

Summary of Regulatory Impact Analysis (RIA)

Department/Office:

Department of Health

Title of Legislation:

Public Health (Tobacco and Nicotine
Inhaling Products) Bill

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?

The policy objectives are to contribute to the implementation of the following recommendations contained in the national tobacco control policy *Tobacco Free Ireland*:

- Develop a licensing system for retailers who sell tobacco products.
- Prohibit sales of tobacco in mobile units/containers.
- Prohibit the sale of tobacco at events/locations primarily intended for those persons under 18 years.
- Prohibit the sale of tobacco products by those under 18 years.
- Prohibit the operation of all self-service vending machines.
- Introduce a minimum suspension period for retailers convicted of an offence.
- Establish a regulatory framework for nicotine products in the context of discussions at EU level.
- Introduce fixed penalty notices (on the spot fines) for offences.
- Introduce legislation for the publication of information in respect of any person on whom a fine, other penalty or conviction was imposed by a Court ('name and shame').

What policy options have been considered?

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

Preferred Option

Approximately 5,900 deaths each year in Ireland are attributable to smoking and exposure to second-hand smoke and it is the cause of over 1000 hospital episodes each week. The national tobacco control policy, *Tobacco Free Ireland*, has set a target to reduce smoking levels to less than 5% of the population by 2025. Currently 20% of the population smoke in Ireland. To do nothing would mean that the disease burden and death from tobacco use in Ireland will continue.

Education or awareness campaigns on their own are not a preferred option. The Health Service Executive's *Tobacco Free Ireland Programme* already produces QUIT campaigns which include award winning advertisement on television, radio and social media therefore additional campaigns would be a duplication of these.

More importantly, the complexity of tobacco use means that a multifaceted approach to the problem is necessary and that education or awareness campaigns alone are not sufficient. The need to address tobacco use from multiple perspectives is reflected in World Health Organisation's MPOWER policy package which informs Ireland's approach to tobacco control and which recommends warning about the dangers of tobacco as only one of six evidenced based policy actions necessary to address tobacco use. In addition the World Health Organisation Framework Convention on Tobacco Control requires Parties to address the problem using a range of measures.

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:

Article 5 General obligations

3. 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.

POLICY OPTIONS

| | COSTS | BENEFITS | IMPACTS |
|------------------------|---|------------------------------------|--|
| Policy Option 1 | Costs to Exchequer No costs. | Benefits to Exchequer None | None |
| 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 None. | None. High quality QUIT campaigns are already being run by the HSE Tobacco Free Ireland programme but these on their own are not enough to address the complex problem of tobacco use. |

| | | | |
|-----------------|--|---|---|
| Policy Option 3 | <p>Costs to Exchequer</p> <p>Dependent on the type of self or co-regulation there may be some start-up costs.</p> | <p>Benefits to Exchequer</p> <p>None.</p> | <p>Likely breach of Ireland’s legally binding obligations under the WHO Treaty - the Framework Convention on Tobacco Control. Reputational damage internationally.</p> |
| Policy Option 4 | <p>Costs to Exchequer</p> <p>There will be IT costs associated with the Environmental Health Service upgrading its current licensing system.</p> | <p>Benefits to Exchequer</p> <p>None</p> | <p>Impact on public health</p> <p>The measures are designed to prevent the initiation of smoking or the use of nicotine inhaling products by children and to strengthen the enforcement of current and future tobacco law in order to reduce the impact of the leading preventable cause of disease and death in Ireland.</p> |

2. Description of Policy context and objectives

Policy context

Tobacco smoking is both addictive and lethal. It is widely accepted that 1 in every 2 smokers will die as a direct result of their smoking.¹

More recent research paints an even grimmer picture in that it is now suggested that 2 in every 3 smokers could be killed as a result of their smoking.² A 2015 large population study from Australia demonstrated that mortality rates increased substantially with increasing intensity of smoking, with rates approximately doubling in those smoking around 10 cigarettes per day and increasing four- to five-fold in current smokers of 25 or more cigarettes per day. The progressive increase in mortality has been attributed to the earlier

¹ Doll et al. Mortality in relation to smoking: 40 years observations on male British doctors. British Medical Journal 1994; 309:901-911).

² 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

commencement of smoking and greater intensity of smoking among successive generations, along with reductions in mortality among those who have never smoked.

Tobacco smoke also harms others. Children and adults are exposed to the harmful effects of second-hand smoke and smoking during pregnancy impacts on both the health of the woman and the foetus.^{3 4}

In addition tobacco smoking has a negative impact on overall welfare; it damages economic productivity, causes fires and creates litter.⁵

Smoking also has a major impact on health inequalities with those least well-off suffering the most from the harmful effects of smoking. It is estimated that smoking is the single largest cause of health inequalities in most western societies.⁶

Smoking in Ireland

Health harms from smoking

Tobacco smoking is the biggest single cause of addiction, ill health and death in Ireland and according to data from the Global Burden of Disease study it remains the leading preventable cause of ill-health, disability and premature mortality here.⁷

In Ireland, an estimated 5,900 people die each year⁸ from tobacco related diseases which can be broken down as follows:

³ Royal College of Physicians *Passive Smoking and Children*. Available at <https://cdn.shopify.com/s/files/1/0924/4392/files/passive-smoking-and-children.pdf?15599436013786148553>

⁴ Royal College of Physicians *Going Smoke Free*. Available at <https://cdn.shopify.com/s/files/1/0924/4392/files/going-smoke-free.pdf?2801907981964551469>

⁵ ICF International (2016) *An assessment of the economic cost of smoking in Ireland*. Available at <https://www.gov.ie/en/publication/a7ee00-an-assessment-of-the-economic-cost-of-smoking-in-ireland/>

⁶ Jha P, Peto R, Zatonski W, et al. Social inequalities in male mortality, and in male mortality from smoking: indirect estimation from national death rates in England and Wales, Poland, and North America. *The Lancet* 2006; 36: 367–370.

⁷ <http://www.healthdata.org/ireland>

⁸ Health Service Executive Tobacco Free Ireland Programme (2018) *The State of Tobacco Control in Ireland*. Available at <https://www.hse.ie/eng/about/who/tobaccocontrol/the-state-of-tobacco-control-in-ireland%E2%80%932018-report.pdf>

- Cancers (44%)
- Circulatory diseases (30%)
- Respiratory diseases (25%)
- Digestive diseases (1%)⁹

In addition smoking related illness is estimated to generate 29,010 inpatient discharges and 10,613 day case admissions to Irish hospitals every year.¹⁰

The impact on health inequalities that is found globally is also reflected in Irish society. A recent National Cancer Registry report showed that not only did people from more deprived areas have a higher incidence of some tobacco related cancers; they also had a poorer survival pattern than those from less deprived areas.¹¹

Economic cost of smoking

ICF International (UK) in association with DKM Economic Consultants (Ireland) carried out a detailed assessment of the economic cost of smoking in Ireland in 2016.⁵

- Estimated healthcare costs are €506 million, made up of:
 - ◆ Hospital based costs- €211 million
 - ◆ Primary care costs- €256 million
 - ◆ Domiciliary care costs- €40 million.

- Estimated lost productivity costs of over €1 billion (€1,071 million) made up of:

⁹ Howell F R & Shelley E (2011) *Mortality attributable to tobacco use in Ireland*. The Faculty of Public Health Medicine RCPI Winter meeting; Dublin.

¹⁰ Health Information and Quality Authority (2017) *Health Technology Assessment of Smoking Cessation Intervention*. Available at <https://www.hiqa.ie/sites/default/files/2017-04/Smoking%20Cessation%20HTA.pdf>

¹¹ Walsh PM, McDevitt J, Deady S, O'Brien K & Comber H (2016) *Cancer inequalities in Ireland by deprivation, urban/rural status and age: a report by the National Cancer Registry*. National Cancer Registry, Cork, Ireland.

- ◆ Smoking breaks- €136 million
 - ◆ Smokers' absence- €224 million
 - ◆ Premature death- €711 million.
- Cost of fires is estimated at €6 million including €2 million due to loss of life.
 - Cost of smoking related litter is an estimated €69 million.
 - The loss of welfare from disease related to smoking is estimated at €1,355 million and from premature death from smoking is nearly €8 billion (€7,657 million).

The total cost of smoking was estimated at €10.6 billion per year.

To put this figure in context, Exchequer earnings from tax paid on tobacco products in the same year as the assessment (2016) was €1,098 million.¹²

Smoking prevalence – Irish adults

It is estimated that approximately 800,000 of the Irish population aged 15 and over are addicted to tobacco¹³ with a further 1 million having successfully overcome their addiction¹⁴.

