**Guidance on the notification of e-cigarettes and refill containers under the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016**

The purpose of this guidance is to provide assistance to manufacturers and importers of e-cigarettes and refill containers on the notification requirements (point A below) under Regulation 26 of the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016).

As interpretation of the law is a matter for the Courts, this guidance is intended to provide general information on the above Regulations and should not be construed as legal advice. It is without prejudice to any other legal obligations under criminal or civil law.

**Background**

The [Tobacco Products Directive 2014/14/EU (TPD)](http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf) introduced new rules for nicotine-containing electronic cigarettes (e-cigarettes) and refill containers (Article 20).

The new rules include:

1. notification requirements for manufacturers and importers of e-cigarettes and refill containers;
2. mandatory safety and quality requirements for e-cigarettes and refill containers, including the setting of maximum nicotine concentration levels and maximum volumes for cartridges, tanks and containers of nicotine liquids;
3. requirements to ensure that e-cigarette ingredients are of high purity and that e-cigarettes deliver the same amount of nicotine for puffs of the same strength and duration;
4. requirements that e-cigarettes and refill containers are child-resistant and tamper proof and have a mechanism that ensures refilling without spillage to protect consumers;
5. obligatory health warnings advising consumers that e-cigarettes contain nicotine;
6. mandatory listing of all ingredients contained in the product, information on the product's nicotine content and a leaflet setting out instructions for use and information on adverse effects, risk groups and addictiveness and toxicity;
7. prohibition of promotional elements on e-cigarette and refill container packaging;
8. prohibition of cross-border advertising and promotion of e-cigarettes and refill containers;
9. stricter rules on monitoring of market developments of e-cigarettes and refill containers;
10. an obligation on manufacturers, importers and distributer of e-cigarettes and refill containers to collect information on suspected adverse effects on human health;
11. an obligation on manufacturers, importers and distributer of e-cigarettes and refill containers to take corrective action and inform the Health Service Executive [competent authority] if he or she believes that an e-cigarette or refill container is not safe or is not of good quality or does not conform with the Regulations; and
12. mandatory registration for retailers engaged in cross-border distance sales of e-cigarettes or refill containers in Member States where such sales are not prohibited. To obtain a Registration Form and information on the registration process please contact the HSE at info.tpd@hse.ie Information is also available on the HSE Tobacco Products Directive webpage [hyperlink to http://www.hse.ie/eng/about/Who/TobaccoControl/Tobaccoproductdirective/

The TPD was transposed into Irish legislation by the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016) (2016 Regulations) which came into operation on 20 May 2016.

Part 5 of the Regulations sets out the requirements for e-cigarettes and refill containers.

The Health Service Executive (HSE) is responsible for implementing and enforcing the provisions under Part 5 of the Regulations and has been designated as the competent authority for the notification process for e-cigarettes and refill containers in the Republic of Ireland.

E-cigarettes or refill containers manufactured or released for free circulation before 20 November 2016, which are not in compliance with the labelling and product composition requirements of the 2016 Regulations may be placed on the Irish market until 20 May 2017. Retailers have until 20 May 2017 to sell through stock of products that do not comply with the labelling and product composition requirements of the 2016 Regulations.

All e-cigarettes and refill containers manufactured or released for free circulation after 20 November 2016 must be in compliance with 2016 Regulations.

The following provisions of the 2016 Regulations are effective from 20 May 2016 for all e-cigarettes and refill containers on the market irrespective of the date on which they entered the market:

* registration of cross-border distance sales of e-cigarettes and refill containers (Regulation 25(3));
* notification of e-cigarettes and refill containers (Regulation 26);
* commercial communications relating to e-cigarettes and refill containers (Regulation 31);
* market developments concerning e-cigarettes and refill containers (Regulation 32); and
* public health concerns relating to e-cigarettes and refill containers (Regulation 33).

**Guidance on notification of e-cigarettes and refill containers**

Under Regulation 26 of the 2016 Regulations, a manufacturer or importer of an e-cigarette or refill container must submit a notification to the Health Service Executive of any such products he or she intends to place on the Irish market.

