

Novel tobacco and nicotine products and their effects on health



Novel tobacco and nicotine products and their effects on health

Abstract

These proceedings summarise the presentations and discussions before the European Parliament's Health Working Group as part of the workshop on 'Novel tobacco products and their effects on health', held on 30 November 2022. The four presentations touched, *inter alia*, upon the current state of research on health effects, their role in harm reduction and regulatory recommendations.

These workshop proceedings were provided by the Policy Department for Economic, Scientific and Quality of Life Policies for the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI).

This document was prepared for the Health Working Group (HWG) of the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI).

AUTHORS

Julia LIETZMANN and Maxime MOULAC, Milieu Consulting SRL

ADMINISTRATOR RESPONSIBLE

Christian KURRER

EDITORIAL ASSISTANT

Catherine Naas

LINGUISTIC VERSIONS

Original: EN

ABOUT THE EDITOR

Policy departments provide in-house and external expertise to support EP committees and other parliamentary bodies in shaping legislation and exercising democratic scrutiny over EU internal policies.

To contact the Policy Department or to subscribe for email alert updates, please write to:
Policy Department for Economic, Scientific and Quality of Life Policies
European Parliament
L-2929 - Luxembourg
Email: Poldep-Economy-Science@ep.europa.eu

Manuscript completed: December 2022

Date of publication: February 2023

© European Union, 2023

This document is available on the internet at:

<http://www.europarl.europa.eu/supporting-analyses>

DISCLAIMER AND COPYRIGHT

The opinions expressed in this document are the sole responsibility of the authors and do not necessarily represent the official position of the European Parliament. Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the European Parliament is given prior notice and sent a copy.

For citation purposes, the publication should be referenced as: Lietzmann, J., Moulac, M., 2023, *Novel Tobacco Products and their effects on health - HWG workshop proceedings*, publication for the Committee on Environment, Public Health and Food Safety, Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg.

© Cover image used under licence from Adobe Stock.

CONTENTS

LIST OF FIGURES	4
LIST OF TABLES	4
LIST OF ABBREVIATIONS	5
EXECUTIVE SUMMARY	6
1. BACKGROUND ON NOVEL TOBACCO PRODUCTS	9
2. WORKSHOP PROGRAMME	13
3. SUMMARY OF THE PRESENTATIONS	14
3.1. Health Risk Assessment of Novel Tobacco Products, electronic cigarettes, and related products	15
3.1.1. Overview of alternative tobacco products	15
3.1.2. Risk assessment: Exposure	15
3.1.3. Risk assessment: Comparison of the contents of selected harmful substances in the emissions of tobacco cigarettes and novel tobacco products	16
3.1.4. Risk assessment: Toxicology of flavours in liquids for electronic cigarettes	17
3.1.5. Policy recommendations	18
3.2. Joint Action on Tobacco Control 2 and scientific evaluation of novel products	19
3.2.1. Joint Action on Tobacco Control 2	19
3.2.2. Work package 7: Health impact and regulatory implications of e-cigarettes and novel tobacco products	19
3.2.3. Flavour accessories for tobacco products	20
3.2.4. Conclusions	20
3.3. Novel nicotine products – The population perspective	21
3.3.1. Benefits of novel nicotine products for the industry	21
3.3.2. Impact on public health	21
3.3.3. Policy recommendations	22
3.4. Novel tobacco products – Regulatory aspects	23
3.4.1. The effectiveness of regulation	23
3.4.2. Current regulatory environment in the EU	23
3.4.3. Future challenges	24
3.4.4. Revision of the Tobacco Products Directive (2023)	24
4. DISCUSSIONS AND Q&A	25
SHORT BIOGRAPHIES OF THE SPEAKERS	28
WORKSHOP PRESENTATIONS	32

LIST OF FIGURES

Figure 1:	Typology of the main novel tobacco products	9
Figure 2:	Novel tobacco products' main characteristics	15
Figure 3:	Contents of six selected harmful substances in novel products	17
Figure 4:	Countries participating in the Joint Action on Tobacco Control (JATC) 2	19

LIST OF TABLES

Table 1:	Future challenges for the assessment and regulation of novel tobacco products	24
----------	-------------------------------------------------------------------------------	----

LIST OF ABBREVIATIONS

BfR	German Institute for Risk Assessment
EC	European Commission
ECR	European Conservatives and Reformists
ENDS	Electronic Nicotine Delivery Systems
ENNDS	Electronic Non-Nicotine Delivery Systems
ENVI	European Parliament Committee on the Environment, Public Health and Food Safety
EP	European Parliament
EU	European Union
JATC	Joint Action on Tobacco Control
HTP	Heated Tobacco Product(s)
MEP	Member(s) of the European Parliament
PG	Propylene glycol
TED	Tobacco Excise Directive
TSNAs	Tobacco-Specific N-nitrosamines
TPD	Tobacco Products Directive
VG	Vegetable glycerine
VOC	Volatile Organic Compound(s)
Q&A	Questions and answers
WHO	World Health Organization

EXECUTIVE SUMMARY

Background

The three main types of **novel tobacco and nicotine products** are either **tobacco-based** products, i.e. heated tobacco products, or **nicotine-based** products, i.e. vapour products (electronic cigarettes) and nicotine pouches. The use of these products is growing very rapidly in Europe, with sharp increases observed in volumes sold in the last fifteen years. In particular, heated tobacco products introduced on the market in 2014 have seen an increase in volumes sold between 2018 and 2020 by a factor of 20. Nicotine pouches introduced in 2016 are used by 0,3% of the European adult population but their usage could triple by 2025.

Pursuant to the Tobacco and related products Directive 2014/40/EU, **novel tobacco products** are those which are not 'cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use', and which have been placed on the market after 19 May 2014, thus covering a large range of products and consumptions methods. In the Directive, a distinction is made between **smokeless and smoking tobacco products**, and electronic cigarettes have been specifically regulated in the Directive. Most recently, as of 23 November 2022, due to a recent substantial change of circumstances in the sales volumes, heated tobacco products have lost the exemption of the Directive, which allowed these products to have characterising flavours (i.e. flavour ban).

Novel nicotine products are marketed as less harmful than cigarette and tobacco smoking. However, **challenges surround the scientific health risk assessment of novel tobacco and nicotine products**, in particular due to the variation of emissions, device-content interactions and specific features resulting in different levels of nicotine and toxicants. Although the content of harmful chemicals in the emissions of these products appears significantly reduced, the assessment of their actual effects on human health still needs further research.

Furthermore, the effectiveness of novel tobacco and nicotine products as **smoking cessation instruments** (tobacco harm reduction approach) **has not been demonstrated**, and dual use of cigarettes and of novel tobacco and nicotine products is common. Furthermore, the World Health Organization highlights that novel nicotine products can double the chance for non-smokers of starting to smoke cigarettes.

Finally, the consideration of novel tobacco products in the **Tobacco Products Directive** suffers from **legal loopholes** due to rapid products developments, and not all of the Directive's rules apply uniformly (e.g. prohibition of flavours). More specifically, nicotine pouches do not fall under the Directive's categories, and their legal status is left to the Member States.

Aim of the workshop

The workshop was conceived to provide the European Parliament with a comprehensive and multidisciplinary overview on novel tobacco products and the current state of knowledge about their effects on health and their role in smoking cessation. This workshop intervenes in the context of **Europe's Beating Cancer Plan** adopted in 2021 with the ambition of a tobacco-free generation by 2040, and the upcoming Commission proposals for revision of the Tobacco Products Directive in 2024 and of the Tobacco Taxation Directive in 2023.

Main discussions at the workshop

Smoking tobacco products is harmful to health.

Assessment of the health risks

All presenters agreed that an in-depth and long-term assessment of the public health risks of novel nicotine and tobacco products is necessary. The risk assessment of novel products requires an analysis of the exposure, of the contents of harmful substances in the emissions of these products and of the toxicology of additives (e.g. flavours).

Regarding **electronic cigarettes** (vapour products), the presence of certain harmful substances in the emissions (vapour) of these products can be lower by around 90 to 95% compared to tobacco cigarettes, although the composition of aerosols depends on the devices, settings used and the composition of the liquid itself. Health risks have been identified with regard to the toxicology of **flavouring substances** contained in liquids when inhaled; the **formation of acetals** (chemicals whose toxicological properties are still unknown) and of **carbonyl compounds** during the heating process; to the presence of carcinogenic metals in the emissions; and the possible contamination of liquids for electronic cigarettes by tobacco-specific N-nitrosamines (important group of carcinogens).