The Healthy Ireland 2018 Survey found that 17% of those 15 years and older smoke daily with a further 3% of the population being occasional smokers (i.e. do not smoke every day), making Ireland's current smoking rate 20% or one in five.¹⁴

¹² Tax Strategy Group (2019) *General Excise Paper*. Available at <https://assets.gov.ie/4447/131218111459-39f9e3ace54f4567a170c3571cf9997e.pdf>

¹³ Healthy Ireland Survey 2017. Available at <https://health.gov.ie/blog/publications/healthy-ireland-survey-2017/>

¹⁴ Healthy Ireland Survey 2018. Available at <https://health.gov.ie/wp-content/uploads/2018/10/Healthy-Ireland-Survey-2018.pdf>

The 2018 survey also found that:

- More men (22%) than women (17%) are current smokers.
- Smoking peaks amongst 25-34 year olds (28%) and declines with age.
- Reflecting inequalities in health, Ireland's smoking rates are much higher in disadvantaged areas (26%) than in more affluent areas (16%).

Finally the survey also reflects the powerfully addictive nature of nicotine, showing that the majority of Ireland's smokers (57%) do not want to smoke and are either trying to, actively planning to or thinking about quitting. The results show that 40% of current smokers made an attempt to quit in the past 12 months but 24% had recommenced smoking within one week of quitting.

Smoking prevalence - Irish children

The 2014 Health Behaviour in School Children Survey¹⁵ found that 8% of those between 10 and 17 years currently smoke (defined as smoking at least once a month), down from 12% in 2010. It also shows that almost equal percentages of boys (8%) and girls (7%) are current smokers with approximately 1-2% of boys and girls in the 10-11 years age group being current smokers, 4-5% of boys and 3-6% of girls in the 12-14 year age group and 12-14% of boys and 10-17% of girls in the 15-17 year age group.

Data from the *European Schools Project on Alcohol and other Drugs 2015 survey*¹⁶ also shows that 13% of 15-17 year olds are current smokers. Of those children who had smoked a cigarette, 7% were 10 years old or younger, 21% were between 11-12 years old, 49% were 13-14 years old, and the remaining 23% were between 15-17 years old.

The young age at which children start to smoke here was reflected in a 2012 Eurobarometer Report in which adult smokers in the EU were asked at what age they had started to smoke at least once a week. Ireland had the youngest average age of starting at 16.4 years¹⁷.

¹⁵The Irish Health Behaviour in School-aged Children Study 2014. Available at: [http://www.nuigalway.ie/media/healthpromotionresearchcentre/hbscdocs/nationalreports/HBSC2014-edit-\(LW\).pdf](http://www.nuigalway.ie/media/healthpromotionresearchcentre/hbscdocs/nationalreports/HBSC2014-edit-(LW).pdf)

¹⁶ ESPAD 2015: European School Survey Project on Alcohol & Other Drugs in Ireland. Available at: http://www.tri.ie/uploads/5/2/7/3/52736649/espac_2015_ireland_final.pdf

¹⁷ European Commission *Special Eurobarometer 385 Attitudes of Europeans towards tobacco*. Available at https://ec.europa.eu/health/sites/health/files/tobacco/docs/eurobaro_attitudes_towards_tobacco_2012_en.pdf

Nicotine inhaling products including e-cigarettes

Nicotine inhaling products (also known as Electronic Nicotine Delivery Systems (ENDS), electronic cigarettes and most commonly as e-cigarettes) are available in a wide variety of models but the mechanism of delivery of nicotine is similar. E-cigarettes heat a solution (e-liquid) to create an aerosol or vapour which users inhale. The e-liquid usually contains nicotine as well as chemicals such as propylene glycol and can also include glycerol and flavourings.¹⁸

In addition to e cigarettes, there are electronic devices on the market which contain tobacco called Heat Not Burn or Heated Tobacco Products. In these products, processed tobacco is heated in a controlled device creating an aerosol that is inhaled. Alternatively the aerosol can be created from non-tobacco sources and passed over processed tobacco for flavouring. In either case the tobacco is heated but is not combusted unlike standard cigarettes or other conventional tobacco products.¹⁹

Health harms and possible benefits of nicotine inhaling products

There is no scientific consensus on the health effects of nicotine inhaling products. Reasons for this include that, the products are relatively new therefore evidence on their long term health effects is not available, the evidence is continuously evolving and new devices and liquids continue to be developed and introduced to the market.

International opinion is divided on nicotine inhaling products. The UK and New Zealand governments recommend e-cigarettes as an alternative to smoking tobacco cigarettes^{20 21}

¹⁸ World Health Organisation *Electronic nicotine delivery systems FCTC/COP/6/10* and *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems FCTC/COP/7/11*. Available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 and https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1

¹⁹ Committees on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment *Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary*. Available at https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

²⁰ NHS advice on quitting using e-cigarettes <https://www.nhs.uk/smokefree/help-and-advice/e-cigarettes>

²¹ New Zealand Ministry for Health advice on vaping to assist quitting <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco>

while Australia and Brazil, among other countries, have banned the sale of some or all elements of e-cigarettes²²²³.

One aspect on which there is consensus is that nicotine is an addictive substance and that its use can lead to dependence. In addition, according to the World Health Organisation, there is sufficient evidence of the potential for foetal and adolescent nicotine exposure to have long-term consequences for brain development such that children and adolescents, pregnant women, and women of reproductive age should be cautioned about its use¹⁸.

Ireland

The current position on e-cigarettes in Ireland is based on advice to the Minister for Health from the Health Information and Quality Authority ('HIQA') in its *Health Technology Assessment of Smoking Cessation Products and Services*²⁴. The Minister for Health requested the health technology assessment based on the recommendation in the national tobacco control strategy *Tobacco Free Ireland*²⁵ to examine the national and international evidence on the effects of the use of nicotine replacement therapy and other interventions that support smokers to quit smoking.

In relation to the safety of e-cigarettes the Health Technology Assessment concluded that this remains an evolving area of research; while potentially safer than smoking, evidence on long-term safety has yet to be established. In relation to e-cigarettes as an aid to smoking cessation HIQA advised the Minister for Health as follows: *Although the currently available results for e-cigarettes are promising, there is insufficient evidence at present to reliably demonstrate their effectiveness as an aid to smoking cessation.*

Although the HIQA assessment was published only in 2017, the evidence on e-cigarettes is rapidly evolving. In that context, in March this year, the Minister for Health asked the Health Research Board to undertake a review and assessment of more recent evidence on e-cigarettes and Heat not Burn products in relation to health harms, effectiveness as an aid to

²² Australian Department of Health on e-cigarettes <https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes>

²³ <https://www.globaltobaccocontrol.org/e-cigarette/brazil>

²⁴ Health Information and Quality Authority (2017) *Health technology assessment (HTA) of smoking cessation interventions* <https://www.hiqa.ie/sites/default/files/2017-04/Smoking%20Cessation%20HTA.pdf>

²⁵ Tobacco Free Ireland. Available at <https://health.gov.ie/wp-content/uploads/2014/03/TobaccoFreeIreland.pdf>

smoking cessation and the existence of a gateway effect i.e. whether use of these products is a gateway to smoking. The evidence review is expected to be completed in March 2020.

Prevalence of e cigarette usage - adults

According to the 2018 Healthy Ireland Survey¹⁴ 4% of the population over 15 currently use e-cigarettes with a further 12% having tried them at some time.

Less than 1% of the population who have never smoked use e-cigarettes whereas 10% of ex-smokers use them and 9% of current smokers. The 2018 survey also found that using e-cigarettes is the second most popular method of quitting smoking with 41% of smokers who successfully quit using e-cigarettes and 42% doing so through willpower alone.

Prevalence of e cigarette usage – children

According to the 2015 *European Schools Project on Alcohol & other Drugs in Ireland* survey²⁶ of almost 1500 students aged 15 or 16 years old, 23% reported having ever used an e-cigarette with 10% reporting using one in the last 30 days. Of the same group 32% reported having ever smoked a cigarette and 13% had smoked a cigarette in the last 30 days.

In addition a 2015 study²⁷ of 821 secondary school students aged 16-17 found that 23.8% of students had tried e-cigarettes and current usage of e-cigarettes was 3.2%. The study found that 4.2% of students who had never smoked had tried e-cigarettes but its overall conclusion was that concurrent or experimental use of e-cigarettes and tobacco is more common than sole use, while only a small number have tried e-cigarettes without having tried tobacco.

