

## Summary of Regulatory Impact Analysis (RIA)

**Department/Office:**

Department of Health

**Title of Legislation:**

Public Health (Nicotine Inhaling Products) Bill 2024

**Stage:**

General Scheme of a Bill

**Date:****Related Publications:**

The national tobacco control policy *Tobacco Free Ireland* available at <http://health.gov.ie/blog/publications/tobacco-free-ireland/>

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**What are the policy objectives being pursued?**

Reduce youth use of nicotine inhaling products to protect young people from addiction and potential harm, while driving down smoking prevalence and its associated disease, disability and death across the population.

**What policy options have been considered?**

1. Do nothing
2. Information and education campaigns
3. Self or co-regulation
4. Legislate to further regulate nicotine inhaling products.

**Preferred Option**

The “do nothing” option would likely mean that the policy objectives are not met, and youth uptake of nicotine inhaling products stays at a high level, or even increases.

Mass media campaigns would be beneficial as part of a suite of measures. However, as is the case for tobacco, media campaigns are not sufficient on their own to address this public health issue.

Self or co-regulation is not an option as Ireland has signed and ratified (in November 2005) the World Health Organisation Framework Convention on Tobacco Control ('WHO FCTC').

The Articles of this international treaty are legally binding and at Article 5.3 the FCTC states that: *In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.*

In this context, the preferred option is to legislate to regulate nicotine inhaling products, via restrictions on packaging, appearance, flavours, advertising and display in retail, and single-use vapes.

### **POLICY OPTIONS**

	<b>COSTS</b>	<b>BENEFITS</b>	<b>IMPACTS</b>
Policy Option 1			Youth uptake of nicotine inhaling products does not decline, with the associated health costs from nicotine addiction and potential for subsequent smoking, and currently unknown long-term health harms.
Policy Option 2	Costs to Exchequer  Dependent on the type and duration of campaign(s). Would include procurement, production and administrative costs.	Benefits to Exchequer  Unlikely to be any.	Would have a positive impact as part of a suite of measures, but on their own are not enough to address the issue.
Policy Option 3	N/A	N/A	N/A

Policy Option 4	<p>There would be a cost to the Exchequer for the increase in enforcement required to ensure compliance with further regulations, of around €3 million per year.</p> <p>There may be costs to retailers to implement point of sale restrictions.</p> <p>There would be costs to manufacturers and distributors to comply with restrictions to product attributes and appearance.</p> <p>There would be loss of revenue for the industry if fewer young people use nicotine inhaling products.</p>	<p>No immediate benefits to the Exchequer. However, given the association between e-cigarettes and subsequent smoking in adolescents, and the uncertainty around long-term health harms from e-cigarettes, there may be further medium-long-term benefits in terms of reduced pressure on healthcare system.</p>	<p>Based on current evidence, there would likely be a reduction in youth uptake of nicotine inhaling products.</p> <p>Further monitoring will be required to understand the impact of the legislation on e-cigarette use in adults and smoking in all cohorts.</p> <p>However, the design of proposals and external measures such as the expansion of State stop smoking support services and Tobacco 21 legislation are expected to mitigate possible unintended consequences.</p>
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## 2. Description of policy context and objectives

### Policy context

Tobacco smoking is both addictive and lethal and remains the biggest risk factor driving disability and death combined in Ireland.<sup>1</sup> The life expectancy of a smoker is on average 10 years shorter than that of a person who has never smoked<sup>2</sup> and two out of three smokers will die as a result of their smoking<sup>3</sup>.

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<sup>1</sup> The Institute for Health Metrics and Evaluation, University of Washington  
<http://www.healthdata.org/ireland>.

<sup>2</sup> Doll R, Peto R, Boreham J, Sutherland I. *Mortality in relation to smoking: 50 years' observations on male British doctors*. BMJ 2004; 328: 1519.

<sup>3</sup> Banks E, Joshy G, Weber MF, et al. *Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence*. BMC Med 2015; 13:38. doi:10.1186/s12916-015-0281-z.

In addition to the death toll of an estimated 4,500 deaths per year in Ireland<sup>4</sup>, smoking and exposure to second-hand smoke cause an enormous range of preventable illness and disability.<sup>5</sup> They are the cause of 13% of all cancers here<sup>6</sup> and account for 2% of day case admissions, 5% of all inpatient admissions and 8% of all bed days in our hospitals<sup>7</sup>. A 2016 estimate of the cost of smoking in Ireland in a single year (including the estimated loss of welfare to individuals from contracting health conditions or dying prematurely) was €10.6 billion<sup>8</sup>.

While Nicotine Replacement Therapy has long been available as a licensed medicine to those wishing to quit smoking, in the last decade or so there has been an increase in the marketing of non-licensed commercial nicotine products, most notably nicotine inhaling products, also known as e-cigarettes or “vapes”.

### ***Prevalence and composition of e-cigarette use***

Prevalence of e-cigarettes in the adult population remains lower than smoking, currently at 8%, compared with 18% for smoking. However, it has doubled from 4% in 2021, with the smoking rate remaining static. There has been a particular increase in 15–24-year-olds, from 4% in 2021 to 18% in 2023 currently vaping. While the majority of adult e-cigarette users are

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<sup>4</sup> *The State of Tobacco Control in Ireland*: HSE Tobacco Free Ireland Programme, 2022.

<https://www.hse.ie/eng/about/who/tobaccocontrol/research/state-of-tobacco-control-report-2022.pdf>

<sup>5</sup> Illnesses and conditions attributable to tobacco smoking and exposure to second-hand smoke include:

- Cancers of the paranasal sinuses and nasal cavity, oral cavity including lips and tongue, larynx, pharynx, oesophagus, lung, liver, pancreas, kidney, stomach, bowel, bladder, ureter, ovary, cervix and myeloid leukaemia which is a type of bone marrow cancer.
- Respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD) which includes emphysema and chronic bronchitis. COPD involves permanent airflow obstruction that is irreversible. Smoking is the dominant cause.
- Cardiovascular diseases including aneurysms, coronary heart disease, peripheral arterial disease (which can lead to gangrene and the necessity for amputation) and stroke.
- Eye diseases such as age-related macular degeneration (AMD), cataracts and diabetic retinopathy which can eventually lead to blindness.
- Reproductive effects from maternal smoking include an increased risk of ectopic pregnancy, premature delivery, low birth weight and perinatal mortality.
- Diabetes
- Rheumatoid arthritis.
- Dementia.

<sup>6</sup> *Modifiable risk factors and cancer in Ireland*. National Cancer Registry Ireland, 2020.

<sup>7</sup> Sheridan A., Quintyne K.I. & Kavanagh P. *Counting the toll of smoking attributable hospitalisations*. Irish Medical Journal – January 2020 Vol. 113 No. 1.

<sup>8</sup> ICF International. *An assessment of the economic cost of smoking in Ireland*. March 2016.  
<https://assets.gov.ie/34808/8b5d52eaea4447419f38b447733d02b9.pdf>.

current or former smokers, there has been an increase in the proportion of e-cigarette users who have never smoked since 2021 from 4% to 13%<sup>9</sup>.

This echoes the trend in youth surveys, with the HBSC study of 12–17-year-olds finding that although the rate of ever-use of e-cigarettes dropped from 22% to 19% between 2018 and 2022, the rate of past-30-day use increased from 9% to 13%. This suggests that the “conversion rate” of experimentation to more regular use may be increasing, which could be reflective of product innovation in newer products<sup>10</sup>. The European School Survey Project on Alcohol and Other Drugs (ESPAD) 2019 report found that 15% of 15-16-year-olds had used e-cigarettes in the last 30 days, and 24% of e-cigarette users had never used tobacco when they started vaping<sup>11</sup>.

### ***Health Harms***

As these are relatively new products, there is a lack of certainty around the possible health harms from e-cigarettes. This is further complicated by the rapid evolution of products on the market.

There is however consensus on the following, which are conclusions from a Health Research Board evidence summary<sup>12</sup> and subsequent international systematic reviews<sup>13 14</sup>:

- E-cigarette use poses harm compared to non-use
- E-cigarettes may reduce harms in those who smoke and switch fully and promptly
- Dual use of e-cigarettes and combustible tobacco is not likely to be less harmful than smoking
- More research is needed on specific health outcomes and the long-term impact of use, including dual use.

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<sup>9</sup> Healthy Ireland Surveys 2021-2023.

<sup>10</sup> Tattan-Birch H et al. Trends in vaping and smoking following the rise of disposable e-cigarettes: a repeat cross-sectional study in England between 2016 and 2023. *The Lancet Regional Health - Europe*, Volume 42, 2024, 100924.

<sup>11</sup> Sunday, S. Keogan, S. Hanafin, J. and Clancy, L. (2020). ESPAD 2019 Ireland: Results from the European Schools Project on Alcohol and Other Drugs in Ireland. Dublin: TFRI

<sup>12</sup> McCarthy et al. 2020. Harms and benefits of e-cigarettes and heat-not-burn tobacco products: A literature map. Health Research Board: Dublin.

<sup>13</sup> Banks et al. 2023. <https://onlinelibrary.wiley.com/doi/10.5694/mja2.51890>

<sup>14</sup> McNeill A, Simonavičius E, Brose LS, et al. Nicotine vaping in England: 2022 evidence update. A report commissioned by the Office for Health Improvement and Disparities. 29 Sept 2022.

The primary established health effects are nicotine dependence, and isolated adverse events such as burns or poisoning<sup>15 16</sup>. The most recent systematic review on the topic found currently insufficient evidence on specific health outcomes such as cancer, cardiovascular or respiratory disease, though it noted some evidence for adverse effects on cardiovascular health measures (including blood pressure and heart rate) and lung function<sup>17</sup>. In line with other reviews, it found that young people and non-smokers are most vulnerable to the risk of adverse effects, without the benefit of their use for smoking cessation.

One systematic review concluded that nicotine may have a greater and/or unique effect on adolescents compared with adults, with possible implications for nicotine dependence and cognitive outcomes such as learning or memory<sup>18</sup>, though further research is needed.

A recent review of systematic reviews on the health effects of e-cigarettes to children and adolescents found strong evidence via longitudinal data of an association between e-cigarette use and subsequent smoking<sup>19</sup>. The review also found cross-sectional evidence to support the association between vaping and having asthma, including exclusive e-cigarette use where smoking behaviour was controlled for.

### ***Relationship between e-cigarettes and smoking***

There is a complex relationship between e-cigarette use and smoking, including differences at individual and population level.

The Health Research Board found that there was an association between e-cigarette use and subsequent smoking in young people<sup>20</sup>, which was supported in the recent review of

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<sup>15</sup> Banks et al. 2023. <https://onlinelibrary.wiley.com/doi/10.5694/mja2.51890>

<sup>16</sup> In an EU context, the Tobacco Products Directive regulates product characteristics to reduce the risk of these types of adverse events, for example maximum nicotine concentrations and child-proof features.

