

# [Act on nicotine products, electronic cigarettes and refill containers for electronic cigarettes]<sup>1)</sup>, No. 87/2018

as amended by Act No. 18/2021 and 56/2022.

1) Act No. 56/2022, Article 24.

Where mention is made in this Act of 'the minister' or 'the ministry' without further definition, the reference intended is to the Minister of Health or to the Ministry of Health, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found <a href="here">here</a>.

# SECTION I General provisions.

Article 1

Aim.

[The aim of this Act is to establish authorisations for the importation, sale, marketing and use of nicotine products, electronic cigarettes and refill containers for electronic cigarettes, and to ensure the quality and safety of nicotine products, electronic cigarettes and refill containers for electronic cigarettes on the market and to ensure, through the measures available, that children neither purchases nor use nicotine products and electronic cigarettes and refill containers for electronic cigarettes.]<sup>1)</sup> *Act No. 56/2022, Article 1.* 

#### Article 2

Scope.

This Act applies to [nicotine products]<sup>1)</sup> 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. [The Act does not apply to nicotine products that are marketed as medicinal products and are classified as medicinal products under the Medicinal Products Act. Furthermore, the Act does not apply to foodstuffs under the Act on Foodstuffs.]<sup>1)</sup> Act No. 56/2022, Article 2.

# 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, [web media or social media]<sup>1)</sup> 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 nicotine products, electronic cigarettes and refill containers: A retail outlet having only nicotine products, electronic cigarettes, refill containers and associated products for sale.]<sup>1)</sup>
- [5. *Nicotine product*: A product containing nicotine, irrespective of whether or not the nicotine is derived from tobacco, if the product does not otherwise contain substances derived from tobacco (e.g. a nicotine pouch) and is not for inhaling.
- 6. *Placement on the market*: Making products accessible to consumers, irrespective of where they are manufactured, and irrespective of whether or not this is done in return for payment, including by distance sale.]<sup>1)</sup>

1) Act No. 56/2022, Article 3.

#### Article 4

...1)

1) Act No. 56/2022, Article 4.

### SECTION II

### Importation, sale and marketing.

### Article 5

Warnings on packaging.

[Nicotine products,]<sup>1)</sup> 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.

[The packaging of nicotine products shall include clear information about the nicotine content.]<sup>1)</sup>

Texts or images that may appeal particularly to children or young people, by means of illustrations or slogans, which encourage the use of [nicotine products and]<sup>1)</sup> electronic cigarettes, may not be displayed on packages of [nicotine products]<sup>1)</sup>, electronic cigarettes or refill containers.

[The minister may issue regulations containing provisions on the appearance of the packaging of nicotine products, electronic cigarettes and refill containers in order to render these products unattractive to children.

Warnings and information that must be displayed on nicotine products, electronic cigarettes and refill containers shall be in Icelandic.]<sup>1)</sup>

1) Act No. 56/2022, Article 5.

# Article 6 *Safety*.

Only [nicotine products]<sup>1)</sup>, 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. [It should be ensured that nicotine products are stored out of the reach of children.]<sup>1)</sup>

1) Act No. 56/2022, Article 6.

# Article 7

Age limits.

[Nicotine products]<sup>1)</sup>, 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 [nicotine products]<sup>1)</sup>, 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 [nicotine products]<sup>1)</sup>, electronic cigarettes and refill containers.

1) Act No. 56/2022, Article 7.

#### Article 8

### Maximum concentrations 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 a regulation<sup>1)</sup> specifying the maximum concentration of nicotine in nicotine products. For the determination of the maximum concentration, the criterion shall be that the absorption of nicotine from the product is not greater than that obtained from the maximum permitted concentration in liquid in refills for electronic cigarettes.]<sup>2)</sup>

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 [nicotine products and]<sup>2)</sup> refills. Furthermore, the minister may issue regulations imposing fees on the manufacturers or importers of [nicotine products]<sup>2)</sup>, electronic cigarettes and refill containers to meet the costs of measurements and tests made under this Article.

