Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable To Tobacco Products and Packaging (WT/DS435, WT/DS441, WT/DS458, WT/DS467)

Additional Information for Submission to the Panel by a Non-Party

on behalf of the

World Health Organization
and
The WHO Framework Convention on Tobacco Control Secretariat

5 October 2015
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BACKGROUND

On 16 February 2015, the World Health Organization (WHO) and the WHO Framework Convention on Tobacco Control Secretariat (Convention Secretariat) submitted information to the Panel in the form of an amicus curiae submission. That submission sought to ensure that the Panel is informed regarding:

1. the history of tobacco control and the global burden of disease associated with tobacco consumption;
2. the evidence base concerning the contribution of plain packaging to protection of human health; and
3. relevant provisions of the WHO Framework Convention on Tobacco Control (WHO FCTC) and its Guidelines.

In a letter dated 14 September 2015, the Panel requested additional information relevant to whether Guidelines for implementation of Articles 11 and 13 of the WHO Framework Convention on Tobacco Control (WHO FCTC) constitute international standards for purposes of the Agreement on Technical Barriers to Trade and to the evidentiary basis for adoption of the Guidelines. Specifically, the Panel requested that by 5 October 2015 WHO and the Convention Secretariat provide information concerning:

• the process through which the Article 11 and Article 13 Guidelines were adopted;
• the nature and intended function of the Article 11 and Article 13 Guidelines with respect to plain packaging of tobacco products;
• the specific aspects of the text of Article 11 and Article 13 Guidelines that are relevant to the implementation of plain packaging of tobacco products; and
• any available preparatory materials (including scientific or technical evidence) considered by the WHO FCTC Conference of the Parties (COP) in its deliberations preceding the adoption of the Article 11 and Article 13 Guidelines.

Before addressing each of these specific points, this submission provides information concerning the role of the COP as an international body (section 1) and WHO’s activities in standard setting (section 2).

The additional information set out below should be read in the context of the information submitted on 16 February 2015. For the avoidance of doubt, neither submission seeks to make legal arguments concerning application of WTO law. Rather, each submission is limited to setting out factual and technical information.
1. **The Role of the COP as an International Body and the Functions of the Convention Secretariat**

The World Health Assembly (WHA) adopted the WHO Framework Convention on Tobacco Control (WHO FCTC) in 2003\(^1\) pursuant to Article 19 of the Constitution of the World Health Organization (WHO).\(^2\) Article 19 of the constitution empowers the WHA to adopt conventions or agreements “with respect to any matter within the competence of the Organization.” Resolution 56.1 (in which the WHO FCTC was adopted) is silent on the question of how the subject matter of the Convention falls within the competence of WHO.

2. When the WHA (one of WHO’s governing bodies) adopted the WHO FCTC, the WHA also made provision for establishment of the Conference of the Parties (COP) to the Convention. Article 23 of the WHO FCTC governs establishment of the Conference of the Parties in the following terms:

**Article 23**

**Conference of the Parties**

1. A Conference of the Parties is hereby established. The first session of the Conference shall be convened by the World Health Organization not later than one year after the entry into force of this Convention. The Conference will determine the venue and timing of subsequent regular sessions at its first session.

2. Extraordinary sessions of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat of the Convention, it is supported by at least one-third of the Parties.

3. The Conference of the Parties shall adopt by consensus its Rules of Procedure at its first session.

4. The Conference of the Parties shall by consensus adopt financial rules for itself as well as governing the funding of any subsidiary bodies it may establish as well as financial provisions governing the functioning of the Secretariat. At each ordinary session, it shall adopt a budget for the financial period until the next ordinary session.

5. The Conference of the Parties shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention, in accordance with Articles 28, 29 and 33. Towards this end, it shall:
   
   (a) promote and facilitate the exchange of information pursuant to Articles 20 and 21;

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\(^1\) WHO Framework Convention on Tobacco Control, WHA56.1.

\(^2\) Constitution of the World Health Organization, 14 UNTS 185.
(b) promote and guide the development and periodic refinement of comparable methodologies for research and the collection of data, in addition to those provided for in Article 20, relevant to the implementation of the Convention;

(c) promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes, as well as policies, legislation and other measures;

(d) consider reports submitted by the Parties in accordance with Article 21 and adopt regular reports on the implementation of the Convention;

(e) promote and facilitate the mobilization of financial resources for the implementation of the Convention in accordance with Article 26;

(f) establish such subsidiary bodies as are necessary to achieve the objective of the Convention;

(g) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as a means of strengthening the implementation of the Convention; and

(h) consider other action, as appropriate, for the achievement of the objective of the Convention in the light of experience gained in its implementation.

6. The Conference of the Parties shall establish the criteria for the participation of observers at its proceedings.

3. The Conference of the Parties serves as the governing body of the Convention. It meets biannually, having met annually for its first three sessions, and takes the decisions necessary to promote effective implementation of the Convention. The Convention has 180 Parties that together comprise the COP.