<sup>17</sup> Banks et al. 2023. <https://onlinelibrary.wiley.com/doi/10.5694/mja2.51890>

<sup>18</sup> Colyer-Patel et al. (2023). *Age-dependent effects of tobacco smoke and nicotine on cognition and the brain: A systematic review of the human and animal literature comparing adolescents and adults*. *Neuroscience and Biobehavioral Reviews* vol. 146.

<sup>19</sup> Reynolds CME, Mack JB, O'Connor L, McAvoy H (2024). *A review of systematic reviews on the health effects of e-cigarette use in children and adolescents*. Institute of Public Health: Dublin and Belfast. Accessed at: <https://www.publichealth.ie/sites/default/files/resources/A%20review%20of%20systematic%20reviews%20on%20the%20health%20effects%20of%20e-cigarette%20use%20in%20children%20and%20adolescents.pdf>

<sup>20</sup> [https://www.hrb.ie/wp-content/uploads/2024/06/Electronic\\_cigarette\\_use\\_and\\_tobacco\\_cigarette\\_smoking\\_initiation\\_in\\_adolescents.pdf](https://www.hrb.ie/wp-content/uploads/2024/06/Electronic_cigarette_use_and_tobacco_cigarette_smoking_initiation_in_adolescents.pdf)

systematic reviews conducted by the Institute of Public Health<sup>21</sup>. There is therefore a concern that large increases in e-cigarette use could in time lead to an increase in smoking rates.

In contrast, e-cigarettes are used by around 17% of Irish adults that are trying to quit smoking<sup>22</sup>.

There are differing views, and policy approaches on the effectiveness and safety of e-cigarettes for smoking cessation.

In the UK e-cigarettes are promoted as a smoking cessation tool, citing a living Cochrane Review which currently considers there to be high-certainty evidence that e-cigarettes with nicotine increase quit rates compared to Nicotine Replacement Therapies (NRT)<sup>23</sup>.

In Ireland, the National Stop Smoking Clinical Guidelines, which were published in 2022 and endorsed by the Minister for Health, do not include e-cigarettes in the recommended interventions for smoking cessation, citing a review by the Health Research Board which found them to be no more effective than NRT, which have an established safety profile<sup>24</sup>. The Guidelines also considered the broader implications of a positive recommendation in the absence of a regulatory framework to prevent youth uptake<sup>25</sup>. In addition, in July 2024 the World Health Organisation published its first global guidelines for smoking cessation and did not recommend e-cigarettes for cessation on similar grounds<sup>26</sup>.

While the question of e-cigarettes' effectiveness for smoking cessation is an important and ongoing consideration in determining a broader policy response, the evidence and debate largely centres around their place within clinical interventions and support, and not the population level impact of these products. It is worth noting that both Aotearoa/New Zealand and the UK (both of which currently recommend e-cigarettes for cessation) have

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<sup>21</sup> Reynolds CME, Mack JB, O'Connor L, McAvoy H (2024). *A review of systematic reviews on the health effects of e-cigarette use in children and adolescents*. Institute of Public Health: Dublin and Belfast.

<sup>22</sup> Healthy Ireland Survey 2023 Report.

<sup>23</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub8/full>

<sup>24</sup> Quigley JM, Walsh C, Lee C, Long J, Kennelly H, McCarthy A, Kavanagh P. Efficacy and safety of electronic cigarettes as a smoking cessation intervention: A systematic review and network meta-analysis. *Tob Prev Cessat*. 2021 Nov 22;7:69.

<sup>25</sup> <https://www.gov.ie/en/publication/4828b-stop-smoking/>

<sup>26</sup> WHO clinical treatment guideline for tobacco cessation in adults. Geneva: World Health Organization; 2024. Accessed at: <https://www.who.int/publications/i/item/9789240096431>

implemented or are planning to introduce much more stringent regulation of these products to reduce their use by children and non-smokers<sup>27 28</sup>.

The biggest cohort of e-cigarette users are former smokers (49% in 2023)<sup>29</sup>. However, at population level, smoking rates have remained static despite an increase in vaping rates, suggesting that vaping is not substituting for smoking. This has been particularly pronounced in the 15–24-year-old cohort, with smoking rates having risen slightly at the same time as rapid increases in vaping (a 7-percentage point increase in 2023<sup>30</sup>).

The second largest cohort of e-cigarette users are dual users (37%). Apart from the health harms from dual use noted above, there is also currently a lack of research on the behaviours or intentions of this cohort. Dual use could represent a trajectory towards quitting smoking entirely for some, but it may also sustain higher levels of nicotine dependence in others, potentially reducing quit attempts and prolonging smoking.

Due to this complex and sometimes contradictory relationship, as well as the lack of long-term longitudinal research, there is uncertainty about the effect of further nicotine inhaling product regulations on smoking behaviour, including initiation, cessation, relapse or dual use of both products. This uncertainty has been factored into the RIA and the subsequent proposals, alongside additional mitigating measures which are currently in place or are planned.

### ***Existing Policy and Legislation***

Ireland's national tobacco control policy, *Tobacco Free Ireland*, sets the target of a smoking prevalence of less than 5% in the population, and recommends a suite of measures to achieve this and reduce the premature death and disability caused by smoking.

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<sup>27</sup> <https://www.gov.uk/government/consultations/creating-a-smokefree-generation-and-tackling-youth-vaping/outcome/creating-a-smokefree-generation-and-tackling-youth-vaping-consultation-government-response>

<sup>28</sup> <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/vaping-herbal-smoking-and-smokeless-tobacco-products-regulation>

<sup>29</sup> Healthy Ireland Survey 2023

<sup>30</sup> Healthy Ireland Survey 2023

Within this framework, the policy recognises the need for less harmful forms of nicotine for smokers who are preparing to or unable to quit. However, it also acknowledges that more evidence is needed in relation to nicotine inhaling products in terms of their health harms and their efficacy as a smoking cessation aid. The policy recommendation is to establish a regulatory framework for nicotine inhaling products in the context of EU law.

E-cigarettes are primarily regulated at EU level by the Tobacco Products Directive (Directive 2014/40/EU). A proposal for a revised Directive is anticipated for 2024 which would likely address some of the same issues as domestic legislation, but the timeline is not certain and even with a proposal in 2024 it would likely be a number of years before any legislation took effect.

The Public Health (Tobacco Products and Nicotine Inhaling Products) Act 2023 introduces additional domestic measures, including:

- A prohibition on the sale of nicotine inhaling products to those aged under 18.
- The creation of an annual licencing system for the retail sale of nicotine inhaling products.
- A prohibition on the sale of nicotine inhaling products from self-service vending machines, temporary or moveable premises, and events aimed at children.
- A prohibition on the advertising of nicotine inhaling products near schools, in cinemas, or on public transport (in addition to existing advertising restrictions under the TPD).
- The introduction of new penalties for retailers who commit offences related to nicotine inhaling products.

### ***Further regulation of nicotine inhaling products***

A number of countries place greater restrictions on e-cigarettes than are currently in place in Ireland. This includes complete prohibitions on their sale in countries such as Mexico. In Australia, a prescription has been required to purchase or import nicotine e-cigarettes since 2012. More recently, countries such as Belgium and France have announced their intention to prohibit some e-cigarettes, in the form of single-use vapes.

Other countries continue to regulate e-cigarettes as consumer products but have implemented further restrictions. These generally echo restrictions previously implemented for tobacco products, with the aim of addressing the appeal, accessibility, affordability, and awareness of e-cigarettes.

There are several such interventions that are likely to be effective to reduce the use of nicotine inhaling products among young people.

### Flavour restrictions

Several countries, including eight EU Member States, have introduced or are planning to introduce flavour restrictions for nicotine inhaling products.

There is evidence that flavours are important for the initiation and continuation of vaping among both children and adults<sup>31 32 33</sup>. Flavours may also decrease harm perceptions amongst young people<sup>34</sup>, and there is also some evidence from qualitative studies that flavour descriptions, labelling and the ability to switch between flavours are important aspects for young people beyond just taste<sup>35</sup>. There are almost 16,000 distinct flavours<sup>36</sup>, and over 50 different names used to describe tobacco flavour<sup>37</sup>.

Research is currently inconclusive as to whether e-cigarette flavours have an impact (positive or negative) on smoking cessation. Smokers using e-cigarettes as part of a quit attempt are

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<sup>31</sup> Zare S, Nemati M, Zheng Y. A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type. *PLoS One*. 2018 Mar 15;13(3).

<sup>32</sup> Meernik C, Baker HM, Kowitt SD, Ranney LM, Goldstein AO. Impact of non-menthol flavours in e-cigarettes on perceptions and use: an updated systematic review. *BMJ Open*. 2019 Oct 16;9(10).

<sup>33</sup> Gades MS, Alcheva A, Riegelman AL, Hatsukami DK. The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and Electronic Cigarette Users: A Systematic Review. *Nicotine Tob Res*. 2022 Aug 6;24(9):1332-1343.

<sup>34</sup> Meernik C, Baker HM, Kowitt SD, Ranney LM, Goldstein AO. Impact of non-menthol flavours in e-cigarettes on perceptions and use: an updated systematic review. *BMJ Open*. 2019 Oct 16;9(10).

<sup>35</sup> Notley C et al. (2022). *Youth use of e-liquid flavours-a systematic review exploring patterns of use of e-liquid flavours and associations with continued vaping, tobacco smoking uptake or cessation*. *Addiction*. May;117(5):1258-1272.

<sup>36</sup> Hsu G et al. (2018). *Evolution of Electronic Cigarette Brands From 2013-2014 to 2016-2017: Analysis of Brand Websites*. *J Med Internet Res*. Mar 12;20(3):e80.

<sup>37</sup> Zhang Y. et al. (2024). *E-Cigarette "Tobacco Flavor," How Do I Name Thee? Let Me Count the Ways...* *Nicotine Tob Res*. Jul 22;26(8):1108-1112.

likely to switch between flavours, though there currently appears to be no association between e-cigarette flavours and smoking cessation<sup>38</sup>.

There is evidence that flavour restrictions are likely to be effective to reduce youth e-cigarette use<sup>39</sup>, with both product restrictions and restrictions by sales location likely to be effective<sup>40</sup>. This is particularly the case as part of a suite of interventions, and existing evidence shows that enforcement is key to effective implementation<sup>41</sup>.

There is currently a lack of evidence on the real-world effects of e-cigarette flavour restrictions on adult e-cigarette use or smoking<sup>42 43</sup>.

### Packaging

Nicotine inhaling products come in many styles and colours and some include cartoons and eye-catching branding. Currently there are some restrictions at EU level on e-cigarette devices and packaging, for example, images of food or cosmetics are not allowed, and the device or packaging cannot suggest health benefits. There is evidence that the appearance of nicotine inhaling products and their packaging may increase their appeal to children and young people. For example, one study found that cartoon imagery decreased the perceived risks of e-cigarette use in adolescents who reported as being insusceptible never-users<sup>44</sup>.

