



ESSENTIAL ELEMENTS OF TOBACCO PRODUCT PACKAGING AND LABELING LEGISLATION

INTRODUCTION

This resource is provided to assist lawyers, advocates, and government officials involved in developing legislation for tobacco control. It provides a framework for analyzing and drafting tobacco product packaging and labeling legislation that reflects FCTC Article 11, the Guidelines for its implementation (“Guidelines”), and lessons learned from a review of tobacco product packaging and labeling laws in many countries.

Effective packaging and labeling legislation fulfills FCTC Article 11 requirements, fully incorporates the Guidelines, which provide direction for developing and successfully implementing Article 11 compliant legislation, and incorporates best practices. Such legislation:

1. defines key terms in accordance with FCTC Articles 1 and 11;
2. applies measures that include:
 - a prohibition on packaging and labeling that promotes a tobacco product by means that are false, misleading, deceptive, or likely to create an erroneous impression about its characteristics, health effects, hazards, or emissions, including through the use of the terms “low tar,” “light,” “ultra-light,” “mild,” “extra,” “ultra”, any similar terms in any language, and any proxies for those terms, such as figuratives, colors, or other signs, and any misleading packaging or product design;
 - a requirement that unit packs (e.g., individual packages) and outside packaging and labeling (e.g., cartons) of all tobacco products carry prescribed pictorial and text health warnings and other appropriate messages that are as large as possible, are displayed at least on each principal display area at the top, and that rotate;
 - a requirement that unit and outside packaging and labeling carry prescribed descriptive information on constituents and emissions, without any yield figures; and
 - a requirement for plain packaging;
3. imposes a legal duties of compliance with packaging and labeling requirements on all tobacco manufacturers, importers, wholesalers, and retailers;
4. specifies inspection and enforcement authorities, their powers and duties, and the responsibilities that fall to each authority if more than one has inspection/enforcement responsibilities;
5. provides a range of deterrent penalties that are proportionate to the seriousness of the violation and the legal duty of the violator;

6. empowers and enables civil society to make complaints and take legal action to compel compliance with the law;
7. requires the appropriate authority to evaluate the effectiveness of both the legislation and its enforcement and make this information readily available to the public; and
8. provides the appropriate authority with broad regulatory power to address implementing details and any other matters necessary or appropriate for effectual implementation of the legislation.

FCTC ARTICLE 11 AND ITS GUIDELINES

FCTC Article 4.1 provides that Parties to the treaty should 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. To give effect to this principle, FCTC Article 11.1 requires Parties to adopt and implement effective measures to ensure that specified packaging and labeling requirements are met within three years of the treaty's entry into force in their countries.

The Guidelines, developed to assist Parties in meeting their FCTC Article 11 obligations and adopted by consensus, propose measures to increase the effectiveness of required packaging and labeling legislation. In addition to incorporating the most widely-accepted scientific evidence and best practices, the Guidelines draw upon lessons learned from Parties' experiences and seek to counter known tobacco industry tactics for circumventing tobacco packaging and labeling regulation.

Parties to the FCTC have a legal obligation to perform their treaty obligations in good faith, in accordance with Article 26 of the Vienna Convention on the Law of Treaties. The Guidelines are a subsequent agreement between the Parties and must be taken into account in interpreting the scope and content of Parties' obligations, in accordance with Article 31 of the Vienna Convention.

Incorporating the Guidelines into domestic legislation will establish the foundation for effectively informing consumers of the harms caused by and risks associated with tobacco use and exposure to tobacco smoke, minimizing loopholes, and facilitating proper implementation of legal requirements.

1. DEFINING KEY TERMS

FCTC Article 1 and Article 11 provide key definitions for implementing packaging and labeling requirements, including definitions for "*tobacco products*"¹ "*tobacco industry*,"² and "*outside packaging and labelling*"³ as follows:

¹ FCTC, Art. 1(f).

² FCTC, Art. 1(e).

³ FCTC, Article 11(4).

- “*tobacco products*”: “products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.”⁴
- “*tobacco industry*”: “tobacco manufacturers, wholesale distributors and importers of tobacco products.”
- “*outside packaging and labelling*” in relation to tobacco products: “any packaging and labelling used in the retail sale of the product.”

Integrating these definitions into domestic legislation is important for proper interpretation and application of tobacco product packaging and labeling requirements.⁵ Without these definitions, there is risk that the terms could be interpreted in a manner that is less comprehensive than required by FCTC Article 11.