For **heated tobacco products**, the presence of certain harmful substances in the emissions of these products can be lower by around 80 to 90% compared to tobacco cigarettes, although the composition of aerosols also depends on the devices, settings used and the composition of the tobacco sticks. Despite the reduction of certain types of chemicals found in emissions, preliminary research has nevertheless found the presence of certain **carcinogenic or mutagenic substances** in heated tobacco products, sometimes in higher concentrations than in the emissions of tobacco cigarettes.

With regard to **nicotine pouches**, the health risks reside primarily in the **high nicotine content** of certain products, leading to similar or higher contents of nicotine in users' blood. Nicotine is very addictive itself and presents its own health threats, in particular for the brain.

The results presented above must be read in light of the fact that a **reduction of 95% of certain harmful chemicals** contained or emitted **is not equal to a 95% reduction in health risks**.

Current actions and policy challenges

The Joint Action for Tobacco Control 2 (JATC2) is a European initiative providing scientific support for the implementation of EU legislation on tobacco control, including with regard to novel tobacco products. It is currently collecting information on the variety of **products sold in the EU**, evaluating the use, abuse potential and **health risks** of novel products, harmonising the collection of **adverse events**, and supporting Member States.

In general, **flavours** make nicotine and tobacco products attractive, reduce harm perception and are linked to increased initiation and consumption of tobacco products. A **legal loophole** identified by the activities of the JATC2 is the marketing and growing use of **flavour accessories** as a response to the characterising flavour ban, which do not contain nicotine or tobacco, and are thus not covered by legislation.

Novel nicotine products have advantages for the industry, as they can generate larger profits through lower taxation, they are not covered by the tobacco legislation in full, they compensate the loss of smokers who quit cigarettes, and **may attract new consumers** of tobacco and/or nicotine products. Although it is claimed that they are intended to help smokers quit, the **marketing clearly targets young people**. Besides, these products often do not replace cigarettes, as a large proportion of users also smoke cigarettes (**dual use or triple use**). More generally, studies show that there is little evidence for the effectiveness of novel tobacco and nicotine products (heated tobacco products, electronic

cigarettes and nicotine pouches) in **smoking cessation**, while they increase the risk of smoking initiation for non-smokers.

Conclusions and recommendations

The experts each provided conclusions and recommendations, which can be summarised as follows:

- The **market for novel nicotine products is rapidly evolving**, via new products, rebranding of existing products and new technologies. The EU will need a **flexible and dynamic legal framework** capable of responding rapidly to developments in tobacco and nicotine products and their accessories, whose characteristics are still unknown at the time of legislating.
- The **results from health risk assessments cannot be generalised per product type**, in view of the importance of the specific characteristics of the products and of the usage conditions. The evolution of product characteristics makes long-term risk assessments more difficult.
- **Tobacco control regulations are effective**, have an impact, and can be successful in saving millions of lives (as proven by the regulation of tobacco cigarettes, as well as more recently, electronic cigarettes).

Experts' policy recommendations for the European Parliament:

- The objective should remain the attainment of a **smoke-free society**, including without addictive nicotine and tobacco products.
- The development of a **science base for harm reduction strategies** for tobacco products, as well as the characterisation of relevant **indicators for high risks** (e.g. ingredients, device settings), are needed.
- A uniform approach to **collect and compare information about adverse health effects** resulting from new devices or ingredients is needed. In this regard, the work of the JATC2 will provide a solid basis to develop common standards.
- **European legislation** should regulate novel tobacco and nicotine products and apply rules applicable to tobacco products (e.g. ban of flavours, enforcement of age restrictions, plain packaging, plain packaging, smoke free areas, higher taxes).
- **Sales and marketing** (including on social media) of novel nicotine and tobacco products should be regulated to support tobacco control policies.

1. BACKGROUND ON NOVEL TOBACCO PRODUCTS

Pursuant to the Tobacco and related products Directive 2014/40/EU, **novel tobacco products** are those which are not 'cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use', and which have been placed on the market after 19 May 2014. The notion of novel tobacco products covers a large range of products and consumptions methods.

Emerging nicotine and tobacco products

Although conventional manufactured cigarettes remain the main mode of tobacco consumption (around 75% of the total sales volume of all tobacco products in the EU in 2020¹), non-combustible tobacco and nicotine products have developed rapidly in the last fifteen years, and their use is expected to continue growing in the coming years. These products include **tobacco-based products**, such as heated tobacco products (HTPs), and purely **nicotine-based products** (not containing tobacco), such as vapour products (electronic cigarettes) and nicotine pouches².

The three main types of products emerging on the European market are:

Figure 1: Typology of the main novel tobacco products



Heated tobacco products, introduced on the EU market in 2014, are the largest group of novel tobacco products in market value and the one with the fastest growing usage rate³. According to a recent Commission report, they represented around 3.5 % of the total sales volume of all tobacco

¹ European Commission, Report from the European Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU, COM(2022) 279 final, June 2022, table 6.

² These new tobacco and nicotine-containing products are not marketed as medicinal NRTs such as nicotine gums, lozenges, inhalers and transdermal patches, which are aids to smoking cessation and freely available "over the counter" in several countries. Rather, such new tobacco and nicotine containing products are marketed as adult consumer packaged goods and may provide adult users of combustible cigarettes with satisfying alternatives to smoking.

³ Tobacco Intelligence, [A Market Snapshot of "Novel Nicotine Products" in the European Union](#), November 2021.

products in the EU for the year 2020⁴ and their sales volume has multiplied by a factor 20 in the EU-27 between 2018 and 2020⁵. The largest markets in the EU include Italy, Germany, Poland, the Czech Republic and Greece⁶. The use of **vapour products** is expected to increase between 2017-2025 from 2.3% to 3.7% of the adult population in the EU.

Nicotine pouches are present on the market since 2016, and while they concern only 0.3% of the European adult population in 2021, their market value is expected to double and their usage rate to triple (to reach 0.9% of the European adult population) by 2025⁷. Nicotine pouches are primarily used by adolescents and young adults, e.g., by 12% of the 15-24-years old in Denmark, and especially by boys/young men⁸. Sales of nicotine pouches are currently concentrated in the Nordic countries and Eastern Europe, largest markets being Sweden, Hungary and Denmark⁹.

Debates over novel products' impacts on health

Challenges surround the scientific assessment of novel tobacco and nicotine products, in particular due to the variation of emissions, device-content interactions and specific features resulting in different levels of nicotine and toxicants¹⁰. Novel tobacco and nicotine products are generally marketed as less harmful than conventional combustible cigarettes and promoted as alternatives to smoking. However, this has been subject to debates as uncertainties remain on the health impacts of novel products.

Several studies showed that **heated tobacco products** exposed users and bystanders to reduced levels of harmful substances compared to conventional cigarettes, although harmful substances are not completely eliminated¹¹. According to a recent systematic literature review of peer-reviewed studies on HTPs, the reduction of levels of harmful compounds ranged between 62-99% depending on the substance¹². The German Federal Institute for Risk Assessment (BfR) also showed that levels of tobacco-specific N-nitrosamines (TSNAs) and other pollutants such as cadmium, polycyclic aromatic hydrocarbons (PAHs), or carbon monoxide were reduced in HTPs compared to conventional cigarette smoke¹³. However, other studies identified potentially toxic substances, including carcinogenic substances, in HTP emissions, in concentrations higher than in conventional cigarette smoke¹⁴. In terms of health impacts, the BfR study pointed out that if there is evidence of reduced exposure to certain substances, reduced health risks had not yet been adequately demonstrated. Based on the state of the research, a recent briefing from the WHO stated that currently there is insufficient evidence to conclude

⁴ European Commission, Report from the European Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU, COM (2022) 279 final, June 2022, table 6.

⁵ *ibid*, table 1.

⁶ Tobacco Intelligence, [A Market Snapshot of "Novel Nicotine Products" in the European Union](#), November 2021.

⁷ *ibid*.

⁸ Danish Health Authority, [Use of smokeless nicotine products among youth](#), February 2022.

⁹ *ibid*.

¹⁰ Euractiv, News article 'Debate heats up over novel tobacco and nicotine products' harmfulness'. Available at: <https://www.euractiv.com/section/health-consumers/news/debate-heats-up-over-novel-tobacco-and-nicotine-products-harmfulness/>.