<sup>1)</sup> Regulation No. 991/2022, cf. 1019/2022 and 1319/2022. Regulation No. 992/2022, cf. 1318/2022. <sup>2)</sup> Act No. 56/2022, Article 8.

# Article 9 *Contents*.

[Nicotine products]<sup>1)</sup>, 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.

1) Act No. 56/2022, Article 9.

# Article 10 *Points of sale.*

[Nicotine products]<sup>1)</sup>, 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.

1) Act No. 56/2022, Article 10.

# Article 11

### Advertisements and visibility at points of sale.

Advertisements of all types for [nicotine products]<sup>1)</sup>, 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 [nicotine products]<sup>1)</sup>, electronic cigarettes or refill containers. [The Consumer Agency monitors the ban on advertising of nicotine products, electronic cigarettes and refills for electronic cigarettes. The procedure of the Consumer Agency, remedies and penalties for violations of this Article and the right of appeal to the Consumer Appeals Committee, are in accordance with the provisions of the Act on surveillance of unfair business practices and market transparency.]<sup>1)</sup>

[Nicotine products]<sup>1)</sup>, 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 [nicotine products]<sup>1)</sup>, electronic cigarettes and refill containers may nevertheless have [nicotine products]<sup>1)</sup>, electronic cigarettes and refill containers visible to customers once they are inside the shop.

<sup>1)</sup> Act No. 56/2022, Article 11.

### SECTION III

### [Restrictions on the use of nicotine products and electronic cigarettes.]<sup>1)</sup>

<sup>1)</sup> Act No. 56/2022, Article 13.

### Article 12

[Restrictions on the authorised use of nicotine products and electronic cigarettes.]<sup>1)</sup> 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.

[The use of nicotine products is prohibited in places where activities for children and young persons take place, such as day-care centres, social, sports and leisure activity centres, pre-schools, junior schools, senior schools, vocational schools and places with other comparable activities while activities are in progress for children aged under the age of 18.]<sup>1)</sup>

# <sup>1)</sup> Act No. 56/2022, Article 12.

# SECTION IV Market monitoring.

#### Article 13

The monitoring authority.

[The Housing and Construction Authority]<sup>1)</sup> shall be in charge of monitoring the market for [nicotine products]<sup>2)</sup>, electronic cigarettes and refill containers for electronic cigarettes in accordance with the provisions of this Act and rules set hereunder. [The Housing and Construction Authority]<sup>1)</sup> 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 [nicotine products]<sup>2)</sup>, electronic cigarettes and refill containers for electronic cigarettes. [Other aspects of monitoring by the Housing and Construction Authority shall be in accordance with the Product Safety and Public Market Monitoring Act.]<sup>2)</sup>

# <sup>1)</sup> Act No. 18/2021, Article 18. <sup>2)</sup> Act No. 56/2022, Article 14.

#### Article 14

*Notifications to [the Housing and Construction Authority.]*<sup>1)</sup>

[Manufacturers and importers of nicotine products, electronic cigarettes and refill containers for electronic cigarettes that contain nicotine who propose to place nicotine products, electronic cigarettes or refill containers for electronic cigarettes on the market in Iceland shall send the Housing and Construction Authority notifications to this effect six months before placement on the market is proposed of electronic cigarettes and refill containers for electronic cigarettes, but three months before placement on the market is proposed of nicotine products.]<sup>2)</sup> A new notification shall be submitted for each substantial change in the product; [the Housing and Construction Authority]<sup>1)</sup> 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<sup>3)</sup> 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 Housing and Construction Authority]<sup>1)</sup> 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 Housing and Construction Authority]<sup>1)</sup> shall publish on its website information about parties that have met the conditions regarding notifications set out in the first paragraph.

<sup>1)</sup> Act No. 18/2021, Article 18. <sup>2)</sup> Act No. 56/2022, Article 15. <sup>3)</sup> Regulation No. 992/2022, cf. 1318/2022.