Standardised or plain packaging for tobacco products was introduced in Ireland in 2017 to reduce the appeal and noticeability of these products, and to increase effectiveness of the text

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<sup>38</sup> Lindson N et al. (2023). *An exploration of flavours in studies of e-cigarettes for smoking cessation: secondary analyses of a systematic review with meta-analyses*. *Addiction*. Apr;118(4):634-645.

<sup>39</sup> Reiter A et al. (2024). *Regulatory Strategies for Preventing and Reducing Nicotine Vaping Among Youth: A Systematic Review*. *Am J Prev Med*. Jan;66(1):169-181.

<sup>40</sup> Yan D et al. (2023). *A systematic review for the impacts of global approaches to regulating electronic nicotine products*. *J Glob Health*. Aug 25;13:04076.

<sup>41</sup> Ibid.

<sup>42</sup> Cadham CJ et al. (2022). *The actual and anticipated effects of restrictions on flavoured electronic nicotine delivery systems: a scoping review*. *BMC Public Health*. Nov 19;22(1):2128.

<sup>43</sup> Yan D et al. (2023). *A systematic review for the impacts of global approaches to regulating electronic nicotine products*. *J Glob Health*. Aug 25;13:04076.

<sup>44</sup> Kirkpatrick MG, Dormanesh A, Unger JB, Allem JP. Cartoon marketing exposure decreases perceived risks of e-cigarette use in adolescents. *Exp Clin Psychopharmacol*. 2023 Dec;31(6):1032-1038. doi: 10.1037/pha0000642. Epub 2023 Feb 9. PMID: 36757963.

and picture health warnings. There is evidence that plain packaging reduces the appeal of tobacco to adolescents<sup>45</sup>, and prevents smoking initiation among non-smokers<sup>46</sup>.

Very few countries have regulated nicotine inhaling product packaging or devices so there is a lack of evidence of its effectiveness. To date only two EU countries have some form of packaging restrictions on e-cigarettes: Finland and Denmark.

However, experimental studies have examined the potential effects of e-cigarette packaging restrictions, generally finding that standardised packaging was less appealing to youth<sup>47 48</sup>. One study examined both young people and adults and found that plain packaging reduced appeal for young people without reducing the appeal for adults, suggesting that intervention in this area was unlikely to have unintended consequences for adults who might switch to these products from smoking<sup>49</sup>.

### Display

Since 2009 the advertising and display of tobacco products has been prohibited in Ireland. Tobacco must be kept out of sight in a closed container. Currently there are no restrictions on how nicotine inhaling products are displayed in shops. Following the prohibition of e-cigarette advertising online, in print, on TV and radio<sup>50</sup>, and more recently near schools, in cinemas and on public transport<sup>51</sup>, display and advertising in retail outlets is an important remaining point of exposure for young people.

There is evidence that e-cigarette advertising lowers harm perceptions and increases intention to use e-cigarettes among young people<sup>52</sup>, and that greater exposure to e-cigarette advertising

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<sup>45</sup> Drovandi, A., Teague, PA., Glass, B. et al. A systematic review of the perceptions of adolescents on graphic health warnings and plain packaging of cigarettes. *Syst Rev* 8, 25 (2019).

<sup>46</sup> Jetly K, Ismail A, Hassan N, Mohammed Nawi A. Perceived Influence of Plain Cigarette Packaging on Smoking Behavior: A Systematic Review. *J Public Health Manag Pract*. 2022 Sep-Oct 01;28(5):E757-E763.

<sup>47</sup> M.N. Gomes, J.L. Reid, D. Hammond. The effect of branded versus standardized e-cigarette packaging and device designs: an experimental study of youth interest in vaping products. *Public Health*. 2024 230:223-230.

<sup>48</sup> Simonavičius E, East K, Taylor E, Nottage M, Reid JL, Arnott D, Bunce L, McNeill A, Hammond D. Impact of E-liquid Packaging on Vaping Product Perceptions Among Youth in England, Canada, and the United States: A Randomized Online Experiment. *Nicotine Tob Res*. 2024 Feb 22;26(3):370-379.

<sup>49</sup> Taylor E, Arnott D, Cheeseman H, Hammond D, Reid JL, McNeill A, Driezen P, East K. Association of Fully Branded and Standardized e-Cigarette Packaging With Interest in Trying Products Among Youths and Adults in Great Britain. *JAMA Netw Open*. 2023 Mar 1;6(3):e231799.

<sup>50</sup> Provided for under the EU Tobacco Products Directive

<sup>51</sup> Provided for under the Public Health (Tobacco Products and Nicotine Inhaling Products) Act 2023

<sup>52</sup> Sharma A, McCausland K, Jancey J. Adolescents' Health Perceptions of E-Cigarettes: A Systematic Review. *Am J Prev Med*. 2021 May;60(5):716-725.

at point of sale is associated with greater odds of e-cigarette current and ever-use<sup>53</sup>. There is also evidence from regulation of tobacco point of sale display that such interventions can reduce experimental use among young people<sup>54</sup>.

### Single-use vapes

While flavours, packaging and display have been features of the e-cigarette market since its inception, the prevalence data above shows that the rise in popularity of single-use vapes in 2021 has coincided with a rise in youth vaping. This has been supported by international evidence suggesting that declining trends in nicotine use have reversed since their introduction to the market<sup>55</sup>, and that use of disposable vapes among adolescents and young adults is associated with higher odds of continued e-cigarette use<sup>56</sup>.

Some of the factors which contribute to the appeal of single-use vapes are common to all e-cigarettes, including flavour, packaging and price. While flavour and packaging are addressed above, and the Department of Finance intends to introduce a taxation regime for all vaping liquids, single-use vapes will remain comparatively cheaper and easier to use than reusable versions, which may increase the risk of impulse purchase and use by children and young people. This is reflected in the recent Eurobarometer survey which found that disposable vapes are disproportionately used by 15-24-year-old vapers compared with vapers in other age groups<sup>57</sup>. This echoes data from Northern Ireland which found that 86% of under 16s who vape regularly used disposable vapes<sup>58</sup>.

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<sup>53</sup> Moola S et al. (2021). *The effects of e-cigarette advertising, promotion, and sponsorship on people's attitudes, beliefs and perceptions, intentions, and behaviours: a mixed methods systematic review*. Sydney: The George Institute for Global Health. Accessed at:

<https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Evidence%20review%20on%20the%20effects%20of%20e-cigarettes%20advertising%2C%20promotion%20and%20sponsorship.pdf>

<sup>54</sup> Shang C, Huang J, Li Q, Chaloupka FJ. The Association between Point-of-Sale Advertising Bans and Youth Experimental Smoking: Findings from the Global Youth Tobacco Survey (GYTS). *AIMS Public Health*. 2015;2(4):832-844.

<sup>55</sup> Tattan-Birch H et al. Trends in vaping and smoking following the rise of disposable e-cigarettes: a repeat cross-sectional study in England between 2016 and 2023. *The Lancet Regional Health - Europe*, Volume 42, 2024, 100924.

<sup>56</sup> Han DH, Harlow AF, Feldstein Ewing SW, Audrain-McGovern JE, Unger JB, Sussman SY, McConnell R, Barrington-Trimis JL, Leventhal AM. Disposable E-Cigarette Use and Subsequent Use Patterns in Adolescents and Young Adults. *Pediatrics*. 2024 Apr 1;153(4):e2023063430.

<sup>57</sup> European Commission. Special Eurobarometer 539: Attitudes of Europeans towards tobacco and related products.

<sup>58</sup> Foster C, Scarlett M, Stewart B. *Young Persons' Behaviour and Attitudes Survey 2022 - Substance Use - (Smoking, Alcohol & Drugs)*. Belfast; 2023.

There are further health considerations in that the National Environmental Health Service of the HSE has found disposable vapes more likely to be non-compliant with existing legislation than other types of e-cigarettes and have issued a number of alerts and recalls in relation to higher than stated and/or permissible nicotine concentrations or larger tank sizes.

Finally, single-use vapes are highly detrimental to the environment, with a number of knock-on health impacts. When improperly disposed of, broken vapes can leach heavy metals, battery acid, and nicotine into the environment<sup>59</sup>. There are also health and safety risks to workers from lithium battery fires in waste management systems when they are disposed of in regular waste streams<sup>60</sup>.

In the EU, Belgium and France intend to prohibit single-use vapes under health law. In March, the EU Commission approved Belgium's provisions, noting that the "proposed prohibition on the placing on the market of disposable electronic cigarettes with nicotine is justified, necessary and proportionate to the aim of protecting public health"<sup>61</sup>. Regulations to prohibit single-use vapes are being introduced in Northern Ireland as part of a coordinated UK-wide entry into force of April 2025.

## **Objectives**

The objectives are two-fold. The short-term objective is to reduce the use of nicotine inhaling products among young people in order to decrease the risk of harmful health outcomes such as increased asthma risk and potential but as yet unknown long-term health impacts.

The second objective, stemming from the *Tobacco Free Ireland* policy, is to achieve a smoking prevalence of less than 5% in the population. Given the association between e-cigarette use and subsequent smoking in adolescents, achieving the first objective may contribute positively to the second in the long-term by preventing smoking initiation.

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<sup>59</sup> Hendlin YH. Alert: Public Health Implications of Electronic Cigarette Waste. *Am J Public Health*. 2018 Nov;108(11):1489-1490.

<sup>60</sup> <https://www.gov.scot/publications/prohibition-sale-supply-single-use-vapes-strategic-environmental-assessment-environmental-report/pages/5/>

<sup>61</sup> [https://health.ec.europa.eu/document/download/2c0e24a7-8ea5-4464-9bf6-eccc2f45c42b\\_en?filename=tobacco\\_c\\_2024\\_1673\\_en.pdf](https://health.ec.europa.eu/document/download/2c0e24a7-8ea5-4464-9bf6-eccc2f45c42b_en?filename=tobacco_c_2024_1673_en.pdf)

However, given the complex relationship between smoking and e-cigarette use in the adult population, with around half of e-cigarette users being former smokers and 38% using both, there is uncertainty as to the short-term impact of further nicotine inhaling product regulation on smoking. Stricter regulation of e-cigarettes may cause a range of consequences for former smokers including causing users to quit e-cigarette use also or lead them to relapse to smoking.

Therefore, the framework for this RIA is to achieve the first objective (reducing nicotine inhaling product use in young people) in a way that supports the second objective (to eliminate smoking across all cohorts) and to mitigate for and monitor possible unintended consequences.