¹¹ Znyk M, Jurewicz J, Kaleta D. Exposure to Heated Tobacco Products and Adverse Health Effects, a Systematic Review. *Int J Environ Res Public Health*. 2021 Jun 21;18(12):6651. DOI 10.3390/ijerph18126651.

¹² Simonavicius E, McNeill A, Shahab L, et al. [Heat-not-burn tobacco products: a systematic literature review](#). *Tobacco Control* 2019, 28:582-594.

¹³ Mallock N, Pieper E, Hutzler C, Henkler-Stephani F and Luch A. Heated Tobacco Products: A Review of Current Knowledge and Initial Assessments. *Front. Public Health* 2019, 7:287. doi: 10.3389/fpubh.2019.00287.

¹⁴ European Commission, Directorate-General for Health and Food Safety, Lupiáñez-Villanueva, F., Gaskell, G., Lecland, I., et al., *Consumer preference and perception of specific categories of tobacco and related products*, European Commission, 2021, <https://data.europa.eu/doi/10.2875/740949>.

that HTPs are less harmful than conventional cigarettes¹⁵. Furthermore, there is evidence of dual use – i.e., consumers using both HTPs and conventional cigarettes¹⁶.

E-cigarette emissions typically contain nicotine and other toxic substances that are harmful to both users, and non-users who are exposed to the aerosols second-hand. Some products claiming to be nicotine-free (ENNDS) have been found to contain nicotine¹⁷. Nicotine is highly addictive, and some evidence suggest that never-smoker minors who use ENDS can double their chance of starting to smoke tobacco cigarettes later in life¹⁸. Some recent studies suggest that ENDS use can increase the risk of heart disease and lung disorders¹⁹. Nicotine exposure in pregnant women can have adverse effects on the brain development of the foetus²⁰. From prenatal development through adolescence and early adulthood, exposure to nicotine poses a serious threat because these are critical times for brain development and brain plasticity²¹.

Regarding **nicotine pouches**, a recent study from the BfR mentioned that if switching from cigarettes to nicotine pouches may reduce risks for smokers, there are some concerns relating to the detection of TSNA in some pouches and uncertainties regarding the long-term effects of consuming these products. The study also reported concerns for young people and other vulnerable groups (pregnant and breastfeeding women and people who suffer from cardiovascular diseases) given the addictive potential of nicotine and its strong effects on the cardiovascular system²².

There are intense debates regarding the extent of the contribution of these products towards reducing smoking and limiting the harm of tobacco consumption. The ‘tobacco harm reduction’ approach puts forward the public health benefits of switching to less harmful forms of tobacco and/or nicotine consumption than smoking combusted cigarettes, as well as the benefits for second-hand smokers. Others support moving away from the use of addictive tobacco and nicotine products altogether, and the use of nicotine replacement therapies. Although these products provide alternatives to cigarette smokers, they have not proven to be risk-free, and may provide a gateway for (young) non-smokers into tobacco and nicotine consumption.

Novel tobacco products in the Tobacco Products Directive and recent developments

Specific types of novel or non-novel tobacco products are classified in the Tobacco Products Directive:

- **Tobacco for oral use** is regulated under Article 18, Chapter III: placing on the market is prohibited in the EU, except in Sweden which was granted a derogation.
- **Electronic cigarettes** are regulated under Article 20, Title III, of the Directive.

The Tobacco Products Directive defines a **novel tobacco product** as a tobacco product that ‘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 is placed on the

¹⁵ WHO, Heated tobacco products: a brief, 2020.

¹⁶ European Commission, Directorate-General for Health and Food Safety, Lupiáñez-Villanueva, F., Gaskell, G., Lecland, I., et al., *Consumer preference and perception of specific categories of tobacco and related products*, European Commission, 2021, <https://data.europa.eu/doi/10.2875/740949>.

¹⁷ WHO, Tobacco: E-cigarettes, <https://www.who.int/news-room/questions-and-answers/item/tobacco-e-cigarettes>

¹⁸ *ibid.*

¹⁹ *ibid.*

²⁰ *ibid.*

²¹ U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016

²² German Federal Institute for Risk Assessment. Health Risk Assessment of Nicotine Pouches. BfR Opinion No. 042/2021 of 21 December 2021. DOI 10.17590/20220204-105615. Updated Opinion on 7 October 2022, DOI 10.17590/20220204-105615.

market after 19 May 2014' (Article 2(14)). As per Article 19 of the Tobacco Products Directive, manufacturers and importers of novel tobacco products are required to submit a notification to the Member State's competent authorities before placing any novel tobacco product on the national market. Novel products placed on the market must respect the requirements of the Directive applicable to them (depending on whether they fall under the definition of a smokeless tobacco product or of a tobacco product for smoking).

The European Commission report on the application of the Tobacco Products Directive from 2021²³ notes a number of problems and regulatory challenges linked to the application of Article 19 on novel tobacco products. Although the definition of novel tobacco product in the Directive was meant to capture new types of products entering the market, it contains '**legal loopholes**' with regards to products not containing tobacco, such as oral nicotine pouches. For instance, the German legislation classifies nicotine pouches as 'novel food' products.

Another regulatory challenge is the difficulty to address **flavoured products** because tobacco products other than cigarettes and roll-your-own tobacco are exempted from the ban on characterising flavours, unless the Commission can demonstrate a 'substantial change of circumstances' (i.e. an increase of sales volumes by at least 10% in at least five Member States and sales volumes exceeding 2.5% of total sales of tobacco products at Union level). A 'substantial change of circumstances' has however been established by the Commission for heated tobacco products²⁴, opening the way to banning flavoured heated tobacco products²⁵.

The Commission report also generally points out the challenges linked to the application of the provisions of the Directive to novel products, as these have been defined for existing product groups and do not necessarily correspond to the characteristics of new products. The report concludes that the EU regulatory framework 'does not currently address all novel tobacco and emerging products, nor provides flexibility to address rapid product developments'.

A group of researchers are conducting research on the properties, health impact and regulatory implications of novel tobacco products and e-cigarettes in the context of the Joint Action on Tobacco Control (JATC), a flagship initiative of Europe's Beating Cancer Plan.

In this context, the Commission is currently working on the **evaluation of the Tobacco Products Directive**, due by the second quarter of 2023, which will address emerging products and has already proposed to prohibit the sale of flavoured heated tobacco products. This will contribute to the objectives of Europe's Beating Cancer Plan, which aims to create a 'tobacco-free generation' where less than 5% of the population uses tobacco by 2040, compared to around 25% today.

²³ European Commission, Report from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products, COM(2021) 249 final, 20 May 2021.

²⁴ European Commission, Report from the European Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU, COM(2022) 279 final, June 2022.

²⁵ Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products.

2. WORKSHOP PROGRAMME



The workshop consisted of four presentations:

Health Risk Assessment of Novel Tobacco Products, E-Cigarettes, and related products

Dr. Elke Pieper (German Federal Institute for Risk Assessment)

Joint Action on Tobacco Control 2 and scientific evaluation of novel tobacco products

Dr. Anne Havermans (Dutch National Institute for Public Health and the Environment)

Novel nicotine products – The population perspective

Dr. Charlotta Pisinger (University of Copenhagen)

Novel tobacco products – Regulatory aspects

Filippos Filippidis (Imperial College London)

3. SUMMARY OF THE PRESENTATIONS

The workshop was chaired by the co-chair of the Committee's Health Working Group, MEP Sara Cerdas.

Opening remarks

Co-Chair MEP Sara Cerdas welcomed the speakers, and the MEPs present at the workshop. The Health Working Group is part of the activities of the ENVI Committee on public health matters and its goal is to discuss strategic issues that affect the health of citizens.

A wide range of decisions adopted by the EP have impacted the field of public health (e.g. nutrition labelling on foods, health warnings on tobacco, research on new cancer treatments, or cross-border organ donations). The recent COVID-19 pandemic furthermore placed public health at the forefront of the political debate and European citizens have increasing expectations towards European policy makers, to solve current crises but also to proactively tackle potential future crises and challenges.

The aim of the workshops organised by the Health Working Group is for MEPs to receive first-hand information from experts about the latest challenges facing public health in Europe and discuss possible issues that need to be addressed at European level.

This specific workshop focusses on novel tobacco products and their effects on health, at individual and population levels. In the recent report of the Beating Cancer Committee (BECA)²⁶, it is emphasised that smoking tobacco products is one of the leading causes of cancer in Europe and worldwide, and one of the modifiable risk factors for developing cancer. In the recent years, efforts have intensified to reduce the prevalence of smoking, but new products have entered the market which allow users to consume tobacco and nicotine in alternative forms.

