



Príomhoifigeach Sláinte Comhshaoil Réigiúnach  
An tSeirbhís Sláinte Comhshaoil  
Feidhmeannacht na Seirbhíse Sláinte  
Páirc Ghnó na Gaillimhe  
An Daingean, Gaillimh.  
H91 EW40

Regional Chief Environmental Health Officer  
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29<sup>TH</sup> January 2024

Ms Violet-Anne Wynne TD,  
Dáil Eireann,  
Leinster House, Kildare Street,  
Dublin 2

Re: PQ ref 1855/24

Dear Deputy Wynne,

Please see response to your PQ

**Question:** To ask the Minister for Health, if he is aware of the wide availability of e-cigarette and vaping products that do not meet standards for these products, and which some estimates put at between 20% to 25% of the market; what actions he and other agencies of the State are taking to combat this and to ensure that only e-cigarettes and vaping products that meet Irish regulatory standards can be sold here; and if he will make a statement on the matter.

**Response:** 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 has a target of 40 inspections of manufactures, 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, of which 24 had unsatisfactory or seriously unsatisfactory inspection outcomes. The following were the issues giving rise to these inspection outcomes:



1. 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.)
2. Products had volumes of nicotine-containing liquid, which exceeded the legal limit of 2ml.
3. No information leaflet provided to inform consumers of the adverse health effects warnings associated with the product.

During inspections where inspectors found such products, these were removed from sale and section Notices were 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 information below details the enforcement action taken by NEHS in 2023:

#### **Type of enforcement action Number of notices served**

*Section 48 Notice 23*

*Compliance Notices 3*

*Prohibition Orders 10*

In addition, to inspections, Environmental Health Officers (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 contained 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/>

Also in 2023, the NEHS has commenced working 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. A total of 36,365 Kg (36.4 tonnes) of non-compliant products were detained and prevented from entering the Irish/EU market.

Whilst the 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 developed 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, appearing to read 'M. Mulcahy', written over a horizontal line.

Dr. Maurice Mulcahy

Regional Chief Environmental Health Officer