### **3. Identification and Description of Options**

*Option 1: Do nothing.*

Currently, nicotine inhaling products are primarily regulated under the EU Tobacco Products Directive (TPD). There is also domestic regulation via the Public Health (Tobacco Products and Nicotine Inhaling Products) Act 2023.

A revision of the TPD is expected in 2024. In its 2021 Application Report on the Tobacco Products Directive<sup>62</sup>, the EU Commission noted that the harmonised approach had been more effective in achieving its objectives than unilateral efforts might have been. In the context of e-cigarettes, the Report identified several areas to consider strengthening or clarifying as part of a revised Directive: tank size or labelling requirements, use of flavours, use of nicotine-free liquids and advertising provisions.

Although several countries have implemented additional restrictions on e-cigarettes, there have been notable challenges in enforcement of this at individual Member State level, for example flavour restrictions in Finland<sup>63</sup>. There are also additional costs associated with enforcing restrictions unilaterally without EU. For example, there are considerable EU advisory mechanisms and standardised procedures in place to support Member States to

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<sup>62</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1621500846386&uri=COM%3A2021%3A249%3AFIN>

<sup>63</sup> <https://tobaccocontrol.bmj.com/content/tobaccocontrol/29/e1/e175.full.pdf>

enforce the prohibition on characterising flavours in tobacco products which would not be available for restrictions outside of the Directive.

Therefore, one available option is not to develop any further domestic legislation and wait for EU-level regulations. However, several EU legislative files and initiatives in relation to tobacco have been delayed in recent years, and even if a proposal is presented in 2024, it would likely still be several years before measures took effect.

#### *Option 2: Information and education campaigns*

The HSE and the Department of Education have already developed SPHE modules on substance use, including e-cigarettes. Mass Media Campaigns are acknowledged to be an effective component of broader tobacco control strategies, and there is some evidence that mass media campaigns are effective in changing attitudes and behaviours of young people in relation to e-cigarettes<sup>64 65 66</sup>.

#### *Option 3: Self or co-regulation*

This option is effectively excluded by Ireland's ratification of the WHO FCTC. Article 5.3 of the FCTC requires that *In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.*

Any form of self or co-regulation would mean that those with a commercial interest in the manufacture, distribution or sale of tobacco would have an involvement in the development of the policy and therefore Ireland would not be compliant with its legally binding obligations under the FCTC.

#### *Option 4: Legislate to further regulate nicotine inhaling products*

Further legislation in relation to taxation of vaping liquids is being progressed by the Minister for Finance and is outside of the scope of this RIA.

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<sup>64</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9561946/>

<sup>65</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8992685/>

<sup>66</sup> <https://pubmed.ncbi.nlm.nih.gov/32521287/>

There is currently insufficient evidence that introducing indoor vaping restrictions would achieve the specific policy objectives<sup>67</sup> of this RIA, though it may contribute to other health-related objectives as further evidence emerges.

Therefore, the main areas not already addressed by existing legislation which could contribute to the policy objectives are regulating flavours, packaging, point of sale display and advertising, and single-use vapes.

The proposed legislation would provide for the following:

- A prohibition of point-of-sale display and advertising, with display exemptions for retailers who only or primarily sell these products.
- Restrictions on colours and imagery on nicotine inhaling product devices and packaging, as well as restrictions on the devices resembling or functioning as other products such as toys or games.
- Prohibiting all flavour descriptors and language other than basic flavour names.
- Limiting flavours in nicotine inhaling products to tobacco with Ministerial powers to further amend this list.
- Prohibiting the import, manufacture and sale of single-use vapes, whether containing nicotine or not.

#### **4. Analysis of Costs, Benefits and Impacts of Options**

*Option 1: Do nothing.*

##### **Costs and Benefits**

None

##### **Impacts**

The current regulatory framework has been insufficient to prevent a rise in youth uptake of nicotine inhaling products, and smoking rates have stalled since 2019. Therefore, maintaining the status quo would not contribute to the policy objectives to reduce youth use of nicotine

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<sup>67</sup> Yan et al. 2023. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10451104/>

inhaling products and continue to drive down smoking rates in the adult population. EU legislation is unlikely to take effect in an appropriate timeframe to address the continuing rise of nicotine inhaling product use among young people. The benefits of further EU-wide regulation will still accrue when the Tobacco Products Directive is revised.

*No obvious impacts on national competitiveness, the socially excluded and vulnerable groups, the environment, whether there is a significant policy change in an economic market, including consumer and competition impact, the rights of citizen, compliance burdens, including administrative burdens and North-South and East-West Relations.*

#### *Option 2: Information and education campaigns*

##### **Costs**

There would be costs to the Exchequer to run a social media focused awareness campaign aimed at young people. The HSE has estimated that such a campaign would cost €400,000 for development of assets, purchasing of media space, social media partnerships etc.

##### **Benefits**

There are unlikely to be short-term tangible benefits to the Exchequer. However, given the association between e-cigarette use and subsequent smoking in adolescents, there may be long-term benefits if such a campaign lowered rates of youth e-cigarette use, and if that in turn reduced smoking initiation.

##### **Impact**

A social-media focused awareness campaign aimed at young people would likely be an effective component to change attitudes and behaviours toward nicotine inhaling products. However, as with strategies to reduce tobacco prevalence, a mass media campaign of this type would be insufficient on its own to achieve the policy objectives.

#### *Option 3: Self or co-regulation*

This is not applicable. Self or co-regulation would not be meaningful unless the regulated, such as the tobacco industry or other vested interests, had influence on the proposed approach

or on its implementation. Ireland is a party to the legally binding Framework Convention on Tobacco Control so is required to act to protect public health tobacco control policies from the tobacco industry or other vested interests. On that basis Ireland could not engage in self or co-regulation.

*Option 4: Legislate to further regulate nicotine inhaling products*

**Costs**

*Exchequer*

There would be a cost to the Exchequer to invest in resources to appropriately enforce further legislation. This would include additional staff within the HSE National Environmental Health Service (NEHS), both at a regional level and a central level to monitor market developments. As these are relatively new and rapidly evolving products, there would be costs involved with training and developing expertise within the NEHS. This is particularly the case as there would not be the support of EU level expertise or frameworks for these measures. Where possible, enforcement costs have been minimised within the proposals, for example the decision to regulate flavour names rather than characterising flavours, which requires sensory testing, or ingredients, which would require large scale chemical testing.

The NEHS has estimated that 40 Whole Time Equivalents (WTE) would be required to effectively enforce the proposed legislative provisions, at a cost of €3,115,737 per year.

*Manufacturers*

There would be costs to manufacturers in order to comply with further regulations on flavour names and packaging. However, there are already country-specific requirements for e-cigarettes and refill containers placed on the market, in that these products must carry health warnings in Irish.

As the stated objective is to reduce youth use of e-cigarettes, this would result in reduced profits for the industry.

*Retailers*

There would be costs to retailers to comply with restrictions on point-of-sale advertising and display, primarily regarding the change of display for these products. In an impact assessment

on similar legislation, the UK Government estimated a cost of £820 (€970) for a retailer to install new storage units<sup>68</sup>. However, it should be noted that these requirements will only apply to general retailers, who often also sell tobacco products and therefore may have shelf space in existing closed containers.

Regarding the product restrictions, there may be disposal costs to retailers if non-compliant products remain in stock. As with other legislation of this nature, a transition period will apply to minimise this.

As the stated objective is to reduce youth use of nicotine inhaling products, this could result in reduced profits for retailers. However, it is possible that money not spent on nicotine inhaling products would be spent elsewhere in retail.

### **Benefits**

There are unlikely to be short-term tangible benefits to the Exchequer. However, given the association between e-cigarette use and subsequent smoking in adolescents, there may be long-term benefits if the legislation has the intended effect of lowering rates of youth nicotine inhaling product use, and if that in turn reduced smoking initiation. Furthermore, given the uncertainty around long-term health impacts of nicotine inhaling products themselves, there may be long-term benefits to reducing nicotine inhaling product use by those who do not smoke.

### **Impact**

The expected impact of the proposals as a suite of measures is a decline in youth use of nicotine inhaling products.

#### *General risks and mitigation*

1. Given that the UK is considering similar proposals to regulate vapes in a context where they are a part of the smoking cessation strategy, there is a risk that different North-South approaches to regulation will weaken the effect of the proposed measures in Ireland.

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<sup>68</sup> <https://assets.publishing.service.gov.uk/media/65f9bd0a9316f5001164c351/tobacco-vapes-bill-impact-assessment.pdf>

However, the direction of travel appears to be broadly similar in the desire to implement restrictions which reduce youth uptake but allow access to nicotine inhaling products for adults who smoke.

2. There is also a risk that further regulation of nicotine inhaling products could lead to:
  - Increased cross-border distance sales from other EU Member States or third countries
  - Increased illicit trade of non-compliant products.

Although the EU Tobacco Products Directive permits a ban on cross-border distance sales, it has been difficult to achieve in practice in those countries who have implemented it, and legal advice was received that it would be challenging to introduce under Irish law. The Minister for Health has called for a complete ban on cross-border distance sales in Europe as part of a revised Tobacco Products Directive. In addition, the impending domestic taxation regime for vaping liquids will increase the oversight of the entry of these products into the State.

Regarding illicit trade, these proposals are measured and are therefore unlikely to cause a substantial increase in comparison with, for example, a complete ban on all flavours. The National Environmental Health Service has estimated an additional annual cost of just over €3 million (40 Whole Time Equivalents at various grades) to effectively enforce the proposed legislation.

3. Finally, given the lack of evidence of real-world effects of further restrictions, there is a risk that the proposals could lead - at least in the short-term - to increases in smoking if there is a reduction in complete switching, or relapse in current vapers.

These proposals are designed to reduce the appeal of nicotine inhaling products to children and young people while leaving them accessible to adults who smoke, and to allow the Minister powers to make changes quickly in response to new evidence that arises. This incremental and responsive approach is a recognised risk management approach considering the uncertainty regarding the risks and benefits of e-cigarettes at population level<sup>69 70</sup>.

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<sup>69</sup> Banks E, Martin M, Harris M. Framework for the public health assessment of electronic cigarettes. *Tob Control*. 2022 Sep;31(5):608-614.

<sup>70</sup> [https://health.ec.europa.eu/system/files/2016-11/policybrief\\_tobacco\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2016-11/policybrief_tobacco_en_0.pdf)

In addition, concerns that the further regulation of nicotine inhaling products will cause an increase in smoking can be mitigated by increasing efforts to reduce smoking initiation and to support effective smoking cessation. These include the Public Health (Tobacco) (Amendment) Bill 2024 which will increase the age of sale for tobacco to 21, in order to reduce smoking initiation and address the stalled decline in smoking rates in the adult population.

There has also been a considerable effort across the health service to implement the Stop Smoking Clinical Guidelines, which recommend reducing barriers to accessing effective stop smoking support. This has included more than doubling the number of stop smoking clinics, and rolling out free Nicotine Replacement Therapies to all who avail of the HSE's Quit Service in 2023. The combined effect of these measures has been enormous with record numbers accessing the service, using NRT to quit alongside behavioural support, and a considerable increase in quit rates.

