



Príomhoifigeach Sláinte Comhshaoil Réigiúnach  
An tSeirbhís Sláinte Comhshaoil  
Feidhmeannacht na Seirbhíse Sláinte  
Páirc Ghnó na Gaillimhe  
An Daingean, Gaillimh.  
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Date 26/02/24

Deputy Bernard J Durkan  
Dáil Éireann  
Leinster House  
Kildare Street  
Dublin 2

**Re:** PQ 5485-24

Dear Deputy Durkan,

The Minister has referred PQ 5485-24 to the Health Service Executive for a direct reply. Please see response to your PQ below.

**Question:**

*To ask the Minister for Health if the Health Service Executive is actively enforcing the relevant provisions of the Public Health (Tobacco Products and Nicotine Inhaling Products) Bill 2023 and the EU 2016 Tobacco Products Directive Regulations in non-traditional retail outlets such as mobile phone shops, computer repair centres, gift shops and discount stores which sell vapes; the number of HSE enforcement visits conducted in these non-traditional outlets in 2023; and if he will make a statement on the matter.*

**Response:**

EU 2016 Tobacco Products Directive Regulations

The Health Service Executive (HSE) is one of the competent authorities for the enforcement of the EU (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016) (as amended by S.I. No. 252 of 2017, S.I. No. 132 of 2018, S.I. No. 365 of 2018, S.I. No. 614 of 2021 and S.I. 335 of 2023), (the Regulations). These Regulations transpose the Tobacco Products Directive 2014/40/EU into law in the Republic of Ireland. Amongst other things, these regulations lay down the safety and quality requirements that electronic cigarettes and e-liquid refill containers containing nicotine for sale on the Irish market must meet. The HSE National Environmental Health Service (NEHS) enforces this legislation.

Each year the NEHS undertakes a programme of inspections of manufacturers, importers, distributors and retailers of electronic cigarettes and refill containers.



The premises/businesses inspected are targeted based on intelligence information and complaints received.

In 2023, the NEHS conducted 45 inspections at retailer, importer and distributor level. Thirty-five of those inspections were conducted in standalone vape shops and discount type stores.

The following were the types of non-compliances observed during inspections:

- Products not notified to the HSE via the EU Common Entry Gate portal. (All products must be notified to the HSE at least 6 months prior to sale on the Irish market.)
- Products had volumes of nicotine-containing liquid, which exceeded the legal limit of 2ml.
- No information leaflet provided to inform consumers of the adverse health effects warnings associated with the product.

During inspections where Environmental Health Officers (EHOs) found such products, these were removed from sale and section 48 Notices served directing that the products not to be sold, removed or distributed from the premises. Where products contained tank sizes in excess of the 2ml legal limit authorised officers served Prohibition Orders directing that the products not be placed on the market and be destroyed by the economic operator. Compliance Notices were served where products were not notified to the HSE or did not contain an information leaflet; this gave the economic operator an opportunity to remedy the situation.

The table below details the enforcement action taken by NEHS in 2023:

Type of enforcement action	Number of notices served	Quantity of Product concerned
Section 48 Notice	23	
Compliance Notices	3	414 e-cigarette units
Prohibition Orders	10	1 116 (e-cigarette units @ retail level)
		9.9 tonnes @ warehouse

In addition, to inspections, EHOs also take samples of electronic cigarettes and e-liquid refill containers. The State Laboratory tests these products for nicotine concentration and volume of e-liquid present. In 2023, 123 samples were taken of which 54 were unsatisfactory as they held nicotine-containing liquid in excess of the legally permitted 2ml. Ten of the samples were classified as potentially hazardous as the nicotine concentration of these products when tested was in excess of the legal limit of 20mg/ml or 2%. This resulted in the NEHS issuing five European Safety RAPEX alerts. These RAPEX alerts also alerted colleagues in other EU countries about the risks posed by the products. A RAPEX is a system for the rapid exchange of information on dangerous non-food products. For more information on RAPEX, visit <https://ec.europa.eu/safety-gate-alerts/> using the words ‘electronic cigarette’ or ‘refill container’.

The NEHS also issued Public Alert Notices and Press Releases to inform the public of the risks associated with the products subject to the RAPEX alerts. For more information on the



Public Alert Notices, visit the HSE tobacco control and compliance webpage at <https://www.hse.ie/eng/about/who/tobaccocontrol/enforcement/>

In January 2024, at Mullingar District Court the Health Service Executive successfully prosecuted the owner of a discount store that was selling non-compliant electronic cigarettes. The prosecution was taken for breaches of the EU (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016, as amended. Products sold by the business had a nicotine content and volume in excess of legally permitted levels and some products on sale were not notified to the HSE. The defendant was convicted; the total fine was €4,000 with €3,500 awarded towards HSE costs.

The NEHS also works with Customs and Revenue to develop a strategic approach to dealing with non-compliant electronic cigarettes and refill containers at import level. The aim of this work is to detain non-compliant products at the port and refuse the products free circulation status into the Irish/EU market. Due to this multi-agency approach, eight consignments of electronic cigarettes with volumes exceeding the legal limit of 2ml were detained and refused free circulation into the Irish/EU market in 2023. A total of 36,365 Kg (36.4 tonnes) of non-compliant products were detained and prevented from entering the Irish/EU market.

#### The Public Health (Tobacco Products and Nicotine Inhaling Products) Act 2023

The Minister commenced specific provisions of this legislation on 22<sup>nd</sup> December 2023, with a planned phased enactment of the remaining provisions throughout 2024-2025. The HSE National Environmental Health Service is the enforcement body for the provisions of this new legislation and has developed a comprehensive compliance building and information programme for both industry and members of the public.

In coming weeks all retailers of tobacco products registered with the HSE, will receive correspondence outlining their legal responsibilities regards the sale of nicotine and inhaling products. As there is currently, no requirement for retailers of nicotine-inhaling products to register with the HSE the number/details of these premises are unknown to the HSE. In addition, EHOs in each county in Ireland will be visiting standalone vape shops and discount stores and other retailers to assess the nicotine inhaling products they stock and informing them of their legal obligations.

Following the compliance building phase, premises retailing nicotine inhaling products will be included in the NEHS annual test purchasing campaign to assess compliance with the legal provisions prohibiting sale of tobacco and nicotine inhaling products to persons under 18 years of age.

The HSE also has the responsibility for the implementation of Section 11 (Licensing) in the Act of 2023. The HSE is currently liaising with the Department of Health in relation to establishing, and operating a mechanism for retailers of tobacco products and nicotine-inhaling products to apply annually to the HSE for a licence to sell such products.

Whilst the HSE NEHS enforces the legislation, it is the responsibility of manufactures and importers of electronic cigarettes and e-liquid refill containers to ensure that the products they place on the Irish market fully comply with all legislative requirements. To assist compliance the HSE National Environmental Health Service has already developed and disseminated



guidance for retailers and importers on their legal responsibilities in terms of buying and selling vape products. More information can be found by visiting the link <https://www.hse.ie/eng/about/who/tobaccocontrol/tobaccoproductdirective/tobaccodirective.html>

Yours sincerely,

A handwritten signature in black ink that reads 'M. Mulcahy'.

Dr. Maurice Mulcahy

Regional Chief Environmental Health Officer