The debate about these new products is intensifying and many questions arise. Do these products help switch away from cigarettes, or do they attract new users in the world of nicotine and tobacco smoking? What is the effect on the health on individuals? What is the impact on the overall population health and the expenditure of the different healthcare systems? How does the EU need to adapt the current regulation to best protect the health of EU citizens?

²⁶ European Parliament's Special Committee on Beating Cancer (BECA). Available at: <https://www.europarl.europa.eu/committees/en/beca/home/highlights>.

3.1. Health Risk Assessment of Novel Tobacco Products, electronic cigarettes, and related products

This presentation was given by **Dr. Elke Pieper**, Senior Research Scientist at the German Federal Institute for Risk Assessment (BfR). The presenter introduced her presentation by reminding that smoking tobacco products is harmful to health, and that an assessment of novel tobacco and nicotine products is necessary.

3.1.1. Overview of alternative tobacco products

The presenter started by describing the main types of novel (alternative) tobacco products currently on the European market.

Figure 2: Novel tobacco products' main characteristics



Heated tobacco products (HTP) are battery powered devices, where specially manufactured tobacco sticks are heated in different ways, at different temperatures. One of the differences compared to traditional cigarettes is that they contain a higher proportion of humectants (water-absorbing substance used to keep things moist) such as propylene glycol and glycerol.

Electronic cigarettes (or e-cigarettes) are also battery powered devices, where no tobacco is used but a liquid containing propylene glycol, glycerol, flavour substances for taste and nicotine is heated to be inhaled. An important point is that the vapour production and nicotine release vary greatly from product to product.

Nicotine pouches are small pouches for oral use containing nicotine salts, microcrystalline cellulose, various other salts (including sodium carbonate and hydrogen carbonate), citric acid and flavourings.

3.1.2. Risk assessment: Exposure

The first step in the assessment of the health risks posed by the novel tobacco products is the evaluation of the exposure to harmful substances in the smoke or vapour emissions. This is achieved via standardised protocols, using smoke extraction machines to collect and quantify emissions.

Electronic cigarettes

Regarding electronic cigarettes, the presence of harmful substances in the emissions (vapour) of these products is often lower by around 90 to 95% compared to tobacco cigarettes, although the composition of aerosols depends on the devices, settings used and the composition of the liquid itself.

The emissions of electronic cigarettes can contain harmful substances. For instance, liquids can contain **flavouring substances**, which could be toxic and/or sensitising by inhalation. Furthermore, **aromatic substances** (aroma aldehydes) can react with propylene glycol (PG) and/or vegetable glycerine (VG) to form acetals, and little is known on the toxicological properties of these new substances. Liquids can also be contaminated by **tobacco-specific N-nitrosamines** (TSNAs, an important group of carcinogens in tobacco and tobacco smoke) found in tobacco extracts.

Furthermore, other harmful substances have been detected in the emissions. **Carbonyl compounds** such as formaldehyde, acetaldehyde or acrolein can be formed by overheating propylene glycol and vegetable glycerine. **Metals** have also been identified in electronic cigarettes' emissions, such as nickel or chromium, which are carcinogenic by inhalation.

Heated tobacco products

For heated tobacco products, the level of harmful substances found in the emissions (aerosol) of these products is lower by around 80 to 90% compared to tobacco cigarettes, although these observations on the composition of aerosols also depend on the devices, settings used, and ingredients found in the tobacco sticks.

Carcinogenic or mutagenic substances such as glycidol, glyoxal and furfural have been identified in heated tobacco products, **sometimes in higher concentrations** than in the emissions of tobacco cigarettes.

Nicotine pouches

The German Institute for Risk Assessment conducted a study on nicotine pouches²⁷, which are not regulated by the Tobacco Products Directive. The main findings of this study are that nicotine pouches can have a **high nicotine content** (up to 50mg per pouch), although the **nicotine content is not declared** on most products.

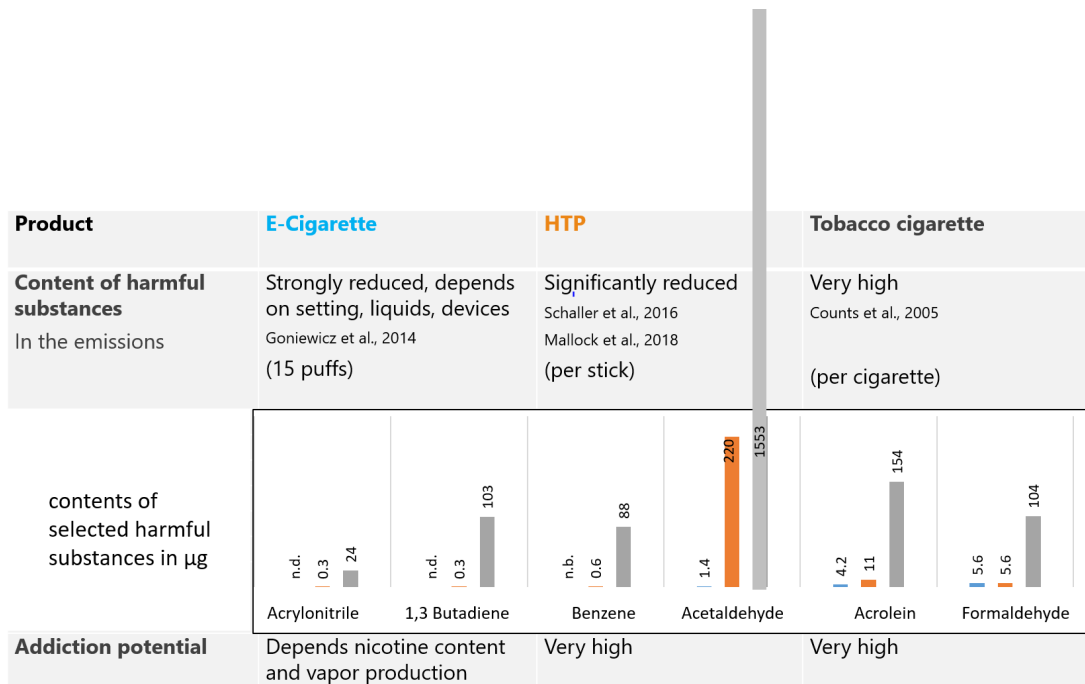
Nicotine is found in its free-base form and its absorption by the organism is enhanced by the permeation through the oral mucosa. At least half of the nicotine of the pouch can be absorbed, and **blood levels** achieved are within the range of conventional cigarettes. The use of **high-dose products** led to significantly **higher nicotine levels than cigarette consumption**.

3.1.3. Risk assessment: Comparison of the contents of selected harmful substances in the emissions of tobacco cigarettes and novel tobacco products

There are many ways to design a risk assessment, with variables such as the specific aim of the risk assessment, the data wanted and the data available. One way to conduct the risk assessment is to identify emissions and the content of selected harmful substances in emissions. For **six selected substances** (Acrylonitrile, 1,3 Butadiene, Benzene, Acetaldehyde, Acrolein, and Formaldehyde), tobacco cigarettes show much higher concentrations.

²⁷ German Federal Institute for Risk Assessment, Health risk assessment of nicotine pouches, Oct 2022. Available at: <https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf>.

Figure 3: Contents of six selected harmful substances in novel products



The analysis focused on **carbonyl compounds** known to be involved in the development of tobacco-related cancers and diseases, as well as **volatile organic compounds (VOCs)**. VOCs are not detectable in the vapour produced by electronic cigarettes as they are produced between 500 and 800 degrees Celsius, which is not reached by electronic cigarettes. For heated tobacco products, acetaldehyde is the dominant carcinogen along with 1,3 Butadiene. The carbonyl compounds can be detected in electronic cigarettes but only in significantly lower proportions compared to emissions of tobacco smoke.

Although these studies provide valuable first indications, their results **cannot be generalised** systematically to all products on the market. The observations result from three different studies using selected devices, and the level of emissions of each compound depends on the puffing regimes which differ significantly from one device to another, in particular for electronic cigarettes.

3.1.4. Risk assessment: Toxicology of flavours in liquids for electronic cigarettes

The risk assessment of the novel tobacco and nicotine products must also include an analysis of the **toxicology of additives**. There is little research on the toxicology of **flavours** added in electronic cigarettes' liquids to improve the taste. Considering their low concentrations in these liquids, they do not have to be indicated on packaging.