APPLYING TOBACCO PRODUCT PACKAGING AND LABELING REQUIREMENTS

FCTC Article 11 requires Parties to adopt and implement effective measures that provide for:

- a prohibition on false, misleading, or deceptive packaging and labeling;
- requirements for the display of health warnings approved by the competent national authority, which may include other appropriate messages, on unit and outside packaging and labeling of tobacco products; and
- requirements for the display on unit and outside packaging and labeling of information on relevant constituents and emissions of tobacco products as defined by national authorities.

Legal measures addressing these requirements should apply to all smoked and smokeless tobacco products, whether domestically manufactured or imported. Exemptions should not be provided for small volume companies or brands or tobacco products intended for duty-free sale.⁶

Prohibition on false, misleading, or deceptive packaging and labeling

FCTC Article 11.1(a) requires effective measures to ensure that tobacco product packaging and labeling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about the product’s characteristics, health effects, hazards or emissions, including any term, descriptor, trademark or figurative or other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others. This may include terms such as “low tar,” “light,” “ultra-light” or “mild” in any language that might mislead consumers. The Guidelines provide that in addition to these terms, legal measures should prohibit terms such as “extra,” “ultra”, and similar terms in any language that might mislead consumers.⁷ Because emission yield figures are misleading, legislation

⁴ The FCTC definition can be modified slightly to be sure it covers all tobacco products regardless of the means by which they are consumed, such as by adding at the end : “or by any other means of consumption.”

⁵ In addition, the Guidelines provide definitions for “inserts” and “onserts”. These definitions should be incorporated if those terms are used in the legislation (with regard to health warning placement, for example).

⁶ Guidelines, paras. 36, 49.

⁷ Guidelines, para. 43.

should prohibit their display, including when used as part of a brand name or trademark (e.g., “Kent 4” or “Kent 7”).⁸

To avoid loopholes, all of these prohibitions should apply to the entire package, inside and out, and to the product itself. Prohibitions on misleading packaging and labeling should be broad enough to cover package and product size, shape, and other characteristics that are likely to be misleading or deceptive to consumers.

Health warnings and other messages

FCTC Articles 11.1(b) and 11.3 require the display of large, clear, visible, and legible health warnings in the principal language(s) of the country on unit and outside packaging and labeling of all tobacco products. The Guidelines elaborate how to effectively address placement/location, size, composition and content, rotation, and color of warnings and messages prescribed by the appropriate authority,⁹ specifically:

Placement/Location

The Guidelines provide that warnings and messages should be required to be placed:¹⁰

- on both the front and back of the unit and outside packaging and labeling and, in the case of packages with more than two main display areas, on each principal display area, at a minimum;¹¹
- at the top of each principal display area rather than at the bottom; and
- in such a way that neither they nor other required pack information are permanently damaged or concealed by normal opening of the package or by other markings, labels, stickers, cases, covers, sleeves, or wrappings, or by tobacco manufacturers’ materials on or in the package.¹²

Legislative drafters should also take into account innovative package design features that can undermine the effectiveness of health warnings/messages. For example, these include hinged packs that open from the middle, “scissor” packs with a sideways opening mechanism, and “accordion” style packs with front panels that slide from the middle to each side. While not permanently damaged or concealed when these packs are opened, the pack warnings are bifurcated, and thus temporarily disrupted, upon opening. If left open, the effectiveness of health

⁸ Guidelines, para. 44.

⁹ Ideally, the authority in charge of the requirements for health warnings/messages would have a health orientation and the necessary health expertise. This will usually be the Ministry of Health rather than, for example, a ministry or authority with a commerce/trade orientation, though jurisdictional issues may dictate otherwise in any given country.

¹⁰ Guidelines, paras. 8-11, 54.

¹¹ Guidelines, paras. 9 and 11, provide that Parties should consider requiring health warnings and messages on all sides of a package and on package inserts and onsets, on the filter overwrap portion of cigarettes, and/or on other related materials and instruments. Related materials might include packages of cigarette tubes, filters, and papers, and related instruments might include those used for water pipe smoking.