#### *The socially excluded and vulnerable groups*

The social gradient of smoking and resulting impact on health inequalities is well established. Between 2015 and 2021, there has been a widening gap in smoking prevalence between the richest and poorest groups in society, with the population-level declines in smoking coming almost entirely from the richest groups, and little change in the poorest groups<sup>71</sup>. There appears to be similar inequity in vaping, with vaping consistently more prevalent in the poorest groups, however this has stayed relatively stable between 2015 and 2021. Therefore, there is currently little to suggest that vaping is contributing to a reduction in smoking inequalities in Ireland, which echoes the theoretical considerations of their potential equity impact<sup>72</sup>.

The proposals in this legislation reflect a step-wise and responsive approach to regulation to allow for monitoring and evaluation of the impacts, including any differing socio-economic

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<sup>71</sup> HSE Tobacco Free Ireland Programme, 2022. *The State of Tobacco Control in Ireland, Second Report: 2022*. <https://www.hse.ie/eng/about/who/tobaccocontrol/research/state-of-tobacco-control-report-2022.pdf>

<sup>72</sup> Lucherini et al. 2019. *Potential for non-combustible nicotine products to reduce socioeconomic inequalities in smoking: a systematic review and synthesis of best available evidence*. BMC Public Health 19, 1469. <https://doi.org/10.1186/s12889-019-7836-4>

impacts. However, the current evidence does not support the assertion that further regulation of nicotine inhaling products will have a negative impact on social inequalities.

Furthermore, there are a range of existing pro-equity actions aimed at supporting effective smoking cessation in certain communities and population groups:

- Our National Clinical Guidelines include specific recommendations for stop smoking advice and interventions regarding pregnant women and persons using secondary mental health settings.
- The Sláintecare Healthy Communities Programme involves tailored stop smoking services across 19 communities where health inequalities are most evident.
- Free NRT was rolled out to all users of the HSE Quit Service in 2023.
- The HSE is currently developing a pilot programme on financial incentives for smoking cessation.

### *The environment*

There would be environmental benefits from all of the proposed interventions. Vapes are resource intensive to produce, contain critical raw materials and present a risk to the environment when disposed of. Some studies have estimated their environmental impact to be greater than cigarettes<sup>73</sup>.

The prohibition on single-use vapes would remove the most environmentally detrimental version of the product from the market as these products are incapable of being reused and are difficult to recycle effectively<sup>74</sup>.

Furthermore, as the intention of all the proposals is to reduce the use of nicotine inhaling products among young people, there would be knock-on environmental benefits. Even refillable and/or rechargeable versions have a finite lifespan, or components which are disposed of after use, for example in pod-based systems. A reduction in use of these products would reduce the energy and raw materials needed to manufacture them, and potential waste and environmental pollution at the end of the life cycle.

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<sup>73</sup> Ngambo G, Hanna EG, Gannon J, Marcus H, Lomazzi M, Azari R. A scoping review on e-cigarette environmental impacts. *Tob Prev Cessat*. 2023 Oct 2;9:30.

<sup>74</sup> Pourchez J, Mercier C, Forest V. From smoking to vaping: a new environmental threat? *Lancet Respir Med*. 2022 Jul;10(7):e63-e64. doi: 10.1016/S2213-2600(22)00187-4. Epub 2022 May 23. Erratum in: *Lancet Respir Med*. 2023 Jul;11(7):e68. PMID: 35617988.

*Whether there is a significant policy change in an economic market, including consumer and competition impact*

There would be a number of changes in the market from the proposals. Consumers would have reduced access to certain types of nicotine inhaling products, namely single-use vapes and a restricted range of flavours. The product-related provisions are being applied equally across the market, therefore it is not expected that there will competition impacts from these proposals. The proposals do not prohibit the manufacture of products for sale outside of the State.

*The rights of citizens*

Article 24 of the UN Convention on the Rights of the Child (UNCRC) requires States to recognize the right of the child to the enjoyment of the highest attainable standard of health.

In its General Comment No. 15 on the right of the child to the enjoyment of the highest attainable standard of health, the UN Committee on the Rights of the Child urges States to place children's best interests at the centre of all decisions affecting their health and development. This includes the development and implementation of policies and interventions that affect the underlying determinants of their health.

As nicotine inhaling products represent an increase in harm for children compared to non-use, measures to prevent uptake would uphold their right to the highest attainable standard of health.

The right to the health also applies to adults. Some advocates of e-cigarettes as a harm reduction tool argue that measures to reduce the appeal of or access to nicotine inhaling products interferes with that right by creating barriers for smokers to access a less harmful form of nicotine.

In balancing these rights, there are a number of unknowns, including but not limited to:

- The long-term health impacts for young people who would have otherwise not used nicotine inhaling products.

- The extent to which nicotine inhaling products help or hinder smoking cessation at population level in the long-term.

The proposed regulatory framework seeks to achieve a high level of protection for young people, while maintaining access to nicotine inhaling products for adults who smoke. The General Scheme includes provisions for a review to evaluate its implementation and the extent to which this has been achieved, as well as considering any further evidence regarding the impact of these products which could further inform this balance.

#### *Compliance burdens, including administrative burdens*

As detailed under costs, there will be initial compliance burdens for manufacturers to develop products which meet the requirements, and for retailers to comply with legislation affecting them.

The proposed restrictions on packaging and the lack of display in general retail may mean that it is harder to identify products when fulfilling an order. However, an evaluation of tobacco plain packaging found that any delays in fulfilling purchases due to plain packaging were short-lived<sup>75</sup>.

#### *North-South and East-West Relations*

The Westminster Tobacco and Vapes Bill, for which a legislative consent motion was passed in Northern Ireland, sought to give Ministers power to regulate flavours, packaging and point of sale<sup>76</sup>. However, the Bill in that form lapsed with the recent elections, so the details or timeline for similar measures being introduced in Northern Ireland are currently unknown. The Department of Health continues to engage with counterparts in Northern Ireland on knowledge sharing and updates with a view to regulatory alignment where possible.

No obvious impacts on *national competitiveness*.

## **5 Consultation**

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<sup>75</sup> <https://tobaccocontrol.bmj.com/content/31/2/263>

<sup>76</sup> <https://www.gov.uk/government/collections/tobacco-and-vapes-bill-2024#:~:text=The%20Tobacco%20and%20Vapes%20Bill%20will%3A,being%20able%20to%20do%20so.>

### *Nicotine inhaling products*

A public consultation was held between November 2023 and January 2024, seeking the views of the public and relevant stakeholders on a range of potential interventions to further regulate tobacco products and nicotine inhaling products. 15,821 responses were received, the majority of which were from members of the public who vape. Less than 0.5% of respondents were under 18, which is the target group for the interventions.

### Advertising and display

There was majority support for regulation of advertising and display in shops, with roughly equal numbers in favour of either a full Point of Sale ban, or products remaining on display but only behind the counter. Many that were not in favour of a full ban pointed out that there should be different rules for specialist and general retailers.

This has been proposed in the General Scheme, as is currently the case in tobacco and alcohol legislation.

### Flavours

Most respondents were not in favour of any regulation of flavours, with many vapers and the industry citing the importance of flavours in attracting adults to switch from smoking or the risks of relapse to smoking if flavours were prohibited. However, a majority of all respondents were in favour of specialist retailers being allowed to sell a greater range of flavours, should restrictions be introduced.

Public health organisations were strongly in favour of restrictions on most flavours, highlighting evidence that flavours attract children to vaping, and that the wide range increases experimentation. They raised concerns about different rules for specialist retailers, given the lack of definition of these retailers or evidence that they are more compliant with existing law to warrant different rules. They also highlighted the issues experienced by New Zealand in implementing a similar approach, with a significant increase in the density of these types of retailers.

The proposed legislation seeks to tightly restrict the descriptions of products and vastly reduce the range of flavours across all retail in a way that reduces their appeal to young

people, while retaining a tobacco flavour initially for adults who smoke. The General Scheme allows for the Minister to amend these restrictions via secondary legislation as evidence develops regarding the risks and benefits of flavour regulation and the impact of the measures.

### Packaging and appearance

Most respondents were in favour of some regulation of packaging and appearance. The most popular option (either as a standalone option or grouped with others) was to prohibit the use of animations, cartoons and child friendly images (60%), followed by colours (25%) and branding/logos (16%). 9.8% of respondents selected all three options.

The proposed legislation restricts the use of imagery on devices and packaging, with the exception of an image of the compliant product on the retail packaging so that consumers are able to identify the specific component or device. In line with the prohibition of child-friendly imagery the General Scheme also prohibits the product itself resembling or functioning as a toy or any other product, for example school stationery or video games. The proposed legislation also allows for the Minister to prescribe the colour of packaging and device, including the colour of any text and trademarks.

### *Single-use vapes*

In 2023, Minister of State Ossian Smyth, T.D., held a public consultation on single-use or “disposable” vapes, which showed strong support (84.9%) from respondents for a ban on single-use vapes on environmental grounds. Many respondents also noted the dual health and environmental concerns with these products<sup>77</sup>.

However, a ban on these devices solely on environmental grounds was considered to be difficult to achieve given that nicotine-containing single-use vapes are regulated EU health law, the Tobacco Products Directive. In light of this and the health rationale outlined above, the Minister for Health has decided to include a prohibition on single-use vapes as part of the proposed General Scheme. The Department of Health will continue to work with the Department of Environment, Climate and Communications as drafting progresses, to ensure that the twin health and environmental aims are being met with this legislation.

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<sup>77</sup> <https://www.gov.ie/pdf/?file=https://assets.gov.ie/277659/bf005f2f-3f20-4233-9b42-06ff63216d50.pdf#page=null>

## **6 Enforcement, compliance and review**

### *Enforcement*

The provisions will be enforced by the HSE National Environmental Health Service, which already enforces the Public Health (Tobacco) Acts 2002-2023 and the relevant provisions of the EU Tobacco Products Directive. The intention of the proposals is that the NEHS will have the same powers of investigation and enforcement tools available for these measures as are currently in place for other tobacco control legislation.

### *Review*

It is intended to provide for a review of these measures 24 months after the commencement of all sections of the Act. This is to allow sufficient time for the measures to bed in following transition times, and for data collection to take place.

Specifically, the review should examine:

- Any early evidence of the effectiveness of measures to decrease youth use of nicotine inhaling products
- Any early evidence of indirect impact on smoking in both children and adults, and e-cigarette use in adults, including dual-use behaviour.
- Enforcement and compliance with legislation, and market responses to restrictions.

