



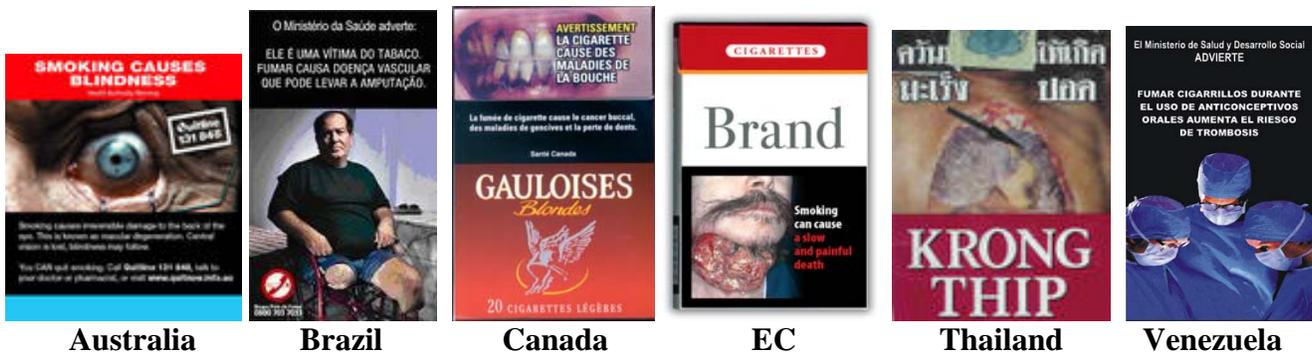
BRIEFING PAPER:
GUIDELINES ON ARTICLE 11
(PACKAGING AND LABELLING OF TOBACCO PRODUCTS)

Second Session of the Conference of the Parties to the WHO FCTC
Bangkok, Thailand
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www.fctc.org

Recommendation

The second session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control should decide to immediately commence the development of guidelines for the implementation of Article 11, with a view to adoption of guidelines at the third session of the Conference of the Parties.



Background

Article 11 of the Framework Convention on Tobacco Control (FCTC), dealing with package health warnings and labelling, contains key obligations. Effective package warnings increase awareness of the health effects of tobacco use and exposure to tobacco smoke, and decrease consumption.¹ Deceptive labelling by the tobacco industry undermines public health objectives. Under Article 11, Parties agree to adopt regulatory measures to deal with these matters.

The importance of Article 11 is underlined by the guiding principle in Article 4.1 that “[e]very person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption”.

¹ See generally: D Hammond, GT Fong, R Borland, KM Cummings, A McNeill, and P Driezen, “Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study” (2007) *American Journal of Preventive Medicine* 32(3): 210-217; D Hammond, GT Fong, PW McDonald, R Cameron, and KS Brown, “Impact of the Graphic Canadian Warning Labels on Adult Smoking Behaviour”, (2003) *Tobacco Control* 12(4): 391-395; D Hammond, GT Fong, PW McDonald, S Brown, and R Cameron, “Graphic Canadian Cigarette Warning Labels and Adverse Outcomes: Evidence from Canadian Smokers” (2004) *American Journal of Public Health* 94(8): 1442-1445; Environics Research Group Ltd, “Evaluation of New Warnings on Cigarette Packages” (prepared for the Canadian Cancer Society, 2001), available online at: http://www.cancer.ca/ccs/internet/standard/0.3182.3172_334419_436437_langId-en.00.html; Canadian Cancer Society, “Controlling the Tobacco Epidemic: Selected Evidence in Support of Banning All Tobacco Advertising and Promotion, and Requiring Large, Picture-Based Health Warnings on Tobacco Packages” (Ottawa: Canadian Cancer Society, International Union Against Cancer, 2001), available online at: <http://www.globalink.org/tobacco/docs/packaging/>; and studies prepared for the Canadian Department of Health (available online at: <http://www.hc-sc.gc.ca/hecs-sesc/tobacco/research/archive/index.html>), the Australian Health Department (available online at: <http://www.health.gov.au/pubhlth/strateg/drugs/tobacco/warnings.htm>), and the New Zealand Health Department (available online at: <http://www.ndp.govt.nz/tobacco/smokefreeenvironments/reviewofregulations.html>).

Under Article 11, Parties agree to require a rotated series of health warnings (which may include other appropriate messages) that should cover at least 50% – and must cover at least 30% – on average of the front and back of the package, with optional use of pictures or pictograms (Article 11.1(b)). This obligation extends to all packaging seen by consumers, such as cartons (Articles 11.1(b), 11.4). The messages must appear in the principal language(s) of the Party (Article 11.3). The messages must be approved by competent national authorities (Article 11.1(b)).

Parties also agree to ensure that “tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra-light”, or “mild”” (Article 11.1(a)).

Parties agree that in addition to the warnings, the package shall also contain information on relevant constituents and emissions of tobacco products to the extent defined by national authorities (Article 11.2).

The obligations in Article 11 apply to all products sold in the country, whether imported or domestically manufactured.

The need for guidelines on Article 11 as a matter of priority

Guidelines on Article 11 are essential to assist Parties in fulfilling their obligations and in implementing best practice for package warnings and labelling. Indeed, Parties have already recognized this – Article 7 requires the Conference of the Parties (COP) to propose appropriate guidelines for the implementation of Article 11.

Guidelines on Article 11 are required as a matter of urgency. Health warnings represent an effective, evidence-based tobacco control measure. The tobacco industry continues to use deceptive packaging including misleading descriptors. Parties have only three years from entry into force of the FCTC to implement their Article 11 obligations.

Regulations on package warnings and labelling are highly cost-effective. Governments determine the regulatory requirements, and the tobacco industry pays for the cost of implementation. A single national law affects every package sold in the country.

At the first session of the Conference of the Parties (COP-1), criteria for prioritization of work with respect to the development of guidelines on Articles 9 to 13, 5.3 and 14 were agreed,² and according to these criteria Article 11 should be a priority. A detailed evaluation of potential Article 11 guidelines against the criteria for prioritization of work on guidelines adopted at COP-1 is annexed to this paper.

² FCTC/COP1(15) Elaboration of guidelines for implementation of the Convention.

Many Parties have not yet modified their national laws to implement their obligations under Article 11. While Article 11 contains several specific requirements, it does not contain enough detail to fully guide Parties in the best practice preparation and implementation of national regulations.

While the Article 11 obligations are a very important part of the FCTC, to date there has been wide variability in implementation. Although some Parties have required picture-based warnings of at least 50% in size, some other Parties have required the bare minimum of text-only warnings with the minimum size of just 30%. Some Parties have only required warnings on the back of the package, and not on the front and back. Some other Parties, subsequent to FCTC ratification, have implemented new national regulations that are not compliant with the FCTC, such as: requiring a 50% warning on either the front or back, not both (thus making the average just 25% of the front and back, less than the 30% minimum); or requiring a single message to appear on packages, instead of the required rotated series of messages.

Package warnings/labelling should be an ongoing process of continuous improvement, and should not be limited to one-time regulatory action. Consequently, guidelines would be beneficial not only to those Parties developing regulations for the first time, but also to those Parties that will be preparing for their next round of regulatory changes.

What guidelines on Article 11 might include

1. Advice on the placement and size of health warnings and other messages

The effectiveness of health warnings increases with size.³ Simply put: size matters – bigger is better. A growing number of countries require sizes larger than 50%. Messages on the front are more effective than on the back. Also, placement at the top instead of the bottom of display surfaces may further increase effectiveness. Guidelines could provide advice on all of this, including how to deal with unusual package formats.

2. Advice on how Parties could select picture warnings for use on packages

Warnings that include pictures are more effective than text-only warnings.⁴ The use of pictures is especially beneficial for low-literacy populations and for people (including immigrants) who speak a language other than a country's official language(s). Surveys have consistently found that the majority of smokers (as well as the general population) support large graphic warnings. A picture is worth a thousand words – but which pictures should be used? Guidelines could assist Parties regarding researching/testing possible picture warnings, implementing best practices, specifying how pictures are to be designed for best visual impact, specifying printing requirements for effective colour appearance and to take account of differing package sizes, and obtaining permission to use picture messages of other countries.