### [Article 14 a

# Licence requirements.

A special licence from the Housing and Construction Authority shall be required in order to retail nicotine products, electronic cigarettes and refills for electronic cigarettes. In addition, a special licence from the Housing and Construction Authority shall be required in order to operate a specialist shop selling nicotine products, electronic cigarettes and refills for electronic cigarettes. Specialist shops selling nicotine products, electronic cigarettes and refills for electronic cigarettes shall be marked in a special way.

Both natural and legal persons may apply for licences; the applicant and/or representative of the applicant, in the case of a legal person, shall be legally competent and registered in the Register of Firms or the Register of Companies. Licences under this Article shall be granted for four years at a time, and licensees shall be able to apply for renewals of their licences at the end of that time. Licences may be granted for shorter periods if the applicant so requests or if particular circumstances favour such a course of action, though not for less than one year at a time. Licences shall pertain to the licensees and shall not be assignable in any way.

The Housing and Construction Authority may charge fees for licences and for monitoring licensees' activities. The minister shall issue regulations<sup>1)</sup> setting out further provisions on licensing and the charging of fees under this Article. The Housing and Construction Authority may revoke licences that have been issued under this Article if the licensee no longer meets the conditions for receiving such licences or violates this Act.

Importers, distributors and other parties selling nicotine products, electronic cigarettes and refills for electronic cigarettes at wholesale may not sell or deliver the products to persons other than those who hold licences to retail nicotine products, electronic cigarettes and refills for electronic cigarettes under this Act.<sup>12)</sup>

<sup>1)</sup> Regulation No. 992/2022, cf. 1318/2022. <sup>2)</sup> Act No. 56/2022, Article 16.

# Article 15

[Obligation to provide information; site inspections and seizure.

The Housing and Construction Authority may demand that manufacturers, importers and sellers of nicotine products, electronic cigarettes and refills for electronic cigarettes, and other persons to whom this Act applies, submit the information and data which the authority considers necessary for monitoring or the investigation of individual cases, such as information on specific parts of the products and their contents.

The Housing and Construction Authority may demand information and data from other government authorities, including the customs authorities, notwithstanding their confidentiality obligations.

The Housing and Construction Authority may demand that manufacturers, importers and sellers of nicotine products, electronic cigarettes and refill containers for electronic cigarettes submit samples of products in the quantities necessary to assess their properties and effects.

The Housing and Construction Authority may inspect sites where nicotine products, electronic cigarettes and refill containers for electronic cigarettes are manufactured and/or sold, whether this is done at wholesale or at retail. In the course of monitoring or investigating cases, the Housing and Construction Authority may carry out the necessary inspections of the premises of the manufacturers, importers or sellers of nicotine products, electronic cigarettes and refills for electronic cigarettes, for example taking samples and making the tests necessary in connection with its monitoring or the investigation of individual cases.

The Housing and Construction Authority may prohibit the continued use, sale and distribution of nicotine products, electronic cigarettes and refills for electronic cigarettes and seize data or products when there is good reason to believe that violations of this Act have taken place. The Housing and Construction Authority may destroy products that do not meet the requirements of this Act, or of regulations issued hereunder, at the expense of those in possession of them.]<sup>1)</sup>

1) Act No. 56/2022, Article 17.

#### Article 16

[Product contents and safety; obligation to rectify irregularities.]<sup>1)</sup>

If manufacturers, importers or distributors of [nicotine products]<sup>1)</sup> electronic cigarettes and refill containers for electronic cigarettes have reason to believe that [nicotine products]<sup>1)</sup>, 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 Housing and Construction Authority]<sup>2)</sup> of the situation immediately.

[Other aspects of the obligations of manufacturers, importers and distributors, including their obligation to report immediately product recalls, monitoring and the handling of cases, shall be in accordance with the Product Safety and Public Market Monitoring Act and the Tort Damages Act, as appropriate.

The minister shall issue regulations<sup>3)</sup> containing further provisions on requirements regarding quality, safety, labelling and descriptions of the contents of nicotine products, electronic cigarettes and refills for electronic cigarettes.]<sup>1)</sup>

<sup>1)</sup> Act No. 56/2022, Article 18. <sup>2)</sup> Act No. 18/2021, Article 18. <sup>3)</sup> Regulation No. 991/2022, cf. 1019/2022 and 1319/2019.