## Appendix 1: SME Test

# Application of the SME Test Public Health (Nicotine Inhaling Products) Bill 2024

## Screening question

**Q. To what extent is the proposed legislation relevant for SMEs?**

Not relevant  Relevant  Highly relevant

The following questions are relevant to consideration of the above question:

- Are SMEs within the scope of the legislative initiative?
- Does the initiative specifically target SMEs?
- Will SMEs be impacted directly or indirectly by the initiative?
- Are SME impacts likely to be more substantial than on other companies, for example, in terms of adverse effects?

If 'Relevant' or 'Highly Relevant', please proceed to complete Sections 1-5.

## 1. Identification of affected businesses

**Q1a: Please identify the types of SMEs that will be directly affected by the proposed legislation.**

Micro (1-9 employees)

Small (10-49 employees)

Medium (50-249) employees

N/A

**Q1b: Please identify the types of SMEs that will be indirectly affected by proposed legislation (i.e. SMEs not in scope, but potentially affected indirectly, for instance through impacts on supply chain)**

Micro (1-9 employees)

Small (10-49 employees)

Medium (50-249) employees

N/A

**Q1c: Has an estimate been carried out of the numbers of micro, small and medium companies affected directly or indirectly by the legislation?**

Yes  No  N/A

**Q1d: Will the proposed legislation have a greater impact on SMEs in any particular economic sector?**

Yes  No

If Yes, please specify.

Manufacturers, distributors and retailers who sell nicotine inhaling products.

**Q1e: Will the proposed legislation have a greater impact on SMEs in any particular region?**

Yes  No

If Yes, please specify.

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## 2. Consultation

**2.1 What consultation will take or has taken place to capture input from the SME community, particularly those potentially most impacted by this initiative?**

Public consultation

Other (e.g. stakeholder meetings, targeted consultation)

N/A

If Other, please provide details:

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### 3. Assessment of the impacts on SMEs

**Q3a What are the expected positive impacts of the legislation on SMEs (e.g. improved regulatory framework or working conditions, cost savings)?**

The overall purpose of the Bill is to reduce potential health harms, which will mean improved productivity and provide for a stronger economy for all SMEs.

**Q3b Will the proposed legislation result in any of the following impacts for SMEs?**

- Administrative costs, including the obligation to provide information on the activities or products of the company, including one-off and recurring administrative cost
- Other compliance costs, including the obligation to pay fees or duties; and costs created by the obligation to adapt the nature of the product/service and/or production/service delivery process to meet economic, social or environmental standards.
- Other impacts, including on business entry and exit; competition and competitiveness, whether proposed regulations might discourage, entrepreneurship or innovation; potential impact of any proposed exemption thresholds on business growth; impacts on SME population composition and location.

Yes  No

**Q3c If yes, please describe impacts, including whether any impacts will affect particular cohorts of SMEs differently, for example based on size (micro, small and medium), age of the business (e.g. start-up costs for new companies), economic sector and geographic location.**

- Medium sized businesses will be less impacted as they will be able to absorb both the monetary and time costs needed to introduce new regulations.

- The purpose of this Bill is to reduce the use of nicotine inhaling products. Therefore, it is possible that less retailers will enter the market.
- There would be costs to manufacturers and distributors to comply with restrictions to product attributes and appearance.
- There may be costs to retailers to implement point of sale restrictions.
- SME retailers who only or primarily sell nicotine inhaling products will have less of a compliance burden as they will not be expected to keep nicotine inhaling products in a closed container.
- There may be disposal costs for non-compliant products that are still in stock after regulations are commenced.

## 4. Assessment of alternative options and mitigating measures

**4a If the analysis above has shown that the draft legislation will result in impacts on SMEs, has there been consideration of any measures to mitigate against these impacts, such as less onerous reporting requirements, exemptions for certain cohorts of SME, simplified language etc? (See list of examples of potential mitigating measures on page 5 above)**

Mitigation of impacts on business by size are not possible as to do so would undermine the intention of the Bill, which is to reduce youth use of nicotine inhaling products. There is no evidence that youth are less likely to access nicotine inhaling products via SMEs than larger retailers.

SME retailers who only or primarily sell nicotine inhaling products will not have to comply with the point of sale display restrictions for general retailers.

Transition periods will apply to all businesses to comply with regulation, which should minimise the risk of disposal of non-compliant goods after the legislation enters into force. It is not possible to apply different transition periods for different businesses as to do so would undermine the effectiveness of the restrictions.

The National Environmental Health Service of the HSE will be responsible for compliance building ahead of entry into force, and enforcement following implementation.

Yes  No  N/A

Please provide details.

## 5. Post-completion of SME Test

**5a Do you intend to summarise the outcome of the SME Test, including identified impacts and provision for mitigating measures, under the Impacts section of any Memorandum for Government proposing the legislation?**

Yes  No  N/A

**5b Do you intend to make this form available publicly on your Department's website?**

Yes  No

This SME test will be included as an appendix to the Regulatory Impact Assessment for the Bill.

**Tobacco & Alcohol Control Unit | Department of Health**

**21.08.2024**

## Summary of addendum to Regulatory Impact Analysis (RIA)

### Additional measures in the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill

**Date:**

#### Related Publications:

**Regulatory Impact Analysis for existing measures in the Public Health (Tobacco Products and Nicotine Inhaling Products) Bill -**

<https://assets.gov.ie/static/documents/regulatory-impact-analysis-public-health-nicotine-inhaling-products-bill-2024.pdf>

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#### What are the policy objectives being pursued?

Reduce and prevent youth use of nicotine containing products to protect young people from addiction and potential harm, and adequately regulate novel nicotine containing products at the point of entry onto the market.

#### What policy options have been considered?

1. Do nothing
2. Information and education campaigns
3. Self or co-regulation
4. Legislate to regulate nicotine containing products.

#### Preferred Option

The “do nothing” option would likely mean that the policy objectives are not met.

Mass media campaigns are beneficial as part of a suite of measures. However, as is the case for tobacco, media campaigns are not sufficient on their own to address this public health issue.

Self or co-regulation is not an option as Ireland has signed and ratified (in November 2005) the World Health Organisation Framework Convention on Tobacco Control (‘WHO FCTC’).

The Articles of this international treaty are legally binding and at Article 5.3 the FCTC states that: *In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.*

In this context, the preferred option is to legislate to regulate nicotine containing products.

### **POLICY OPTIONS**

	<b>COSTS</b>	<b>BENEFITS</b>	<b>IMPACTS</b>
Policy Option 1			Youth uptake of nicotine containing products increases, with the associated health costs from nicotine addiction, and currently unknown long-term health harms.
Policy Option 2	Costs to Exchequer  Dependent on the type and duration of campaign(s). €200,000 allocated to HSE in Budget 2026 for vaping (and nicotine product) prevention campaign.	No immediate benefits to the Exchequer	Would have a positive impact as part of a suite of measures, but on their own are not enough to address the issue.
Policy Option 3	N/A	N/A	N/A

Policy Option 4	<p>There would be a cost to the Exchequer for enforcement required to ensure compliance with further regulations.</p> <p>There may be costs to retailers to implement point of sale restrictions.</p> <p>There would be loss of revenue for the industry if fewer young people use nicotine containing products unless use by other cohorts compensates.</p>	No immediate benefits to the Exchequer.	Likely reduction in youth uptake of nicotine containing products.
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## 2. Description of policy context and objectives

### Policy context

While Nicotine Replacement Therapy has long been available as a licensed medicine to those wishing to quit smoking, in recent years there has been an increase in the marketing of non-licensed commercial nicotine containing products which have become increasingly popular with young people. The most common, nicotine inhaling products, are subject to both EU and domestic regulation, and further regulation is being developed in the form of a Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill and a Public Health (Single Use Vapes) Bill.

However, a range of commercial nicotine containing products are currently not captured by this law. These are products that do not contain tobacco and do not fall under the definition of nicotine inhaling products. This addition to the Regulatory Impact Analysis for the above Bills will set out the policy context of these products and examine the impact of adding measures to on these products to the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill.

### *Product Types*

The most common products in this category are nicotine pouches. These are small bags (filled with nicotine, fillers, flavourings and alkaline substances) that are kept in the mouth.

They are often referred to as ‘snus’, though snus is a separate oral product containing tobacco which is prohibited in every EU country except Sweden.

The majority of research and surveillance on novel nicotine containing products relates to nicotine inhaling products or pouches. However, more recently other variants such as “pearls”, gel strips and toothpicks have been placed on the market either in Ireland, or in other EU Member States and the UK. Market presence and use prevalence are not currently known for these variants.

### ***Prevalence and composition of nicotine pouch use***

According to the Healthy Ireland 2025 survey, 1% of the population currently use nicotine pouches either daily (1%) or occasionally (<1%), with 6% saying they have tried them in the past but no longer use them. Men (2%) are more likely than women (<1%) to be current users of nicotine pouches.

Current smokers (3%) and ex-smokers (2%) are more likely to use nicotine pouches than those who have never smoked (<1%).

Younger people are more likely to use nicotine pouches, with 3% of people those 15 to 24 saying they use them daily or occasionally, with usage being highest among men in this age group (5%).<sup>1</sup>

This is mirrored in the European Survey Project on Alcohol and Drugs (ESPAD) which found that 7.6% of 15-16 year olds had ever used nicotine pouches, with 3.6% having used them in the last 30 days.<sup>2</sup>

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<sup>1</sup> Healthy Ireland Survey 2025 Report. <https://www.gov.ie/en/healthy-ireland/collections/healthy-ireland-survey-documents/>

<sup>2</sup> Hanafin J, Sunday S, Fitzmaurice H, Clancy, L. (2025). ESPAD Ireland 2024: Results from the European School Survey Project on Alcohol and Other Drugs. Dublin: TobaccoFree Research Institute Ireland for the Department of Health Ireland. ISBN: 978-1-90-045497-1. DOI: 10.21427/bqh8-5p87

Reflecting the above figures, research found that the marketing of nicotine pouches was aimed at younger people and that awareness of these products is much greater in this cohort.<sup>3</sup>

### ***Health Harms***

As nicotine pouches are very new products, there is a lack of independent evidence of health harms, though there is some evidence to suggest that nicotine pouches may be detrimental to oral health<sup>4</sup>.

A scoping review on the public health impact of nicotine pouches found that non-industry funded studies had found the presence of some harmful or potentially harmful constituents in pouches including some considered to be carcinogenic, though at lower levels than tobacco products.<sup>5</sup> Further research is required to understand the health implications.

Existing systematic review evidence suggests that nicotine may have a greater and/or unique effect on adolescents compared with adults, with possible implications for nicotine dependence and cognitive outcomes such as learning or memory, though again further research is needed.<sup>6</sup>

### ***Relationship between nicotine containing products and smoking***

A recent systematic review of randomised control trials found no statistically significant evidence yet that nicotine pouches were more effective than other products for smoking cessation.<sup>7</sup> However (as has been the case with e-cigarettes) this relates to their clinical

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<sup>3</sup> Travis N, Warner KE, Goniewicz ML, Oh H, Ranganathan R, Meza R, Hartmann-Boyce J, Levy DT. The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review. *Nicotine Tob Res.* 2025 Mar 24;27(4):598-610. doi: 10.1093/ntr/ntae131. PMID: 38880491; PMCID: PMC11931220.

