



VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

Act on electronic cigarettes and refill containers for electronic cigarettes, No. 87/2018.

SECTION I

General provisions.

Article 1

Aim.

The aim of this Act is to establish authorisations for the importation, sale, marketing and use of electronic cigarettes, to ensure the quality and safety of electronic cigarettes and refill containers for electronic cigarettes on the market and to ensure, through the measures available, that children are not able to purchase electronic cigarettes.

Article 2

Scope.

This Act applies to electronic cigarettes and refill containers for electronic cigarettes, irrespective of whether or not they contain nicotine.

This Act does not apply to electronic cigarettes that are classified as medical devices under the Medical Devices Act or to refill containers for electronic cigarettes that are classified as medicinal products under the Medicinal Products Act.

Article 3

Definitions.

1. *Advertising*: When a product or brand is presented to the public with the aim of increasing sales of the product, including any form of product promotion, displays in shops or in other places or by discussion in the media or by distribution of product samples to consumers.
2. *Refill container*: A receptacle that contains nicotine liquid or other liquid intended to refill an electronic cigarette.
3. *Electronic cigarette*: A product that can be used for the consumption of vapour that contains nicotine, via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes may be disposable or refillable by means of a refill container and a tank, or rechargeable with single-use cartridges.
4. *Special retail outlet for electronic cigarettes and refill containers*: A retail outlet having only electronic cigarettes, refill containers and associated products for sale.

Article 4

At least 0.9% of gross sales of electronic cigarettes shall go to the Public Health Fund (*cf.* the Directorate of Health and Public Health Fund Act).

SECTION II
Importation, sale and marketing.

Article 5

Warnings on packaging.

Electronic cigarettes and refill containers may only be held for sale or distribution if their packaging carries health warnings and they are accompanied by directions on their use and storage.

Texts or images that may appeal particularly to children or young people, by means of illustrations or slogans, which encourage the use of electronic cigarettes, may not be displayed on packages of electronic cigarettes or refill containers.

Article 6

Safety.

Only electronic cigarettes and refill containers that are considered safe and that meet the provisions of this Act or of regulations issued hereunder may be imported, sold or manufactured.

Electronic cigarettes and refill containers shall be child-proof and it shall be ensured that they do not leak and ensures refill without leakage.

Article 7

Age limits.

Electronic cigarettes and refill containers may not be sold or handed over to children. This prohibition shall be clear to all persons where electronic cigarettes and refill containers are sold. In the event of doubt as to the age of purchasers of electronic cigarettes or refill containers, the sale may only proceed if the purchaser demonstrates by means of identification documents that he or she is aged 18 or older.

Only persons aged 18 or older may sell electronic cigarettes and refill containers.

Article 8

Maximum strengths and sizes.

Nicotine containing liquid for disposable electronic cigarettes, cartridges or refill containers for electronic cigarettes may only be sold if the concentration of nicotine does not exceed 20 mg/ml.

The minister shall issue regulations containing rules on the size of refill containers and cartridges, whether these are disposable or rechargeable, in millilitres.

The minister may issue regulations containing detailed provisions on measurements and surveillance to ensure compliance with the authorisations regarding the size, strength and contents of refills. Furthermore, the minister may issue regulations imposing fees on the manufacturers or importers of electronic cigarettes and refill containers to meet the costs of measurements and tests made under this Article.

Article 9

Contents.

Disposable electronic cigarettes, cartridge or refill containers for electronic cigarettes containing the following additives may not be imported, manufactured or sold:

- a. Vitamins or other additives that create the impression that the product has a health benefit.
- b. Caffeine, taurine or other additives and stimulants associated with energy and vitality.
- c. Additives that colour the emissions.
- d. Substances that facilitate the inhalation or uptake of nicotine.
- e. Substances that have carcinogenic, mutagenic or reprotoxic properties ('CMR properties') in the form in which they are consumed.

The minister may issue regulations restricting the marketing of flavourings in electronic cigarettes, particularly as regards flavourings that may appeal to children. The minister may make provisions in regulations on the appearance of packaging so as not to make the products attractive to children.

Article 10

Points of sale.

Electronic cigarettes or refill containers for electronic cigarettes may not be sold in schools or other places intended for the social, sporting and leisure activities of children and young people, or in healthcare institutions and other places where healthcare services are provided.

Article 11

Advertisements and visibility at points of sale.

Advertisements of all types for electronic cigarettes or refill containers for electronic cigarettes are prohibited. It is also prohibited to show, in advertisements, the consumption or any type of handling of electronic cigarettes or refill containers.

Electronic cigarettes and refill containers shall be placed in such a way at points of sale that they are not visible to customers. Special retail outlets for electronic cigarettes and refill containers may nevertheless have electronic cigarettes and refill containers visible to customers once they are inside the shop.

SECTION III

Restrictions on the use of electronic cigarettes.

Article 12

Restrictions on the authorised use of electronic cigarettes.

Electronic cigarettes may not be used:

- a. in the service areas of public institutions and non-governmental organisations;
- b. in nursery schools, junior schools, senior schools and other educational institutions, or in other premises intended for the day care and the social, sporting or leisure activities of children and young persons;
- c. in healthcare institutions and other places where healthcare services are provided, with the exception of residents' rooms in nursing homes and homes for the elderly, and
- d. in public transport vehicles.