²⁶ Available at http://www.tri.ie/uploads/5/2/7/3/52736649/espac_2015_ireland_final.pdf

²⁷ Babineau K, Taylor K, Clancy L(2015) *Electronic Cigarette Use among Irish Youth: A Cross Sectional Study of Prevalence and Associated Factors*. PLoS ONE 10(5):e0126419.doi:10.1371/journal.pone.0126419

Tobacco control policy

Tobacco control policy is framed by the national tobacco control policy, *Tobacco Free Ireland*²¹, and by international considerations such as EU Tobacco Policy²⁸, The World Health Organisation *Framework Convention for Tobacco Control*²⁹ and the fundamental obligation of the State to protect the public health.

Tobacco Free Ireland

Ireland's national tobacco control policy is *Tobacco Free Ireland*, the report of the Tobacco Policy Review Group, which was endorsed by Government, and published in October 2013. It builds on pre-existing tobacco control policies and legislation and sets a policy objective for Ireland to be tobacco free (i.e. with a smoking prevalence rate of less than 5%) by 2025. That policy objective is also one of five key public health interventions highlighted in the current *Programme for a Partnership Government*³⁰.

The two strategies underpinning the over 60 recommendations in *Tobacco Free Ireland* are the protection of children and the denormalisation of smoking.

The protection of children is prioritised because of the vulnerability of children to this lifelong addiction. The data shows that in order to maintain smoking rates the tobacco industry needs to recruit at least 50 new smokers every day and since approximately 80% of smokers start when they are children; most of these new smokers are children. Children and young people smoke because adults inadvertently or otherwise encourage it and children become addicted very quickly, and the earlier they begin to smoke, the harder it becomes for them to quit at a later stage because of the impact that nicotine has on their developing brains.

The denormalisation of tobacco is the second major principle underpinning *Tobacco Free Ireland*. This prioritises denormalising the use of tobacco across society, increasing its social unacceptability and making it less attractive to children and young people. Because one of

²⁸ Available at http://ec.europa.eu/health/tobacco/policy/index_en.htm

²⁹ Available at <https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=929AE905B032D53F536119DEDD187E31?sequence=1>

³⁰ Programme for Partnership Government. Available at https://www.merrionstreet.ie/MerrionStreet/en/ImageLibrary/Programme_for_Partnership_Government.pdf

every two children that smoke a cigarette will become a smoker³¹ denormalisation is important in preventing children from wishing to try cigarettes and therefore from half of those children becoming smokers.

The recommendations in *Tobacco Free Ireland* that are relevant to this general scheme are the following:

- Develop a licensing system for retailers who sell tobacco products.
- Prohibit sales of tobacco in mobile units/containers.
- Prohibit the sale of tobacco at events/locations primarily intended for those persons under 18 years.
- Prohibit the sale of tobacco products by those under 18 years.
- Prohibit the operation of all self-service vending machines.
- Introduce a minimum suspension period for retailers convicted of an offence.
- Introduce fixed penalty notices (on the spot fines) for offences.
- Introduce legislation for the publication of information in respect of any person on whom a fine, other penalty or conviction was imposed by a Court ('name and shame').

Irish Tobacco control law

Tobacco control measures under the Public Health (Tobacco) Acts Public Health 2002-2017 include the following:

- Work-place smoking ban (2004)
- Ban on the advertising of tobacco products in accordance with Directive 2003/33/EC (2004)
- A ban on packets containing less than 20 cigarettes (2007)
- A ban on the sale of confectionaries that resemble cigarettes (2007)
- A ban on the point of sale display and point of sale advertising of tobacco products (2009)

³¹ DiFranza et al, *The Natural History and Diagnosis of Nicotine Addiction. Current Periodic Reviews*, 2011,7, 88-96 Available at https://www.researchgate.net/profile/Jonathan_Winickoff/publication/233499414_The_Natural_History_and_Diagnosis_of_Nicotine_Addiction/links/0deec52b855e3e328b000000/The-Natural-History-and-Diagnosis-of-Nicotine-Addiction.pdf

- A requirement for all tobacco products to be stored within a closed container which can only be accessed by the retailer (2009)
- A requirement for all retailers who wish to sell tobacco products to register with the National Tobacco Control Office (2009)
- A prohibition on self-service vending machines except in licensed premises or in registered clubs (2009)
- Combined text and photo warnings (graphic warnings) (2013)
- A ban on smoking in cars when children are present (2016)
- Standardised Packaging of Tobacco Products (2017)

EU Tobacco Products Directive

At EU level, Directive 2014/40/EU³², the Tobacco Products Directive, is the major law on tobacco products and nicotine inhaling products. The Directive highlights that tobacco products are not ordinary commodities and in view of their particularly harmful effects, health protection should be given high importance, in particular, to reduce smoking prevalence among the young.

The Directive was brought into Irish law by S.I. No. 271/2016 - European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016³³.

Under the Regulations, health warnings which advise consumers that e-cigarettes contain nicotine which is a highly addictive substance are mandatory. The Regulations also provide for mandatory safety and quality requirements for e-cigarettes and refill containers, including maximum nicotine concentrations for e-cigarettes containing nicotine, and maximum volumes for cartridges, tanks and nicotine liquid containers.

The Regulations require e-cigarette manufacturers or importers to notify the Health Service Executive of all products that they place on the market and, if a manufacturer, importer or

³² Available at https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf

³³ Available at <http://www.irishstatutebook.ie/eli/2016/si/271>

distributor has a reason to believe that a product is not safe, they are required to immediately notify the Health Service Executive and to explain what corrective action has been taken.

In relation to advertising, the Regulations prohibit advertisements for e-cigarettes online and in printed publications except for those directed at persons in the e-cigarette industry or publications printed and published outside the EU and intended for markets outside the EU. In addition, advertisements for e-cigarettes are prohibited on television and on radio. Finally, any form of contribution to an event, activity or person with the aim of promoting e-cigarettes and with a cross-border effect is also prohibited

The Directive harmonises the legislation in EU Member States for many issues relating to e-cigarettes and related products but it does not introduce an age limit for their sale. However, it outlines that Member States are free to regulate such matters within their own jurisdiction and are encouraged to do so.

Traceability and Security Features Systems

In addition to the above, the Tobacco Products Directive provided for the establishment of a traceability and a security features system for all unit packets of tobacco products manufactured in or imported into the European Union. The aim of the two systems is to fight the illicit trade in tobacco products which undermines the free circulation of compliant products and the overall protection provided by tobacco control legislation. The systems are designed to reduce the circulation of tobacco products that are not compliant with tobacco control legislation and to reduce the circulation of artificially cheap supplies of illegal tobacco products that affect the uptake and general prevalence of smoking. A reduction in the availability of “black market” tobacco products will contribute to improving the public health, protecting revenue to the Exchequer and ensuring that there is a level playing field for those businesses that comply with law.

Articles 15 and 16 of the Tobacco Products Directive provide for the two systems and the detail of their operation is set out in two Implementing Acts from the European Commission: Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products (‘the Regulation’) and Decision

(EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products ('the Decision') determine the technical details and key elements of the systems and ensure aspects such as the systems' interoperability.

The Regulation and the Decision were adopted by the EU Commission in December 2017 and apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

1. Traceability system.

Under the traceability system (Article 15 TPD and the Regulation):

- All unit packets of tobacco products (e.g. a box of cigarettes) produced in, destined for, or placed on the EU market will display a unique identifier. The identifier will be an alpha-numeric code with predefined information including the location and date of manufacture of the product.
- The movement of each unit pack will be recorded throughout the supply chain from the manufacturer to the last level before the first retail outlet.
- Information on recorded movements will be stored by independent data storage providers and the data will be made accessible to the relevant authorities in Member States and the Commission for enforcement purposes.

The overall purpose of the system is to enable the movement of legal tobacco products to be monitored (tracking) and to allow the relevant authorities to determine at which point a product was diverted into the illicit market, or vice versa (tracing).

2. Security Features system

Under the security features system (Article 16 TPD and the Decision):

- Unit packets of tobacco products placed on the EU market will be marked with a tamper-proof security feature composed of visible and invisible elements to enable consumers and relevant authorities to determine if the product is genuine or illicit.

Article 16 and the Decision provide that Member States may use their tax stamp as the security feature as long as it meets the technical requirements. The Office of the Revenue Commissioners was designated as the competent authority for the traceability and security features system in 2018³⁴ and has designated the Irish tax stamp as the security feature for tax-paid tobacco products.

WHO Framework Convention on Tobacco Control

The WHO *Framework Convention on Tobacco Control*²³ ('FCTC') is a legally binding evidence-based treaty that was ratified by Ireland in November 2005. The FCTC was developed by the World Health Organisation in response to what it calls the tobacco epidemic. The treaty provides for a multi-faceted response to address the variety of complex factors which facilitate this epidemic. Parties to the FCTC are required to comply with the Articles of the Treaty and the World Health Organisation provides Implementation Guidelines in relation to certain Articles³⁵ to facilitate that compliance.

