

ENSP FACT SHEET

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Emerging and Novel
Tobacco Products



ENSP

European Network
for Smoking and Tobacco Prevention

What are 'novel tobacco products'?

According to the EU Tobacco Products Directive (2014/40/EU), a 'novel tobacco product' is defined as a tobacco product which does not fall into any of the following categories: cigarettes, roll-you-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use ; and was placed on the market after 19 May 2014.ⁱ

- Cigarette sales have steadily decreased in most high-income countries over the past decade.ⁱⁱ (WHOHTP)
 - This has led to the development and marketing of products the tobacco industry has claimed to have lower health risks.
- Examples of novel tobacco products include: electronic cigarettes and heated tobacco products (HTPs).



Current Regulation & Public Policy Outlook

- Range of potential policy responses: no regulations, softer variations than current tobacco products, similar regulations as current tobacco products, complete bans on novel products.ⁱⁱⁱ(UHTP)
- The EU has adopted a precautionary approach to NTPs in Chapter III of the 2014 Tobacco Products Directive.
 - Article 19 calls for mandatory notification of NTPs.
- WHO favours stricter regulation; FCTC obligations apply in respect of all NTPs.^{iv}
 - WHO stresses importance of surveillance and reporting to identify and track NTPs.
 - FCTC/COP7(14): Further development of the partial guidelines for implementation of Articles 9 and 10 of WHO FCTC calls for monitoring and examination of marketing developments and usage of novel products

Product Comparison: ENDS v. HTP

Similarities:

- Both deliver an aerosol of nicotine into the lungs using a behaviour that mimic the physical act of smoking.^{viii} (UHTP)

Differences

- HTPs heat tobacco to generate nicotine while e-cigarettes heat e-liquid.
 - E-liquid usually doesn't contain tobacco and may contain nicotine.



Electronic Cigarettes

Introduction

- Definition: a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.^v (TPD)
- Refill containers are receptacles containing nicotine-containing liquid, which can be used to refill an e-cigarette.^v (TPD)
- The two most popular types of e-cigs are rechargeables with disposable cartridges and refillable e-cigarettes, with refillable being the most prominent across the EU member states.^{vi} (PRECISE) *continued*



Introduction continued

- Context (PRECISE)
 - There has been continuous expansion of the e-cigarette market in Europe since 2008.
 - The e-cigarette market was estimated to be worth approximately 2.16 Billion Euro in 2014, according to Euromonitor international report.
 - The Member States (MS) with the largest markets are the UK, Italy, Poland, and France.
- Current Market:
 - Companies: MarkTen, XL, Logic. Vuse, Blum JUUL
 - Altria Group, Inc. British American Tobacco, Imperial Brands, International Vapor Group, Japan Tobacco International, NicQuid, Philip Morris International Inc., R.J. Reynolds Vapor Company, Shenzhen IVPS Technology Co, Ltd., Shenzhen KangerTech Technology Co., LTD

Current Research

- Limited availability on quality control and chemical testing.
- Chemical components in liquids: humectants, nicotine, flavours, impurities, etc.
 - Flavour additives (some that had CLP classifications that warrant further investigation) are prevalent.
- Adverse effects have found in cellular, animal, and human studies.^{vii}(JOurnal)
 - Cytotoxic effects of refill liquids (especially when nicotine and flavour substances are present); oxidative stress; inflammation of the respiratory system and effects on blood glucose in animal or tissue models.
 - Other effects reported including: pneumonia, chest pain, hypotension, dizziness, nausea.
- Broad lists of unwarranted claims on smoking cessation and health benefits .
- Refillable e-cigs are responsible for nearly all cases of unintentional exposure.

