



Electronic cigarettes and heated tobacco products

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Tobacco Products Directive (TPD)

- **TPD (2014)** sets rules for tobacco and related products
- **Main additional provisions**
 1. Ingredients
 2. Labelling
 3. Tracking and tracing
 4. **E-cigarettes and novel tobacco products**
- **Expected outcomes**
 - Decreased tobacco consumption
 - Strengthened functioning of the EU internal market
 - Ensuring a high level of health protection (initiation & young people)



Need for EU action on e-cigarettes

- **Differing or non-existent rules**
 - E.g.: under legislation of pharmaceuticals, consumer products or tobacco products
- **Growth of the EU market**
 - Significant market growth and market expansion
- **Public health concerns**
 - misleading / inconsistent product information & marketing
 - differing qualities
 - lacking information on long-term health effects
 - inconclusive evidence on initiation & cessation
 - safety concerns
 - lacking authorisation mechanism

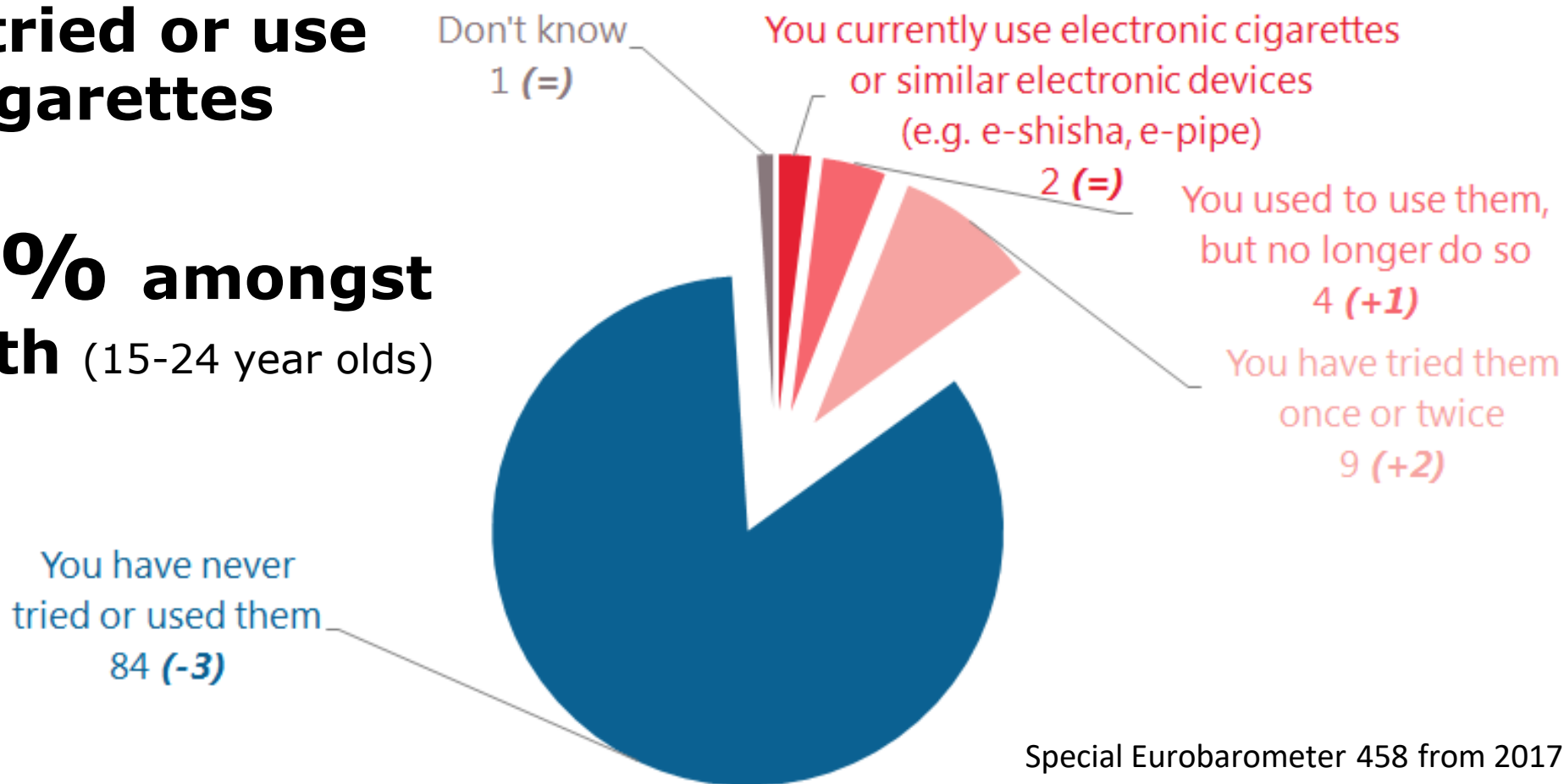


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Prevalence of use

15% of respondents
have **tried or use**
e-cigarettes

25% amongst
youth (15-24 year olds)



E-cigarettes in the TPD

- Safety and quality (e.g.; ban on vitamin additives)
- Packaging and labelling (health warning)
- Prior notification (6-months), market surveillance & reporting obligations
- Advertising restrictions
- Content thresholds:
 - Refill container: 10ml
 - Nicotine concentration: 20mg / ml
 - Cartridge/tank size: 2ml
- Rules for "refillables": nozzle, flow control, docking system
- Member States have the option to:
 - ban flavours
 - ban cross-border distance sales (e.g.; internet sales)
 - regulate cannabis extract (e.g.; CBD)



Heated tobacco products in the TPD

- Regulated as 'novel tobacco product' which:
 - a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and
 - b) is placed on the market after 19 May 2014.
- Prior notification with possibility to introduce authorisation
 - Additional studies/evidence requested
- No further specific rules once a product on the market
 - Provisions for smokeless OR smoking tobacco apply accordingly

Heated tobacco - challenges

- Very dynamic market
 - Products of various construction increasingly entering the EU-market
 - Market situation varies among Member States