In November 2012 the World Health Organisation adopted a Protocol to the FCTC called the *Protocol to Eliminate Illicit Trade in Tobacco Products*³⁶. Ireland signed the Protocol in 20 December 2013 but has not yet ratified it. The Articles of the treaty and the Protocol which deal with the issues under consideration in this general scheme are the following:

Treaty

- Article 13 Tobacco advertising, promotion and sponsorship.

³⁴ European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) (No. 3) Regulations 2018. Available at <http://www.irishstatutebook.ie/eli/2018/si/504/made/en/pdf>

³⁵ http://www.who.int/fctc/treaty_instruments/adopted/guidel_2011/en/

³⁶ The Protocol is available here: https://apps.who.int/iris/bitstream/handle/10665/80873/9789241505246_eng.pdf;jsessionid=171535FB364998FEF1E7139201FBEB67?sequence=1

Article 13 of the FCTC requires each Party to the treaty undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. The guidance on the implementation of Article 13 clarifies that: *Vending machines should be banned because they constitute by their very presence a means of advertising or promotion under the terms of the Convention*³⁷.

- Article 15 Illicit trade in tobacco products.

Article 15.7 requires each Party to the treaty to endeavour to adopt measures including licensing where appropriate in order to prevent illicit trade.

- Article 16 Sales to and by minors.

Article 16.1 and 16.7 also calls for Parties to the FCTC to prohibit the sale of tobacco products to, and by persons under the age set by domestic law, national law or eighteen. In addition Article 16.1(d) requires Parties to ensure that tobacco vending machines are not accessible to minors and do not promote the sale of tobacco products to minors.

Protocol

- Article 6 Licence, equivalent approval or control system.

Article 6.2 requires that Parties shall endeavour to license, to the extent considered appropriate, and when the following activities are not prohibited by national law, any natural or legal person engaged in retailing of tobacco products;

³⁷https://apps.who.int/iris/bitstream/handle/10665/80510/9789241505185_eng.pdf;jsessionid=EA6F9E65D7076D052B6021A0FABEF203?sequence=1

The Future

Much progress has been made in reducing smoking prevalence. In 2007 29% of the population smoked – now it is 20%. The proportion of schoolchildren who smoke dropped from 23% in 1998 to 8% in 2014. However this progress is not enough as the target is less than 5% of the population and it appears that the tobacco industry is continuing to evolve its product in order to survive. In the most recent report on the health consequences of smoking from the US Surgeon General³⁸, it was recognised that the decline in smoking rates being experienced will not be sufficiently rapid without additional action if we are to avoid the burden of preventable disease and premature death that is currently experienced. This report also evidenced that cigarettes today pose an even greater risk of disease than the cigarettes sold when the first Surgeon General’s report was issued in 1964 and concludes that “the evidence is sufficient to infer that the relative risk of dying from cigarette smoking has increased over the last 50 years in men and women...”.

In a 2014 report from the Campaign for Tobacco-Free Kids³⁹, detailed evidence is provided as to how the tobacco industry has used the last 50 years to make cigarettes more dangerous, more addictive and more appealing to young people and other non-smokers. The report states *they took a bad product and made it worse with design changes and ingredients that:*

- *increased the risk of disease to cigarette smokers;*
- *made it easier to become addicted and harder to quit; and*
- *made cigarettes more appealing to youth, women and other populations.”*

These findings underscore the need for countries to continue to act to counter these developments in order to protect public health from what continues to be the greatest threat to it in Ireland.

³⁸ The Health Consequences of Smoking- 50 years of progress: A Report of the Surgeon General 2014 is available at: <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/>

³⁹ Campaign for Tobacco-Free Kids Report “Designed for addiction”, June 2014 is available at: https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/product_manipulation/2014_06_19_DesignedforAddiction_web.pdf

Objectives of the proposed legislation

The objective of the proposed legislation is to contribute to achieving a Tobacco Free Ireland by 2025 with particular emphasis on the protection of children and the denormalisation of smoking through:

- introducing a licensing system for the sale of (a) tobacco products and (b) nicotine inhaling products to include an annual fee per premises for the sale of such, in such an amount as may be determined by the Minister.
- prohibiting the sale of tobacco products from self-service vending machines.
- prohibiting the sale of tobacco products from mobile units/containers.
- prohibiting the sale of tobacco products and nicotine inhaling products by those under 18 years.
- prohibiting the sale of nicotine inhaling products to persons under 18 years (the sale of tobacco products to persons under 18 years is already prohibited under the Public Health (Tobacco) Acts 2002-2017).
- prohibiting the sale of tobacco products at events/locations primarily intended for those persons under 18 years.
- introducing minimum suspension periods for tobacco retailers convicted of offences.
- introducing fixed penalty notices (on the spot fines) for offences.
- providing for the publication of information in respect of any person on whom a fine, other penalty or conviction is imposed by a court ('name and shame').

3. Identification and Description of Options

Option 1: Do nothing.

Tobacco use remains the leading preventable cause of ill-health, disability and premature mortality in Ireland. *Tobacco Free Ireland* has set a target to reduce smoking levels to less than 5% of the population by 2025. Currently one in five of the Irish population over the age of 15 smokes and the evidence shows that one out of every two of those smokers will die because of their smoking.

Tobacco smoking is implicated in many conditions including more than eight out of ten of lung cancers⁴⁰ and according to the World Health Organisation it is estimated that 14% of Alzheimer's Disease cases worldwide are potentially attributable to smoking⁴¹. To do nothing would represent a failure to address this threat to the public health.

Option 2: Information and education campaigns

The QUIT campaigns from the Health Service Executive's *Tobacco Free Ireland Programme* already deliver high quality information and education on tobacco control and these run on television, radio and social media.

To use the approach of information and education on its own is not preferred as it is generally accepted that the complexity of tobacco use means that a multifaceted response to the problem is necessary and that education or awareness alone is insufficient.

The World Health Organisation's MPOWER policy package recommends six evidenced based policy actions necessary to address tobacco use as follows:

- Monitor tobacco use and prevention policies,
- Protect people from tobacco smoke,
- Offer help to quit tobacco use,
- Warn about the dangers of tobacco,
- Enforce bans on tobacco advertising, promotion and sponsorship, and
- Raise taxes on tobacco.

The WHO FCTC treaty also addresses the tobacco epidemic from multiple perspectives with measures relating to the reduction of demand for tobacco including price and tax measures, protection from exposure to tobacco smoke, regulation of packaging and labelling of tobacco

⁴⁰ Irish Cancer Society <https://www.cancer.ie/reduce-your-risk/lung-cancer-awareness/lung-cancer-prevention#sthash.lvwAboah.dpbs>

⁴¹ World Health Organisation (2014) *Tobacco & Dementia*. Available at https://apps.who.int/iris/bitstream/handle/10665/128041/WHO_NMH_PND_CIC_TKS_14.1_eng.pdf?sequence=1

products, education, communication, training and public awareness, tobacco advertising, promotion and sponsorship, supply of tobacco such as illicit trade and sales to and by minors.

In view of the complexity of the tobacco epidemic, education or information campaigns are not considered sufficient to achieve the objectives and are not the preferred option.

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 *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 be in breach of its obligations. For this reason this option is not preferred.

Option 4: Legislate to further control tobacco products and nicotine inhaling products.

This is the preferred option to address the continuing disease and death caused in Ireland by tobacco use.

4. Analysis of Costs, Benefits and Impacts of Options

Option 1: Do nothing

Costs

None

Benefits

None

Impacts

No obvious impacts for the following: *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 impacts, the rights of citizens, compliance burdens, including administrative burdens and North-South and East-West Relations.*

Option 2: Information and education campaigns

Costs

The cost of an advertising campaign would be dependent on the type of media used and the number and duration of campaigns. However any campaign would include production costs, purchase of airtime or publication space and administrative costs associated with the procurement process to select a provider and ongoing management of the campaign.

Benefits

No obvious benefits in view of the existence of the high quality QUIT campaigns that are already being run by the HSE Tobacco Free Ireland programme and the multi-faceted approach that is required to tackle the problem.

Impacts

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

Costs

Initial costs are likely and would depend on the type of oversight structure chosen.

Benefits

None.

Impacts

Ireland has built a strong international reputation as a leader in tobacco control particularly as it was the first country in the world to ban smoking in the workplace in 2004. A breach of the FCTC treaty would cause severe reputational damage to Ireland's standing and undermine the hard fought progress made against the biggest public health threat facing the population.

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 impacts, the rights of citizens, compliance burdens, including administrative burdens and North-South and East-West Relations.*

Option 4: Legislate to further control tobacco products and nicotine inhaling products.