<sup>4</sup> Rungraungrayabkul, D., Gaewkhiew, P., Vichayanrat, T. *et al.* What is the impact of nicotine pouches on oral health: a systematic review. *BMC Oral Health* **24**, 889 (2024). <https://doi.org/10.1186/s12903-024-04598-8>

<sup>5</sup> Travis N, Warner KE, Goniewicz ML, Oh H, Ranganathan R, Meza R, Hartmann-Boyce J, Levy DT. The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review. *Nicotine Tob Res.* 2025 Mar 24;27(4):598-610. doi: 10.1093/ntr/ntae131. PMID: 38880491; PMCID: PMC11931220.

<sup>6</sup> Colyer-Patel *et al.* (2023). Age-dependent effects of tobacco smoke and nicotine on cognition and the brain: A systematic review of the human and animal literature comparing adolescents and adults. *Neuroscience and Biobehavioral Reviews* vol. 146.

<sup>7</sup> Heshmati J, Shahan S, Bates EL, Visintini S, Quirouette E, Mullen K-A, *et al.* Nicotine pouches and clinical outcomes related to smoking cessation: A systematic review of randomized trials. *Addiction.* 2025. <https://doi.org/10.1111/add.70193>

utility, rather than what the population-wide public health impact might be from their use as consumer products.

In addition, one review found evidence that the marketing and product characteristics of nicotine pouches may be contributing to situational and dual/poly-use alongside tobacco or e-cigarettes among adults.<sup>8</sup>

As noted above, use of nicotine pouches among current and former smokers is low. There are a range of licensed medical nicotine containing products (Nicotine Replacement Therapies) available at similar price points to nicotine pouches for those who wish to quit smoking, including gum, lozenges, inhalers and patches. These were approved for general retail by HPRA in 2014, VAT was removed on these products in Budget 2023, and the HSE provides free Nicotine Replacement Therapies via the Quit Service.

### ***Existing Policy***

Ireland's national tobacco control policy, *Tobacco Free Ireland*, sets the target of a smoking prevalence of less than 5% in the population, and recommends a suite of measures to achieve this and reduce the premature death and disability caused by smoking.

The policy recognises the need for less harmful forms of nicotine for smokers who are preparing to or unable to quit, under an appropriate regulatory framework. At the time of publication of the policy, e-cigarettes were the primary recreational nicotine product other than tobacco, and thus the policy focuses on those.

Ireland is a Party to the WHO Framework Convention on Tobacco Control. Article 5(2)(b) obliges Parties to “*adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke*”.<sup>9</sup>

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<sup>8</sup> Travis N, Warner KE, Goniewicz ML, Oh H, Ranganathan R, Meza R, Hartmann-Boyce J, Levy DT. The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review. *Nicotine Tob Res.* 2025 Mar 24;27(4):598-610. doi: 10.1093/ntr/ntae131. PMID: 38880491; PMCID: PMC11931220.

<sup>9</sup> <https://fctc.who.int/resources/publications/i/item/9241591013>

### ***Regulation of nicotine containing products***

As these products are not covered by harmonised EU tobacco control law, regulation of these products differs considerably between Member States. For those who have regulated these products, the measures mirror evidence-based interventions for tobacco and nicotine inhaling products.

Several Member States have baseline regulation of all nicotine containing products entering the market, which predominantly consists of age of sale and marketing restrictions.

Regarding nicotine pouches, four Member States have banned their sale outright, either through specific law or by classifying them as an ‘unauthorised novel food’, as is the case in Germany. A further eight Member States have regulated them in different ways to reduce their appeal and accessibility to young people, including advertising, packaging and flavour restrictions, licensing, nicotine limits and health warnings.

### ***Taxation***

A proposal to recast the EU Tobacco Tax Directive is currently being negotiated. The EU Commission’s proposal includes including all nicotine containing products under the EU tax regime, in part to support the public health objectives regarding youth use of these products.<sup>10</sup>

## **Objectives**

The objectives are to reduce and prevent further youth uptake of nicotine containing products and create a baseline regulatory framework for nicotine containing products before they enter the market.

## **3. Identification and Description of Options**

*Option 1: Do nothing.*

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<sup>10</sup> [https://taxation-customs.ec.europa.eu/document/download/420ebf11-933d-46c0-8915-5a306c6bcb47\\_en?filename=COM\\_2025\\_580\\_1\\_EN\\_ACT\\_part1\\_v7.pdf](https://taxation-customs.ec.europa.eu/document/download/420ebf11-933d-46c0-8915-5a306c6bcb47_en?filename=COM_2025_580_1_EN_ACT_part1_v7.pdf)

These products would remain legally available to minors and on display in everyday shops. There would be no regulation of these products other than that future law on some aspects of these products will likely be included in a revised EU Tobacco Products Directive.

### *Option 2: Information and education campaigns*

Work is already ongoing within the HSE to increase access to information on nicotine products for young people, parents and schools:

- Junior Cycle SPHE resources were published in 2023 on the impact of nicotine, tobacco use, second-hand smoke, e-cigarettes and vaping.
- The HSE’s guidance for schools on vaping includes information on the impact of nicotine on adolescents.
- The HSE is currently updating its public-facing resources on recreational nicotine containing products (such as e-cigarettes and nicotine pouches).
- Funding was allocated in Budget 2025 for a youth vaping prevention media campaign. The main focus of the campaign will be on vaping, but other nicotine containing products (such as pouches) will also be addressed. The HSE has conducted research with parents and audiences under 18 to help inform the content and tone of the campaign, and it will be rolled out in Q4 of 2025.

### *Option 3: Self or co-regulation*

This option is effectively excluded by Ireland’s ratification of the WHO FCTC. Article 5.3 of the FCTC requires that *“in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.”*

Any form of self or co-regulation would mean that those with a commercial interest in the manufacture, distribution or sale of tobacco would have an involvement in the development of the policy and therefore Ireland would not be compliant with its legally binding obligations under the FCTC.

#### *Option 4: Legislate to further regulate nicotine inhaling products*

It is acknowledged that EU-wide regulation of nicotine containing products would be most effective, as measures could not be circumvented via cross-border purchases. There have been challenges enforcing unilateral restrictions on e-cigarettes and nicotine containing products in Member States who have moved ahead of EU regulation, even in countries where cross-border distance sales are banned.

For this reason, the Minister for Health, with the support of a majority of Member States, has formally called on the EU Commission to urgently publish a revision of the Tobacco Products Directive to include novel products.<sup>11</sup> A Commission evaluation of the legislation is expected in early 2026.

Even with the introduction of EU law, several measures would still fall to domestic regulation, including age of sale legislation, retail marketing and display as well as some domestic physical advertising and licensing. For this reason there is a policy basis for a set of baseline regulations for all consumer nicotine containing products to adequately protect children. The introduction of measures that will apply to all recreational nicotine containing products (current and future) will also avoid the necessity for “catch-up” regulations each time a new nicotine containing product enters the market.

In that context the following are the proposed additions to the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill:

- A mandatory minimum legal age of sale of 18
- A prohibition on advertising in all retail premises
- A prohibition on display of products in retail premises, other than those which wholly or mainly sell nicotine inhaling products or nicotine containing products, provided that the only other products sold are non-nicotine vapes or liquids, and accessories for the maintenance of these devices.

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<sup>11</sup> <https://www.consilium.europa.eu/en/meetings/epsco/2025/06/20/>

## 4. Analysis of Costs, Benefits and Impacts of Options

*Option 1: Do nothing.*

### **Costs and Benefits**

None

### **Impacts**

Under the ‘do nothing’ option, nicotine pouch use is likely to continue to increase among young people, given the marketing strategies highlighted above. Nicotine pouch use may also increase among adults and at this point in time it is uncertain whether this would contribute to further dual and poly-use or lead to reduced smoking rates. Certainty is not possible but the evidence from nicotine inhaling product use trends in Ireland does not support a prediction that the unregulated availability of nicotine-containing consumer products will bring a public health benefit at population level.

While some areas of nicotine containing product regulation may shortly come under a revised EU Tobacco Products Directive, certain measures such as age of sale and point of sale display are likely to be left to domestic regulation, as is the case for tobacco and nicotine inhaling products.

No obvious impacts on *national competitiveness, the socially excluded and vulnerable groups, the environment, whether there is a significant policy change in an economic market, including consumer and competition impact, the rights of citizen, compliance burdens, including administrative burdens and North-South and East-West Relations.*

*Option 2: Information and education campaigns*

### **Costs**

Funding of €200,000 has already been allocated for the HSE’s vaping/nicotine product prevention campaign in 2026.

### **Benefits**

Campaigns may contribute to reducing youth use as part of a suite of measures.

## **Impact**

Effective campaigns tailored for young people may contribute to changing attitudes and behaviours toward nicotine containing products, however as with all public health prevention issues, a multi-faceted approach is necessary in order to impact behaviours and education is insufficient on its own.

*No obvious impacts on national competitiveness, the socially excluded and vulnerable groups, the environment, whether there is a significant policy change in an economic market, including consumer and competition impact, the rights of citizen, compliance burdens, including administrative burdens and North-South and East-West Relations.*

### *Option 3: Self or co-regulation*

This is not applicable. Self or co-regulation requires that affected stakeholders, such as the tobacco industry or other vested interests, have influence on the proposed approach or on its implementation. Ireland is a party to the legally binding Framework Convention on Tobacco Control so is required to act to protect public health tobacco control policies from the tobacco industry or other vested interests. On that basis Ireland could not engage in self or co-regulation.

### *Option 4: Legislate to further regulate nicotine containing products*

## **Costs**

### *Exchequer*

Enforcement of these proposed additional measures will add to the workload of the enforcement authority, the National Environmental Health Service (NEHS) of the HSE, which is already facing significant additions from the Public Health (Single-Use Vapes) Bill and the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill. The NEHS received funding for two additional WTEs to enforce existing law in the recent budget which is welcome as adequate resourcing for enforcement is essential to meet the policy objectives.

### *Manufacturers of nicotine containing products*

As the stated objective is to reduce and prevent youth use of nicotine containing products, this would likely result in reduced profits for the industry unless there is a compensating increase in adult use.

### *Retailers*

The published RIA for the restrictions on point-of-sale advertising and display of nicotine inhaling products assessed possible costs for retailers in changing the display for these products.<sup>12</sup> As nicotine containing products generally occupy the same shelf space as nicotine inhaling products it is not anticipated that there will be significant additional costs to incorporate compliance with this measure.

