Towards the Protection of Consumers in the EU Single Market: The Case of Novel Products

Timely and efficient regulation is essential for any new emerging product category to ensure consumer safety as well as fair market conditions. This holds particular significance for products affecting public health, such as novel nicotine products. Notably, nicotine pouches have recently gained popularity, demonstrating success in encouraging some smokers to transition away from traditional products. While nicotine pouches may serve as a valuable harm reduction tool, they also represent a regulatory challenge for policymakers across the EU. Swift action is necessary to mitigate potential adverse effects, especially concerning youth access to these products.

This policy paper, led by the Chair of Interdisciplinary Research at the Anglo-American University in Prague, addresses the increasing demand to analyse the current regulatory landscape and to contribute to evidence-based policy-making, both at the EU and Member State levels. Specifically, the paper examines the framework around tobacco-free nicotine pouches – a relatively understudied product category that is currently gaining momentum among many former smokers and the young generation.

Research focus

The paper employs a research methodology centred around a comparative analysis of regulations across several EU Member States. Additionally, it incorporates findings from surveys conducted among an internal panel of experts and the informed public. The surveys, which include perspectives from medical, addictology, public health, and economic professionals, are designed to extract valuable insights. Through this comprehensive approach, the objective is to compile a list of concrete recommendations and guidelines that can be used by policymakers and relevant stakeholders involved in shaping the forthcoming regulations.

EU Member States' legislation

Significant attention is directed towards Sweden and the Czech Republic, two EU Member States with a track record of implementing evidence-based regulations that effectively reflect principles of harm minimization. These two countries may serve as a laboratory for evaluating what approaches proved effective. In addition, the research extends its scope to Slovakia, Germany, Austria and Poland. This broader comparative analysis allows for a comprehensive evaluation of regulatory frameworks across a diverse set of EU Member States and, thus, also for a deeper understanding of the regulatory landscape surrounding novel nicotine products within the European Union.

	Czechia	Slovakia	Germany	Austria	Poland	Sweden
Regulatory category for nicotine pouches created	Yes	Yes	Yes*	No	No	Yes
Ban on under-18 usage in place	Yes	Yes	No	No	No	Yes
Packaging regulation	Yes	Yes	No	No	No	Yes
Display ban / Point of sale advertising regulation	No	No	No	No	No	No
Marketing regulation	Yes	Yes	No	No	No	Yes
Nicotine content regulation	Yes	Yes	No	Yes	No	Yes
Pouches per package regulation	Yes	No	No	No	No	Yes
Flavors regulation	No	No	No	No	No	No
Excise tax imposed	Yes	No	No	No	No	Yes

Comparison of regulation of nicotine pouches across the examined EU Member States

**Nicotine pouches not regulated as a specific category but within the food category.*

*** Minimal limit set by the National Tobacco Monopoly through an implementing regulation.*

Way forward

The interaction between EU Member States' best practices and EU-level policy is central to formulating and implementing efficient, evidence-based policy. As the regulation of new substances and products is increasingly driven by Member States, transferring best practices to the EU level is essential. If this exchange is not facilitated, there is a risk of creating a patchwork of national approaches that undermines overall effectiveness, including of the single market. Furthermore, for novel products that may pose risks, particularly to the younger population, evidence-based policy-making and adherence to harm minimization principles are paramount for public health and safety.

In this context, a solid link between science and regulation is essential, bridging the expertise of academics and experts with regulators. This synergy will ensure that policy-making leads to improving the quality and effectiveness of regulation. Furthermore, it is crucial to consider the role of the EU Presidency.

Although this role requires a Member State to act as an honest broker, it also allows critical issues to be brought into EU discussions. A notable example is the Czech Presidency, which played a pioneering role in bringing the issue of for example mental health into a high-level EU discussion.

Conclusion

This study aims to contribute to the discussions mentioned above by providing a comparative analysis of different Member States' approaches to nicotine pouches and to facilitate the flow of information between research and science on the one hand and policymakers on the other. As the revision of the key nicotine-related legislation, the EU Tobacco Products Directive is expected to focus on incorporating strategies to realize the goal of delivering a tobacco-free generation in the context of the Europe's Beating Cancer Plan and extending the scope of the legislation to alternative nicotine and tobacco products, the insights of Member States that already have such legislation are all the more valuable.

Key elements for regulation of nicotine pouches

The paper seeks to establish not only overarching guiding principles but also specific components that should shape the regulatory framework for nicotine pouches. Drawing insights from the analysis of regulatory approaches in six diverse EU countries and the expertise of consulted professionals, the authors contend that the primary foundation for crafting regulations for nicotine pouches should be assessing the relative harm associated with these products, versus continuing to smoke. Simultaneously, a pivotal aspect integral to the broader discourse on nicotine pouch regulation is the imperative to prevent youth access.

Minimization of the largest risks and youth access: *Regardless of the relative risk compared to other products, a new product is always a risk of attracting previous non-smokers, which could include the underage. This situation needs to be addressed with urgency to ensure those aged under 18 do not use these products.*

Taxation proportional to harm: *Taxes imposed on nicotine pouches should be proportionate to their relative harm level versus cigarettes, if they are to be an effective cessation tool.*

Regulation proportional to harm: *Given that nicotine pouches are assumed to be as risky or less risky as other alternative products, it is reasonable to contend that they should therefore be regulated commensurately i.e. the should be regulated as strictly or less strictly as those products. Ideally, any regulation (both MS and EU level) should be based on a four-tier regulatory schedule, with cigarettes being the most restricted, followed by heated tobacco products, then e-cigarettes, and nicotine pouches in the final least restrictive group.*