### Article 17

Information on sales and consumer behaviour.

Each year, manufacturers and importers of [nicotine products]<sup>1)</sup>, electronic cigarettes and refill containers for electronic cigarettes shall give the Directorate of Health and [the Housing and Construction Authority]<sup>2)</sup> information on sales of [nicotine products]<sup>1)</sup>, electronic cigarettes and refill containers for electronic cigarettes and consumer behaviour in accordance with a regulation issued by the minister.

<sup>1)</sup> Act No. 56/2022, Article 19. <sup>2)</sup> Act No. 18/2021, Article 18.

### SECTION V

### Education and public awareness.

Article 18

Education and awareness-raising.

[The Directorate of Health shall, in consultation with the Ministry of Health, ensure that regular awareness-raising activities take place regarding the effects of nicotine products and electronic cigarettes on health with a view to reducing the use of nicotine products and electronic cigarettes, particularly by children and young persons. Special emphasis shall be placed on awareness-raising in junior and senior schools and in educational institutions training persons for work in the care and education of children and in the health services.]<sup>1)</sup>

1) Act No. 56/2022, Article 20.

### SECTION VI

[Sanctions, etc.]<sup>1)</sup>

<sup>1)</sup> Act No. 56/2022, Article 23.

Article 19

Referrals and appeals.

[Decisions by the Housing and Construction Authority made on the basis of this Act may be referred to the Environmental and Natural Resources Board of Appeal. Decisions may not be referred to a court of law until the Board of Appeal has delivered its ruling. If a party does not accept a ruling by the Board of Appeal, 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 Board of Appeal. The bringing of a court action shall not defer the entry into force of the board's ruling or the authorisation for the taking of enforcement measures. With regard to the party, deadline for appeals, procedure and other issues regarding the appeal, the provisions of the Act on the Environmental and Natural Resources Board of Appeal shall otherwise apply.]

<sup>1)</sup> Act No. 18/2021, Article 19.

### Article 20

[Sanctions, criminality, confiscation, attempted violations and acting as an accessory.] $^{l}$ 

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.

[Violations of this Act shall be punishable by fines or imprisonment, irrespective of whether they are committed on purpose or through negligence.

Direct or indirect profit resulting from violations of the provisions of this Act may be confiscated in accordance with a court judgment.]<sup>1)</sup>

[The General Penal code shall apply to attempted violations or acting as an accessory to violations.]<sup>1)</sup> *Act No. 56/2022, Article 21.* 

# [Article 20 a *Per diem fines.*

Where a party fails to act on orders from the Housing and Construction Authority regarding conduct that is in violation of Articles 5–17 of this Act before the stated deadline, the authority may impose *per diem* fines on the party until the situation has been rectified.

*Per diem* fines may amount to as much as ISK 200,000 per day. When the amount of *per diem* fines is determined, consideration shall be given to matters including the scope and severity of the violation, how long it has lasted and whether repeated violations have taken place.

Decisions by the Housing and Construction Authority regarding *per diem* fines are enforceable in law. If a fine imposed under this Article is not paid within 30 days of the decision by the Housing and Construction Authority, arrears interest shall be paid on the amount of the fine. The imposition of arrears interest, and calculation of the interest, shall be in accordance with the Interest and Indexation Act. Uncollected *per diem* fines imposed up to the date of compliance shall not be waived if the party complies with the demand in question at a later date, unless the Housing and Construction Authority decides this specifically. Fines shall go to the Treasury following deduction of collection costs.]

1) Act No. 56/2022, Article 22.

# [Article 20 b *Administrative fines.*

The Housing and Construction Authority may impose administrative fines on natural or legal persons that violate the provisions on:

- 1. Warnings on packaging (cf. Article 5).
- 2. Safety (cf. Article 6).
- 3. Age limits (*cf.* Article 7).
- 4. Maximum concentrations and sizes (cf. Article 8).
- 5. Contents (cf. Article 9).
- 6. Points of sale (*cf.* