENT OF THE GUIDELINES

6. As Articles 9 and 10 of the Convention deal with strongly interrelated aspects of the “contents and emissions of tobacco products”, the approach chosen by the working group was to develop a single set of guidelines covering both articles.

7. As explained in the working group’s progress reports, the complex nature of tobacco product regulation and disclosure, as well as the fact that there is limited experience in implementing the relevant measures at country level, mean that much discussion and work have been required over several working group meetings to develop the guidelines.

8. The mandate of the working group included looking first at cigarettes and, later, at other tobacco products. Parties may apply the recommendations directed at cigarettes to other tobacco products, should they so wish.

9. Another particularity of the guidelines is their step-by-step development, as mandated by the Conference of the Parties,¹ enabling the working group to put forward partial guidelines until a complete set is achieved. Hence, the current draft guidelines include sections labelled “This section

¹ See decision FCTC/COP3(9).

has been left blank intentionally”, which identify areas not yet developed, but whose inclusion help the reader understand the overall structure of the guidelines.

10. With respect to Article 10, it should be noted that the draft guidelines currently only deal with the first sentence of the Article, that is, disclosure to governmental authorities. The working group did not have the opportunity to explore other disclosure issues fully.

11. Parties are invited to note that the draft guidelines include a recommendation on the disclosure of market data, namely sales information. Although this clearly falls outside the scope of Article 10, the working group felt that it was useful guidance to Parties, as it would enable them to improve their understanding of the market for tobacco products in their country or territory.

PROPOSED FUTURE WORK

12. At its third session, the Conference of the Parties requested¹ the Convention Secretariat to invite WHO’s Tobacco Free Initiative, *inter alia*, to submit a report to the Conference of the Parties at its fourth session, identifying best practices in providing information to the public; and to validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the second progress report of the working group.² Should the Conference of the Parties mandate the working group to continue to operate, the above information would be used to complete the guidelines, in step-by-step fashion.

13. The working group asked the Conference of the Parties, at its second session, whether “contents and emissions” were understood to include the characteristics of the tobacco product itself. The Conference of the Parties decided³ that the working group could include in its work product characteristics, such as design features, to the extent that they affect the objectives of the Convention. The working group proposes to examine the regulation of cigarette ignition propensity, should the group be mandated to continue its work. As the working group is uncertain as to the applicability of the previous decision on “ignition propensity” as a product characteristic, the Conference of the Parties is invited to indicate whether it agrees that such a product characteristic should be addressed in the guidelines.

14. Parties in the working group, as well as other Parties, have commented that the work of the working group should be extended to cover electronic nicotine delivery systems (also known as “e-cigarettes”). As these systems do not contain tobacco, it is not readily apparent whether they meet the definition of “tobacco products” set out in Article 1 of the Convention. The Conference of the Parties is invited to indicate whether it agrees that electronic nicotine delivery systems are to be considered “tobacco products” and should be part of future work of the working group. The Conference of the Parties is further invited to specify which questions should be addressed in this future work.

¹ See decision FCTC/COP3(9).

² See document FCTC/COP/4/INF.DOC./2.

³ See decision FCTC/COP2(14).

ACTION BY THE CONFERENCE OF THE PARTIES

15. The Conference of the Parties is invited to note this report, to review and consider adopting the guidelines.

ANNEX

**DRAFT 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. 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 ~~provided for~~ **recommended** by these guidelines.¹

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 Convention.²

¹ 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.

² 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 Convention, 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.¹)

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.²

~~“Cigarette-like tobacco products” includes cigarettes, little cigars and roll-your-own tobacco products.~~

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

¹ 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)).

² WHO. **The scientific basis of tobacco product regulation: Report of a WHO Study Group.** WHO Technical Report Series 945. Geneva, Switzerland: World Health Organization Press; 2007.

- “Constituents” ~~include substances that occur naturally in tobacco and substances found in tobacco as a result of agricultural practices.~~ **(This section has been left blank intentionally to indicate that guidance will be proposed at a later stage.)**

Or

- “Constituents” include substances that occur naturally in tobacco ~~and substances found in tobacco as a result of agricultural practices.~~
- “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~~ **the specific substances to avoid confusing with contaminants (processing aids, etc.) or poor quality papers.**

“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 Framework Convention on Tobacco Control, “tobacco manufacturers, wholesale distributors and importers of tobacco products”.

“Tobacco products”, as defined in Article 1 of the WHO Framework Convention on Tobacco Control, 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 Framework Convention on Tobacco Control, 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 Framework Convention on Tobacco Control, 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.¹

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.

¹ 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 in 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 purpose¹ 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.

¹ 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 when determining new measures on ingredients 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 Framework Convention on Tobacco Control 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 Framework Convention on Tobacco Control, 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 ~~Cigarette-like~~ Tobacco products (comments from key facilitators: lack of country experience for most 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 ~~cigarette-like~~ tobacco products contain added sugars and sweeteners. High sugar content improves the palatability of ~~cigarette-like~~ tobacco products to smokers. 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 ~~cigarette-like~~ tobacco products. Examples include cinnamon, ginger and mint.