4. The COP and its subsidiary bodies are supported by the Convention Secretariat, the functions of which are set out in Article 24.3 of the Convention as follows:

(a) to make arrangements for sessions of the Conference of the Parties and any subsidiary bodies and to provide them with services as required;

(b) to transmit reports received by it pursuant to the Convention;

(c) to provide support to the Parties, particularly developing country Parties and Parties with economies in transition, on request, in the compilation and communication of information required in accordance with the provisions of the Convention;

(d) to prepare reports on its activities under the Convention under the guidance of the Conference of the Parties and submit them to the Conference of the Parties;

(e) to ensure, under the guidance of the Conference of the Parties, the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;

(f) to enter, under the guidance of the Conference of the Parties, into such administrative or contractual arrangements as may be required for the effective discharge of its functions; and

(g) to perform other secretariat functions specified by the Convention and by any of its protocols and such other functions as may be determined by the Conference of the Parties.
5. Article 21 of the Rules of Procedure of the Conference of the Parties establishes the Bureau of the COP, comprising one member from each WHO region. The Bureau is responsible for examining the credentials of Parties at the COP,\(^3\) for consulting with the Convention Secretariat as it prepares the provisional agenda for each session of the COP,\(^4\) as well as for ad hoc functions granted through decisions of the COP.

6. Additional information concerning openness of the COP and participation by Parties and observers is set out below in section 3.2.

2. The Role of the WHO as an International Organization

7. WHO has 194 Member States, is a specialized agency within the terms of Article 57 of the Charter of the United Nations and acts as the directing and coordinating authority on international health work.\(^5\)

8. Article 2 of the Constitution of the WHO defines the functions of the Organization. Paragraph 2(u) establishes one of those functions as being “to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products”. In addition to this express reference to standardization, paragraph 2(v) empowers WHO “generally to take all necessary action to attain the objective of the Organization.” That objective is defined in Article 1 of the Constitution as “the attainment by all peoples of the highest possible level of health.”

9. Within this constitutional mandate, WHO engages in standard setting through a wide variety of bodies and processes. Examples include standard setting:
   - by the Secretariat (through the WHO Guidelines Review Committee);
   - through specific programmes of work on quality, safety and efficacy of medicines and international nonproprietary names;
   - in some decisions and resolutions of the World Health Assembly; and
   - through a more specialized inter-governmental body adopting international instruments (the Codex Alimentarius Commission).

10. Distinct institutional arrangements and processes lead to the adoption of a range of instruments in different policy contexts with different names, such as standards, guidelines, recommendations and global strategies.

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\(^4\) Ibid, Rules 6 and 9.

\(^5\) Constitution of the WHO, 14 UNTS 185, Article 2(a).
11. As is recognized in the publicly available WHO Handbook for Guideline Development, the WHO Guidelines Review Committee oversees four primary types of Guidelines developed by the WHO Secretariat. These are standards, consolidated guidelines, interim guidelines and guidelines produced in response to an emergency or urgent need. These guidelines cover a wide range of issues, including clinical interventions, health-care system or policy approaches, public health interventions or exposures, diagnostic tests or surveillance and monitoring. Some of the most recent guidelines concern topics such as child health, chronic diseases, injuries and disability, communicable diseases, environmental health, HIV/AIDS, health systems, malaria, maternal, reproductive health and women’s health, mental health and substance abuse, nutrition, patient safety and tuberculosis. A list of guidelines overseen by the WHO Guidelines Review Committee since 2008 is set out in Annex 1.

12. Standard-setting activities with respect to the quality, safety and efficacy of medicines provide a more specific example of WHO’s activities. In this context, WHO provides guidance on regulation, safety and quality assurance of medicines. This includes publishing The International Phamtacopeia (Ph. Int.), which has the aim of achieving harmonization of quality specifications for selected pharmaceutical products, excipients and dosage forms.

13. International nonproprietary names provide another context in which WHO engages in standard setting activities. International nonproprietary names (generic names) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients globally. In this context WHO collaborates with experts and national nomenclature committees to select a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical.

14. The Codex Alimentarius Commission is an example of a more specialized inter-governmental standard setting body established partly under the auspices of WHO. A 1963 decision of the World Health Assembly approved the establishment of the Joint FAO/WHO Food Standards Programme with the Codex Alimentarius Commission as its principal organ. Membership of the Codex Alimentarius Commission is open to all Member Nations and Associate Members of the FAO and WHO. As the Panel is no doubt aware, standards, guidelines and recommendations established by the Commission may constitute international standards, guidelines or recommendations under the WTO Agreement on the Application of Sanitary and

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7 Ibid., p.6.


9 Further information is available at [http://www.who.int/medicines/services/inn/en/](http://www.who.int/medicines/services/inn/en/).

Phytosanitary Measures (SPS Agreement). The WTO Appellate Body has also found Codex Alimentarius Commission standards to constitute international standards for purposes of the Agreement on Technical Barriers to Trade.

15. Other bodies under the auspices of WHO also serve a normative role, albeit in a way that is not explicitly labeled as standard setting. For example, the World Health Assembly adopts resolutions and decisions that may relate inter alia to policy approaches or public health interventions for implementation by WHO Member States. Similarly, under the International Health Regulations (2005) the Director-General and WHO are called upon to make recommendations in the event of a public health emergency of international concern. WHO also publishes the International Classification of Diseases, which is the standard diagnostic tool for purposes of epidemiology, health management and clinical purposes. Finally, the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits is under the auspices of WHO.

16. As this short description illustrates, WHO’s functions include standard setting. These functions are explicit in the Constitution of the WHO and reflected in the everyday work of the Organization. However, WHO’s normative work is carried out through bodies that take a variety of forms and in the development of international instruments with common characteristics but different labels. It is in this broader context of WHO’s standard setting activities that information concerning the role of the COP as an international body is set out above.