Costs

There are likely to be initial costs for the Environmental Health Service to develop its current IT system to provide for the proposed licensing system. The costs involved will become clearer as the legislation is being drafted and the necessary functionality that will be required for the proposed system is finalised.

Benefits

The proposed annual licence fee will represent a benefit to the Exchequer.

The measures are designed to prevent the initiation of tobacco and nicotine inhaling products use by children and to continue to reduce the number of smokers in Ireland. As tobacco use currently costs the Exchequer an estimated €10.6 billion per annum any measures to reduce the number of smokers and this cost will, if successful, reduce this cost and benefit the Exchequer accordingly.

Impacts

The primary intended impact is a reduction in the number of smokers in Ireland and therefore in the health harms associated with smoking. The proposals are designed to deliver on the strategies underlying *Tobacco Free Ireland*: the protection of children and the

denormalisation of smoking.

Although Ireland's smoking rates are steadily decreasing there are observable trends that certain cohorts of the population are more affected by tobacco use than others.

According to the 2018 Healthy Ireland survey¹⁴ smoking prevalence in Ireland is highest in the 25-34 year old age group at 28% - this is 8% higher than the overall national average. This is a concern as this age group have grown up in an era when the health harms of smoking are well known but this clearly this information did not prevent the initiation of tobacco use. It is an indication that more needs to be done to prevent the initiation of this deadly addiction and to ensure that smoking rates continue to decline and the progress made is not lost. The focus on the protection of children and denormalisation in the proposed legislation is designed to address this trend for future generations.

The socially excluded and vulnerable groups

The proposals are designed to positively impact on the socially excluded and vulnerable groups as it is these groups that carry the highest burden of tobacco related disease. According to the 2018 Healthy Ireland survey smoking rates are 10% higher (at 26%) in disadvantaged areas in Ireland than in more affluent areas.

The environment

If the measures are effective, the reduction in the number of cigarettes smoked will reduce litter and litter costs from smoking and positively impact on the environment. According to the Department of Communications, Climate Action and Environment, cigarette related litter (54.4%) continues to constitute the highest percentage of litter in the locations surveyed – this is comprised mainly of cigarette ends which constitute 51.1% of all litter items nationally and cigarette related litter, and more specifically cigarette ends, continues to be the greatest component of litter nationally.⁴²

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

⁴² The Litter Monitoring Body (2019) *National Litter Pollution Monitoring System: System Results 2018* Available at <https://www.dccae.gov.ie/documents/NLPMS%20Report%202018.pdf>

The proposals include the introduction of a prohibition on the sale of:

- nicotine inhaling products to those under 18
- tobacco products from self-service vending machines.
- tobacco products from mobile units/containers.
- tobacco products at events/locations primarily intended for those persons under 18 years.

The places at which consumers can buy tobacco products will be reduced which will reduce consumer choice. However nicotine is a highly addictive drug and in Ireland the majority of smokers here (57%) do not want to smoke and 24% of those who tried to quit in 2018 had recommenced smoking within one week¹⁴. In this context the reduction in the number of places where tobacco products can be bought could prove of assistance to those trying to quit smoking as well as contribute to the denormalisation of smoking and to preventing children starting to smoke and becoming addicted to a product that for 50% of its users will be the cause of their death.

Consumers under 18 will no longer be able to purchase nicotine inhaling products if the proposed prohibition is introduced. This is clearly a reduction in consumer choice but it is proposed in order to ensure that children cannot purchase a product which allows them to inhale nicotine which according to the World Health Organisation has long-term consequences for adolescent brain development¹⁸.

The rights of citizens

The overall purpose of the provisions is to protect citizens' right to health.

Compliance burdens, including administrative burdens

The proposed licensing system will increase the administrative burden on retailers who wish to sell tobacco products and nicotine inhaling products as there will be a requirement to renew the licence each year and to pay a fee. The purpose of the licensing system is to modernise the current register system which was established in 2004 to better reflect the seriousness of the product being sold and to ensure that the information available to the

Environmental Health Service in carrying out its enforcement activities is comprehensive and accurate.

No obvious impacts on *national competitiveness* or *North-South and East-West Relations*

5 Consultation

In order to inform the Regulatory Impact Analysis and the drafting of this General Scheme a comprehensive consultation exercise was carried out by the Department of Health during December 2014 and January 2015⁴³. Following the consultation the Institute of Public Health in Ireland was engaged to develop a consultation report.

Key findings of the report are outlined below:

- There were some similarities but also notable differences in the issues that arose in the context of the sale of tobacco products and the sale of nicotine inhaling products. The two products should be clearly delineated in the final wording of the legislation and in monitoring the impact of the legislation.
- The safety and quality of nicotine inhaling products was highlighted as a significant concern across most respondent categories. There were varying views on the value of nicotine inhaling products as contributors to tobacco harm reduction and to smoking cessation.
- Health organisations were strongly in support of the proposed measures as a means to reduce young people's ease of access to tobacco and to denormalise smoking.
- Among those with a direct or indirect commercial interest in the sale of tobacco products, concerns were raised in terms of potential trade impact and illicit trade.
- Prohibiting employees under 18 years of age from selling tobacco products or nicotine inhaling products was seen as important in protecting them from peer-pressure to sell to

⁴³ <https://www.gov.ie/en/news/cobe90-public-consultation-on-legislation-in-relation-to-the-sale-of-tobacc/>

other persons under 18 years of age but concerns were raised that it could limit the employability of young people.

- The retail sector proposed that the licence fee be proportionate to the number of operating outlets or volume of sales. The retail sector also proposed that sanctions in respect of fines and publication of information on breaches of licence conditions be proportionate to the gravity of the offence.

6 Enforcement, compliance and review

The provisions will be enforced by the Environmental Health Service which already enforces the Public Health (Tobacco) Acts 2002-2015 and related EU legislation. It is not proposed to insert any specific review provisions.

1(i) Licensing system for the retail sale of tobacco products and nicotine inhaling products.

Part 2 Heads 8-15

Licensing system for the retail of tobacco products and nicotine inhaling products

What are the policy objectives being pursued?

The establishment of a fit for purpose licensing system for retailers of tobacco products as required by the national tobacco control policy, *Tobacco Free Ireland*, and the World Health Organisation Framework Convention on Tobacco Control Treaty and Protocol and the establishment of a similar system for the sale of nicotine inhaling products in order to regulate their sale.

What policy options have been considered?

1. Do nothing
2. Legislate for the licensing of the retail sale of tobacco products and nicotine inhaling products

Preferred Option

The preferred option is to legislate for a licensing system.

POLICY OPTIONS

| | COSTS | BENEFITS | IMPACTS |
|------------------------|---------------------------------|-----------------------------------|-------------------------------------|
| Policy Option 1 | Costs to Exchequer None. | Benefits to Exchequer None | Impact on public health None |

| | | | |
|---------------|---|--|---|
| Policy Option | <p>Costs to Exchequer</p> <p>There are likely to be costs to the Exchequer for the development of the IT system required for the proposed licensing system.</p> | <p>Benefits to Exchequer</p> <p>The proposed annual licence fees will benefit the Exchequer.</p> | <p>Impact on public health</p> <p>The introduction of a licensing system will facilitate the enforcement of tobacco control law and law on nicotine inhaling products and is ultimately designed to reduce the number of smokers.</p> |
|---------------|---|--|---|

Description of Policy context and objectives

The relevant recommendation in *Tobacco Free Ireland* is to develop a licensing system for retailers who sell tobacco products. In addition Article 15.7 of the WHO FCTC requires each Party to the treaty to endeavour to adopt measures including licensing where appropriate in order to prevent illicit trade and Article 6.2 of the Protocol requires that Parties shall endeavour to license, to the extent considered appropriate, any natural or legal person engaged in retailing of tobacco products.

There is currently a registration system in place for the sale of tobacco products. Under section 37 of the Public Health (Tobacco) Act 2002 (as amended), a retailer must register with the Environmental Health Service and pay a once-off fee of €50. Once registered, the retailer can sell in any number of retail outlets for any number of years without a necessity to register again. In addition there are few requirements on who can register to sell tobacco products, e.g. no age minimum age limit, no necessity to show tax compliance or to show compliance with tobacco control law. Under the current system the Environmental Health Service has no power to refuse an application.

The proposed new licensing system for tobacco products and nicotine inhaling products will require that a licence will be required for each outlet where tobacco is sold, that there must be annual renewal of a licence and that a licence can be refused by the competent authority. In addition an annual fee will be charged and the level of that fee will be determined by the Minister for Health.

The overriding rationale for introducing a licensing system is to facilitate the enforcement of key tobacco control measures such as the prohibition on sales to minors or on advertising at the point of sale. The new system will provide the regulatory authority with up to date information on where tobacco is sold and will thus facilitate the monitoring and enforcement of the relevant legislation.