As the stated objective is to reduce youth use of nicotine containing products, this could result in reduced profits from these products for retailers unless there is a compensating uptake by other cohorts. Overall, it is possible that money not spent on nicotine containing products may be spent on other products therefore lessening the impact.

### **Benefits**

There are unlikely to be short-term tangible benefits to the Exchequer, however a stable regulatory framework for recent and future products will provide clarity for businesses and so facilitate their future planning. It will also deter non-compliant operators from trying to enter the market and unfairly compete with those that are compliant.

The proposals are likely to contribute to improved health and wellbeing for young people, with potential mid to long-term benefits for the Exchequer through reduction in pressure on the healthcare system.

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<sup>12</sup> <https://assets.gov.ie/static/documents/regulatory-impact-analysis-public-health-nicotine-inhaling-products-bill-2024.pdf>

## Impact

The expected impact of the proposals is a decline in youth use of nicotine containing products while not affecting the availability of these products for adults who smoke. These measures also take place in the same context of mitigating factors outlined in the 2024 published RIA, namely continued measures to reduce smoking initiation such as Tobacco 21, and the increasing investment in free and effective stop smoking support for adults.<sup>13</sup>

The Minister for Health wishes to act quickly to establish baseline regulation of all non-medicinal nicotine containing products while prevalence remains low (in the case of nicotine pouches) or non-existent (future nicotine containing products). The intention is to adequately protect youth before product use becomes normalised in this cohort.

### *The environment*

As with other tobacco and nicotine products, nicotine pouches produce solid waste as well as chemical leakage into the environment.<sup>14</sup> Measures which reduce consumption of these products among young people would therefore have environmental benefits.

### *The rights of citizens*

Article 24 of the UN Convention on the Rights of the Child (UNCRC) requires States to recognize the right of the child to the enjoyment of the highest attainable standard of health.

In its General Comment No. 15 on the right of the child to the enjoyment of the highest attainable standard of health, the UN Committee on the Rights of the Child urges States to place children's best interests at the centre of all decisions affecting their health and development. This includes the development and implementation of policies and interventions that affect the underlying determinants of their health.

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<sup>13</sup> <https://assets.gov.ie/static/documents/regulatory-impact-analysis-public-health-nicotine-inhaling-products-bill-2024.pdf>

<sup>14</sup> <https://iris.who.int/server/api/core/bitstreams/531014bb-58f7-4bd1-bbd8-0aefc07a44c5/content>

As nicotine containing products represent an increase in harm for children compared to non-use, measures to prevent uptake would uphold their right to the highest attainable standard of health.

#### *Compliance burdens, including administrative burdens*

It is not anticipated that there will be significant compliance burdens on retailers over and above those already examined for the further regulation of nicotine inhaling products in the published 2024 RIA.<sup>15</sup> There may be additional time burdens to include nicotine containing products in the retail protocols for age restricted products, however, this has been already promoted as a voluntary measure by retail organisations.<sup>16</sup>

#### *North-South and East-West Relations*

The UK Tobacco and Vapes Bill seeks to, among other things, introduce an age of sale and restrict point of sale display for nicotine containing products. Therefore North-South divergence is unlikely.

No obvious impacts on *the socially excluded and vulnerable groups, whether there is a significant policy change in an economic market, including consumer and competition impact or national competitiveness.*

## **5 Consultation**

Under Article 5.3 of the WHO Framework Convention on Tobacco Control, Ireland is obliged to protect tobacco control policy from the commercial and other vested interests of the tobacco industry, including those representing the industry, and those seeking to further the commercial interests of the tobacco industry.

In 2023/2024 a public consultation on the further regulations of nicotine inhaling products was carried out. As set out in the published Report there were certain irregularities in relation

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<sup>15</sup> <https://assets.gov.ie/static/documents/regulatory-impact-analysis-public-health-nicotine-inhaling-products-bill-2024.pdf>

<sup>16</sup> <https://csna.ie/nicotine-pouches-best-practice-would-be-that-your-staff-should-be-instructed-to-apply-an-age-restriction-on-these-products/>

to submissions to the consultation.<sup>17</sup> In this context and as the proposals are introducing only minimal regulation as soon as possible a full public consultation is not proposed.

#### *Call for Evidence – public health and civil society organisations*

A Call for Evidence was conducted from May to June 2025 with the HSE Tobacco Free Ireland Partners Group, to inform the ongoing review of the *Tobacco Free Ireland* policy. This group is made up of representatives from across organisations with an interest in tobacco control.<sup>18</sup>

The need to enhance regulation of novel nicotine products such as e-cigarettes and nicotine pouches was cited by many of the respondents. Suggestions included limiting flavours, introducing restrictions on point of sale displays and packaging, and establishing or increasing the age of sale for these products. It was recommended that legislation is introduced to future proof against new products and marketing tactics.

These proposals are a first step in regulating these products and future-proofing against new products. This does not preclude future regulation at EU level or at domestic level and particularly in the context of a new *Tobacco Free Ireland* policy.

#### *Enforcement*

The provisions will be enforced by the NEHS whose existing powers of investigation and enforcement will apply.

#### *Review*

These measures will fall under the review already proposed in the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill.

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<sup>17</sup> <https://www.gov.ie/en/department-of-health/consultations/public-consultation-on-further-regulation-of-tobacco-and-nicotine-inhaling-products/#public-consultation-report> Page 11

<sup>18</sup> HSE Tobacco Free Ireland Programme. *APPENDIX D TFI Partners Group*. Tobacco Free Ireland Programme Plan 2022-2025. <https://www.drugsandalcohol.ie/36369/1/tobacco-free-ireland-programme-plan-2022-2025.pdf>

## Appendix 1: SME Test

### Application of the SME Test

#### Regulation of nicotine containing products under the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill 2025

### Screening question

**Q. To what extent is the proposed legislation relevant for SMEs?**

Not relevant     Relevant     Highly relevant

The following questions are relevant to consideration of the above question:

- Are SMEs within the scope of the legislative initiative?
- Does the initiative specifically target SMEs?
- Will SMEs be impacted directly or indirectly by the initiative?
- Are SME impacts likely to be more substantial than on other companies, for example, in terms of adverse effects?

If 'Relevant' or 'Highly Relevant', please proceed to complete Sections 1-5.

### 1. Identification of affected businesses

**Q1a: Please identify the types of SMEs that will be directly affected by the proposed legislation.**

Micro (1-9 employees)

Small (10-49 employees)

Medium (50-249 employees)

N/A

**Q1b: Please identify the types of SMEs that will be indirectly affected by proposed legislation (i.e. SMEs not in scope, but potentially affected indirectly, for instance through impacts on supply chain)**

Micro (1-9 employees)

Small (10-49 employees)

Medium (50-249) employees

N/A

**Q1c: Has an estimate been carried out of the numbers of micro, small and medium companies affected directly or indirectly by the legislation?**

Yes  No  N/A

**Q1d: Will the proposed legislation have a greater impact on SMEs in any particular economic sector?**

Yes  No

If Yes, please specify.

Manufacturers, distributors and retailers who sell nicotine containing products.

**Q1e: Will the proposed legislation have a greater impact on SMEs in any particular region?**

Yes  No

If Yes, please specify.

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## 2. Consultation

**2.1 What consultation will take or has taken place to capture input from the SME community, particularly those potentially most impacted by this initiative?**

Public consultation

Other (e.g. stakeholder meetings, targeted consultation)

N/A

If Other, please provide details:

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### 3. Assessment of the impacts on SMEs

**Q3a What are the expected positive impacts of the legislation on SMEs (e.g. improved regulatory framework or working conditions, cost savings)?**

The overall purpose of the Bill is to reduce potential health harms, which will mean improved productivity and provide for a stronger economy for all SMEs. In addition timely regulation of recent and future products will provide clarity for businesses and so facilitate their future planning. It will also deter non-compliant operators from trying to enter the market and unfairly compete with those that are compliant.

**Q3b Will the proposed legislation result in any of the following impacts for SMEs?**

- Administrative costs, including the obligation to provide information on the activities or products of the company, including one-off and recurring administrative cost
- Other compliance costs, including the obligation to pay fees or duties; and costs created by the obligation to adapt the nature of the product/service and/or production/service delivery process to meet economic, social or environmental standards.
- Other impacts, including on business entry and exit; competition and competitiveness, whether proposed regulations might discourage, entrepreneurship or innovation; potential impact of any proposed exemption thresholds on business growth; impacts on SME population composition and location.

Yes  No

**Q3c If yes, please describe impacts, including whether any impacts will affect particular cohorts of SMEs differently, for example based on size (micro, small and medium), age of the business (e.g. start-up costs for new companies), economic sector and geographic location.**

- Should retailers wish to continue selling nicotine containing products, there may be costs to implement point of sale restrictions and include nicotine containing products in the list of age restricted items for sale in the shop.
- Medium sized businesses will be less impacted as they will be able to absorb both the monetary and time costs needed to comply with new regulations.
- SME retailers who only or primarily sell nicotine inhaling products or nicotine containing products will have a reduced compliance burden as they will not be expected to keep nicotine products in a closed container.

## 4. Assessment of alternative options and mitigating measures

**4a If the analysis above has shown that the draft legislation will result in impacts on SMEs, has there been consideration of any measures to mitigate against these impacts, such as less onerous reporting requirements, exemptions for certain cohorts of SME, simplified language etc? (See list of examples of potential mitigating measures on page 5 above)**

Yes  No  N/A

Please provide details.

Ireland is legally bound to protect tobacco control policy from the commercial interests of the tobacco industry, including those representing or seeking to further its interests.

Mitigation of impacts on business by size are not possible as to do so would undermine the intention of the Bill, which is to reduce youth use of nicotine products. There is no evidence that youth are less likely to access nicotine products via SMEs than larger retailers.

SME retailers who only or primarily sell nicotine inhaling products or nicotine containing products will not have to comply with the point of sale display restrictions applicable for general retailers.

As mentioned above, nicotine containing products in general retail tend to occupy the same shelf space as nicotine inhaling products, therefore it is not anticipated that costs will exceed those already envisaged for the existing display and advertising restrictions in the Public Health (Tobacco Products and Nicotine Inhaling Products) (Amendment) Bill.

The National Environmental Health Service of the HSE will be responsible for engagement and compliance building with retailers ahead of entry into force, and enforcement following implementation.

## 5. Post-completion of SME Test

**5a Do you intend to summarise the outcome of the SME Test, including identified impacts and provision for mitigating measures, under the Impacts section of any Memorandum for Government proposing the legislation?**

Yes  No  N/A

**5b Do you intend to make this form available publicly on your Department's website?**

Yes  No

This SME test will be included as an appendix to the Regulatory Impact Assessment for the additional measures.

**Tobacco & Alcohol Control Unit | Department of Health**

**24.10.2025**