- Classification of products
 - Depends on presence of “combustion”
 - Assessment requested (Mandate COP8(22)) for potentially adapting the FCTC guidelines and prevent circumvention of smoke-free and advertising legislation
- Regulation of devices
 - Emissions depend on specific combination of a device and a tobacco product
 - Heating devices not in the scope of the TPD
 - FCTC COP8 decision recommends Parties apply regulatory measures to the devices where appropriate
- Promotion as “better” products

Commission 5-year implementation report – May 2021

Application of directive, amongst other products special attention to:

- **Electronic cigarettes and refill containers:** use patterns, role of these products for the initiation of consumption of such products and tobacco products by young people and non-smokers and the impact of such products on cessation efforts, including the role of dual use;
- **Slim cigarettes:** consumer perception of the harmfulness as well as the misleading character of these products;
- **Water pipes:** use patterns and consumer preferences with a particular focus on its flavours, role of dual use;
- Experience gains with **design of package surfaces** (e.g. plain packaging);
- **Market developments: novel products, e-cigarettes**, water pipes, slims, sales and use by product category
- **Feasibility, benefits, possible impact of a European system** for the regulation of ingredients and of a Union database on ingredients; positive/negative list

Data gathering & information sources

- Discussions with Member States
 - Expert Group, Subgroup on e-cigarettes, Joint Action, etc.
- Eurobarometer survey (next 2020) & data from Member States
- Studies and assessments
 - SCHEER scientific opinion
 - Product perceptions study: 5 product categories, including e-cigarettes
- Discussions in international fora (WHO FCTC)





Scientific assessment

SCHEER (Scientific Committee on Health, Environmental and Emerging Risks):

- Final deliverable: scientific opinion on e-cigarettes (health effects, cessation, initiation)
- Preliminary planning:
 - Draft opinion and public consultation Spring 2020
 - Final opinion: September/October 2020
- mandate accepted and published:

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_013.pdf





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Thank you

https://ec.europa.eu/health/tobacco/overview_en