

The Legal Aspects of the Tobacco Products Directive Proposal

Outline

1. The Proposal
2. Legal Basis TPD Proposal
3. Subsidiarity
4. Proportionality
5. Intellectual Property Rights

Key Measures in the Proposal

Policy Areas Covered

- New TPD proposal
- Focus on 5 policy areas:
 1. Smokeless tobacco products (extension of the scope of the current TPD)
 2. Packaging & Labelling
 3. Ingredients/additives
 4. Cross border distance sales
 5. Traceability and security features

Packaging and Labeling

- Mandatory pictorial health warnings
- Plain packaging measures

Main features – Labeling and Packaging

- **Mandatory** pictorial health warnings
- **75%** pictorial health warnings
- **Front and back** of the pack
- **Regulation of the size and shape** of the pack
- **Getting rid of the TNCO label**
- Member States free to adopt **plain packaging measures at national level**

Legal Basis TPD Proposal

Article 114 TFEU

- The Parliament and the Council can adopt harmonisation measures, which have as their object the **establishment and functioning of the internal market**
- In its proposal, the Commission shall take as a base a **high level of health protection and consumer protection,**
- taking into account any **new developments based on scientific facts.**

Legal Basis for the Proposal

- Current situation: some Member States have adopted pictorial health warnings, while others have not.
 - This creates **obstacles to the functioning of the internal market**
 - In addition, **new scientific and international developments**: WHO FCTC and evidence that large pictorial warnings and plain packaging work.
- => Therefore, the current TPD needs to be revised.**

2. Subsidiarity

What is subsidiarity?

(Article 5.3 TEU)

“in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the **objectives** of the proposed action **cannot be sufficiently achieved by the Member States... but can rather... be better achieved at Union level.**”

Subsidiarity - Why does it matter?

- **Maximum Harmonization:** the measures cannot be changed at national level, except in very specific circumstances
- **Minimum Harmonization:** Member States can go further at national level, on specific grounds
- **No harmonization:** Member States can adopt national measures. If they are likely to create obstacles to trade, they must meet certain requirements under the Treaty.

Pictorial Health Warnings

Fully harmonised measures

Under the current TPD and proposal,

- The Member States cannot go further than the EU Directive regarding the size of the health warnings.
- **EXCEPT in very specific circumstances (threshold is very high to meet)**

=> It is therefore important to have a high standard (75%)

Health Warnings - Delegated Acts

- **Drawback of fully harmonized measures: lack of flexibility** in case of new development. The Member States must wait for the revision or adoption of a new Directive to adapt the fully harmonized measures to the new evidence.
- Solution in the current proposal: **delegated acts**, namely, at the request of a Member State or at its own initiative, **the Commission can update** the existing requirements in the light of new technical/scientific development or substantial change
- It then gathers a **Committee of scientific experts** to discuss the topic and adapt the Directive if needed.
- Little experience with delegated act so far

Plain packaging – non harmonised area

Plain Packaging – No harmonized measures

- Art. 13 Proposal does not regulate the entire pack
- Therefore, Member States can adopt plain packaging measures at national level, even if they **constitute technical barriers to trade**
- **Article 36 FTEU - a high level of health protection** can justify the interference with free circulation of goods
- **EU Case law – very wide margin of discretion** of the Member States when adopting measures based on **health protection**

Plain packaging – non harmonized area (cont'd)

Conditions (Art. 24.3 Proposal)

- “overriding reason” of public interest
- Necessary and proportionate to the aim
- Not a means of arbitrary discrimination or a disguised trade restriction

Plain packaging – non harmonized area (cont'd)

- Wording should include “**grounds of protection of health**” (art. 36 TFEU), which gives **more margin of discretion to Member States**:
- In these circumstances, the ECJ has considered that the **national court is in a better position to address the proportionality and effectiveness of the measures.**
- By contrast, the ECJ does not leave any margin of discretion to the Member States for technical obstacles to trade based on overriding requirements of public importance, like consumer protection

=> Adoption of plain packaging at national level would be possible

Case C-322/01 Deutscher
Apothekerverband [2003] ECR I-14887,
paragraph 103

“the health and life of humans rank first among the property or interest protected under art. 36 and **it is for Member States**, within the limits imposed by the Treaty, **to decide what degree of protection** they intend to assure and in particular, how strict checks to be carried out are to be.”

3. Proportionality

Proportionality (art. 5.4 TEU)

- **The content and form of the Union action shall not exceed what is necessary to achieve the objectives of the Treaty**
- Opponents to the Proposal say proposal is excessive.
- However, **in the area of health**, the EU legislature has a **broad discretion**
- The measure is legal if not **manifestly inappropriate** in the light of the objective pursued

=> The impact assessment recognizes the proportionality of the measures adopted in the Proposal

Proportionality - Pictorial Health Warnings

- 75% - No lawsuit
- Evidence that larger warnings work better is recognized in Impact Assessment
- EU is behind!

4. Intellectual Property Rights

Large PHW/Plain Packaging & Intellectual Property

Common legal arguments against large pictorial health warnings and plain packaging:

- It **violates intellectual property rights** and will result in very costly litigation and compensation to the tobacco industry

What is Intellectual Property Law?

(Articles 2 and 5 of the Trademark Directive 2008

Article 15.4 TRIPS)

Protections	Compatibility with plain Packaging?
1. Preserve brands so that consumers can distinguish products	YES
2. Right to register a trademark and to have exclusive ownership of the trademark	YES
3. Protection against unauthorized use by a 3 rd party	YES

The use of a trademark is a **PRIVILEGE, not a right**

Related Aspects of Intellectual Property Rights (TRIPs Agreement)

Article 20 (interpretation *a contrario*) - The use of a trademark can be encumbered if it is justifiable.

Article 8(1) "members may adopt measures necessary to protect public health, provided that such measures are consistent with the provisions of this Agreement."

Existing Precedents in the EU

- **Possible prohibition of the use of trademarks Precedent -** TPD, Art. 7 – Prohibition of the use of terms "light", "mild" resulted in prohibiting the use of some trademarks (e.g. "Malboro Light")
- **Possible regulation of the use of trademarks Precedent –** 2001 *Directive on Medicinal products and Guidelines* prohibits the use of "elements of a promotional nature on the packaging" and regulates the use of the logo.

Can an EU Member State adopt Plain Packaging Measures?

- As long as the TPD does not regulate packaging, an EU Member State can go ahead and adopt Plain Packaging measures
- Legal basis: Article 36 Fundamental treaty of the European Union - a high level of health protection can justify the interference with free circulation of goods

What should a country when adopting Plain Packaging measures?

- It needs to **check its trademark law** – if there is a positive right to use trademark, then could carve out an exception based on public interest to adopt plain packaging.
- This would need to be checked against the **Constitution.**
- It also needs to look at its **bilateral investment treaties**

Conclusion

Current TPD Proposal

- Strong legal basis
- Pictorial Health Warnings – Keep it at 75%!
- Plain packaging at national level needs to be possible
- Proportionality of the measures in the proposal
- Intellectual Property Rights – no violation of EU/IP law