SECTION IV

Market monitoring.

Article 13

The monitoring authority.

The Consumer Agency shall be in charge of monitoring the market for electronic cigarettes and refill containers for electronic cigarettes in accordance with the provisions of this Act and rules set hereunder. The Consumer Agency shall establish a collaborative committee to handle collaboration with other monitoring authorities and testing centres (as provided for under Article 16 of Act No. 134/1995) in order to exercise monitoring of electronic cigarettes and refill containers for electronic cigarettes.

Article 14

Notifications to the Consumer Agency.

Manufacturers and importers of electronic cigarettes and refill containers for electronic cigarettes that contain nicotine who propose to place electronic cigarettes or refill containers on the market in Iceland shall send the Consumer Agency notifications to this effect six months before placement on the market is proposed. A new notification shall be submitted for each substantial change in the product; the Consumer Agency shall decide whether a change is considered substantial. Products that have not been notified in accordance with this provision, and regulations issued hereunder, may not be imported or sold.

The minister may issue regulations setting more detailed provisions on notifications under the first paragraph, including as regards the information accompanying notifications, the receiving of notifications and the storage, treatment and analysis of information accompanying notifications.

The Consumer Agency may charge a fee for receiving a notification (*cf.* the second paragraph) in order to meet the costs of the receiving, storage, handling and analysis of information it receives.

The Consumer Agency shall publish on its website information about parties that have met the conditions regarding notifications set out in the first paragraph.

Article 15

Product contents and safety.

The Consumer Agency may demand that manufacturers and importers of electronic cigarettes and refill containers for electronic cigarettes provide information on specific components of their products and their contents. The Consumer Agency may also demand that manufacturers and importers of electronic cigarettes and refill containers for electronic cigarettes submit samples of their products in the quantities necessary so as to assess their characteristics and effects.

Manufacturers', importers' and distributors' obligations not covered by this Act, including the obligation to give immediate notification of product recalls, and monitoring and procedure, shall be in accordance with the Product Safety and Public Market Monitoring Act and the Tort Damages Act, as appropriate.

Article 16

Obligation to take remedial measures.

If manufacturers, importers or distributors of electronic cigarettes and refill containers for electronic cigarettes have reason to believe that electronic cigarettes or refill containers that are in their keeping and that they intend to place on the market, or are on the market, are not safe or in some other respects are not in conformity with the law, the party concerned shall immediately take the necessary remedial measures so as to bring the product in question into line with this Act, withdraw it or recall it from the market, as appropriate. In addition, the parties listed in the first sentence shall inform the Consumer Agency of the situation immediately.

The minister may issue regulations setting more detailed provisions on demands regarding the quality, safety, labelling and description of the contents of electronic cigarettes and refill containers for electronic cigarettes.

Article 17

Information on sales and consumer behaviour.

Each year, manufacturers and importers of electronic cigarettes and refill containers for electronic cigarettes shall give the Directorate of Health and the Consumer Agency information on sales of electronic cigarettes and refill containers for electronic cigarettes and consumer behaviour in accordance with a regulation issued by the minister.

SECTION V

Education and public awareness.

Article 18

Education and awareness-raising.

In consultation with the ministry in charge of health, the Directorate of Health shall ensure that regular educational and awareness-raising activities take place, particularly for young persons, regarding the impact on health of using electronic cigarettes.

SECTION VI

Miscellaneous provisions.

Article 19

Referrals and appeals.

Decisions by the Consumer Agency made on the basis of this Act may be referred to the Consumer Appeals Committee which operates under the Consumer Agency Act. Decisions by the Consumer Agency may not be referred to a court of law until the Consumer Appeals Committee has delivered its ruling. If a party does not accept a ruling by the appeals committee, it may then bring an action before a court to have it set aside. Such actions shall be brought within six months of the date on which the party received a notification of the ruling by the appeals committee. The bringing of a court action shall not defer the entry into force of the committee's ruling or the authorisation for the taking of enforcement measures.

Article 20

Sanctions.

Violations of this Act, or of rules issued hereunder, shall be punishable by fines or up to two years' imprisonment in the case of gross or repeated violations.

The General Penal Code shall apply to attempted violations or acting as an accessory to violations. Where violations are committed in the course of a legal person's operations, the legal person may be fined in accordance with Chapter II A of the General Penal Code.

Article 21

Commencement.

This Act shall take effect on 1 March 2019.

Article 22

Amendments to other Acts of law.

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Interim provisions.

Without prejudice to Article 21, manufacturers and importers of electronic cigarettes and refill containers for electronic cigarettes that contain nicotine who propose to place electronic cigarettes or refill containers on the market in Iceland shall, as from 1 September 2018, send the Consumer Agency a notification to this effect as provided for in Article 14, six months before placement on the market is proposed.

The provisions of Article 14, including those of the third paragraph, on fees, and the fourth paragraph, on the publication of information.

*[This translation is published for information only.
The original Icelandic text is published in the Law Gazette.
In case of a possible discrepancy, the original Icelandic text applies.]*