3. The Process for Adoption of the Guidelines for Implementation of Articles 11 and 13 of the WHO FCTC

17. In light of the Panel’s request for additional information concerning the process for adoption of the Guidelines for Implementation of Articles 11 and 13, this section summarizes key events in adoption of the Guidelines, openness of the process and the procedures for achieving consensus.

3.1 Key Events in the Adoption of Guidelines for Implementation of Articles 11 and 13

18. The key events in adoption of Guidelines for Implementation of Articles 11 and 13 are summarized below in the form of three separate timelines. The first timeline is relevant to a number of WHO FCTC provisions, including Articles 11 and 13. The second and third timelines address Articles 11 and 13 respectively.

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11 Agreement on the Application of Sanitary and Phytosanitary Measures, Annex A.
13 International Health Regulations (2005), WHA58.3.
14 Further information is available at http://www.who.int/classifications/icd/en/.
15 Further information is available at http://www.who.int/influenza/resources/pip_framework/en/.
19. As the timelines indicate, it was evident in Article 7 of the WHO FCTC that the Guidelines for Implementation of Articles 11 and 13 would be developed after the Convention came into force. A more specific decision on this process was adopted in March 2006 at COP1 before a decision establishing the relevant working groups was adopted in July 2007 at COP2. That COP2 decision marked the beginning of the drafting process, which permitted members of the working groups to provide input into the drafts, permitted all Parties to the COP to provide comments on the second drafts of the Guidelines for Implementation of Articles 11 and 13 and permitted access to the final drafts to all Parties and the public prior to COP3. All Parties to the Convention had a final opportunity to introduce amendments to the Guidelines at COP3, or to oppose adoption of the Guidelines.

Timeline 1: key events at the World Health Assembly and COP relevant to a number of WHO FCTC provisions:

- May 2003 – The WHA adopted the WHO FCTC, including Article 7 of the Convention, which specifies that the COP shall propose appropriate guidelines for the implementation of Articles 8 – 13 of the Convention.
- 23 March 2006 – COP1 issued the decision ‘Elaboration of Guidelines for Implementation of the Convention’ (FCTC/COP1(15)), which:
  - considered that Article 7 requires the COP to propose guidelines for Articles 8 – 13 of the Convention;
  - recognized “the assistance that such guidelines may provide to Parties in the development and implementation of policies and programmes related to the non-price measures for tobacco control that are set out in Articles 8 to 13”; and
  - established a criteria for determining how to prioritize the order in which guidelines would be developed. (Annex 2)

Timeline 2: key events specific to adoption of the Guidelines for Implementation of Article 11

- 6 July 2007 – COP2 established a working group to elaborate guidelines on implementation of Article 11 (FCTC/COP2(14). The decision establishing the working group inter alia:
  - mandated the working group to present draft guidelines to COP3;
  - identified four key facilitators and 23 partners (including the European Community) from among the Parties to serve on the working group; and
  - was published on the public website of the Convention Secretariat on 20 September 2007. (Annex 3)
- 7 – 9 November 2007 – The first meeting of the working group was hosted by the government of the Philippines in Manila. Participants included the key facilitators, partners, representatives of civil society as well as the Convention Secretariat and WHO. The working group formed a drafting group that included representatives from nine Parties, civil society and experts.
8 February 2008 – A first draft of the Guidelines (prepared by the drafting group) was sent to members of the working group. Comments on the draft from members of the working group were sent to the drafting group in advance of the second meeting.

4 – 5 March 2008 – The second meeting of the working group was hosted by the government of Brazil in Brasilia. The working group formulated a second draft of the Guidelines, taking account of the comments received from members of the working group on the first draft.

23 May 2008 – The Convention Secretariat made the second draft of the Guidelines accessible to all Parties to the COP via a password protected website.

- Parties were informed of this by note verbale sent to permanent missions in Geneva on 16 May 2015. (Annex 4)
- Parties were given until 1 July 2015 to comment on the draft.
- Twelve Parties made comments with respect to the draft. These comments were distributed to the working group and the key facilitators subsequently amended the draft.

20 August 2008 – The Convention Secretariat sent invitations to COP3 to Parties.

21 August 2008 – The draft guidelines for presentation to COP3 (FCTC/COP/3/7) were published on the Convention Secretariat’s public website. (Annex 5)

8 October 2015 – The Convention Secretariat held a briefing for permanent missions to WHO at which the provisional agenda for COP3 was outlined, including the agenda item of Guidelines for Implementation of Article 11.

22 November 2008 – The Guidelines for Implementation of Article 11 were adopted by consensus of COP3 (FCTC/COP3(10)), which was hosted by the government of South Africa in Durban. Hard copies of the draft decision were available to Parties at COP3. The draft decision was also published on the public website of the Convention Secretariat.

16 February 2009 – The Guidelines for Implementation of Article 11 were published on the public website of the Convention Secretariat with other decisions adopted by the COP. (Annex 6)

**Timeline 3: key events specific to adoption of the Guidelines for Implementation of Article 13**

- 6 July 2007 – COP2 established a working group to elaborate guidelines on implementation of Article 13 (FCTC/COP2(8)). The decision establishing the working group inter alia:
  - mandated the working group to present draft guidelines to COP3;

identified three key facilitators (including the European Community) and 15 partners from among the Parties to serve on the working group; and
was published on the public website of the Convention Secretariat on 20 September 2007. (Annex 7)

27–29 November 2007 – The first meeting of the working group was hosted by the government of Finland in Helsinki.
The working group mandated the key facilitators to continue work on the draft guidelines in advance of the second meeting of the working group.