The proposed system will better reflect the very harmful nature of product being sold and bring it more into line with licensing regimes for the retail of other potentially harmful products such as alcohol, firearms/ammunition and petroleum. Currently there is an annual fee of €500 per category of alcohol product to be sold and it is considered that the fee to sell tobacco products should be equivalent so as to represent the seriousness of the product being sold.

The proposed licensing system will also cover nicotine inhaling products. The sale of nicotine inhaling products is being licensed as nicotine is an addictive drug. The licensing system will facilitate the monitoring and enforcement of current law on e-cigarettes and the proposed prohibition on the sale of such products to and by persons under 18.

It is proposed that there be one license to sell all tobacco products and nicotine inhaling products and one (at a lesser cost) to sell nicotine inhaling products and Heat Not Burn tobacco products . This will avoid the administrative burden that would arise if those who wish to sell both types of products had to apply for two separate licences.

Identification and Description of Options

Option 1: Do nothing.

To do nothing will mean that the current system of once off registration for multiple outlets will continue and the Environmental Health Service will not have access to up to date and comprehensive information on where tobacco products are sold. In addition it will mean that the sale of nicotine inhaling products will remain unlicensed and there will be no information on the sellers of such products for enforcing compliance with the current law.

Option 2: Introduce a licensing system for tobacco products and nicotine inhaling products.

The introduction of a licensing system will facilitate the enforcement of tobacco control law and law on nicotine inhaling products. It will also align the licensing system for tobacco and nicotine inhaling products with licensing for like products to reflect the serious nature of the products being sold. In addition it will require applicants to provide information to show that they are a fit and proper person to engage in such sales and allow the Environmental Health Service to refuse a licence if this proves not to be the case.

Analysis of Costs, Benefits and Impacts of Options

Option 1: Do nothing

Costs to Exchequer

No costs to the Exchequer.

Benefits to Exchequer

No benefits to the Exchequer.

Impacts

The current once-off registration system will continue for tobacco products meaning that the Environmental Health Service will continue without up to date information on tobacco retailers for the purposes of enforcement and without the ability to refuse an application to sell tobacco products. The sale of nicotine inhaling products will continue unlicensed which will mean that the Environmental Health Service will continue to enforce the law applicable to these products with a database of information on the identity or location of retailers.

No obvious impacts for the following: *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 impacts, the rights of citizens, compliance burdens, including administrative burdens and North-South and East-West Relations.*

Option 2 Legislate for the licensing of the retail sale of tobacco products and nicotine inhaling products

Costs to Exchequer

There will be costs associated with the upgrading of the IT system of the Environmental Health Service from its current once-off registration system only to accommodate an annual licensing system for both tobacco products and nicotine inhaling products.

Benefits to Exchequer

There will be an increase in revenue to the Exchequer as the current once-off tobacco products registration fee of €50 for any number of retail outlets is replaced by a fee per outlet per year and as there will now be a similar licence fee for the sale of nicotine inhaling products.

Impacts

An increase in the fee to sell tobacco products may act as a disincentive to stock tobacco as occurred in South Australia in 2007 when the fee to sell tobacco products increased from Aus\$12.90 to Aus\$200 dollars per annum⁴⁴. Of the 1144 entertainment licensees holding valid licences in December 2007, 30.9% no longer held a licence by December 2009, and 19.9% had reduced the number of points of sale within the same venue. There is evidence to show that the density of retail outlets selling tobacco products is associated with youth smoking^{45 46 47 48} and is a risk factor for relapse by smokers who have quit^{49 50} therefore a reduction in the number of outlets may contribute to the protection of children and the denormalisation of smoking.

⁴⁴ Bowden JA, Dono J, John DL, et al, *What happens when the price of a tobacco retailer licence increases?* Tobacco Control 2014;23:178-180.

⁴⁵ Lipperman-Kreda S1, Grube JW, Friend KB., *Local tobacco policy and tobacco outlet density: associations with youth smoking.* J Adolesc Health. 2012 Jun; 50(6): 547–552.

⁴⁶ Novak SP, Reardon SF, Raudenbush SW, Buka SL. *Retail tobacco outlet density and youth cigarette smoking: a propensity-modeling approach.* Am J Public Health. 2006 Apr;96(4):670-6. Epub 2006 Feb 28.

⁴⁷ Chan, Wing C. and Leatherdale, Scott T., *Tobacco retailer density surrounding schools and youth smoking behaviour: a multi-level analysis.* Tobacco Induced Diseases 2011, 9:9

⁴⁸ Shortt NK, Tisch C, Pearce J, et al, *The density of tobacco retailers in home and school environments and relationship with adolescent smoking behaviours in Scotland.* Tobacco Control 2016; 25:75-82.

⁴⁹ Halonen JI1, Kivimäki M, Kouvonon A, Pentti J, Kawachi I, Subramanian SV, Vahtera J. *Proximity to a tobacco store and smoking cessation: a cohort study.* Tob Control. 2014 Mar;23(2):146-51.

⁵⁰ Reitzel LR, Cromley EK, Li Y, et al. *The effect of tobacco outlet density and proximity on smoking cessation.* Am J Public Health. 2011;101(2):315–320.

Compliance burdens, including administrative burdens

There will be an increase in administrative burdens for retailers who will be required to purchase and then renew an annual licence. In view of the very harmful public health impacts of the products being sold this burden is considered proportionate as it will reflect the seriousness of the products being sold and ensure that the Environmental Health Service have comprehensive and up-to-date information on retailers around the country.

The rights of citizens and the socially excluded and vulnerable groups

The provisions are designed to ensure that the Environmental Health Service has an up to date and comprehensive database of information on the retailers of tobacco products and nicotine inhaling products for enforcement purposes. Ensuring efficient enforcement of the relevant law, particularly as it relates to the sale of such products to those under 18, is expected to reduce the likelihood of young persons becoming addicted to nicotine and on that basis protect the right to health of citizens and reduce the burden of tobacco related disease on the socially excluded and vulnerable groups who proportionally carry the greatest burden.

No obvious impacts in relation to: *Whether there is a significant policy change in an economic market, including consumer and competition impacts, National competitiveness, The environment or North-South and East-West Relations*

Consultation

Responses to the consultation expressed concern that an increase in the fee to sell tobacco products would lead to increased prices and therefore an increase in illicit trade in tobacco products as consumers may seek cheaper alternatives.

The traceability system and security features systems under the Tobacco Products Directive which applies to cigarettes and roll-your-own tobacco from 20 May 2019 and is enforced by the Revenue Commissioners is designed to address illicit trade and to reduce such risks.

Enforcement, compliance and review

The licensing system will be enforced by the Environmental Health Service.

1(ii) Restrictions on the sale of tobacco and nicotine inhaling products

Part 3 Heads 16-21 and Part 6 Head 35

Restrictions on the sale of tobacco products and nicotine inhaling products

What are the policy objectives being pursued?

The primary policy objective for Ireland to be tobacco free (i.e. with a smoking prevalence rate of less than 5%) by 2025 with particular focus on the protection of children and the denormalisation of smoking. The proposed restrictions are designed to reduce children's exposure to and access to tobacco products and to further denormalise tobacco products by restricting the places from which they can be sold.

The national tobacco control policy, *Tobacco Free Ireland*, contains the following recommendations which are being provided for in the proposals:

- Prohibit sales of tobacco in mobile units/containers.
- Prohibit the sale of tobacco at events/locations primarily intended for those persons under 18 years.
- Prohibit the sale of tobacco products by those under 18 years.
- Prohibit the operation of all self-service vending machines.

What policy options have been considered?

1. Do Nothing
2. Legislate for further restrictions on the sale of tobacco and nicotine inhaling products

Preferred Option

To do nothing would allow the current disease and death associated with smoking in Ireland to continue unaddressed therefore the preferred option is to legislate.

| POLICY OPTIONS | | | |
|------------------------|---------------------------------|------------------------------------|---|
| | COSTS | BENEFITS | IMPACTS |
| Policy Option 1 | Costs to Exchequer None. | Benefits to Exchequer None | Impact on public health None |
| Policy Option 2 | Costs to Exchequer None. | Benefits to Exchequer None. | Impact on public health The protection of children and the denormalisation of smoking will reduce the tobacco related disease and death. |

Description of Policy context and objectives

Ireland’s current smoking rate is at 20% and the target set in the national tobacco control policy, *Tobacco Free Ireland*, is to become tobacco free i.e. with a smoking rate of less than 5% by 2025. At international level public health experts now speak of tobacco control in terms of the “tobacco endgame” i.e. how to eliminate smoking completely and therefore eliminate the death and disease that go along with it.