³ See generally above n 1.

⁴ See generally above n 1.

3. Advice on the text to accompany pictures

Guidelines could provide advice on the content and appearance of the text to be used in conjunction with pictures. This would assist Parties in maximizing the overall effectiveness of messages.

4. Advice on rotation of messages

There is a clear need to not only have a series of messages appearing on packages at any one time, but also to regularly update and change messages to keep the messaging fresh and to reflect emerging best practices. Guidelines could assist with the number of warnings to be included in a series of messages, and how frequently they should be changed. Guidelines could also assist in responding to claims by the tobacco industry regarding alleged technical impediments to more extensive rotation.

5. Advice on package inserts

Package inserts are found in packages in Canada and Mexico and provide additional information on health effects and/or quitting tips. Guidelines could provide advice on this approach.

6. Advice that ISO⁵ yield numbers for tar, nicotine and carbon monoxide should not appear on packages

It is now widely accepted that the ISO method does not accurately reflect human smoking behaviour. Most people smoke because they are addicted to nicotine, and smokers, unlike machines, alter the way they smoke to achieve their preferred nicotine levels, a process known as compensation. Smokers can alter the way they smoke by taking more or deeper puffs or covering the ventilation holes. These holes are positioned in the filter where smokers place fingers or lips, and therefore are easy to block. The ISO method thus cannot be used to measure what smokers are actually taking in from their cigarettes and does not accurately reflect exposure of smokers to carcinogens and other toxins, largely underestimating exposure particularly with ‘lower tar’ cigarettes.⁶ There is a widespread mistaken consumer perception that a cigarette brand with a lower ISO tar yield is safer for health. Guidelines can assist Parties on these issues. Guidelines would build on the recommendation of the WHO Scientific Advisory Committee on Tobacco Product Regulation that “Tar, nicotine and CO numerical ratings based upon current ISO/FTC methods and presented on cigarette packages and in advertising as single numerical values are misleading and should not be displayed.”⁷

⁵ ISO means International Organization for Standardization. The methodology used in the ISO test was first introduced by the U.S. Federal Trade Commission and subsequently adopted by ISO.

⁶ For further background, see: Framework Convention Alliance for Tobacco Control, “Tobacco Product Regulation” (Factsheet #4), available online at <<http://ftc.org/factsheets/4.pdf>>; Framework Convention Alliance for Tobacco Control, “Developing Effective Product Regulation Under the FCTC” (Briefing Paper prepared for the first session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, February 2006), available online at <http://ftc.org/iwg_cops/COPI/bp5.pdf>.

⁷ WHO Scientific Advisory Committee on Tobacco, “SACTob Conclusions on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield” (2002) 4, available online at <http://www.who.int/tobacco/global_interaction/tobreg/en/iso_ftc_en.pdf>.

7. Advice on how countries should ban misleading descriptors including but not limited to “light” and “mild”

Tobacco manufacturers are getting around bans on “light” and “mild” descriptors through various package labelling techniques, as discussed below. Parties have sought advice on how to respond to these industry practices, and guidelines could provide assistance on this issue.

8. Advice on legislative drafting

Guidelines could assist Parties in drafting laws to ensure that the government’s policy intent will be implemented without loopholes or other weaknesses.

Overview of International Experience

Some Parties have made considerable progress in improving package warnings and labelling. At the same time, some Parties have experienced difficulties as tobacco companies have found ways to reduce the intended impact of regulatory requirements. All of this international experience would be of tremendous benefit in the guideline development process to assist all Parties.

The summary information below outlines the international context in which guidelines would be developed. Issues related to implementation of Article 11 are being faced by Parties in all parts of the world.

Package Warnings

At least 14 jurisdictions have finalized requirements for picture warnings: Australia, Belgium, Brazil, Canada, Chile, Hong Kong, India, Jordan, New Zealand, Panama, Singapore, Thailand, Uruguay and Venezuela. Many other countries are in the process of doing so.

