Document 1.2

European Commission

Tobacco Products Directive 2014/40/EU

European Commission's
Directorate General for Health and Food Safety, Unit D4

September 2015

Outline

1. Introduction – facts and figures
2. Rationale for the new Directive
3. Main elements of the new Directive
4. Implementation calendar

1. Introduction - facts and figures (I)

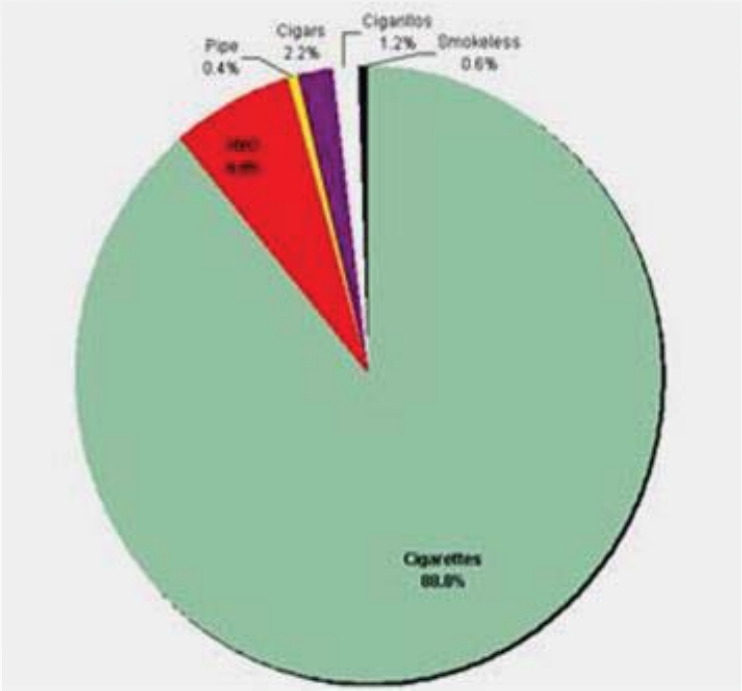
Effects of smoking

- Tobacco is the largest avoidable health threat in the EU
  - Causes nearly 700,000 premature deaths per year
  - Half of all smokers die prematurely (on average 14 years)
  - Smokers have more life years in poor health conditions (cancer, cardiovascular, respiratory diseases)
- Annual EU public healthcare expenditure on treating diseases caused by tobacco: 25 bEUR per year
- Productivity losses due to tobacco: 8.5 bEUR per year
- Governments' revenues from excise duty and VAT on the sale of tobacco products in the EU are estimated at 77 bEUR and 22 bEUR, respectively.

1. Introduction - facts and figures (II)

EU Tobacco Market

- 4 big players in cigarettes and Roll-Your-Own tobacco. Other tobacco products - mostly smaller companies
- Cigarettes represent 89% of the market value, Roll-Your-Own tobacco 7%
- The total value of the EU Tobacco Market at retail level including taxes is 130.5 bEUR (before taxes value: 31 bEUR)



2. Rationale for the new Directive (I)

Main reasons of the revision

Previous Tobacco Products Directive dated from 2001– since then:

- Market developments (new marketing strategies/new products);
- Scientific developments (new studies);
- International developments (EU/MSs Parties to WHO FCTC).

The main objective is to guarantee proper functioning of the internal market, while ensuring a high level of health protection, Art. 114 TFEU

Internal market

- Update and modernise already harmonised areas
- Remove divergences of national provisions
- Address circumvention (safeguards of TPD should reach consumers)

Health

- Limit smoking initiation, in particular by young people

2. Rationale for the new Directive (II)

Socioeconomic impact of the revision

- The new Directive is expected to lead to a drop of tobacco consumption of 2% within five years. This corresponds to 2.4 million smokers less in the EU;
- Reduction of health care expenditure of 506 mEUR annually;
- Reduction of productivity losses of 165 mEUR annually;
- Possible losses for tobacco industry mitigated by savings through harmonisation and by measures against illicit trade (current tax losses: 10 bEUR annually);
- Overall, positive impacts on employment.

3. Main elements of the new Directive (I)

Ingredients

- Ban of characterising flavours;
- 4 year transitional period for flavoured products with market share › 3% (e.g. menthol);
- Certain additives (vitamines, caffeine, etc.) are prohibited;
- Reporting obligations for all ingredients and enhanced reporting obligations for additives on a so-called priority list;

3. Main elements of the new Directive (II)

Packaging and labelling

- Mandatory combined (picture and text) warnings (65%) on both sides of the unit packet;
- No ban of slim cigarettes;
- Pack standardisation to ensure visibility warnings;
- No promotional elements;
- MS can introduce plain packaging.

Future pack of cigarettes

3. Main elements of the new Directive (III)

Illicit trade

- EU-wide tracking and tracing system at unit pack level;
- Independent third party to provide the data storage facility;
- In addition (anti–counterfeit) security features on all packs;
- Longer transitional period for products other than cigarettes and RYO.

Smokeless tobacco products (STP)

- Ban on oral tobacco (e.g. snus) maintained;
- Reinforced labelling provisions (both sides of the pack);
- No ingredients regulation for snus; limited regulation for other STPs.

3. Main elements of the new Directive (IV)

Electronic cigarettes

- MS may choose to subject e-cigs to pharma legislation if justified;
- All other e-cigs fall under TPD rules, including: safety and quality requirements, notification obligation, rules on packaging and labelling, rules on advertising, and monitoring and reporting on market developments;
- Special rules for "refillables".

3. Main elements of the new Directive (V)

Cross border distance (internet) sales

- Notification obligation for cross border distance retailers and age verification system;
- Member States are entitled to ban cross border sales.

Novel tobacco products

Herbal products for smoking

Internal market clause

4. Implementation calendar

- **10 acts for adoption before May 2016**
- **3 acts for adoption by mid-2017**

Thank you!

Any questions?

Further Information

http://ec.europa.eu/health/tobacco/policy/index_en.htm