¹² The Guidelines’ recommendation that legislation require warning placement so that normal opening does not *permanently* damage or conceal the warning is meant to accommodate packaging such as flip top packs, common in many jurisdictions, which *temporarily* disrupt the warning on opening.

warnings would be substantially undermined. “Book packs” with perforated removable front panels also create the possibility that warnings printed on them could be removed. These and other pack designs that can create a legislative drafting challenge can be viewed at the websites of commercial packaging companies, such as:

<http://www.amcor.com/productSearch/?2871=860777&c=y&2891=148662>.

Size

Warnings and messages should cover as much of each main display area as possible. They should be required to occupy at least 50% or more, but must not be less than 30%, of each principal display area, not counting space taken up by any border around them.¹³

Concurrent display of warnings/messages

FCTC Article 11.1(b)(ii) requires rotating warnings/messages. The most effective rotation, as provided in the Guidelines, requires:¹⁴

- development by the Ministry of Health or other appropriate authority of different sets (at least two sets initially) of multiple warnings/messages;
- concurrent display of the different prescribed warnings/messages in a set so that each appears on an equal number of retail packages for each brand family and for each brand within the brand family for each package size and type; and
- change in warning/message sets after a specified period (e.g., 12 to 36 months).

The legislation, or regulations, should establish the requirement for rotating warnings/messages and set out the rotation scheme, including:

- the minimum number of warnings/messages comprising each warning/message set to be displayed concurrently;
- the maximum length of the period that each set is to be displayed; and
- the method for changing the warnings/message sets at the end of a period, which should include a phase-in time between sets during which both sets may be used.

The Ministry of Health or other appropriate authority should be given clear power to create new sets of health warnings and messages to address future periods.

Composition and content

Warnings and messages should be required to consist of pictures and accompanying text in the principal language(s) of the country.¹⁵ Pictorial warnings will help ensure impact and allow illiterate populations to be informed. The picture and text should be required to appear together rather than having the text on one display area and the picture on the other.

¹³ FCTC Article 11.1(b)(iv); Guidelines, paras. 12 and 13.

¹⁴ Guidelines, paras. 19-22.

¹⁵ Guidelines, paras. 14-17.

The legislation should provide the Ministry of Health or other appropriate authority with clear power to prescribe the content of the warning/message text and pictures.¹⁶ Warnings or messages that are not government-prescribed prescribed should be prohibited.

Color

To ensure realistic images and easy-to-read text, legislation or regulations should require four-color printing for pictures and specify contrasting text color to background color.¹⁷

Constituents and emissions information

FCTC Article 11.2 requires the display of information on relevant constituents and emissions of tobacco products, as defined by national authorities, on unit and outside packaging and labeling. This should be implemented by requiring prescribed *descriptive* (non-numerical) constituent/emissions statements in the country's principal language(s).¹⁸ Yield figures, and any descriptive statements about constituents or emissions that might imply one brand is less harmful than another, should be not be required. This includes tar, nicotine, carbon monoxide, and other emissions figures and descriptive statements that could be interpreted as suggesting reduced or comparatively lower constituents/emissions levels.¹⁹

In addition to what the government *requires* as the statements on constituents and emissions pursuant to FCTC Art. 11.2, legislation should also, pursuant to FCTC Art. 11.1(a), *prohibit* tobacco companies from voluntarily placing yield figures anywhere on or in the package or on the product, including when part of the brand name or trademark.²⁰ It is critical that this prohibition also apply to include proxies for these figures, such as figuratives, colors, or other signs because tobacco companies commonly use proxies such as these to get around bans that only refer to misleading descriptors or terms (See "*Prohibition on misleading packaging and labeling*," above).

Source Document

The Guidelines recommend that Parties consider providing a source document containing high-quality samples of how all health warnings and messages and other required information are to

¹⁶ In accordance with Guidelines para. 23, warnings and messages should address the variety of issues related to tobacco use in addition to health harms from tobacco use and exposure to tobacco smoke, such as advice on cessation, the addictive nature of tobacco, adverse economic and social consequences, and the impact of tobacco use on significant others.

¹⁷ Guidelines, para. 18.

¹⁸ A descriptive constituents and emissions statement might list some of the chemicals along with their effects on the body. It would not show the corresponding yield numbers. An example of a descriptive constituents and emissions statement from Australia is: "Smoking exposes you to more than 40 harmful chemicals. These chemicals damage blood vessels, body cells and the immune system..." In contrast, a numerical statement would show yield figures measured by a testing machine. An example of a numerical statement from the E.U. is: 10 mg tar, 0.9 mg nicotine, 10 mg carbon monoxide.