The size of warnings is increasing, with more and more countries requiring warnings even larger than the 50% FCTC recommended standard in terms of an average of the package front and back: Australia (60%), New Zealand (60%), Belgium (56%), Switzerland (56%) and Finland (52%).

The front of the package is more important than the back. The largest size so far required on the front is 50%, required by at least 8 jurisdictions: Canada, Chile, Hong Kong, India, Madagascar, Singapore, Thailand, and Uruguay

Misleading Descriptors

At least 43 countries have specifically banned the descriptors “light” and “mild” for cigarettes, including the 27 countries in the European Community⁸ as well as 16 other countries.⁹ However,

⁸ The 27 members of the European Community are Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

⁹ Based on available information, the 16 other countries known to have specifically banned the descriptors “light” and “mild” are: Armenia, Australia, Brazil, Canada, Chile, Iceland, India, Iran, Israel, Norway, Peru, Switzerland, Thailand, Ukraine, Uruguay,

after bans on “light” and “mild” descriptors have been implemented, tobacco companies have typically responded with other approaches to distinguish brand extensions. These industry techniques include:

- using terms such as “full flavour”, “classic”, “smooth” and “fine”
- using colour names as descriptive terms, e.g. Carlton Red, Carlton Silver, Carlton Blue (at right is a package insert used in Switzerland)
- using ISO yield numbers for tar as part of the brand name, e.g. Kent Blue 8, Kent Silver No 4
- using different package colours, e.g. using different colours for the Marlboro chevron logo (red for “full flavour”; gold for “light”; silver for “ultra-light” and green for menthol)
- using an increasing amount of white on packaging of “light” and “ultra-light” brands

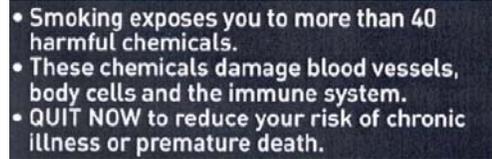


Parties would benefit from guidelines on how to respond to industry practices which undermine bans on misleading descriptors.

Cigarette Emissions Labelling

In many countries, ISO yield numbers appear on the side of packages for tar, nicotine and carbon monoxide. This may be as a result of a national law, or because of voluntary industry practice. As discussed, ISO yield numbers are misleading.

Some countries are now eliminating a previously existing requirement to print ISO yield numbers for tar, nicotine and carbon monoxide on the side of cigarette packages. At least four countries (Australia, Brazil, New Zealand, and Venezuela) have now required qualitative text instead of yield numbers, a far superior approach. At right is the side panel required in Australia, with a similar panel to soon appear in New Zealand.



Civil society participation in the development of guidelines

The important role of civil society in the implementation and further development of the FCTC is recognized in the preamble to the Convention and in Article 4.7. Civil society should be invited to actively participate in the development of the guidelines, as has been the case for guideline development work so far undertaken by the COP (on Article 8 and Articles 9 and 10, pursuant to the decision of the first session of the Conference of the Parties “to invite the relevant intergovernmental and nongovernmental organizations with specific expertise in the guideline matters to actively participate and contribute to the further elaboration and development of the guidelines, as per request from the Convention Secretariat”).¹⁰

and Venezuela. Undoubtedly other countries could be added to this list. For Australia and Canada, this was done through court-enforceable settlements between the national competition authority and major tobacco manufacturers.

¹⁰ FCTC/COP1(15) Elaboration of guidelines for implementation of the Convention, para 6.