Although much has been achieved in terms of reducing the number of smokers in Ireland, the Health Service Executive has estimated that at current rates of reduction, Ireland will not become tobacco free until 2052⁸. There is an urgency to try to reach the proposed target as each year that Ireland is not tobacco free is another year in which Ireland will gain new smokers, the majority of which will be children, and the toll of disease and death from this highly addictive and lethal consumer product will continue.

The over 60 recommendations in *Tobacco Free Ireland* are all underpinned by the principles of the protection of children and the denormalisation of smoking. The proposed restrictions on the sale of tobacco products in this Part are directly related to these two principles.

Identification and Description of Options

Option 1: Do nothing.

No further restrictions on the sale of tobacco products and nicotine inhaling products would be introduced and therefore no additional progress will be made toward denormalisation and the protection of children.

Option 2: Legislate for further restrictions on the sale of tobacco and nicotine inhaling products.

Head 16 prohibits the sale of tobacco products from temporary or movable premises e.g. vehicles such as vans or temporary units such as kiosks, stalls or marquees at festivals or markets. *Tobacco Free Ireland* contains a recommendation to prohibit sales of tobacco from mobile units/containers and this recommendation was endorsed in the Report of the Joint Committee on Health and Children on the General Scheme of the Public Health (Standardised Packaging of Tobacco) Bill 2013.

The purpose of this prohibition is to assist in the denormalisation of tobacco products by excluding their sale from certain events or locations especially those which are frequented by young people. The prohibition will ensure that the sale of tobacco products is not associated with music festivals or similar events which will contribute to reducing their appeal to children and young people. In addition the prohibition of sale from temporary premises will mean that tobacco products can no longer be sold from places that are difficult to monitor for compliance with law owing to their temporary nature.

Head 18 prohibits the sale of tobacco products and nicotine inhaling products by persons under 18 except for close relatives of the licensee. Prohibiting the sale of tobacco products by those under 18 is a recommendation of *Tobacco Free Ireland*. This exemption for relatives of

the licensee is modelled on section 38 of the Intoxicating Liquor Act 1988. The licensee of the retail outlet is liable for the offence rather than the person under 18 that undertook the sale according to this Head.

This provision is designed to reduce the exposure of young retail workers to tobacco and nicotine inhaling products. It will also serve to highlight the serious and addictive nature of the products through providing that only an adult may sell them. Finally, it is designed to reduce instances of peer pressure on minors to sell to other minors and so will serve to protect the seller and the buyer.

Head 19 prohibits the sale of nicotine inhaling products to persons under 18. The current governing law on nicotine inhaling products is the EU Tobacco Products Directive. The Directive does not introduce an age limit for their sale but paragraph 48 of the Preamble to the Directive sets out that Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so²⁹.

The World Health Organisation has recommended since July 2014 that sales of e-cigarettes to minors be prohibited¹⁸ as there is sufficient evidence of the potential for adolescent nicotine exposure to have long-term consequences for brain development and also to prevent minors becoming exposed to nicotine with the risk that this may act as a gateway to the use of tobacco products.

Head 21 proposes to prohibit the sale of tobacco products at events or places intended for children. *Tobacco Free Ireland* sets out that children and young people smoke because adults inadvertently or otherwise encourage it. The purpose of this provision is to ensure that children can attend events and places intended for them without being exposed to the sale of cigarettes.

Head 35 amends section 43 of the Public Health (Tobacco) Act 2002. Section 43 prohibits the sale of tobacco products by means of self-service but provides an exemption for vending machines in licensed premises and registered clubs. This exemption is removed by Head 35 and therefore the effect of the Head is to prohibit self-service vending machines entirely.

The *Tobacco Free Ireland* policy contains a recommendation to prohibit the operation of all self-service vending machines. 60% of all Parties to the World Health Organisation FCTC Treaty have prohibited tobacco sales from self-service vending machines⁵¹ and their use has been banned in England since 2011, Wales and Northern Ireland since 2012 and Scotland since 2013⁵².

There is strong support from the public in Ireland for prohibiting sales of tobacco products from vending machines. A 2012 Eurobarometer survey found that support for the banning of sales of tobacco products through vending machines was second highest in Ireland (73%) with only Cyprus being ahead (79%) among all EU countries (the EU average was 54%)¹⁷.

Currently self-service vending machines in Ireland are regulated under section 43 of the Public Health (Tobacco) Act 2002 and the Public Health (Tobacco) (Self Service Vending Machines) Regulations 2009. The machines are restricted to licensed premises and registered clubs and must be operated with either a disc or card obtained from a member of staff or by a device controlled by a member of staff. In addition the machine must be within the line of sight of a staff member at all times.

According to the *State of Tobacco Control Report*⁸ there are currently 7,690 premises with self-service vending machines⁵³ as compared with 13,195 counter sales outlets.

The proposal to ban self-service vending machines is for the protection of children and to contribute to the denormalisation of tobacco use.

In relation to the protection of children there is evidence that despite the regulations on self-service vending machines on the use of discs or cards obtained from staff and the necessity for oversight by staff, self-service vending machines have consistently proven to be more accessible to minors than over the counter sales.

⁵¹ https://www.who.int/fctc/reporting/WHO-FCTC-2018_global_progress_report.pdf

⁵² <https://researchbriefings.files.parliament.uk/documents/SN05536/SN05536.pdf>

⁵³ A more recent figure has been received by email to the Department of Health from the National Tobacco Control Operational Unit of the Environmental Health Service of 23 September 2019. Vendors registered on the NRTR (National Register of Tobacco Retailers): 126 and Vending Machine Premises registered on NRTR: 8122

Data from the Environmental Health Service’s enforcement test purchase programme from 2014 to 2018 is set out below. In an enforcement test purchase, a minor is asked to purchase cigarettes on behalf of the Environmental Health Service in order to test whether he or she will be prevented in accordance with the law. The percentage of enforcement test purchases which resulted in a volunteer minor being able to successfully purchase cigarettes despite being underage over the counter and from a self-service vending machine are highlighted in yellow. The highlighted percentages show that over the last 5 years the proportion of successful purchases from self-service vending machines has consistently been much higher than the proportion of successful purchases over the counter.

| | | Counter | Counter Sales expressed as % of Total Counter TTP | Vending | Vending Machine Sales expressed as % of Total Vending Machine TTP | Total |
|-------------|-----------------------|----------------|--|----------------|--|--------------|
| 2014 | Satisfactory | 341 | 81.58% | 37 | 57.81% | 378 |
| | Unsatisfactory | 77 | 18.42% | 27 | 42.19% | 104 |
| | | 418 | | 64 | | 482 |
| 2015 | Satisfactory | 443 | 83.90% | 17 | 70.83% | 460 |
| | Unsatisfactory | 85 | 16.10% | 7 | 29.17% | 92 |
| | | 528 | | 24 | | 552 |
| 2016 | Satisfactory | 440 | 89.80% | 34 | 70.83% | 474 |
| | Unsatisfactory | 50 | 10.20% | 14 | 29.17% | 64 |
| | | 490 | | 48 | | 538 |
| 2017 | Satisfactory | 324 | 91.78% | 75 | 81.52% | 400 |
| | Unsatisfactory | 28 | 7.93% | 17 | 18.48% | 45 |
| | | 353 | | 92 | | 445 |
| 2018 | Satisfactory | 369 | 86.82% | 113 | 69.75% | 482 |
| | Unsatisfactory | 56 | 13.18% | 49 | 30.25% | 105 |
| | | 425 | | 162 | | 587 |

In addition, data received from the Environmental Health Service⁵⁴ from its 2018 Tobacco Inspections to Licensed Premises/Hotels Inspections shows a 91% compliance with the provision requiring that self-service vending machines must be within the line of sight of a member of staff. Although this compliance rate seems high, it does mean that approximately 1 in 10 vending machines (226 out of 2430) were not in the line of sight of a member of staff and therefore were unsupervised.

The prohibition on self-service vending machines is also proposed in order to meet Ireland's obligation under Article 13 of the FCTC which requires each Party to the treaty to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. As previously noted the guidance on the implementation of Article 13 clarifies that: *Vending machines should be banned because they constitute by their very presence a means of advertising or promotion under the terms of the Convention*⁵⁵.

According to an assessment of implementation of the required advertising and display ban at point of sale by the World Health Organisation Ireland has not met the requirement for a comprehensive ban because, among other things, vending machines have not been completely prohibited⁵⁵. It recommends that Ireland should pursue a comprehensive ban and eliminate existing exemptions.

Analysis of Costs, Benefits and Impacts of Options

Option 1: Do nothing

Costs to Exchequer

None.

Benefits to Exchequer

None.

⁵⁴ Email to Department of Health from the Environmental Health Service of 22 May 2019.