Flavours are generally recognised as safe (GRAS) for oral consumption, but little is known on their effects on the respiratory tract²⁸. Preliminary results using in vitro experiments with cells shows **clear differences in the impact of different liquids** for electronic cigarettes, as well as **of different flavourings**, on the metabolic activities of cells²⁹. However, further research is needed with different

²⁸ Dinu, V, *et al*, Policy, toxicology and physicochemical considerations on the inhalation of high concentrations of food flavour, npj Sci Food 4, 15 (2020). Available at: <https://doi.org/10.1038/s41538-020-00075-y>.

²⁹ Hua, M, *et al*, Identification of Cytotoxic Flavor Chemicals in Top-Selling Electronic Cigarette Refill Fluids, Sci Rep 9, 2782 (2019). Available at: <https://doi.org/10.1038/s41598-019-38978-w>.

concentrations and cell types. It is also difficult to extrapolate these results from in vitro tests on cells to their impact on tissues and humans.

3.1.5. Policy recommendations

Dr. Elke Pieper completed her presentation with conclusions and recommendations for regulation:

- The results from individual health risk assessment studies cannot be generalised to all products, considering the diversity of products.
- The development of an **appropriate quality control** with standard products is required.
- The development of a **science base for harm reduction strategies** for tobacco products is needed, including the
 - identification of valid surrogate biomarkers,
 - measurement of toxicants when switching from one product to another, and
 - understanding of how the motivation of abstinence is influenced when switching.
- The characterisation of relevant **indicators for high risks** (e.g. ingredients, device settings) is needed.
- A uniform approach to **collect and compare information about adverse health effects** resulting from new devices or ingredients is needed.

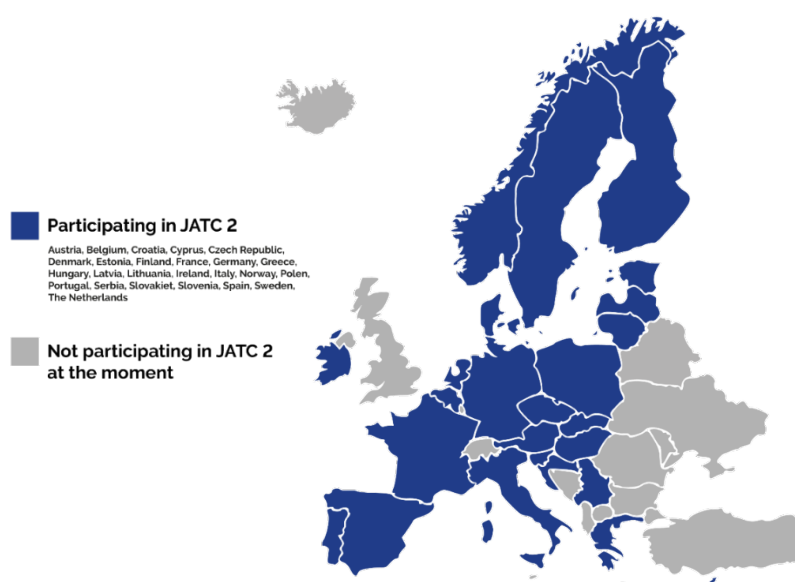
3.2. Joint Action on Tobacco Control 2 and scientific evaluation of novel products

This presentation was given by **Dr. Anne Havermans**, Scientific Advisor at the Dutch National Institute for Public Health and the Environment (RIVM), and leader of the Joint Action on Tobacco Control 2's Work Package 7 (Health impact and regulatory implications of e-cigarettes and novel tobacco products).

3.2.1. Joint Action on Tobacco Control 2

The Joint Action on Tobacco Control 2 (JATC2) is an EU funded 36-month project, launched in October 2021, following up on the Joint Action on Tobacco Control 1. The JATC2 brings together researchers from 21 countries, 36 institutes and 13 collaborating stakeholders.

Figure 4: Countries participating in the Joint Action on Tobacco Control (JATC) 2



Dr. Havermans started by presenting the aims and objectives of the Joint Action, namely facilitating the exchange of **good practices** between participating countries to improve the implementation and enforcement of tobacco control measures, ensuring greater **consistency in the implementation of EU legislation**, promoting activities pursuing the objectives of the WHO Framework Convention on Tobacco Control, addressing **emerging challenges** and further **developing the regulatory framework** and addressing areas **beyond product regulation**.

These goals are implemented through work packages, respectively focusing on EU Common Entry Gate (CEG) data and enhanced capacity for regulatory purposes (WP5), enforcement of tobacco product regulation (WP6), health **impact and regulatory implications of e-cigarettes and novel tobacco products** (WP7), smoke-free environments, tobacco advertising, promotion and sponsorship legislation (WP8), and best practices to develop an effective and comprehensive tobacco endgame and support of WHO FCTC policies in the EU (WP9).

3.2.2. Work package 7: Health impact and regulatory implications of e-cigarettes and novel tobacco products

The European Tobacco Products Directive was implemented in 2016, and the **market has since changed a lot**. The main question which the work package aims at addressing is whether current EU

legislation is still sufficient and whether it can keep up with the developing tobacco products landscape, with new products being developed by industry that evade the current regulations.

The four sub-objectives to understand the health impact and regulatory implications of electronic cigarettes and novel tobacco products are to **gain insight on product variety** in countries (in particular via an analysis of the data entered on the European CEG and a survey to national regulators whose results have been recently published³⁰), **evaluate the use, abuse potential and health risks**, harmonise the collection of **adverse events** in the EU, and support **training**, capacity building and **information sharing** in the Member States.

3.2.3. Flavour accessories for tobacco products

Flavours in tobacco products make nicotine and tobacco products **attractive, reduce harm perception**, are often **targeted at youth**, and are **linked to increased initiation and consumption** of tobacco products. To protect citizens and youth, governments have initiated flavour bans, such as the ban on characterising flavours in the Tobacco Products Directive for cigarettes and roll-your-own tobacco.

There are challenges to this ban, in particular **flavour accessories** (e.g. capsules to press into a filter of a cigarette, cards to place into cigarette packs, sprays for cigarettes or tobacco). This range of products does not contain tobacco or nicotine, cannot be used on its own and is **not covered in tobacco or nicotine legislation**.

The research conducted by the JATC2 shows that these products are marketed in 18 Member States, and that three Member States are currently specifically banning these products. In the Netherlands, a survey was conducted in 2021, revealing that about 10% of smokers were using flavour accessories, 21% ever used flavour accessories, and around 75% of all users of flavour accessories preferred a menthol flavour. These products have seen a 10% increase in sales since the menthol ban came into force in May 2020.

3.2.4. Conclusions

Dr. Anne Havermans concluded her intervention with four observations and recommendations:

- **European collaboration** is valuable for harmonised implementation and enforcement of tobacco control policies.
- **Flavour accessories** are on the rise and are likely to increase the tobacco product appeal.
- Research is needed to determine whether they lead to an increase in smoking prevalence overall or in specific subgroups.
- **Advertising and sales** should be restricted in order to support tobacco control policies.

³⁰ Joint Action on Tobacco Control 2, Report on regulation of novel tobacco products and e-cigarettes in different EU MS, September 2022. Available at: <https://jaotc.eu/wp-content/uploads/2022/11/T7.1-b-Report-Final-220929.pdf>.

3.3. Novel nicotine products – The population perspective

This presentation was given by **Dr. Charlotta Pisinger**, Medical Doctor and Professor in Tobacco Control, associated with the University of Copenhagen and the Danish Heart Foundation.

3.3.1. Benefits of novel nicotine products for the industry

Novel nicotine products have significant benefits for the tobacco industry. They generate larger profits through lower taxation, can circumvent the tobacco legislation (e.g. marketing bans, bans of flavours), can prevent the loss of smokers who quit tobacco cigarettes, and can attract persons who would not have started smoking cigarettes. Finally, novel products normalise the tobacco industry by the promotion of ‘harm reduction products’ and the industry thus receives access to policy makers.

Dr. Pisinger presented claims by the industry and emphasised the false character of these claims:

- Claim 1: These products are intended for smokers reluctant or unable to quit.

Reality shows a different picture. Most of the **marketing** has been **aimed at young people**, the future consumers. Furthermore, these products are cheap, easily available and sold as regular consumer products, frequently sold next to candy and taste like candy. Therefore, the risk assessment of authorising novel nicotine products cannot only be done through the prism of benefits for cigarette smokers switching to these products, but their role must be looked at from a **population level**.

