

Guidance

Electronic cigarettes and /or refill containers

The purpose of this guidance is to provide assistance to manufacturers, importers, distributors and retailers of e-cigarettes or refill containers on the rules for electronic cigarettes and refill containers in so far as they relate to:

- Safety and quality requirements;
- Refill mechanism;
- Information and labelling;
- Product presentation; and,
- Public health concerns.

As interpretation of the law is a matter for the Courts, this guidance is intended to provide general information on the Regulations and should not be construed as legal advice nor should it be inferred that all of your legal responsibilities have been identified in this guidance. It is without prejudice to any other legal obligations under criminal or civil law.

Background

The [Tobacco Products Directive 2014/14/EU \(TPD\)](#) introduced new rules for nicotine-containing e-cigarettes and refill containers. These new rules were 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) (the Regulations) and subject to Regulation 47 (transitional provisions), are effective from 20th May 2016.

This guidance applies to e-cigarettes and refill containers that are, or are intended to be placed on the market in Ireland.

The Regulations do not apply to e-cigarettes and refill containers that are subject to an authorisation as medicinal products for human use, or meeting the criteria for medical devices. The Regulations do not apply to nicotine-free e-liquids.

Please note that e-cigarettes and refill containers are also required to comply with other relevant European legislation.

Under Regulation 26, 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 and a notification of a new or a substantially modified product must be submitted not less than 6 months before placing it on the Irish market (please see [guidance on notification of e-cigarettes and refill containers](#) for more information).

Requirements under these Regulations

The new rules require:

1. 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 (Regulation 27);
2. that ingredients of e-cigarettes are of high purity and that they deliver the same amount of nicotine for puffs of the same strength and duration (Regulation 27);
3. that e-cigarettes and refill containers are child-resistant and tamper proof and have a mechanism that ensures refilling without spillage to protect consumers (Regulation 27);
4. refill mechanisms for electronic cigarettes (Regulation 28);
5. obligatory health warnings advising consumers that e-cigarettes contain nicotine (Regulation 29);
6. obligatory 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 (Regulation 29);
7. prohibition of promotional elements on e-cigarette and refill container packaging (Regulation 30);
8. manufacturers, importers and distributors of e-cigarettes and refill containers to collect information on suspected adverse effects on human health (Regulation 33);
9. manufacturers, importers and distributor of e-cigarettes and refill containers to take corrective action and inform the Health Service Executive 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 (Regulation 33).

The Health Service Executive (HSE) is responsible for implementing and enforcing the provisions under these Regulations.

Where a manufacturer of e-cigarettes or refill containers is not established in the European Union, the importer of the product bears the responsibilities relating to the compliance of the products with the Regulations.

Safety and quality requirements for e-cigarettes and refill containers

Regulation 27 sets out the maximum nicotine concentration levels and maximum volumes for cartridges, tanks and containers of nicotine liquids. It requires that nicotine-containing liquid be contained in dedicated refill containers not exceeding a volume of 10 mls, with the nicotine concentration not exceeding 20 mg/ml. Nicotine containing liquid contained in disposable e-cigarettes, single use cartridges or tanks must not exceed a volume of 2ml.

Nicotine containing liquids cannot contain vitamins or other additives which might infer that the product has health benefits or presents reduced health risks. Similarly, they cannot contain caffeine, taurine, other additives or stimulant compounds that are associated with energy and vitality. Likewise, nicotine containing liquids cannot contain additives which have colouring properties for emissions or which have carcinogenic, mutagenic or reprotoxic properties in unburnt form.

Only ingredients of the highest purity must be used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients that have been notified under Regulation 26 can be present, but only in trace levels¹ provided that such traces are unavoidable during the manufacturing process. With the exception of nicotine, only ingredients that do not pose a risk to human health in heated or unheated form can be used in the nicotine-containing liquid.

Under Regulation 27, e-cigarettes must deliver the nicotine doses at consistent levels under normal and reasonably foreseeable conditions of use. (This may be measured by the nicotine content per puff and ideally should be determined over a set number of such puffs (e.g. 10)). E-cigarettes and refill containers must be child and tamper-proof, protected against breakage and leakage and have a mechanism to ensure that they can be refilled without leakage.

Refill mechanism of electronic cigarettes

Regulation 28 requires refillable e-cigarettes to either use a refill container with a securely attached nozzle at least 9mm long which fits into the opening of the tank of the e-cigarette and emits no more than 20 drops of liquid per minute (when placed upright and subjected to atmospheric pressure at 20°C ± 5°C), or operated by means of a docking system which only releases the liquid into the tank when the e-cigarette and refill container are connected.

The width of the nozzle or opening of the tank for refillable e-cigarettes must be set out clearly in the instructions to enable the customer to refill the product. The instructions should also outline the types of docking system with which the e-cigarette and refill containers can be used.