Recommendation:

Parties should either **restrict or prohibit** ~~or restrict~~ ingredients that may be used to increase palatability, ~~such as sugars and sweeteners, flavouring substances, and spices and herbs,~~ in ~~cigarette-like~~ tobacco products **unless these ingredients are critical for the manufacturing of these products and are not linked to attractiveness.**

Or

Parties should ~~either prohibit or restrict~~ **regulate** ingredients that may be used to increase palatability, such as sugars and sweeteners, flavouring substances, and spices and herbs, in ~~cigarette-like~~ tobacco products **unless these ingredients are critical for the manufacturing of these products and are not linked to attractiveness.**

Or

Parties should ~~either prohibit or restrict~~ ingredients that may be used to increase palatability, such as sugars and sweeteners, flavouring substances, and spices and herbs, in ~~cigarette-like~~ tobacco products **unless these ingredients are critical for the manufacturing of these products and are not linked to attractiveness.**

Or

Parties should either prohibit or restrict ingredients that may be used to increase palatability, such as sugars and sweeteners, flavouring substances, and spices and herbs **that can impact over taste or flavours**, in ~~cigarette-like~~ tobacco products.

(ii) Ingredients that have colouring properties

Colouring agents are added to various components of ~~cigarette-like~~ 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, ~~such as inks and pigments~~, in ~~cigarette-like~~ tobacco products. However, Parties should consider allowing the use of colouring agents for tax-related markings or for health warnings and messages.¹

Or

Parties should **either restrict or** ~~prohibit or restrict~~ ingredients that have colouring properties, ~~such as inks and pigments~~, in ~~cigarette-like~~ tobacco products. However, Parties should consider allowing the use of colouring agents for tax-related markings or for health warnings and messages.¹

Or

Parties should ~~prohibit or restrict~~ ingredients that have colouring properties, ~~such as inks and pigments~~, in ~~cigarette-like~~ tobacco products. However, Parties should consider allowing the use of colouring agents for tax-related markings or for health warnings and messages.¹

¹ Parties should only permit colouring agents that do not increase the overall toxicity of the tobacco products.

Or

Parties should ~~prohibit or restrict~~ **regulate** ingredients that have colouring properties, ~~such as inks and pigments,~~ in ~~cigarette-like~~ tobacco products. However, Parties should consider allowing the use of colouring agents for tax-related markings or for health warnings and messages.¹

Or

Parties should prohibit or restrict ingredients that have colouring properties, such as inks and pigments, in ~~cigarette-like~~ tobacco products. However, Parties should consider allowing the use of ~~colouring agents~~ for tax-related markings or for health warnings and messages **on the packages**.¹

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

Various ingredients have been used in ~~cigarette-like~~ 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 ~~either prohibit or restrict~~ ingredients in ~~cigarette-like~~ tobacco products that may create the impression that they have a health benefit, ~~such as vitamins, mineral nutrients, fruit and vegetables (and products resulting from their processing), amino acids, and essential fatty acids.~~

Or

Parties should ~~either prohibit or restrict~~ ingredients in ~~cigarette-like~~ tobacco products that may create the impression that they have a health benefit, ~~such as vitamins, mineral nutrients, fruit and vegetables (and products resulting from their processing), amino acids, and essential fatty acids.~~

Or

Parties should ~~either prohibit or restrict~~ **regulate** ingredients in ~~cigarette-like~~ tobacco products that may create the impression that they have a health benefit, ~~such as vitamins, mineral nutrients, fruit and vegetables (and products resulting from their processing), amino acids, and essential fatty acids.~~

Or

Parties should either **restrict or** ~~prohibit or restrict~~ ingredients in ~~cigarette-like~~ tobacco products that may create the impression that they have a health benefit, ~~such as vitamins, mineral~~

¹ Parties should only permit colouring agents that do not increase the overall toxicity of the tobacco products.

~~nutrients, fruit and vegetables (and products resulting from their processing), amino acids, and essential fatty acids.~~

(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 ~~either prohibit or restrict~~ ingredients associated with energy and vitality, ~~such as stimulant compounds, in cigarette-like~~ tobacco products.

Or

Parties should ~~either prohibit or restrict~~ **regulate** ingredients associated with energy and vitality, ~~such as stimulant compounds, in cigarette-like~~ tobacco products.

Or

Parties should either **restrict or** prohibit ~~or restrict~~ ingredients associated with energy and vitality, ~~such as stimulant compounds, in cigarette-like~~ tobacco products.

~~3.1.2.3 All other tobacco products~~

Recommendation:

~~Parties should consider collecting information on the ingredients found in all other tobacco products, and review this information to assess whether to regulate these ingredients as recommended above.~~

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 cigarette-like tobacco products disclose information on design features to governmental authorities at specified intervals, 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 cigarette-like 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 Framework Convention on Tobacco Control, 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~~ **may** 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~~ **may** 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~~ **may** 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~~ **may** 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~~ **may** 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~~ **may** consider ~~making the results of enforcement action public in order to~~ **sending** 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, ~~AND~~ FORFEITURE AND DESTRUCTION

Parties should ensure that they have authority to have non-compliant tobacco products seized, ~~and~~ forfeited **and destroyed under supervision**.

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 Framework Convention on Tobacco Control provide for the exchange of knowledge and experience to promote implementation. As stated in Article 22 of the Convention, 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 CONVENTION

In the spirit of Articles 11 and 13 of the WHO Framework Convention on Tobacco Control, 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 cigarettes¹

- (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)²
- (m) Type of filter (for example, cellulose acetate) and other characteristics, where applicable (for example, charcoal content)

¹ See ISO 9512 (Cigarettes – Determination of ventilation – Definitions and measurement principles) for an explanation of the terms used here.

² See Horwitz W, Latimer G, eds. *Official methods of analysis*, 18th ed., Revision 3. Gaithersburg, MD, AOAC International, 2010.

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)*.¹ 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”.² It is very similar to headspace analysis, but differs in that the headspace is concentrated.

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¹ 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).

² 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).