- Claim 2: These products are harm reduction products.

The tobacco industry highlights the merits of these products as **harm reduction products**, containing 95% less harmful chemicals compared to cigarettes. However, the United States’ Food and Drugs Administration (FDA) concluded that the data from a major manufacturer of heated tobacco products failed to show consistently lower risks of harm in humans compared to conventional cigarettes. **A reduction of 95% of harmful chemical produced is not equal to a 95% reduction in risk**. Smoking even one cigarette per day generates more than 50% of the risk of coronary heart disease for men, as smoking 20 cigarettes a day (and not 5%)³¹.

- Claim 3: These products replace tobacco cigarettes (smoking alternatives).

Contrarily to this claim, studies show that most users of these products continue to smoke (i.e. **dual users or triple users**). The population-based surveys show that dual use of electronic cigarettes or heated tobacco products (with tobacco cigarettes) is high, and that they are used in addition to tobacco cigarettes³². Studies highlight that they do not reduce the number of cigarettes smoked³³.

3.3.2. Impact on public health

The calculation of the impact of novel tobacco and nicotine products on public health is the **product of the relative toxicity and of the number of persons exposed**. Therefore, a product with low toxicity may have a high impact on public health if its use is spread to a large part of the population. A lot of studies, especially on electronic cigarettes, but also on heated tobacco products, show evidence of harmful effects. However, there is only little evidence of reduced harm.

³¹ Hackshaw A, *et al*, Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports. *BMJ*. 2018 Jan 24;360:j5855. Available at: <https://pubmed.ncbi.nlm.nih.gov/29367388/>.

³² 45% of dual users for e-cigarettes in the United Kingdom: Buss V, *et al*, Trends in electronic cigarette use in England, Oct. 2022. Available at: <https://smokinginengland.info/graphs/e-cigarettes-latest-trends>. 67% of dual users for e-cigarettes in Sweden: Hedman L, *et al*, Association of electronic cigarette use with smoking habits, demographic factors, and respiratory symptoms, *JAMA Netw Open*, 2018;1(3):e180789. Available at: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2688346>.

³³ Beard E, *et al*, Is prevalence of e-cigarette and nicotine replacement therapy use among smokers associated with average cigarette consumption in England? A time-series analysis, *BMJ Open* 2018;8:e016046. Available at: <https://bmjopen.bmj.com/content/bmjopen/8/6/e016046.Full.pdf>.

Dr. Pisinger provided illustrations of the little evidence of the reduced harm through studies conducted in different parts of the world. Comparing countries with excellent tobacco control (**Australia, England, and United States of America**), only England recommended that tobacco cigarette smokers should switch to electronic cigarettes. However, the decline in the prevalence of smoking has been the same in Australia and in the United States of America. In **Norway**, the prevalence of smoking tobacco has dramatically decreased in the past years, at the same rate for men and women, although women have taken up **snus** only recently. These achievements are thus better explained by effective tobacco control than thanks to snus. In **South Korea**, heated tobacco products have become popular, followed by an increase in sale of tobacco and conventional tobacco cigarettes. In adolescents, there has been stagnation in the smoking rate in boys and an increase among girls³⁴. In **Italy**, a large survey of the general population showed that relapse to smoking was 4 times more likely among e-cigarettes users and 3 times among HTP users than among non-users of these products. Continued smoking was significantly more frequent among current novel product users³⁵. Studies have followed adolescents between half a year up to two years, showing that **users of electronic cigarettes had triple the risk of smoking initiation**³⁶.

Beside tobacco, nicotine products also create health risks. From prenatal development to adolescence and early adulthood, **exposure to nicotine poses a serious threat to the brain**. It is addictive, can be a gateway to smoking or other drugs, increases the risk of disturbed cognitive function, anxiety and depression, and stress, lowers self-control and causes inflammation of the brain³⁷.

3.3.3. Policy recommendations

The tobacco industry wants policy makers to compare novel nicotine products with cigarettes. Because cigarettes are the most harmful legal product on the market, everything will obviously seem less harmful. However, the **real balance is between cigarettes and clean air**. Taking inspiration from the Hippocratic Oath (“First, do no harm”), **Dr. Pisinger** presented her policy recommendations, applicable to the extent that there is no solid evidence of benefits of novel nicotine products at population level:

- **Strong regulation, i.e. the same as for tobacco products.**
- Ban on flavours, including menthol.
- Marketing bans, also online and on social media.
- Enforcement of age restrictions (18 years old) to access novel tobacco and nicotine products.
- Plain packaging as for tobacco cigarettes.
- Point-of-sale display ban.
- Indoor use ban.
- Ban on use at school premises, etc.
- **Higher taxes.**

³⁴ Lee, CM, The Impact of Heated Tobacco Products on Smoking Cessation, Tobacco Use, and Tobacco Sales in South Korea, Korean Journal of Family Medicine, 41(5), 273–281. Available at: <https://www.koreamed.org/SearchBasic.php?RID=2506731>.

³⁵ Gallus, S, *et al*, Impact of electronic cigarette and heated tobacco product on conventional smoking: an Italian prospective cohort study conducted during the COVID-19 pandemic, BMJ Tobacco Control. Available at: <https://tobaccocontrol.bmj.com/content/early/2022/10/07/tc-2022-057368>.

³⁶ Zhang, Y-Y, *et al*, The effect of e-cigarettes on smoking cessation and cigarette smoking initiation: An evidence-based rapid review and meta-analysis, Tob. Induc. Dis. 2021;19(January):4. Available at: <http://www.tobaccoinduceddiseases.org/The-effect-of-e-cigarettes-on-smoking-cessation-and-cigarette-n-smoking-initiation,131624,0,2.html#sec1>.

³⁷ United States of America’s National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General, 2016. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK538680/>.

3.4. Novel tobacco products – Regulatory aspects

This presentation was given by **Dr. Filippos Filippidis**, Director of Education of the School of Public Health, Imperial College London.

3.4.1. The effectiveness of regulation

Regulation can make a difference in public health and peoples' lives. Taking the example of MPOWER³⁸, a toolkit of tobacco control measures developed by the World Health Organization (WHO) and intended to assist in the country-level implementation of effective interventions to reduce the demand for tobacco, Dr. Filippidis illustrated that **regulation has an impact and can be successful in saving millions of lives**. The same conclusion can be derived from the analysis of deaths averted in the EU due to the introduction of new health warnings on packages following the 2014 Tobacco Products Directive. Looking at the effect of the ban on menthol tobacco products, it has been observed in the Netherlands, between 2020 and 2021, that smokers of menthol tobacco products were more likely to attempt quitting or quitting smoking cigarettes as a result of the ban³⁹. Another example is a recent study also highlighting a **positive link between tobacco taxation and reduced neonatal and infant mortality** globally⁴⁰.

3.4.2. Current regulatory environment in the EU

The **Tobacco Products Directive** is the main regulatory document from 2014, implemented in 2016, at a time when many of the 'novel tobacco products' were not available on the market. Novel tobacco products are defined in the Directive as products that do not fall in the categories of cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use, placed on the market after 19 May 2014.

The relevant distinction in the Directive is between **smokeless tobacco products** and **smoking tobacco products**. In the case of smoking tobacco products, a set of rules apply in terms of warnings, ban on characterising flavours. In absence of classification at EU level of certain products, there is **variability in regulatory decisions** in EU Member States (e.g. Germany classifying nicotine pouches as 'food').

In contrast, **electronic cigarettes** (electronic nicotine delivery devices) have been **regulated in the TPD** with specific requirements, i.e. maximum nicotine concentration, maximum volume for refillable tanks child-resistant caps, notification regarding constituents of liquids, information leaflets and text warnings. The experience with this regulation has been relatively good (good compliance with safety regulations, protection of youth against highly addictive electronic cigarettes compared to other parts of the world), despite incorrect representations of nicotine contents on packaging.⁴¹

Regarding the increasingly popular **heated tobacco products**, a clause of the Tobacco Products Directive, in situations of 'substantial change of circumstances' (i.e. increased sales volumes), has been activated and allows amendments to the Directive. As a result, heated tobacco products have been

³⁸ Levy, D, *et al*, Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check, *Tobacco Control* 2019; 28:629-635. Available at: <https://tobaccocontrol.bmj.com/content/28/6/629.citation-tools>.