Associated Public Health Risks

- Experimentation by non smokers and serving as a gateway into nicotine addiction and traditional tobacco consumption as the mimic and normalize the action of smoking.^v (TPD)
- Design and production flaws such as leakage and spillage threaten the exposure of e-liquid via skin and/or eyes.
- When within reach of minors (a little under half of industry websites have an age verification request).
- Inadequate or misleading information about product constituents or unwarranted claims on smoking and cessation.
- Possibility to modify and/or blend refill liquids for refillable e-cigs can result in production of harmful compounds or allow consumption of illegal substances.
- Uncertainty about long-term effects (some evidence associates e-cigs with reduced quit attempts, dual product use or retained nicotine addiction.
- Use of e-cigs where smoking isn't allowed (need more about the risks of passive vaping).

Current Regulations

- Central Ideas: 1. Safety and Quality Requirements,
2. Packaging and Labeling Rules,
3. Monitoring and Reporting of Related Developments
- Electronic submission of a form, detailed description and instruction for use and information on ingredients and emissions at least six months before intended placement of the product on the market.^v (TPD)
 - Must also provide authorities with: available related scientific studies on toxicity, addictiveness, and attractiveness; market research on consumer demographic groups; risk/benefit analysis; expected tobacco initiation and cessation effects.
 - Labelling and packaging: must display sufficient and appropriate information on their safe use, carry appropriate health warnings, and not include any misleading elements or features.^v(TPD)
 - Nicotine specific regulations: Nicotine-containing liquid only allowed to be placed on market where nicotine concentration is less than 20 mg/ml (similar to the permitted does derived from a standard cigarette used for the same amount of time) and must deliver nicotine at consistent levels under normal conditions (to avoid the risk of accidental consumption of high doses).^v (TPD)
 - Maximum sizes for refill containers, tanks, and cartridges should be set.^v (TPD)
 - Ensure e-cigs do not break or leak during use and refill.^v (TPD)

E-Cigarette Specific Recommendations

- Adopt a restrictive approach to advertising of e-cigarettes and refill containers
- Use a high level of public health protection when regulating products
- When deciding upon policies regarding flavours, Member States should be aware of the attractiveness of the products for young people and non smokers.^v
 - Though it is necessary to justify any prohibition of flavored products.
 - Member States maintain control on adopting rules on flavours.
- As member states have jurisdiction to introduce a system for authorisation, these should be developed and monetized to charge manufacturers and importers proportionate fees for authorisation.^v

Heated Tobacco Products

Introduction

Definition: a product that produces aerosols containing nicotine and other chemicals, which are inhaled through the mouth and contain highly-addictive nicotine; they mimic the behavior of conventional cigarette smoking.ⁱⁱⁱ

- HTP Specific
 - Currently in 40 countries as of September 2017.ⁱⁱ
 - Total sales for HTPs were US \$2.1 billion (according to data released in Euromonitor in 2017), expected to reach US \$17.9 billion by 2021
 - Profit margins are 30-50% higher than for conventional cigarettes for PMI.ⁱⁱ
- Current Market
 - Companies promote HTP as nicotine delivery products with lower risk and capable of use for cessation.ⁱⁱⁱ
 - Major Playersⁱⁱ
 - Phillip Morris International (PMI) - iQOS
 - Japan Tobacco International (JTI) - Ploom HTP and Ploom TEC H
 - British American Tobacco (BAT) - iFuse



Current Regulations/Position of the Union

- Ban indoor use of HTP.ⁱⁱⁱ
- Ban advertising, promotion and sponsorship activities
- Prohibit claims that HTPs assist in smoking cessation, potential to reduce willingness to quit smoking and about the impact of dual use with cigarettes until independent evidence is gathered.ⁱⁱⁱ

HTP Specific Recommendations

- When making policy, keep in mind that industry research dominates published scientific literature.ⁱⁱⁱ
 - Potential benefits/risks are undetermined but independent research shows tobacco companies are understating the risks
 - Wait for independent assessment of health effects rather than taking industry assertions as the truth before allowing for sales of products
- Incorporate HTP into the regular monitoring framework of tobacco use in the country
- Further develop national surveillance mechanisms to monitor HTP marketing (improve legislation to monitor sales volume, collect information on user demographics, etc.)
 - Would provide countries with the data needed to establish more sound regulatory frameworks
- Conduct independent research to find sufficient evidence on potential effects (not just relying on industry research)

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