Information and labelling on electronic cigarettes and refill containers

Regulation 29 sets out the labelling requirements for e-cigarettes and refill containers. The TPD defines unit packet as the smallest individual packaging of a product that is placed on the market. For the purposes of the TPD, a refill container is considered as a unit packet. Outside packaging is defined in the TPD as any packaging in which products are placed on the market and includes a unit packet or an aggregation of unit packets. Transparent wrappers are not regarded as outside packaging.

Regulation 29 requires that each unit packet must include a leaflet with information:

- on instructions for use and storage and instruction for refilling;
- outlining that the product is not recommended for use by young people and non-smokers;

¹ Trace levels are classified as individual ingredients used in quantities below 0.1% of the final formulation by category.

- on contra-indications, warnings for specific risk groups, possible adverse effects and addictiveness and toxicity;
- on contact details of the manufacturer or importer and a contact person within the European Union.

In addition, each unit packet and any outside packaging of an electronic cigarette or a refill container must include a list of all the ingredients in descending order of the weight, an indication of the nicotine content, and the batch number. For e-cigarettes, the delivery per dose must be indicated. A recommendation that the product be kept out of reach of children must be included on each unit packet and any outside packaging.

Each unit packet and any outside packaging of e-cigarettes and refill containers must carry this health warning:

“Cuimsíonn an táirge seo nicitín, ar substaint an-andúile é
This product contains nicotine which is a highly addictive substance.”

Please note the health warning also applies to e-cigarettes which do not contain nicotine when sold, but can contain nicotine when used.

The health warning must be displayed on the 2 largest surfaces and cover 32% of the surfaces of the unit packet and any outside packaging. In the case of a cylindrical packet (e.g. refill containers), they must display 2 health warnings, on the respective half of the curved surface. The health warning must be centred, printed in black Helvetica bold type on a white background and occupy as much of the surface reserved for it as possible. The health warning must be parallel to the main text on the surface reserved for these warnings.

Prohibition of promotional elements

Regulation 30 prohibits the labelling of a unit packet or any outside packaging of e-cigarettes and refill containers to include an element or feature² which promotes consumption by containing information or statements that create an erroneous impression of its characteristics, health effects risks or emissions. Any representation of a food ingredient, such as a picture of fruit on the packet, is only permitted if the product contains that ingredient or flavouring (e.g. picture of an apple for apple flavour). Such references to food ingredients should not suggest however that the product is a 'healthy' option.

Elements or features which suggest that an e-cigarette or refill container is less harmful than other e-cigarettes or refill containers or that they aim to reduce the effect of some of the harmful components of smoke are also prohibited. Similarly, elements or features which suggest that the product has

² Elements or features include texts, symbols, names, trademarks, figurative or other signs. Please note that this is not an exhaustive list.

vitalizing, healing or organic properties or indicates it has health or lifestyle benefits are also prohibited.

Likewise, elements or features that reference the taste or smell of the e-cigarette or refill container, resemble a food or a cosmetic product or suggest that they have improved biodegradability or other environmental advantages are prohibited. However, accurate statements of fact relating to the inclusion of particular components are permitted.

Promotional elements such as printed vouchers, 2-for-1 offers, free distribution, price reductions or similar offers are prohibited.

Public health concerns

Manufacturers, importers and distributors of e-cigarettes and refill containers are required to monitor and record any suspected adverse effects of their products.

Similarly, if they have reason to believe or consider that such products are not safe, of good quality or do not comply with the Regulations, they must immediately do what is necessary to ensure the product complies with the Regulations otherwise the product must be withdrawn or recalled as appropriate. Manufacturers, importers and distributors must inform the Health Service Executive and indicate the risk to human health, advise of any remedial action they have taken, and advise of the outcome of such remedial action.

Transitional provision

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 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 Regulations.

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

Please note that Regulation 30 is effective from 20 May **2016** for all e-cigarettes and refill containers on the market irrespective of the date on which they were placed on the market.

Further Guidance on Electronic Cigarettes and Refill Containers

The Department has also issued guidance documents in relation to other aspects of the TPD namely:

- notification requirements for manufacturers and importers of e-cigarettes and refill containers ([see guidance on notification of e-cigarettes and refill containers](#))
- prohibition of cross-border advertising and promotion of e-cigarettes and refill containers ([see guidance on commercial communications restrictions for e-cigarettes and refill containers](#))
- 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 ([see guidance on cross-border distance sales of tobacco products, e-cigarettes and/or refill containers](#))

Discussion papers were developed by Member States and are set out below. These papers provide guidance to manufacturers and importers submitting notifications for their products and are as follows:

- [Chapter 1 – Submission Type](#)
- [Chapter 2 – Product Type](#)
- [Chapter 3 – Emissions from Electronic Cigarettes](#)
- [Chapter 4 – Dose of Nicotine Delivered & Uptake and Consistency of Dose](#)

Contact

- To contact the Tobacco and Alcohol Control Unit of the Department of Health, please email tobacco@health.gov.ie
- To contact the National Tobacco Control Operational Unit of the Health Service Executive, please email info.tpd@hse.ie.

Tobacco and Alcohol Control Unit

May 2017