³⁹ Kyriakos C, *et al*, Impact of the European Union's menthol cigarette ban on smoking cessation outcomes: longitudinal findings from the 2020–2021 ITC Netherlands Surveys, *Tobacco Control*, Sep 2022. Available at: <https://tobaccocontrol.bmj.com/content/early/2022/09/13/tc-2022-057428>.

⁴⁰ Radó M, *et al*, Cigarette taxation and neonatal and infant mortality: A longitudinal analysis of 159 countries, *PLOS Glob Public Health* 2(3): e0000042. Available at: <https://doi.org/10.1371/journal.pgph.0000042>.

⁴¹ Vardavas C, European Tobacco Products Directive (TPD): current impact and future steps, *Tob Control*; 31(2): 198-201, 2022 03. Available at: <https://tobaccocontrol.bmj.com/content/tobaccocontrol/31/2/198.full.pdf>.

recently grouped with cigarettes and roll-your-own tobacco, leading to a prohibition of characterising flavourings and mandatory health warnings.

3.4.3. Future challenges

Dr. Filippidis then presented the future challenges that will affect risk assessment and the preparation of regulation on tobacco.

Table 1: Future challenges for the assessment and regulation of novel tobacco products

Products
<p>Products are evolving constantly due to:</p> <ul style="list-style-type: none"> • Introduction of entirely new products • Rebranding of existing products • Rapidly changing technologies
Data and research
<p>The evolution of products creates difficulties for researchers assessing risks:</p> <ul style="list-style-type: none"> • Hard to keep pace with developments (old assessments not relevant for the new products) • Scientific uncertainty • Long-term (10 or 20 years) health consequences unknown
Industry
<p>The industry will:</p> <ul style="list-style-type: none"> • Lobby, market and promote novel products (in particular through social media which are hard to regulate) • Distort research (industry not reliable in producing truthful research) • Use the opportunity created by these products to undermine tobacco control (allow people to take nicotine when smoking is not allowed)
Member States
<p>In case of lack of regulation at EU level, Member States will make decision themselves. This could lead to different policies influenced by local markets and cultures, as well as by commercial interests. Decisions taken by Member States in the absence of EU-level regulations are difficult to harmonise once national level policies are in place.</p>

3.4.4. Revision of the Tobacco Products Directive (2023)

The EU should create a **regulatory environment** which is **flexible** (possibly via a constant implementation-evaluation loop), and which can **respond rapidly** to market developments. If policy makers wait 10 years to act, the damage caused by new products will have been done, to a large extent.

While regulation must consider the relative harm of each product (they are not all harmful to the same extent), policy makers must not fall into the trap of the industry that these products are less harmful and, hence could remain unregulated. The **ambition of a smokefree generation** in a few years should be kept in mind to save millions of lives.

4. DISCUSSIONS AND Q&A

Members of the European Parliament and participants to the workshop could raise questions to the expert-speakers during two Q&A sessions. The discussions are presented below:

- **Remarks by MEP Alessandra Moretti**

MEP Alessandra Moretti highlighted the delicate character of the issue of novel tobacco products for the health of European citizens, especially the most exposed, young people and women. The scientific evidence demonstrates that new tobacco products are not harmless at all, and that they are dangerous not only for health-related reasons but also culturally. Efforts have been made with significant results to make cigarettes unattractive, essentially for young people. With these new products, there is a risk of condemning the new generations to a very dangerous additional risk. The commitment of public institutions must be strong and decisive. MEP Alessandra Moretti is convinced that the EU will have to act on all levels to protect citizens and young people, through taxation, ban on the promotion of these products, reducing spaces for smoking, educational and informational campaigns, as well as ban on promoting these new products on social networks.

Question: MEP Alessandra Moretti asked the speakers for their opinion on the notion of harm reduction and the alleged effectiveness of novel tobacco products for smoking cessation. MEP Alessandra Moretti deems it a very dangerous road and found it unfair to abandon people addicted to nicotine to themselves, but also to tools that reinforce their addiction. Today, effective methods to quit smoking exist.

Dr. Anne Havermans provided insights on harm reduction. From a scientific point of view, some studies show that e-cigarettes can be helpful for some smokers to quit. But overall, the evidence for their effectiveness in smoking cessation is not overwhelming. It should also be noted that these products are harmful themselves and switching to them is not completely risk-free.

- **Remarks by MEP Peter Lundgren**

MEP Peter Lundgren stated that it is widely known that electronic cigarettes and modern oral products reduce risks compared to traditional cigarettes. According to MEP Peter Lundgren, these tools cannot be ignored to reduce the health risks to consumers and fight cancer, as highlighted in the BECA report of January 2022⁴². In view of the upcoming legislative dossiers on tobacco, such as Tobacco Excise Directive (TED) and Tobacco Products Directive (TPD), MEP Peter Lundgren considered it important to recognise the role of novel tobacco products in the future legislation.

Questions:

- Against the possible lower harmfulness of novel products, would regulation of these products as traditional tobacco, or the prohibition of these products, harm health policies?
- In Germany, a recent assessment by the German Institute for Risk Assessment concluded that switching from cigarettes to nicotine pouches could represent a reduction of a smoking individual's health risk. Does Elke Pieper share this assessment?
- In the report on strengthening Europe's fight against cancer, the EP calls for scientific evaluations of the health risks of novel tobacco products. Is a thorough examination of such products necessary?

⁴² European Parliament's Special Committee on Beating Cancer (BECA), REPORT on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy, February 2022. Available at: https://www.europarl.europa.eu/doceo/document/A-9-2022-0001_EN.html.

- Sweden is the country with snus, and the smallest number of smokers, as well as low rates of lung cancers. Do the speakers think that increasing taxes (700%) on a product which prevents lung cancer is a good idea?
- What novel products have been recently brought onto the market or are being developed, and how do they affect the health of their users? What impact do these products have on the overall effort in reducing tobacco use? What drives the development of these novel tobacco products and what regulatory challenges do they bring about?

Dr. Anne Havermans confirmed that a health evaluation of novel tobacco products is very necessary, and this is what the Joint Action on Tobacco Control is trying to do. It is important to understand the health effects of these products on the one hand for people who want to switch from smoking and to see if there are any benefits, and on the other hand for people who start using these products who have not been using nicotine or tobacco products before. For the latter group, addictiveness is an important factor to be considered in health evaluation. Once people become addicted to a product, it is very difficult to quit and thus users continue to be exposed to (potentially) harmful products. Moreover, once addicted, people may move on to more harmful products.

Dr. Elke Pieper specified that there is no standard that novel tobacco products can be compared to, and this remains very challenging for risk assessment.

- **Remarks by MEP Romana Jerković**

Tobacco legislation is one of the few legislative instruments at the disposal of the EU to achieve the goals set in Europe's Beating Cancer Plan⁴³. MEP Romana Jerković stressed that scientific evidence demonstrates that new alternative tobacco and nicotine products are not harmless. Furthermore, new tobacco products do not help cigarette smokers to quit (absence of overwhelming evidence even via electronic cigarettes).

- **Remarks by MEP Pietro Fiocchi**

MEP Pietro Fiocchi agrees that quitting smoking would be the best solution to reduce harm. However, from a pragmatic perspective, the effects of taxation and limitations on cigarettes and alcohol, are not the best solution and can lead to people resort to worse practices for health.

Question:

- Harm reduction is fantastic compared to inaction. In Italy and Japan, there is a stable or lower number of smokers with a great increase in the heated tobacco community. Is there already some feedback regarding the harm reduction despite the need for long-term studies?

Dr. Pisinger conceded that it would take decades to be sure, but it is known about electronic cigarettes that there is no reduction in cancer or smoking-related diseases. Dr. Pisinger emphasised that these products are not "90% less harmful". There is still little evidence on the benefits, and those identified only concern persons who quit completely, i.e., a minority of people. The novel products are not alternatives to smoking cigarettes, but they are used as complements.

Dr. Filippidis is not aware of any studies at population or study level which show lower chances of getting cancer when switching to heated tobacco products.

- **Remarks by MEP Kateřina Konečná**

MEP Kateřina Konečná stressed the need for regulations, which must be based on scientific knowledge. Many experts have the opinion that completely eradicating addictive behaviours is an unrealistic

⁴³ European Commission, Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM(2021)44 final, 3 February 2021. Available at: https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf.

objective. In the field of nicotine products, the most harmful is the burning of tobacco, responsible for most of the diseases associated with smoking. If the BECA strategy states that no stone must remain unturned, the role of new tobacco products and their potential to reduce harm compared to traditional smoking should be seriously considered. The goal of a smokefree EU after 2040 will not be achieved without novel tobacco products.