31 March – 2 April 2008 – The second meeting of the working group was hosted by the government of India in New Delhi.
The group mandated the key facilitators to finalize the draft, based on the discussions of the working group, and asked them to invite – as necessary – other members of the group and experts in this process.
Following this, a drafting meeting was held in New Delhi on 3 and 4 April 2008. All members of the working group were given the opportunity to comment on the draft.

23 May 2008 - The Convention Secretariat made the subsequent draft of the Guidelines accessible to all Parties to the COP via a password protected website.
Parties were informed of this by note verbale sent to permanent missions in Geneva on 16 May 2015. (Annex 4)
Parties were given until 1 July 2015 to comment on the draft.
Nine parties submitted comments. These comments were distributed to the working group and the key facilitators subsequently amended the draft.

20 August 2008 – The Convention Secretariat sent invitations to COP3 to Parties.
2 September 2008 – The draft guidelines for presentation to COP3 (FCTC/COP/3/9) were published on the Convention Secretariat’s public website. (Annex 8)
8 October 2015 – The Convention Secretariat held a briefing for permanent missions to WHO at which the provisional agenda for COP3 was outlined including the agenda item of Guidelines for Implementation of Article 13.

22 November 2008 – The Guidelines for Implementation of Article 13 were adopted by consensus of COP3 (FCTC/COP3(12)). Hard copies of the draft decision were available to Parties at COP3. The draft decision was also published on the public website of the Convention Secretariat.

16 February 2009 – The Guidelines for Implementation of Article 13 were published on the public website of the Convention Secretariat with other decisions adopted by the COP. 17

17 Ibid.
3.2 Openness of the Processes

This section describes rules governing participation of Parties and observers in the COP and in subsidiary bodies such as the Article 11 and 13 working groups.

3.2.1 Participation of Parties in the Development of Guidelines to Articles 11 and 13

Pursuant to Article 34 of the Convention the WHO FCTC is open to:

- all Members of WHO;
- States that are not Members of WHO, but that are members of the United Nations; and
- regional economic integration organizations.\(^{18}\)

All Parties to the WHO FCTC may participate fully in the work of the COP. In its openness to States, the COP is, therefore, comparable to the Codex Alimentarius Commission, which is open to all Member Nations and Associate Members of the FAO and WHO. (See section 2 above)

The participation of Parties in subsidiary bodies, such as the working groups mandated by the COP to draft the Guidelines for Implementation of Articles 11 and 13 is not expressly governed by the Rules of Procedure of the Conference of the Parties. Participation in the working groups established to prepare Guidelines for Implementation of Articles 11 and 13 was open to all Parties. Parties were permitted to offer themselves as either key facilitators or partners in the working groups established by COP2.

It should also be noted that it is a practice of the Convention to extend travel support to low- and lower-middle-income countries to ensure wide and meaningful participation of Parties in the work of the COP. When the Guidelines for Implementation of Articles 11 and 13 of the Convention were adopted at COP3 in 2008, financial support under these arrangements consisted of the provision of an economy air ticket and payment of a subsistence allowance (per diem) for one representative from each low- and lower-middle-income country Party.\(^{19}\) This support was available both for participation in the work of the working groups and for attendance at COP3.

Finally, Rule 59 of the Rules of Procedure of the Conference of the Parties requires that all official COP documents be made available in the six official languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish). Rule 8 requires that for each regular session of the COP the provisional agenda, together with other conference documents, be distributed by the Convention Secretariat in the six official languages at least 60 days before opening of

\(^{18}\) WHO Framework Convention on Tobacco Control, Article 34.

\(^{19}\) For discussion of this practice, which was amended at COP4, see FCTC/COP/6/INF.DOC./2 available at [http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_INF2-en.pdf](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_INF2-en.pdf).
the session. Simultaneous translation is provided in the six official languages at meetings of the plenary of the COP and its committees.

3.2.2 Participation of Observers to the COP

26. In accordance with Article 23.6, the COP has also established criteria for the participation of observers at its proceedings. Under the Rules of Procedure of the Conference of the Parties observers fall within one of three categories.

27. Rule 29 governs States and regional economic integration organizations and permits those bodies to attend public or open sessions of the COP and to speak after the Parties. Rule 29 states:

1. Any Member State of WHO which is not a Party to the Convention, any Associate Member of WHO, or any other State which is not a Party to the Convention but which is a Member of the United Nations, or its specialized agencies or of the International Atomic Energy Agency, and any regional economic integration organization, as defined in Article 1(b) of the Convention, which is not a Party to the Convention, may attend the public or open sessions of the Conference of the Parties or meetings of its subsidiary bodies as an observer.

2. Observers under this Rule may participate without the right to vote in the public or open meetings of the Conference of the Parties and its subsidiary bodies and may speak only after the Parties. Regional economic integration organizations may speak only on matters within their competency.