Further information

For further information, the following websites may be accessed:

- Graphic Warnings – Campaign for Effective Health Warnings (supported by GLOBALink): <www.graphicwarnings.org> [English]
- Nuigrav – Campagne pour des Avertissements Illustrés sur les Paquets de Cigarettes (appuyé par GLOBALink): <www.nuigrav.org> [Français]
- Physicians for a Smoke-free Canada: <<http://www.smoke-free.ca/warnings/default.htm>> [English]
- Packaging and Labeling – Pan American Health Organization (PAHO): <http://www.paho.org/English/AD/SDE/RA/Tob_pack_index.htm> [English]
- European Pictorial Warning on Tobacco Products 07 – Association European Cancer Leagues (ECL): <http://www.europeancancerleagues.org/index.cfm?fuseaction=Content.DisplayCat&Category_ID=9684A77C-0368-11E3-6F0BD5E935906503&lang=EN> [English]

ANNEX

Evaluation of guidelines on Article 11 against the criteria for prioritization of work on guidelines adopted at the first session of the Conference of the Parties¹¹

1. ***Request from Parties:*** *there is an expressed need for the guidelines to assist Parties in implementing the Framework Convention.*

Yes. Many Parties have requested technical assistance to enhance the effectiveness of measures relating to package warnings/labelling. Guidelines would be of assistance to these and all other Parties.

2. ***Existing work on the topic:*** *there is relevant existing work, e.g. Tobacco Free Initiative guidelines, so guidelines can be developed more quickly and efficiently.*

Yes. There is abundant existing international experience and a large volume of academic and practical literature to inform the process of developing guidelines for the implementation of Article 11. Many countries have legislation that could be used to inform best practice guidelines.

3. ***International value added:*** *international guidelines may be of particular assistance to Parties to implement some obligations, while involving a number of Parties allows expertise and costs to be shared.*

Yes. Guidelines would be an efficient means to assist Parties in implementing their obligations under Article 11 by describing best practices based on worldwide experience and knowledge. Parties can learn from other Parties' experiences – both successes and challenges – regarding package warnings and labelling. In particular, Parties can learn from each other's experiences how best to prevent legislative loopholes and to respond to industry practices that undermine their regulatory measures.

4. ***Potential impact of the measure covered by the guidelines:*** *measures are known to be effective at reducing the impact of tobacco.*

Yes. Effective package warning and labelling requirements for tobacco products discourage consumption. Given that the tobacco industry pays the cost of package warning and labelling requirements, these requirements are highly cost-effective with broad reach across the entire population.

5. ***Ease of implementation:*** *this includes cost of implementation.*

Yes. Parties can easily use the guidelines to develop their legislation and their monitoring and enforcement practices.

¹¹ FCTC/COP1(15) Elaboration of guidelines for implementation of the Convention.

6. ***Willingness of Parties to lead:*** *Parties have volunteered as key facilitators, partners or reviewers.*

It is anticipated that Parties will volunteer to do so at COP-2.

7. ***Outcome measurability:*** *this is relevant to reporting (Article 21) and the potential to measure and analyse data.*

Yes. Parties can report on the warnings they require and the laws they have adopted, and can provide information on the implementation of, and compliance with, these requirements.

8. ***Contribution to maintaining momentum in implementing the Framework Convention:*** *this is particularly important in the early stages of implementation.*

Yes. Regulation of package warnings/labelling is a critical tobacco control measure, and a highly visible signal of a country's position on tobacco and tobacco control. It would be impossible for a country that did not effectively meet its Article 11 obligations to project an image of being serious about FCTC implementation. At present there is considerable and increasing worldwide momentum in improving tobacco package warnings and labelling. Guidelines would add to this momentum, especially given the pending 3-year deadline for Parties to implement their obligations under Article 11.

9. ***Cost of guidelines development:*** *guidelines should be developed efficiently.*

Yes. Given existing international experience and research, the cost of developing guidelines would be minimal. Guidelines can be developed by Parties, with the input of civil society, sharing relevant expertise and experiences and consulting with relevant expert bodies – both national and international – as required.

10. ***International cooperation and cost sharing*** *are essential to effectively implement the elements of the guidelines.*

Yes. Without such international cooperation and sharing of information, expertise and experience, it is likely that many Parties' implementation of their Article 11 obligations will fall short of best practice. Many Parties will need information and guidance to assist them in complying with their obligations. Guidelines would reduce the work necessary by Parties to make their laws on package warnings/labelling more effective.