

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).

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

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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.

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Administrator responsible: Christian KURRER

Editorial assistant: Catherine NAAS

Contact: Poldep-Economy-Science@ep.europa.eu

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