28. Rule 30 governs international intergovernmental organizations, which may be granted observer status by the COP. Rule 30 states:

1. Any international intergovernmental organization may apply, in accordance with its internal rules, to the Secretariat for observer status, which may be granted by the Conference of the Parties, based on the report from the Secretariat, taking into account the 17th and 18th preambular paragraphs as well as Article 5.3 of the Convention. Such applications, duly endorsed by the governing body of the organization concerned, should be submitted to the Secretariat not later than ninety days before the opening of the session.

2. Observers under this Rule may participate without the right to vote in public or open meetings of the Conference of the Parties and its subsidiary bodies and may speak after the observers referred to in Rule 29.

29. Rule 31 governs the participation of nongovernmental organizations, which may also be granted observer status by the COP. Rule 31 states:

1. Nongovernmental organizations which participated in the Intergovernmental Negotiating Body on the WHO Framework Convention on Tobacco Control and in the Open-ended Intergovernmental Working Group on the WHO Framework Convention on Tobacco Control are accredited as observers to the Conference of the Parties.

2. Other international and regional nongovernmental organizations whose aims and activities are in conformity with the spirit, purpose and principles of the Convention, may apply for observer status, which may be granted by the Conference of the Parties, based on the report of the Secretariat, and taking into account the 17th and 18th preambular paragraphs as well as Article 5.3 of the Convention. Such applications should be submitted to the Secretariat not later than ninety days before the opening of the session.
3. The Conference of the Parties shall review the accreditation of each nongovernmental organization at any of its regular sessions and thus determine the desirability of maintaining its observer status.

4. Observers under this Rule may participate without the right to vote in public or open meetings of the Conference of the Parties and of its subsidiary bodies and may speak after the observers referred to in Rules 29 and 30.

30. As is stated in Rules 30 and 31, the COP may consider whether international intergovernmental organizations and nongovernment organizations engage in activities that are not in conformity with the spirit, purpose and principles of the Convention, taking into account the 17th and 18th preambular paragraphs as well as Article 5.3. This approach does not restrict participation of Parties or States, but does, in effect, limit the ability of tobacco companies to participate in the work of the COP other than through the relevant bodies of States. This limitation does not discriminate between tobacco companies.

31. Paragraphs 17 and 18 of the preamble to the WHO FCTC state:

Emphasizing the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts,

Recognizing the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts,

32. Article 3 establishes the objective of the Convention in the following terms:

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

33. Article 5.3 states:

In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.

34. These provisions reflect the unique regulatory environment of tobacco control. In this respect, the 2011 Political Declaration of the High Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases recognized "the fundamental conflict of interest between the tobacco
industry and public health.” Notably, the United Nations General Assembly adopted this declaration by consensus.

35. Guidelines for Implementation of Article 5.3 also state that “[t]here is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests.” The Guidelines establish a number of other principles, namely:

• Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent.
• Parties should require the tobacco industry and those working to further its interests to operate and act in a manner that is accountable and transparent.
• Because their products are lethal, the tobacco industry should not be granted incentives to establish or run their businesses.

36. The conflict of interests referred to above is also reflected in a history of misleading conduct by tobacco companies that has perverted regulation and standard-setting. The history of international and domestic standards for tobacco product testing provide one example of this.

37. In 1966, the United States Federal Trade Commission (US FTC) permitted tobacco companies to advertise tar and nicotine yields of different products provided the companies used a standard machine testing method adopted by the US FTC. Tobacco companies often used the tar and nicotine yields as a basis for and in association with descriptors such as light, ultra-light and mild.

38. It was not publicly understood until much later that the machine testing method used by the US FTC was flawed in a number of ways. The machine testing method did not replicate human behaviour partly because smokers compensated for lower tar and nicotine yields by taking larger puffs and taking more puffs of a cigarette (known as compensation). The machine testing method also failed to account for the presence of holes in cigarette filters, some of which were blocked by smokers’ fingers during the act of smoking. Accordingly, the evidence available today is overwhelming to the effect that low tar, low nicotine, light, ultra-light, mild and similar brand variants are no less harmful to health than “regular” or original brand variants.

21 Guidelines for Implementation of Article 5.3 of the Convention, principle 1.
39. This issue led to an action brought by the US government under the Racketeer Influenced and Corrupt Organizations Act (RICO). In that action, the US government alleged that a number of tobacco companies falsely marketed light, low tar and similar brands as a less harmful alternative to regular or full flavored cigarettes. Relying on internal tobacco industry documents and witness testimony, the US District Court for the District of Columbia agreed. The court made a number of findings of fact, including that:

(a) light, low tar and similar cigarettes offer no clear health benefit over regular cigarettes;
(b) the US FTC testing method does not measure actual tar and nicotine delivery;
(c) tobacco companies internally recognized that light, low tar and similar products are not less harmful than full-flavor cigarettes;
(d) tobacco companies had an extensive and sophisticated understanding of smoker compensation;
(e) tobacco companies recognized that smokers switch to light / low tar cigarettes rather than quit smoking because they believe they are less harmful; and
(f) despite this internal knowledge, tobacco companies denied that compensation is nearly complete and that the US FTC testing method was flawed.24

40. A similar testing method was adopted by the International Standards Organization (ISO).25 Internal tobacco industry documents released to the public through litigation show that tobacco companies played a major role in adoption of that testing method as an ISO standard.26 Subsequently, tobacco companies used results derived from that method globally as a basis for misleading descriptors like light and mild.