¹⁹ Guidelines, paras. 32 through 35.

²⁰ Guidelines, paras. 43-45.

appear on packaging.²¹ This can be accomplished by authorizing the Ministry or other appropriate authority to provide samples of the warnings and messages, constituent and emissions disclosures, and other required information in an electronic file and requiring that these be reproduced and displayed on packaging and labeling as closely as technologically possible.

Plain packaging

The Guidelines provide that Parties should consider adopting plain packaging measures that restrict or prohibit the use of logos, colors, brand images, or other promotional information on or in packaging, other than brand and product names²² displayed in a standard color and font style.²³ Plain packaging can enhance the visibility of the warnings/messages, prevent promotional features from detracting from them, and prevent the use of misleading techniques that suggest some tobacco products are less harmful than others.²⁴

Restricting or prohibiting other pack and product design features also should be considered. For example, prohibitions or restrictions with respect to pack product and pack shape and dimensions, mechanism for pack opening, and other design features could become an increasingly effective way to prevent the tobacco industry from using the product and pack to suggest that some tobacco products are less harmful than others, to target certain populations (e.g. long, thin products and packs aimed at girls and women), to obscure or disrupt required pack information (as discussed in the section on Health Warnings and Other Messages), or to provide hidden spaces for brand and other promotional elements.²⁵

Supply deadline

It is important that a single supply deadline be provided (e.g., up to 12 months from the enactment date of the relevant legal measure that prescribes the content and details of the required pack information and specifies other implementing requirements) after which manufacturers, importers, wholesalers, or retailers may only supply products that comply with the new requirements.²⁶ Experience has shown that a single supply deadline is important for preventing old stocks from lingering in the market, especially following a purposeful increase in production of products in the old packs prior to the enactment date. If legislation only provides a date by which tobacco manufacturers and importers must supply the new packaging and labelling without also prohibiting them, along with wholesalers and retailers, from supplying products in old packaging after that date, a potential loophole is created. After the supply

²¹ Guidelines, para. 53.

²² Product/brand names would still be prohibited from including any misleading descriptor or element, such as “Kent 4”, “Mild Seven” or “Marlboro Lights”.

²³ Guidelines, para. 46. Applying similar prohibitions to the product will prevent the tobacco industry from doing with the product what it no longer can do with the packaging and labeling.

²⁴ Guidelines, para. 46.

²⁵ For example, see the “accordion pack” that, in addition to disrupting the health warning/message, “offers additional print area for interaction with consumer” and the “scissor pack” that “opens with a novel sideways opening mechanism to reveal hidden branding elements inside”. These pack designs are also referenced in footnote 12 and are available at <http://www.amcor.com/productSearch/?2931=143066>.

²⁶ Guidelines, para. 59.

deadline, non-compliant products, packaging, and labeling in the possession or under the control of those entities should be subject to confiscation and destruction in addition to the application of appropriate penalties.

3. APPLYING DUTIES OF COMPLIANCE ON ALL ENTITIES INVOLVED IN THE MANUFACTURE, IMPORT, AND SALE OF TOBACCO PRODUCTS

Legislation should impose legal duties of compliance with packaging and labeling requirements on all tobacco product manufacturers, importers, wholesalers, and retailers.²⁷ As provided in the Guidelines, legislation should also explicitly state that the requirement to display health warnings/messages and other required information on tobacco product packaging and labeling does not remove or diminish any other industry obligations, including but not limited to, obligations to warn consumers about the health hazards from tobacco use and exposure to tobacco smoke.²⁸

4. SPECIFYING INSPECTION AND ENFORCEMENT AUTHORITIES, POWERS, AND DUTIES

Legislation should specify the ministries or authorities that have the power and duty to inspect for compliance with packaging and labeling provisions at the different points in the manufacture-import-distribution-retail chain, investigate complaints, and take enforcement action. Powers should include the right to enter relevant premises, obtain evidence, and seize non-compliant products, packaging, and labeling.

5. PROVIDING A RANGE OF PENALTIES

Penalties that are sufficiently large to deter violations and proportionate to the nature and seriousness of the violation and legal duties of the violator are necessary for effective enforcement. Legislation should provide a range of penalties that increase for repeat violations. Appropriate penalties may include:²⁹

- fines;
- business or operating licensure sanction;
- publication of the violations, with the associated costs levied against the violator(s); and
- other appropriate penalties.

