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Bill on an Act

on electronic cigarettes and refill containers for electronic cigarettes.

Presented by the minister of health.

SECTION I

General provisions

Article 1

Aim.

The aim of this Act is to establish rules on the importation, sale, marketing and use of electronic cigarettes and on active monitoring of the market for electronic cigarettes and refill containers for electronic cigarettes ('refill containers') in Iceland.

Article 2

Scope.

This Act applies to electronic cigarettes and refill containers in Iceland, 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 that are classified as medicinal products under the Medicinal Products Act.

Article 3

Definitions.

Advertisements: 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.

Electronic cigarette: A product that can be used for the consumption of vapour, irrespective of whether or not it contains nicotine, via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank.

Refill container: A receptacle that contains a nicotine-containing liquid or other liquid intended to refill an electronic cigarette.

Special retail outlet for electronic cigarettes and refill containers: A retail outlet having only electronic cigarettes, refill containers and associated products for sale.

SECTION II

Importation, sale and marketing

Article 4

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.

Article 5

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 that they contain devices that ensure that they do not leak when being refilled.

Article 6

Age restrictions.

Electronic cigarettes and refill containers may not be sold or handed over to persons under the age of 18. 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 a purchaser of an electronic cigarette or refill containers, the person concerned shall be required to prove his or her age by means of an identity document.

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

Article 7

Maximum strength and size of refill containers.

Only refill containers with liquid containing 20 mg/ml or less of nicotine may be sold.

Refill containers which hold more than 10 ml of liquid may not be sold.

Disposable refill cartridges for electronic cigarettes containing more than 2 ml of liquid may not be sold.

The minister may issue regulations containing more detailed provisions on measurements and monitoring to ensure compliance with these limits. Furthermore, the minister may issue regulations requiring that manufacturers or importers of refill containers pay a fee covering measurements and tests made under this Article.

Article 8

Contents of refill containers.

Refill containers containing the following additives may not be imported, manufactured or sold in Iceland.

- a. Vitamins or other additives that create the impression that the product has a health benefit or reduced health risks.
- 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.

Manufacturers and importers of electronic cigarettes and refill containers may be charged a fee, in accordance with a scale of charges set by the minister, for assessing whether prohibited additives or flavourings are used in their products or whether the products contain additives in quantities that increase, to a significant or measurable degree, their toxicity, addictiveness or CMR properties.

Article 9

Points of sale.

Electronic cigarettes and refill containers may not be sold in schools, institutions for children and teenagers or healthcare institutions or other places where healthcare services are provided.

Article 10

Advertisements and visibility at points of sale.

Advertisements of all types for electronic cigarettes and refill containers are prohibited in Iceland. 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 11

Restrictions on the use of electronic cigarettes.

Electronic cigarettes may not be used:

- a. in the service areas of institutions, undertakings and non-governmental organisations and where cultural and social activities, including sporting and leisure activities, are held.
- b. in nursery schools, junior schools, senior schools and other educational institutions, or in other premises intended for children's or young people's sporting or leisure activities.
- c. in healthcare institutions and other places where healthcare services are provided, with the exception of the dwelling rooms of the inmates of nursing homes and residential homes.
- d. in public transport vehicles.

The directors of undertakings and institutions not listed in the first paragraph shall be obliged to set rules on the use of electronic cigarettes in their premises, and such rules shall be visible in the areas in question.

SECTION IV **Market monitoring.**

Article 12

The monitoring authority.

The Consumer Agency (Neytendastofa) shall be in charge of monitoring the market for electronic cigarettes and refill containers in accordance with the provisions of this Act and rules set hereunder.

Article 13

Notifications to the Consumer Agency.

Manufacturers and importers of electronic cigarettes and refill containers who propose to place electronic cigarettes and refill containers on the market in Iceland shall send the Consumer Agency notifications to this effect six months before the placing 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 receipt of notifications and the storage, treatment and analysis of information accompanying notifications.

The Consumer Agency may charge a fee for the receipt of notifications (*cf.* the second paragraph) in order to meet the costs of the receipt, 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 14

Contents of the product; safety.

The Consumer Agency may demand that manufacturers or importers of electronic cigarettes and refill containers provide information on specific parts of their products or their contents.

The Consumer Agency may demand that manufacturers or importers of electronic cigarettes and refill containers submit samples of their products in the quantities necessary so as to assess their characteristics and effects.

Where no provisions are made here, the obligations of manufacturers, importers and distributors, including as regards immediate notifications of the recall of products from the market, monitoring and procedure, shall be subject to legislation on product safety and public market supervision, and also legislation on liability for harmful products, as appropriate.

Article 15

Obligation to take remedial measures.

If manufacturers, importers or distributors of electronic cigarettes and refill containers have reason to believe that electronic cigarettes and 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 this Act, 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 descriptions of the contents of electronic cigarettes and refill containers.

Article 16

Appeals and referrals.

Appeals against decisions taken by the Consumer Agency under this Act may be made to the consumer affairs appeals committee operating under Article 4 of the Consumer Agency Act, No. 62/2005. Decisions by the Consumer Agency may not be referred to a court of law until the consumer affairs appeals committee has delivered its ruling. If a party does not accept a ruling by the consumer affairs appeals committee, it may bring an action before a court of law to have it annulled. Actions shall be brought within six months of the date on which the party in question becomes aware of the ruling by the consumer affairs appeals committee. The bringing of an action shall not defer the taking of effect of the committee's ruling or the authorisation for taking enforcement measures.

Article 17

Information on sales and consumer behaviour.

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

SECTION V

Education and awareness-raising.

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 regarding the impact on health of using electronic cigarettes and the dangers involved in handling electronic cigarettes and refill containers.

SECTION VI
Miscellaneous provisions.

Article 19

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, No. 19/1940, 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 20

Commencement

This Act shall take effect on 1 June 2018. The provisions of Article 15 shall take effect on 1 January 2018.