



The new EU Tobacco Directive

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Health Impacts



- **Smoking prevalence** in the EU has decreased, but 26% of all EU citizens and 25% of 15-24 year olds still smoked in 2014 (EB 2015).
 - 70% start up to the age 18 (EB 2015).
- Tobacco is the largest avoidable **health threat** in the EU
 - Responsible for 697000 deaths (8,5 million life years)
 - Half of all smokers die prematurely (on average 14 years)
- Annual EU **public healthcare expenditure** on treating diseases caused by smoking is estimated around 25bEUR.
- **Productivity losses** amount to 8,3 bEUR per year.



Nota bene: EU has limited competence for health

Legal Acts

- Tobacco Products Directive 2014/40/EU
- Tobacco Advertising Directive 2003/33/EC
- Audio-Visual Media Services Directive 2010/13/EU
- Directive 2011/64/EU (sets minimum taxation levels for tobacco products in the EU)

Council Recommendations

- Recommendation 2003/54/EC on the prevention of smoking and on initiatives to improve tobacco control
- Recommendation 2009/C 296/02 on smoke-free environments

Other Initiatives

- Anti-smoking campaigns
- Research





Ingredients

➤ **Main provisions in the TPD**

- Regulation of ingredients including ban of tobacco products with characterising flavours
- Reporting obligations for ingredients / electronic reporting format
- Priority list of additives incl. enhanced reporting obligations

➤ **Implementing power**

- Establishing the procedure for determining characterising flavours
- Setting up an advisory panel (flavour testing)
- Establishing the list of priority additives
- Establishing the reporting format



Labelling and packaging

- **Main provisions in the TPD**
 - 65% combined health warnings on cigarettes and RYO
 - Certain pack standardisation
 - Ban on misleading elements

- **Implementing power**
 - Position of warnings on RYO pouches
 - Layout, design and shape of combined health warning,



E-cigarettes

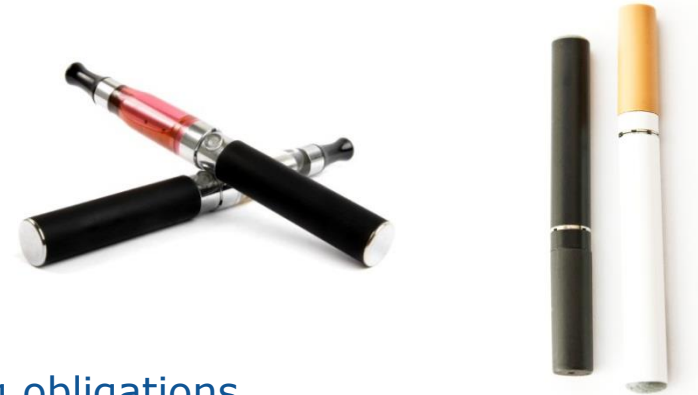
➤ Main provisions in the TPD

- E-cigarettes consumer v. pharma products
- Safety and quality
- Packaging and labelling
- Notification, market surveillance and reporting obligations
- Advertising
- Special rules for "refillables"

National competence: flavours, age limits, sales points, nicotine free ecigs

➤ Implementing power

- Common notification format
- Technical standards for the refill mechanism
- Risks to public health associated with refillable e-cigarettes





Illicit Trade

- **Main provisions in the TPD**
 - Unique identification of tobacco products at the unit packet level
 - Full traceability from the manufacturer to the last point before retail
 - Independent data storage
 - Obligatory tamper proof security feature at the unit packet level

- **Implementing power**
 - Technical standards for the tracking and tracing system, incl. the unique identifier
 - Key elements of the data storage contracts, incl. the oversight of the audit functions
 - Technical standards for the security feature, incl. its rotation



Other TPD provisions

- **Cross border distance sale**
 - Notification and age verification systems, MS may prohibit.

- **Smokeless tobacco**
 - Ban on oral tobacco (snus), reinforced labelling

- **Novel tobacco products**
 - Notification obligation. TPD provisions remain applicable.

- **Herbal products for smoking**
 - Labelling, ingredients reporting



- **On-going studies/External contractors**
- **Stakeholder involvement**
 - Member States (Expert Group, subgroups, TP Committee)
 - Industry (Art 5(3) FCTC)
- **Secondary legislation**
 - 10 acts for adoption before May 2016, 3 acts 2017
 - Intra SANTE, ISC, TBT-notification, adoption procedure
- **Further challenges/tasks**
 - Reporting obligations, additional implementing power, enforcement, court cases



Court of Justice of the EU

a) Philip Morris/BAT

- Validity of the Directive in all aspects relating to tobacco (in particular as regards labelling provisions).

b) E-cigarette company 'Totally Wicked'

- Validity of e-cigarette provisions

c) Poland

- Menthol ban

Other cases: access to documents; damage claims (picture warnings)

2. WTO cases (plain packaging)



Member States can take additional measures

Notification under Directive 98/34/EC

Member States must notify the Commission of its draft technical rules or regulations. The aim is to ensure that these rules are compatible with EU law and the Internal Market principles.

Standardised packaging

- Three MS have notified their intention to introduce standardised packaging (FR, IE and UK). Norway also intends to introduce standardised packaging for smoked and oral tobacco.
- The European Commission will represent MS before WTO.

Electronic cigarettes

- A number of MS have notified measures relating to e-cigarettes, including introducing certain TPD requirements early or requiring all e-cigarettes to be sold as medicines.



Thank you!

Any questions?