Briefing on the revision of the **Tobacco Products Directive**

Background and Context

Pictorial warnings:

Tobacco warning labels in the European Union are governed by the provisions of the 2001 **Tobacco Products Directive** ("TPD").[1] Black and white text warnings have been mandatory since 2002 but the use of pictorial warnings is voluntary, as set out under Article 5.3 of the Directive.[2]

In 2003, a **Commission Decision**,[3] in reference to Article 5.3 TPD, was adopted in order to provide detailed rules for Member States choosing to use pictorial warnings from the EU Library on cigarette packs. According to the Commission Decision, pictorial warnings must be combined with text warnings, they must be rotated on a regular basis, printed on the back of the package,[4] surrounded by a black border[5] and covering at least 40% of the surface of the packet.[6]

There are now 10 EU countries requiring pictorial warnings. **Belgium** was the first country to implement the option in 2006, followed by **Romania** (2008), the **UK** (2008), **Latvia** (2010), **Malta** (2011), **France**[7] (2011), **Spain** (2011, **Denmark** (2012)), **Hungary** (as of Sept 2012) and **Ireland** (as of 2013). In the wider EURO region, **Switzerland** (2008), **Turkey** (2010) and **Norway** (2011) have adopted pictorial warnings, based on the Commission's 42 image library, and **Ukraine** will follow suit in September 2012. Worldwide, at least 50 jurisdictions have required pictorial warnings.

---

[1] Directive 2001/37/EC of the European Parliament and of the Council of June 2001on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:194:0026:0034:EN:PDF The TPD was adopted in 2001 under **Article 95 EC (renumbered as Article 114 after the Lisbon Treaty)**, which deals with the achievement of the internal market, and **Article 133 EC (now Article 207)**, which deals with common commercial policy. It should be noted that Article 152 EC (now Article 168, which deals with public health) is **not** the legal basis.

[2] Article 5.3 TPD states: *"The Commission shall…adopt rules for the use of colour photographs or other illustrations to depict and explain health consequences of smoking, with a view to ensuring that internal market provisions are not undermined. Where Member States require additional warnings in the form of colour photographs or other illustrations, these shall be in accordance with the abovementioned rules"*

[3] Commission Decision of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages, 2003/641/EC: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:226:0024:0026:EN:PDF

[4] *Ibid*. Article 4(2)(b)

[5] *Ibid*. Article 4(2)(e)

[6] *Ibid*. Article 4(3). This proportion shall be increased to 45% for Member States with two official languages and 50% for those with three. For tobacco products other than cigarettes, the most visible surface of which exceeds 75cm^2, the combined warning must cover an area of at least 22.5cm^2.

[7] France was previously non-compliant with the EU Directive. In revising its warning requirements, France has now corrected the placement of the black border (3-4 mm in width) that is to surround the warning. Previously in France, the border was located inside the space reserved for the warning (30% front, 40% back), thus making the warning size smaller. For unilingual countries, the EU Directive requires warnings to appear on 30% of the front and 40% of the back, plus a border which is to be in addition to this space. By having proper compliance with the border/size requirement, the effective size used on the package is 43% front and 53% back, though this can vary slightly depending on package format. See, In French only: http://www.smokefreepartnership.eu/IMG/pdf/French_arrete.pdf

Standardised packaging:

The review of the 2001 Tobacco Products Directive constitutes a major opportunity to introduce mandatory pictorial warnings combined with **standardised packaging** in the European Union.

In its **Guidelines for the implementation of Article 11 FCTC**, the WHO recognises that plain packaging:

> *"may increase the noticeability and effectiveness of health warnings and messages, prevent the package from distracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others."*[8]

The adoption of mandatory pictorial warnings and standardised packaging would enable consumers to make a fully informed choice. Indeed, marketing literature routinely highlights the critical role played by pack design in marketing, emphasising that the "product package is the communication life-blood of the firm", the "silent salesman" that reaches out to customers.[9] In this context, it is clear that the effect of pictorial warnings alone would be undermined by the presence of appealing trademarks on the same package.