41. This brief example illustrates the unique regulatory environment in which tobacco control is undertaken and the rationale for limiting participation by tobacco companies and those working to further their interests in the work of the COP as observers. As is stated above, however, these rules did not in any way limit the ability of States to participate in the work of the COP with respect to the Guidelines

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for Implementation of Article 11 or 13, whether as a Party or observer. This limitation also does not discriminate between tobacco companies.

3.2.3 Participation in the Work of Working Groups

42. The participation of observers in subsidiary bodies of the COP, such as working groups, is subject to different rules. In the case of subsidiary bodies, Rule 27 provides that:

> Sessions or meetings of subsidiary bodies shall be held in public, unless the Conference of the Parties or the subsidiary body concerned decides that they shall be open or restricted. This rule shall be implemented in conformity with Article 5.3 of the Convention.

43. Pursuant to COP2 decisions establishing the working groups, observers were permitted to attend the meetings of the working groups mandated to draft guidelines to Articles 11 and 13, but the meetings were closed to the public. More specifically, given the nature of the working group as a drafting exercise, observers with specific expertise on the subject matter of the work were permitted to participate.

44. In the case of the Guidelines for Implementation of Article 11, COP2 requested the working group “to invite the relevant intergovernmental and nongovernmental organizations with specific expertise in the matters to actively participate and contribute to the work of the working group, as per request from the Convention Secretariat”.

45. In the case of the Guidelines for Implementation of Article 13, COP2 requested the working group to invite two groups. First, COP2 requested the working group to invite experts to participate in the work as necessary and, in particular, officers of an expert group formed by COP1 to examine cross-border advertising promotion and sponsorship. Second, COP2 requested the working group “to invite the relevant intergovernmental and nongovernmental organizations with specific expertise in the matters to actively participate and contribute to the work of the working group, as per request from the Convention Secretariat.”

3.3 Procedure for Achieving Consensus

46. Rule 50.2 of the Rules of Procedure of the COP requires that the COP make “every effort to reach agreement by consensus.” Rule 50.3 provides that if all efforts

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27 Elaboration of guidelines for implementation Articles 5.3, 9 and 10, 11, 12 and 14, Conference of Parties to the WHO Framework Convention on Tobacco Control, Second Session, FCTC/COP2(14), A/FCTC/COP/2/DIV/9, 20 September 2007, para. 5(b).
29 Ibid, para. 3.
to reach consensus have been exhausted and no agreement has been reached the COP shall proceed as a last resort and make decisions on substantive matters by a three fourths majority vote. As was noted above, both the Guidelines for Implementation of Article 11 and 13 were adopted by consensus of the COP.

47. The process of reaching consensus permitted:
   • any Party to participate in the work of the working groups by offering itself as a key facilitator or partner;
   • submission of comments on drafts through a password protected website; and
   • consideration of those comments, as is reflected in the fact that changes to the drafts of both the Guidelines for Implementation of Article 11 and 13 were made by the key facilitators of the working groups after comments were received.

48. In addition:
   • the Guidelines for Implementation of Articles 11 and 13 were disseminated publicly online through the Convention Secretariat’s public website;
   • no fees are charged to access the Guidelines;
   • there are no restrictions on transposing the Guidelines into a regional or national standard; and
   • in accordance with Article 28 of the Convention, amendments to the Guidelines for Implementation of Article 11 and 13 may be adopted by the COP.


49. Neither the Convention Secretariat nor WHO has a mandate to interpret the WHO FCTC or its Guidelines. Neither the Convention Secretariat nor WHO can offer an opinion concerning what function the Parties intended the Guidelines to serve. Instead, this section sets out those provisions of the Convention, the Guidelines, and COP decisions that are relevant to the nature and functions of the Guidelines. In addition, this section provides a brief description of how the Guidelines have been implemented by Parties, including in the specific context of plain packaging.

4.1 The Convention, Guidelines and COP Decisions Relevant to the Nature and Intended Function of the Guidelines

50. In the context of a framework convention, Article 7 provides context for interpretation of the Guidelines for Implementation of Article 11 and 13 in two respects. First, Article 7 obliges Parties to adopt effective measures to implement Articles 8 – 13. Second, Article 7 specifies that the COP shall “propose appropriate guidelines for the implementation of the provisions of these Articles.” (Our emphasis). In full, Article 7 states:

The Parties recognize that comprehensive non-price measures are an effective and important means of reducing tobacco consumption. Each Party shall adopt and implement effective legislative, executive, administrative or other measures necessary to implement its
obligations pursuant to Articles 8 to 13 and shall cooperate, as appropriate, with each other directly or through competent international bodies with a view to their implementation. The Conference of the Parties shall propose appropriate guidelines for the implementation of the provisions of these Articles.

51. The overarching obligation to implement effective measures is also reflected in the wording of Articles 11 and 13 of the Convention. Article 11 obliges Parties to implement effective measures to ensure that tobacco packaging and labelling does not promote tobacco products by means that are false, misleading or deceptive (Article 11.1(a)) and to ensure that tobacco packaging carries health warnings describing the harmful effects of tobacco use (Article 11.1(b)). Similarly, Article 13 obliges Parties to undertake a comprehensive ban on tobacco advertising, promotion and sponsorship.

52. The preamble to the COP decision adopting Guidelines for Implementation of Article 11 emphasizes “that the aim of these guidelines is to assist Parties to meet their obligations under Article 11 of the Convention and that they are not intended to increase Parties’ obligations under this Article.” In this context, paragraph 1 of the Guidelines for Implementation of Article 11 states the intention of the Parties in the following terms:

Consistent with other provisions of the WHO Framework Convention on Tobacco Control and the intentions of the Conference of the Parties to the Convention, these guidelines are intended to assist Parties in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labelling measures. Article 11 stipulates that each Party shall adopt and implement effective packaging and labelling measures within a period of three years after entry into force of the Convention for that Party. (our emphasis)

53. The preamble to the COP Decision adopting the Guidelines for Implementation of Article 13 (FCTC/COP3(12)) emphasizes “that these guidelines are to assist Parties in meeting their obligations under Article 13 of the Convention and to provide guidance for implementation of this Article.” In this context, paragraph 1 of the Guidelines on Implementation of Article 13 describes the purpose and function of the Guidelines in the following terms:

The purpose of these guidelines is to assist Parties in meeting their obligations under Article 13 of the WHO Framework Convention on Tobacco Control. They draw on the best available evidence and the experience of Parties that have successfully implemented effective measures against tobacco advertising, promotion and sponsorship. They give Parties guidance for introducing and enforcing a comprehensive ban on tobacco advertising, promotion and sponsorship or, for those Parties that are not in a position to undertake a comprehensive ban owing to their constitutions or constitutional principles, for applying restrictions on tobacco advertising, promotion and sponsorship that are as comprehensive as possible. (our emphasis)
54. In summary, the WHO FCTC seeks to address the consequences of tobacco consumption “by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels.” The Guidelines for Implementation of Articles 11 and 13 propose measures to increase the effectiveness of packaging and labelling measures, and establish guidance on introducing and enforcing a comprehensive ban on tobacco advertising, promotion and sponsorship.

4.2 Regional and National Implementation

55. A number of regional bodies have adopted instruments that may be relevant to the nature and intended function of the guidelines.

56. In 2011 the Gulf Cooperation Council (GCC), acting through the GCC Standardization Organization (which consists of national standards bodies of GCC member states) adopted GSO Standard 246/2011 on Labeling of Packages Tobacco Products. In their official implementation reports, GCC countries that are Parties to the WHO FCTC have referred to this instrument as a means of implementing Article 11 of the Convention.


58. In 2014 the European Union (EU) adopted the EU Tobacco Products Directive (TPD). The preamble to the 2014 EU TPD makes a number of references to WHO FCTC guidelines. This includes a reference to aligning the rules that apply at the EU level to international developments, such as a number of aspects of

30 WHO Framework Convention on Tobacco Control, Article 3.
32 Reports by Parties are available at http://apps.who.int/fctc/implementation/database/.
Guidelines for Implementation of Article 11.\textsuperscript{35} Article 24(2) expressly preserves the rights of EU Member States to implement plain packaging.

59. At the national level, examples specific to plain packaging include the following:

- In Ireland, the Public Health (Standardised Packaging of Tobacco) Act 2015, which is specific to plain packaging, expressly states that it is to give effect in part to the 2014 EU TPD.\textsuperscript{36}
- In the United Kingdom of Great Britain and Northern Ireland, an official public consultation document on plain packaging indicated that the proposal reflected the WHO FCTC Guidelines (although the regulations to implement plain packaging do not expressly refer to the Guidelines).\textsuperscript{37}
- In France, Regulations to implement plain packaging notified to the European Commission (but not yet passed into law) indicate that the Regulations are based on Article 24 of the 2014 EU TPD.\textsuperscript{38}
- In Norway, a public consultation on the introduction of plain packaging stated that implementation of the measure would “contribute toward enabling Norway to fulfil the obligations of the FCTC.”\textsuperscript{39}

5. \textbf{Specific Aspects of the Text of the Guidelines for Implementation of Articles 11 and 13 that are Relevant to the Implementation of Plain Packaging}

60. Specifically with respect to plain packaging, paragraph 46 of the Article 11 Guidelines states:

> Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.

\textsuperscript{35} \textit{Ibid}, para. 24.
\textsuperscript{38} See the message accompanying the notification, available at \url{http://ec.europa.eu/growth/tools-databases/tris/fr/index.cfm/search/?trisaction=search.detail&year=2015&num=241&mLang=EN}, para. 8.
\textsuperscript{39} Consultation on the Proposal for Standardised Tobacco Packaging and the Implementation of Article 5.3 of the Framework Convention on Tobacco Control, Norwegian Ministry of Health and Care Services, available at \url{https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/132085/2015/TBT/NOR/15_1975_00_e.PDF}, Para. 3.1.2.
61. As is noted in our 16 February 2015 submission, this paragraph specific to plain packaging must be read in the context of other paragraphs in the Guidelines. These include paragraphs addressing industry design techniques that may suggest some products are less harmful than others and paragraphs addressing the size of health warnings. Moreover, paragraph 46 of the Guidelines for Implementation of Article 11 must be read in light of the obligations in Article 11 and other provisions of the Convention. These paragraphs and provisions are also relevant to implementation of plain packaging.