The notification must be submitted through a European Union Common Entry Gate (EU-CEG) made available by the European Commission. Guidance on the EU-CEG and how to apply for a submitter ID and a European Commission Authentication Account (ECAS) account is available from the European Commission’s website here <http://ec.europa.eu/health/euceg/>

Notification of a product on the Irish market before 20 May 2016 must be submitted by 20 November 2016. Notification of a new or a substantially modified product must be submitted not less than 6 months before placing it on the Irish market.

The obligation to notify a product does not apply to retailers unless he or she also falls within the definition of a manufacturer or importer.

A manufacturer is defined as any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark.

If a retailer also qualifies as a manufacturer, he or she must submit a notification for each relevant product.

An importer is defined as the owner of, or a person having the right of disposal over, tobacco or related products that have been brought into the territory of the European Union.

If a retailer also qualifies as an importer, he or she should check with his or her manufacturer if they have already submitted a notification for each relevant product.

If the manufacturer has already done so, the importer does not need to submit a duplication notification.

**Guidance on the content and format of notifications**

The content and format of a notification are set out in Regulation 26 of the 2016 Regulations and Commission Implementing Decision (EU) 2015/2183 of 24 November 2015

Discussion papers developed by Member States are set out below (see links). The aim of the papers is to provide guidance to manufacturers and importers submitting notifications for their products

E-cigarette Working Group Discussion Papers on Submission of Notifications under Article 20 of Directive 2014/40/EU:

* [Chapter 1 - Submission Type](file:///C:\Users\hickey_p\Documents\CyberLink\MS%20Discussion%20paper%201%20Submission%20type.pdf)

* [Chapter 2 - Product Type](file:///C:\Users\hickey_p\Documents\CyberLink\MS%20Discussion%20Paper%202%20Product%20type.pdf)

* [Chapter 3 – Emissions from Electronic Cigarettes](file:///C:\Users\hickey_p\Documents\CyberLink\MS%20Discussion%20Paper%203%20Emissions.pdf)

* [Chapter 4 – Dose of Nicotine Delivered & Uptake and Consistency of Dose](file:///C:\Users\hickey_p\Documents\CyberLink\MS%20Discussion%20Paper%204%20Nicotine%20Dose.pdf)

**Fees**

Under the 2016 Regulations, there is no fee for notifying e-cigarettes or refill containers. This reflects the current legislative position and is subject to any future legislative amendment.

**Contacts**

Should you experience technical difficulties with the EU-CEG, please contact

[SANTE-EUCEG-ITSUPPORT@ec.europa.eu](mailto:SANTE-EUCEG-ITSUPPORT@ec.europa.eu)

(include in your message a ‘print screen’ of the window where the problem appears)

For general matters related to the functioning of the EU-CEG, please contact [SANTE-EU-CEG@ec.europa.eu](mailto:SANTE-EU-CEG@ec.europa.eu)

To contact the National Tobacco Control Operational Unit of the Health Service Executive, please email info.tpd@hse.ie

To contact the Tobacco and Alcohol Control Unit of the Department of Health, please email [tobacco@health.gov.ie](mailto:tobacco@health.gov.ie)

**Data Protection**

The HSE fully respects your right to privacy. Any personal information relating to a notification of e-cigarettes or refill containers will be treated in accordance with the Data Protection Acts, 1988 and 2003 (and any amending or substituting legislation). Your personal information will be used only for the purposes for which it is provided, for example, for conducting regulatory checks or requirements or to comply with a legal process. You are entitled to access information that the HSE holds relating to you and can do so by applying to the HSE in writing and on payment of the prescribed statutory fee. The HSE reserve the right to charge a reasonable administration fee for each access request. The HSE are entitled to take reasonable steps to establish your identity in relation to any query, amendment, access or deletion request in respect of the information notified.

**Freedom of Information**

The Department of Health and the HSE are both prescribed as a ‘Public Body’ within the meaning of the Freedom of Information Act 2014. Pursuant to the provisions of the Freedom of Information Act 2014, certain information provided to either the Department of Health or the HSE may form the subject of a Freedom of Information request. Personal information concerning identifiable individuals is not disclosable under the Freedom of Information Act other than to the individual concerned except under limited circumstances provided for in the legislation.