⁵⁵ Best practices on implementation of the tobacco advertising and display ban at point of sale (Article 13 of the WHO FCTC) https://www.who.int/fctc/publications/best_practices_art13_whofctc.pdf

Impacts

No obvious impacts for the following: *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: Legislate for further restrictions on the sale of tobacco and nicotine inhaling products

Costs to Exchequer

None.

Benefits to Exchequer

None.

Impacts

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

The proposals will have consumer impacts. They will restrict the locations from which tobacco products can be sold including the prohibition of self-service vending machines. They will also restrict who can sell tobacco products and nicotine inhaling products, i.e. it must be persons aged 18 or over, which may have consumer impacts.

Persons under 18 will also no longer be able to purchase nicotine inhaling products however it is not clear how much of a consumer impact this will have as some vendors already voluntarily restrict sales to those over 18⁵⁶.

⁵⁶ Irish vape vendors association Code of Conducts includes no sales to those under 18, see <https://www.ivva.ie/join-the-ivva/code-of-conduct/>

The proposals, despite these impacts, are considered necessary and proportionate in the context where use of tobacco continues to be the top risk factor driving disability and death in Ireland (both in 2007 and in 2017) according to the latest data from the Global Burden of Disease study⁵⁷

The socially excluded and vulnerable groups and the rights of citizens

The provisions are designed to reduce sales opportunities for tobacco products and to prevent children from purchasing nicotine inhaling products in order to reduce the likelihood of young persons in particular becoming addicted to nicotine or becoming smokers with all of the disability and death that this lethal practice brings.

In addition the provisions are designed to denormalise tobacco products by restricting the general availability of these products. The intended effect of these measures is to reduce the smoking and reach Ireland's target of becoming tobacco free. This will serve to protect the right to health of citizens and to reduce the burden of tobacco related disease on the socially excluded and vulnerable groups who proportionally carry the greatest burden.

No obvious impacts on the following: National competitiveness, The environment, Compliance burdens, including administrative burdens or North-South and East-West Relations

Consultation

A concern raised in the consultation regarding the proposed provisions on restricting sales at certain events or locations was that such prohibitions would mean that the vacuum would be filled by illicit trade e.g. if the legal sale of cigarettes is prohibited at a festival this will encourage the sale of illicit tobacco.

⁵⁷ <http://www.healthdata.org/ireland>

In response to this concern it must be noted that the consultation was carried out in late 2014 and early 2015 which was before the introduction and operation of the traceability and security features systems provided for under the Tobacco Products Directive. The systems now apply to cigarettes and roll-your-own tobacco from 20 May 2019 and will apply to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024. The purpose of these two systems is to reduce the illicit trade in tobacco across the European Union and from Ireland's perspective reduce the likelihood that an illicit trade will arise in places from which the legal trade has been prohibited.

In relation to the prohibition on self-service vending machines the primary objection arising in the consultation was that it will put people out of business and cause job losses. The proposed prohibition is considered necessary to meet the two primary objectives of the *Tobacco Free Ireland* policy, denormalisation and the protection of children. Self-service vending machines act as an advertisement for tobacco products and the data shows that cigarettes in these machines are more accessible to minors than cigarettes sold from behind the counter therefore it is considered necessary to ban them in order to achieve the target of making Ireland smoke free.

Enforcement, compliance and review

The proposed provisions will be enforced by the Environmental Health Service.

1(iii) Compliance and Enforcement provisions

Parts 5, 6 and 7

Compliance and Enforcement provisions

What are the policy objectives being pursued?

The primary policy objective is for Ireland to become tobacco free (i.e. with a smoking prevalence rate of less than 5%) by 2025, with particular focus on the protection of children and the denormalisation of smoking. The proposed provisions are to provide the Environmental Health Service with a range of additional enforcement tools to enforce Public Health Tobacco law and will implement the following recommendations from *Tobacco Free Ireland*:

- introducing minimum suspension periods for tobacco retailers convicted of offences.
- introducing fixed penalty notices (on-the-spot fines) for offences.
- providing for the publication of information in respect of any person on whom a fine, other penalty or conviction is imposed by a court ('name and shame').

What policy options have been considered?

1. Do Nothing
2. Legislate to provide further enforcement tools to the Environmental Health Service

Preferred Option

The preferred option is to legislate to ensure that the Environmental Health Service has an up to date range of enforcement tools at its disposal in order to ensure that tobacco control law is complied with and ultimately to lead to a smoke free Ireland.

| POLICY OPTIONS | | | |
|------------------------|----------------------------|---|---|
| | COSTS | BENEFITS | IMPACTS |
| Policy Option 1 | Costs to Exchequer None | Benefits to Exchequer None | Impact on public health None |
| Policy Option 2 | Costs to Exchequer None | Benefits to Exchequer The introduction of fixed penalties (on-the-spot fines) may result in the intake of some monies. | Impact on public health Improved enforcement and compliance should ultimately lead to a reduction in the number of smokers and therefore in the associated death and disease from tobacco use. |

Description of Policy context and objectives

The Public Health (Tobacco) Acts date back to 2002 and in general the only legal action open to an Environmental Health Officer to enforce compliance with the law is to take a prosecution which if successful will result in the defendant being convicted of a criminal offence. Some additional enforcement tools were introduced in the 2016 Regulations which transposed the EU Tobacco Products Directive but for the majority of offences it is the enforcement approach from the 2002 Act enforcement which applies.

The effect of the proposed provisions will be to provide additional enforcement options, already in use in other public health law, to offences in the Public Health (Tobacco) Acts. The objective is to allow for enforcement to be carried out without the necessity to seek criminal convictions in all cases but to retain the right of recourse to the courts for all parties.

The additional enforcement tools include:

- introducing fixed penalty notices (on-the-spot fines) (Head 26) for offences.
- introducing compliance notices and orders (Head 22) and prohibition notices (Head 23) which will give the opportunity for rectification of breaches of the law.

It is also proposed to introduce minimum and maximum suspension periods for tobacco retailers convicted of offences (Head 29). The introduction of minimum suspension periods is a recommendation of *Tobacco Free Ireland*. The purpose of providing for such periods in law is to ensure that the suspension periods imposed will be sufficient so as to deter breaches of the law.

Data from the Environmental Health Service⁵⁸ shows that in 2018 there were a number of instances where retailers were removed from the register (equivalent of licence suspension) for one day or two days and in one instance for one hour. In order to more properly reflect the seriousness of tobacco control law and to ensure that penalties imposed are seen as a deterrent, it is proposed that a minimum suspension period for what are considered lower grade offences (e.g. failure to display a licence) will be two days and the minimum for more serious offences (e.g. selling cigarettes to a minor) will be seven days.

Finally, and to act as a further deterrent, it is proposed to provide the Environmental Health Service with the power to publish information in respect of any person on whom a fine, other penalty or conviction is imposed by a court (Head 25).

Identification and Description of Options

Option 1: Do nothing.

To do nothing will mean that the Environmental Health Service will continue to be restricted in its enforcement options and its primary method to ensure compliance will remain that of taking court actions for breaches of the Tobacco Acts.

⁵⁸ <https://www.hse.ie/eng/about/who/tobaccocontrol/enforcement/>

Option 2: Legislate to provide further enforcement tools to the Environmental Health Service.

The new proposals will ensure that compliance with the law can be enforced without the necessity of recourse to the courts. In addition the proposals for minimum suspension periods and publication of information in relation to breaches will increase the deterrent effect of tobacco control law and will serve to reflect the serious nature of public health threat from tobacco related disease.

Analysis of Costs, Benefits and Impacts of Options

Option 1: Do nothing

Costs to Exchequer

None.

Benefits to Exchequer

None.

Impacts

No obvious impacts for the following: *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: Legislate to provide further enforcement tools to the Environmental Health Service

Costs to Exchequer

None

Benefits to Exchequer

The introduction of fixed penalties (on-the-spot fines) may result in the intake of some monies.

Impacts

The socially excluded and vulnerable groups and the rights of citizens

As with the other provisions, the additional enforcement measures are designed to contribute to the national policy target of making Ireland tobacco free and therefore to protect the right to health of citizens and to reduce the burden of tobacco related disease on the socially excluded and vulnerable groups who proportionally carry the greatest burden.

No obvious impacts on the following: National competitiveness, The environment, Compliance burdens, including administrative burdens or North-South and East-West Relations

Consultation

Responses to the consultation from health organisations called for penalties to be sufficient to act as a deterrent whereas there was an opinion from a respondent involved in the industry that these matters should be left to the courts to determine. As previously outlined the additional enforcement tools proposed provide for recourse to the courts.

Enforcement, compliance and review

The proposed provisions are designed to assist with the enforcement of and compliance with tobacco control law.