In November 2009, a **Council Recommendation on smoke-free environments**[10] was adopted, which invites Member States to adopt mandatory pictorial warnings (under Art. 5.3 TPD and the Commission Decision on Pictorial Warnings), but also called on the European Commission to *'analyse the legal issues and the evidence base for the impact of plain* (or, standardised) *packaging'*.

This Recommendation follows the adoption of the **WHO Framework Convention on Tobacco Control** ("FCTC"),[11] in particular Paragraph 46 of the **Guidelines for Implementation of Article 11,**[12] which states that:

> *'[p]arties 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 size (plain packaging).'*

Australia has announced plans for new rules forcing tobacco companies to use standardised packaging with pictorial health warnings covering 75% of the front and 90% of the back of packets, to come into effect December 2012. The UK, France, Belgium and Norway expressed their support for standardised packaging and their intention to adopt such measures at national level. In April 2012, the UK Department of Health launched a public consultation on the introduction of standardised packaging of tobacco products.[13]

---

[8] Guidelines for Implementation of Article 11 of WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products), Paragraph 46, http://www.who.int/entity/fctc/guidelines/article_11.pdf

[9] B. Freeman, S. Chapman, M. Rimmer, *The Case for Plain Packaging for Tobacco Products*, University of Sidney, School of Public Health p. 7, 2008, referring to Underwood RL, Ozanne J. *Is your Package an Effective communicator? A Normative Framework for Increasing the Communicative Competence of Packaging*. J. Marketing Communication 1998: 207-220.

[10] Council Recommendation on smoke-free environments, 30 November 2009 (COM 2009/328) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:296:0004:0014:EN:PDF

[11] Please see: http://whqlibdoc.who.int/publications/2003/9241591013.pdf. It should be noted that the European Union has ratified the FCTC, along with all but one EU Member State. All Parties are legally bound under the FCTC.

[12] Please see: http://www.who.int/fctc/guidelines/article_11.pdf

[13] http://consultations.dh.gov.uk/tobacco/standardised-packaging-of-tobacco-products/consult_view

Elsewhere in the world, Canada have passed a law allowing for pictorial warnings to be extended to cover 75% of the front and back of packaging, and the US will introduce pictorial warnings for the first time, covering 50% of the front and back of packaging. Uruguay's legislation also requires pictorial warnings to cover 80% of the front and the back of tobacco packages.

Timeline for the revision of the Tobacco Products Directive

1. <u>First Report on the application of the Tobacco Products Directive:</u>

→ The First Report was published on 27 July 2005.[14]

→ The Commission encouraged Member States' uptake of the newly available pictorial warnings and also promised consideration of further developments of labelling.[15]

2. <u>Second Report on the application of the Tobacco Products Directive:</u>

→ The Second Report was published on the 27th November 2007.[16] The report contains the second assessment of application of the Directive.

→ It is primarily based on the information given by Member States over the previous two years in the **Tobacco Products Regulatory Committee** (as provided for under Article 10 of the TPD). The report incorporates views of stakeholders in the field of tobacco control, the European Parliament and the Member States. The Commission decided to examine:

"….the possibilities with regard to ***an increased size for the warnings*** *[and]* ***mandatory pictorial warnings on both sides of the package."***[17]

3. <u>Impact Assessment:</u>

The Impact Assessment (IA)[18] on the possible revision of the Tobacco Products Directive is currently being carried out.[19] The basic work for the Impact Assessment started mid-2009. The IA is carried out in order to prepare evidence for political decision-makers on the 'advantages' and 'disadvantages' of possible policy options. The IA addresses the economic, social and health impacts as well as the legal feasibility of different policy options. **The SFP believes that the IA must recommend mandatory pictorial warnings and standardised packaging in order for the proposal to be revised effectively.**

[14] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, First Report on the application of the Tobacco Products Directive, COM (2005) 339 final (Brussels 27.07.2005): http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/com_2005_339_en.pdf
[15] *Ibid*. 3.3
[16] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Second Report on the application of the Tobacco Products Directive, COM (2007) 754 final (Brussels 27.11.2007): http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_products_en.pdf
[17] *Ibid*. p.7
[18] For further details on Impact Assessments, please see: http://ec.europa.eu/governance/impact/index_en.htm
[19] For further, please see DG SANCO's 'Roadmap' on revision of the Tobacco Products Directive: http://ec.europa.eu/governance/impact/planned_ia/docs/46_sanco_tobacco_products_directive_en.pdf

Consultation on the Interim Report on the IA – December 2009:

- The relevant stakeholders have been consulted on the Interim Report on the Impact Assessment that outlined a baseline scenario, which took place in December 2009.

Consultation on the RAND Technical Report [20] – October 2010:

- A study to support the Impact Assessment for the TPD revision was ordered by DG SANCO and conducted by the independent consultancy RAND. It was released in September 2010.

- In October 2010, DG SANCO held three consultation meetings on the RAND report with stakeholders. The purpose of these meetings was to get the input and comments of stakeholders on the report. The first meeting was held with Member State representatives, the second was held with representatives of non-governmental organisations, and the third meeting was held with representatives from the tobacco industry.

- The comments from these meetings will be taken into consideration by DG SANCO and incorporated into its IA.

Public Consultation on the policy options for the Revision of the TPD – December 2010

- The online stakeholder consultation took place, after several months' delay, from October to December 2010.[21]
- The consultation generated more than 85 000 contributions from a wide range of stakeholders, including citizens, industry, NGOs, governments and public authorities.
- The responses were analysed and a report was prepared by the European Commission's Directorate-General for Health and Consumers.
- It was clear that there were huge, industry-coordinated 'petitions', with the aim of delaying the process.

European Commission internal processes for the IA

- Firstly, a central IA unit, existing within each DG, controls the operational units when they prepare a draft IA
- The second level of scrutiny is provided by the Commission Secretariat General, which offers guidance and quality control on the draft IA
- Thirdly, the **Impact Assessment Board** (IAB) delivers an opinion on the quality of the draft IA report with respect the IA Guidelines.
- Finally, all DGs, with the Secretariat-General, control the IA report through the **Impact Assessment Steering Group** (IASG)

[20] RAND Europe, *Assessing the Impacts of revising the Tobacco Products Directive*, http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf
[21] http://ec.europa.eu/health/tobacco/docs/tobacco_consultation_en.pdf

4. Commission's Proposal:

→ DG SANCO should prepare a **draft Proposal** by late 2011/early 2012, taking into account the Impact Assessment.
→ The draft Proposal will go into inter-service consultation (consultation between the different departments of the European Commission). This process can take up to 8 months.
→ Some Departments of the Commission will play an important role during the inter-service consultation. Indeed, the possible revision of the TPD would have an impact on the activities of DG Internal Market, DG Employment, DG Trade, DG Agriculture and DG Education. Therefore, the role of these DGs will be crucial during the inter-service consultation and can influence the adoption of the proposed revised Directive and its content.

If the Proposal is adopted within the Commission, the proposed Directive will be released publicly, along with the IA. This was originally scheduled by mid-2012, but it is our understanding that it will be in the last quarter of the year, under the Cypriot Presidency, with an aim for the discussions to start in the first half of 2013, under the Irish Presidency.

5. Co-Decision Procedure:

→ The European Commission's proposed Directive will go through the Co-decision Procedure,[22] shared between the European Parliament[23] and the Council[24] (EU Member States). (see below a brief explanation of the process)
→ Because of the complexity and political weight of the Directive, we don't expect the Parliament and Council to agree on an amended TPD text during the first reading.
→ We expect the proposed text to go through a second reading.
→ The agreement should take place during 2014 (hopefully before the new European Parliament elections in June 2014).

6. Implementation:

→ Once adopted, the revised TPD should start being implemented between 2014 and 2016.

7. Relevant Presidencies:

2012	January-June Denmark July-December Cyprus
2013	January-June Ireland Jul-Dec Lithuania
2014	January-June Greece July-December Italy

[22] For details on legislative procedures, please see: http://europa.eu/institutions/decision-making/index_en.htm
[23] For the European Parliament's website, please see: http://www.europarl.europa.eu/news/public/default_en.htm
[24] For the Council's website, please see: http://www.consilium.europa.eu/showPage.aspx?lang=EN&id=1