Questions:

- Vulnerable and socially excluded people should be given specific attention. Many people from these groups do not have sufficient information on options to reduce or quit smoking completely. Could new tobacco products be an option for these groups, to improve their health? If so, how can we make sure that these alternatives are available to them?

Dr. Pisinger raised doubts concerning the harm reduction potential of using heated tobacco product, as there is no clear evidence. There is no doubt that harm can be reduced a little, but really quitting smoking reduces the harm to zero, and there are many good methods and dedicated support in the Member States to quit. However, in Europe, after the introduction of electronic cigarettes, people resort less to smoking cessation services.

Dr. Filippidis highlighted that tobacco control policies do work, in particular taxation, and help mostly young people and people in vulnerable groups. If those products were used in smoking cessation only and tested in controlled clinical settings, and that they were found to improve cessation rates, researchers would have only limited arguments against novel tobacco products. However, these products are produced to make profit, so they are advertised to young people and non-users. The latter group is larger than those who may experience harm reduction. The balancing act that policy makers will undertake must consider all population groups.

Closing remarks

MEP Sara Cerdas closed the workshop by thanking the four speakers for their contributions and Members for the lively Q&A. This issue remains on the political agenda and will remain high in the coming months and years. It is of the utmost importance that policy makers have access to the best available expertise.

SHORT BIOGRAPHIES OF THE SPEAKERS



Dr. Elke Pieper

Senior Research Scientist, German Federal Institute for Risk Assessment (BfR)

Dr. Elke Pieper studied chemistry in Berlin, Germany from 1999 to 2005 and gained her PhD in chemical biology at Humboldt University of Berlin. From 2010 to 2013, she worked as a postdoctoral fellow at the Department of Biology and Chemistry at the Massachusetts Institute of Technology in Cambridge, US, in the field of biomolecular research. Since 2016, she is a senior scientific officer at German Federal Institute for Risk Assessment (BfR), working in the field of tobacco research and risk assessment. In this time, she has worked on seven publications on risks of e-cigarettes and heated tobacco products as first or co-author so far. She conducts research on the toxicological impact of flavours in e-liquids as well as on the emission of heated tobacco products. She is also involved in the preparation of expert reports and the approval of novel tobacco products. Dr Pieper joined the team of the Joint Action on Tobacco Control II in October 2021 and is working among others in the work package 7 to gain insights into health impacts and regulatory implications of e-cigarettes and novel tobacco products.

The [German Federal Institute for Risk Assessment](#) is the scientific agency of the Federal Republic of Germany responsible for preparing expert reports and opinions on food and feed safety as well as on the safety of substances and products. The assessment of the impact and risks of tobacco products and their consumption is part of the remit of Institute.



Dr. Anne Havermans

Scientific Advisor, Dutch National Institute for Public Health and the Environment (RIVM)

Dr. Anne Havermans studied neuropsychology in Maastricht, the Netherlands, from 2006-2011 and obtained her PhD at Maastricht University in 2016. Her doctoral thesis explored neural and cognitive determinants of smoking addiction and cessation. Since 2017, she works as a scientific advisor in the field of tobacco product regulation at the RIVM. She conducts research with a particular focus on addictiveness and attractiveness of tobacco and related products. In this time, she has published 16 scientific articles and co-authored several expert reports and WHO background papers. In the Joint Action on Tobacco Control (JATC, 2017-2020), Dr. Havermans was work package leader of WP 9, in which independent scientific experts evaluated tobacco industry studies on the use of priority additives. Since October 2021, Dr. Havermans is leading WP 7 in JATC 2. The aim of this WP is to gain insights into health impacts and regulatory implications of e-cigarettes and novel tobacco products.

The Dutch [National Institute for Public Health and the Environment](#) (RIVM) is a governmental research and institute providing policy support to the Dutch government. RIVM performs tasks to safeguard and promote public health and environmental quality in the Netherlands. It is also a leading organisation in the field of tobacco regulatory science, both nationally and internationally. For WHO, RIVM hosts a Collaborating Centre for Tobacco Product Regulation and Control. RIVM's tobacco product research group conducts independent research on toxicity, addictiveness and attractiveness of tobacco and related products to gain insight in their health effects. Its research contributes to drafting and enforcement of tobacco product regulation.



Dr. Charlotta Holm Pisinger

Medical Doctor and Professor, associated with the University of Copenhagen and the Danish Heart Foundation

Dr. Charlotta Pisinger is a medical doctor, has a Ph.D. and a Master of Public Health, and is Denmark's first professor in tobacco prevention. She is professor at the University of Copenhagen and adjunct professor at the University of Southern Denmark. Dr Pisinger is in the top 1% of scholars writing about Smoking Prevention over the past 10 years (labelled as Expert). She is working as a national tobacco expert, has written the national smoking cessation guidelines, published many tobacco-related reports, and presented scientific evidence in the European Parliament. She has written a background paper on e-cigarettes and health for WHO and has been an investigator in several large intervention trials. Dr Pisinger has until recently been head of the tobacco committee in the European Respiratory Society and on the board of the Danish Society of Public Health. She is the former president of the Danish Society of Tobacco Research and former vice-president of the Danish Society of Epidemiology. She is also a very active communicator to e.g. public health journals and newspapers and other media, and she has, in cooperation with other important stakeholders, contributed to implementation of one of the most ambitious public health initiatives in Denmark, the new tobacco action plan.

Charlotta Pisinger is affiliated with the [University of Copenhagen](#) and works as senior researcher at the Centre for Clinical Research and Prevention. She collaborates with all tobacco researchers in Denmark. The topic investigated are e.g., the health effects of dual use of e-cigarettes and conventional cigarettes, predictors of nicotine pouch use, e-cigarette use across Nordic countries, and the effects of legislation on youths' use of novel nicotine products.



Dr. Filippidis
*Director of Education of the School of Public Health,
Imperial College London*

Dr. Filippidis is a Senior Lecturer in Public Health and the Director of Education of the School of Public Health, Imperial College London. Dr Filippidis studied Medicine, Health Promotion and Epidemiology at the University of Athens and has earned an MPH from Harvard School of Public Health, with a focus on quantitative methods (epidemiology and biostatistics). His doctoral thesis explored the effects of the economic crisis on risk factors, such as obesity, smoking, diet and physical activity. His current research is focused on the epidemiology of tobacco use, novel tobacco/nicotine products and the evaluation of tobacco control policies in Europe, as well as globally. He is a member of the Tobacco Control Committee of the European Respiratory Society (ERS). He has published more than 140 articles in peer-reviewed journals.

[Imperial College London](#) is consistently ranked among the top-10 universities in the world. The School of Public Health has recently been ranked as the top School of Public Health in the United Kingdom in terms of research output and impact. Dr Filippidis works within the Public Health Policy Evaluation Unit. The PHPE Unit has produced multiple high-profile publications on policy evaluation related to tobacco control, food and physical activity, which have been cited by governmental and international organisations and policy makers.

WORKSHOP PRESENTATIONS

The slides of the presentations are available on the website of the European Parliament:

1. [Health Risk Assessment of Novel Tobacco Products, E-Cigarettes, and related products](#), by Dr. Elke Pieper (German Federal Institute for Risk Assessment).
2. [Joint Action on Tobacco Control 2 and scientific evaluation of novel tobacco products](#), by Dr. Anne Havermans (Dutch National Institute for Public Health and the Environment, RIVM).
3. [Novel nicotine products – The population perspective](#), by Dr. Charlotta Pisinger (University of Copenhagen).
4. [Novel tobacco products – Regulatory aspects](#), by Dr. Filippos Filippidis (Imperial College London).

ACCESS TO THE FULL CONTENT OF THE PRESENTATIONS IS ALSO AVAILABLE HERE:

ENVI HEALTH WORKING GROUP – WORKSHOP ON NOVEL TOBACCO PRODUCTS:

<https://www.europarl.europa.eu/committees/en/novel-tobacco-products-and-their-effects/product-details/20221124WKS04721>

These proceedings summarise the presentations and discussions before the European Parliament's Health Working Group as part of the workshop on 'Novel tobacco products and their effects on health', held on 30 November 2022. The four presentations touched, inter alia, upon the current state of research on health effects, their role in harm reduction and regulatory recommendations.

These workshop proceedings were provided by the Policy Department for Economic, Scientific and Quality of Life Policies for the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI).