62. Specifically with respect to plain packaging, paragraphs 15 and 16 of the Guidelines for Implementation of Article 13 state:

15. Packaging is an important element of advertising and promotion. Tobacco pack or product features are used in various ways to attract consumers, to promote products and to cultivate and promote brand identity, for example by using logos, colours, fonts, pictures, shapes and materials on or in packs or on individual cigarettes or other tobacco products.

16. The effect of advertising or promotion on packaging can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products.

63. Subsequently, the following recommendation is made in paragraph 17:

Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive.

64. Like the relevant passages in the Guidelines for Implementation of Article 11, these paragraphs need to be read in their context, which includes other passages in the Guidelines, Article 13 and other obligations set out in the Convention.

6. Preparatory Materials

65. COP2 requested the Article 11 working group to "take into account existing resources and expertise from governmental, intergovernmental and nongovernmental organizations, as well as from scientific studies and best practices." COP2 also requested the Article 13 working group to take into account

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40 Elaboration of Guidelines for Implementation Articles 5.3, 9 and 10, 11, 12 and 14, FCTC/COP2(14), para. 5(a).
a report of an expert group on cross-border advertising, promotion and sponsorship presented to the Conference of the Parties at COP2.41

66. In the case of both the Guidelines for Implementation of Article 11 and 13, COP3 was presented with a draft of the Guidelines along with a description of the drafting process undertaken by the working group. These documents are reproduced in Annexes 5 and 8.

67. A review of the official records of COP3 (summary records of committees42 and verbatim records of the plenary43) indicates that Parties discussed whether plain packaging should be included in the guidelines. That discussion focused on whether plain packaging would be obligatory and whether plain packaging would infringe legal rights in the territory of Parties. However, at COP3 Parties did not question whether the Article 11 working group had complied with its mandate and taken into account scientific studies and best practices or whether the Article 13 Working Group had complied with its mandate and taken into account the expert group report. Nor did Parties question whether there was a sufficient evidence base supporting inclusion of plain packaging in the guidelines or the draft text. On the contrary, COP3 agreed by consensus to paragraph 1 of the Guidelines for Implementation of Article 13, which states that “[they] draw on the best available evidence and the experience of Parties that have successfully implemented effective measures against tobacco advertising, promotion and sponsorship.”

6.1 Preparatory Materials considered by the Working Group

68. In the case of each working group, the fact that the working groups were closed to the public means that the Convention Secretariat does not have a standing mandate to disclose preparatory materials from the working groups.

69. In the case of the Guidelines for Implementation of Article 11, this restriction on the mandate of the Convention Secretariat to share information was partially lifted by Decision FCTC/COP3(10). That decision requested the Convention Secretariat “to make accessible, via a web site, the studies, research and other reference material used in the development of the guidelines for implementation of Article 11.” To assist in implementation of this provision the key facilitators of the working group provided the Convention Secretariat with a list of resources that were subsequently made publicly available at http://www.who.int/fctc/treaty_instruments/adopted/eleven/en/. (Annex 10)

41 The report is Elaboration of Protocols (decision FCTC/COP1(16)): Elaboration of a Template for a Protocol on Cross-Border Tobacco Advertising, Promotion and Sponsorship, A/FCTC/COP/2/10.


Additional materials were available to members of the working group during the drafting process, but neither the Convention Secretariat nor WHO is in a position to comment on the extent to which members of the working group used those additional materials in preparing the draft.

70. In the case of the Guidelines for Implementation of Article 13, there has not been a COP decision mandating that the Convention Secretariat make preparatory materials public.

6.2 Developments Since Adoption of the Guidelines at COP3

71. As is apparent in our 16 February 2015 submission, the evidence base relevant to plain packaging has grown since adoption of the Guidelines for Implementation of Articles 11 and 13 in 2008.

72. In this respect, the process of developing guidelines under the auspices of the WHO FCTC is an ongoing and iterative process rather than a static one. The WHO FCTC includes rules that permit Parties to address new evidentiary developments, such as Article 28 of the Convention, which permits the COP to adopt amendments to WHO FCTC guidelines. For example, at COP5, Parties amended partial guidelines for implementation of Articles 9 and 10 of the Convention, which had been adopted at COP4.44

73. It is also the case that a single Party to the Convention may add a proposal for amendment of guidelines to the provisional agenda of the COP. In this respect, Rule 7(g) of the Rules of Procedure of the Conference of the Parties provides that the provisional agenda of the COP shall include “any other item relevant to the implementation of the Convention proposed by a Party and received by the Secretariat prior to circulation of the provisional agenda.”

74. However, amendments to the Guidelines for Implementation of Articles 11 and 13 have not been proposed at COP4, COP5, or COP6.

75. Finally, the growing body of evidence concerning plain packaging strengthens the conclusions drawn in the Guidelines for Implementation of Articles 11 and 13 of the WHO FCTC. This view is substantiated in our 16 February 2015 submission, as well as in the three systematic reviews of the evidence commissioned by WHO Member States in 2011 and 2014.45

44 See http://www.who.int/fctc/treaty_instruments/adopted/article_9and10/en/.
45 With respect to those reviews see Australia – Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable To Tobacco Products and Packaging (WT/DS434) and Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable To Tobacco Products and Packaging (WT/DS435, WT/DS441, WT/DS458, WT/DS467), Information for Submission to the Panel by a Non-Party on behalf of the World Health Organization and the WHO Framework Convention on Tobacco Control Secretariat, 16 February 2015, paras 49 – 58.