I - Agenda of the workshop session

The workshop will have a duration of one hour and a half, including four ten-minute interventions by high-level speakers from diverse horizons in the field of research on novel tobacco and nicotine products’ effects on health, representing academia and Member States Agencies. It is divided into two parts each followed by a Q&A session.

The Members of the European Parliament will be able to ask specific questions on each topic, but more time will be dedicated for the second Q&A session, considering potential remaining questions linked to Part one.

Agenda of the workshop “Novel tobacco and nicotine products and their effects on health”

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:30</td>
<td>Introductory remarks&lt;br&gt;&lt;i&gt;Co-Chairs of the Health Working Group, MEPs&lt;/i&gt;&lt;br&gt;Sara CERDAS (S&amp;D) and Dolors MONTSERRAT (EPP)</td>
</tr>
<tr>
<td>12:35</td>
<td>Part one&lt;br&gt;Health Risk Assessment of Novel Tobacco Products, E-Cigarettes, and related products&lt;br&gt;&lt;i&gt;Dr. Elke Pieper (Federal Institute for Risk Assessment, Germany)&lt;/i&gt;</td>
</tr>
<tr>
<td>12:45</td>
<td>Joint Action on Tobacco Control 2 and scientific evaluation of novel tobacco products&lt;br&gt;&lt;i&gt;Dr. Anne Havermans (National Institute for Public Health and the Environment (RIVM), the Netherlands)&lt;/i&gt;</td>
</tr>
<tr>
<td>12:55</td>
<td>Q&amp;A session with Members</td>
</tr>
<tr>
<td>13:10</td>
<td>Part two&lt;br&gt;Novel nicotine products – The population perspective&lt;br&gt;&lt;i&gt;Dr. Charlotta Pisinger (University of Copenhagen)&lt;/i&gt;</td>
</tr>
<tr>
<td>13:20</td>
<td>Novel tobacco products – Regulatory aspects&lt;br&gt;&lt;i&gt;Dr. Filippos Filippidis (Imperial College London)&lt;/i&gt;</td>
</tr>
<tr>
<td>13:30</td>
<td>Q&amp;A session with Members</td>
</tr>
<tr>
<td>13:55</td>
<td>Closing remarks Sara CERDAS, MEP, and Dolors MONTSERRAT, MEP</td>
</tr>
<tr>
<td>14:00</td>
<td></td>
</tr>
</tbody>
</table>
II – Presentation of the expert-speakers and affiliations

This section presents the expert-speakers and their short biographies, along the thematic parts, including the respective affiliations relevant for the workshop.

### Part 1

- **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, National Institute for Public Health and the Environment (RIVM), the Netherlands

  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. Here 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 workpackage 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.

  RIVM is a governmental research and knowledge 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.

### Part 2
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 EU 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 Center 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. Filippos 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.
III - Context of the workshop

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 2020), 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 pouches.

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

- **Heated tobacco products**
  - Devices heating a small amount of tobacco to produce an emission containing nicotine and other chemicals, which is inhaled by users.
  - Contrarily to electronic cigarettes, these products do contain tobacco.

- **Vapour products (electronic cigarettes)**
  - Devices heating a liquid to create aerosols that are inhaled (no combustion of tobacco)
  - E-liquids may or may not contain nicotine
  - Also known as 'electronic nicotine delivery systems' (ENDS) and sometimes 'electronic non-nicotine delivery systems' (ENNDS)

- **Nicotine pouches**
  - Tobacco-free pouches for oral use containing nicotine and other chemicals and flavourings, which is placed under the consumer's upper lip.
  - Their tobacco-containing counterparts (*snus*) are considered ‘tobacco for oral use’ and their marketing is prohibited in the EU pursuant to Article 17 of the Tobacco Products Directive.

**Heated tobacco products**, introduced on the EU market in 2014, are the largest

---


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.
group of novel tobacco products in market value and the one with the fastest growing usage rate. According to a recent Commission report, they represented around 3.51% of the total sales volume of all tobacco products in the EU for the year 2020 and their sales volume has increased in EU-27 by 2009% between 2018 and 2020. The largest markets in the EU include Italy, Germany, Poland, the Czech Republic and Greece. The use of vapour products increases between 2017-2025 from 2.3% to expected 3.7% of the adult population in the EU.

Nicotine pouches are present on the market since 2016, and although 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 2025. 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 men. Sales of nicotine pouches are currently concentrated in the Nordic countries and Eastern Europe, largest markets being Sweden, Hungary and Denmark.

**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 toxicants. 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 eliminated. 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 substance. The German Federal Institute for Risk Assessment (BfR) also showed that levels of tobacco-specific N-nitrosamines (TSNAs) and other pollutants such as cadmium, 3

---

5 ibid, table 1.
7 ibid.
8 Danish Health Authority, Use of smokeless nicotine products among youth, February 2022.
9 ibid.
PAHs, or carbon monoxide were reduced in HTPs compared to conventional cigarette smoke. However, other studies identified potentially toxic substances, including carcinogenic substances, in HTP emissions, in concentrations higher than in conventional cigarette smoke. 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 that HTPs are less harmful than conventional cigarettes. Furthermore, there is evidence of dual use – i.e., consumers using both HTPs and conventional cigarettes.

**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 nicotine. 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 life. Some recent studies suggest that ENDS use can increase the risk of heart disease and lung disorders. Nicotine exposure in pregnant women can have adverse effects on the brain development of the fetus. 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 plasticity.

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 TSNAs 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 system.

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

---

18 Ibid.
19 Ibid.
20 Ibid.
harmful forms of tobacco and/or nicotine consumption than smoking combusted cigarettes, as well as the benefits for secondhand 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 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 2021 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 products\textsuperscript{24}, opening the way to banning flavoured heated tobacco products\textsuperscript{25}.

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 (Work Package 7) 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.