In addition to authority to apply appropriate penalties, the legislation should specify the power of enforcement authorities to order a recall and/or to confiscate and destroy any noncompliant

²⁷ Guidelines, para. 55.

²⁸ Guidelines, para. 51. The ability to do this may depend on the legal system in the country.

²⁹ Guidelines, paras. 56, 58.

products, packaging, and labeling, and to levy the associated costs against the responsible party or parties.³⁰

6. EMPOWERING AND ENABLING CIVIL SOCIETY

The Guidelines state that Parties should consider encouraging the public to report violations in order to further promote compliance with the law, and ensure that complaints are investigated and dealt with in a timely and thorough manner.³¹ As provided in the FCTC Article 8 and 13 Guidelines, authorizing individuals and civil society organizations to initiate complaints and undertake legal action to compel compliance will also enhance the effectiveness of the inspection and enforcement program.³² This would, as appropriate, include legal action against the government if it fails to fulfill its inspection or enforcement duties.

7. EFFECTIVENESS EVALUATION

Monitoring of tobacco-industry compliance and evaluation of the impact of packaging and labeling legislation should be undertaken and Parties should consider making the results publically available.³³ Imposing a duty on the relevant authority to track compliance and evaluate effectiveness of the enforcement system and of the legislation will help ensure these activities are undertaken and sustained. Making information from these activities readily available to the public will help civil society fulfill a robust monitoring role.

8. GRANTING THE APPROPRIATE AUTHORITY SUFFICIENTLY BROAD REGULATORY POWER

The appropriate ministry or authority should be given power to address a broad range of matters in regulations, including but not necessarily limited to:

- prescribing the content, display, rotation, and all other details related to health warnings and messages and other required information on tobacco product packaging and labeling;
- providing electronic samples of the warnings and messages and of any other required information;
- providing the requirements for plain packaging or otherwise restricting or prohibiting the use of logos, colors, brand images or other promotional information anywhere on or in packaging or on the product;
- restricting or prohibiting any specific means of packaging or labeling that is or is likely to be false, deceptive, or misleading, that could interfere with required pack information, or that could otherwise undermine packaging and labeling requirements or prohibitions; and

³⁰ Guidelines, para. 58 and 65.

³¹ Guidelines, para. 65.

³² FCTC Article 8 Guidelines, para. 45; FCTC Article 13 Guidelines, paras. 66 and 67.

³³ Guidelines, paras. 66-69, 71.

- any other matter necessary or appropriate for implementing the law.

Care should be taken to avoid inadvertently limiting regulatory power, such as by granting only some powers and expressing them in an exhaustive way.

ADDITIONAL PROVISIONS

Including the following legislative provisions can be helpful in preventing or resolving interpretation issues, ensuring the ability of the strongest possible packaging and labeling legislation to emerge in a country, and facilitating civil society's role as an active partner in monitoring.

- ***Rights statement***

A rights statement can be provided reiterating the language of FCTC Article 4.1, stating that every person has the right to be informed of the health consequences, addictive nature, and mortal threat posed by tobacco consumption and exposure to tobacco smoke. The articulation of the right could be expanded to include receiving this information without direct or indirect promotional or other undermining messages in any form. Such a statement can be helpful in providing context for interpreting any specific provision.

- ***Sub-national authority to enact stronger measures***

Where applicable, providing sub-national jurisdictions with clear authority to enact and implement measures that are stronger and more protective than the measures provided in the legislation will allow the strongest measures to emerge. Stronger sub-national measures can create pressure to strengthen national legislation. Care should be taken to ensure that language used in the legislation does not inadvertently restrict sub-national jurisdictions' ability to enact and implement stronger measures.

- ***Waiver of fees and cost recovery for public interest litigation***

Providing for waiver of court fees and recovery of litigation costs can enable civil society to exercise any authority given it to undertake legal action to compel compliance.

- ***Origin and Destination of Product***

The requirement in FCTC Article 15.2 to mark products to assist in determining their origin (e.g., "Made in Country X"), as well as the requirement in FCTC Article 15.2(a) to indicate the final destination (e.g., "Sales only allowed in (insert name of the country, sub-national, regional or federal unit)") on packaging and labeling can either be provided required along with packaging and labeling measures or with measures addressing illicit trade.

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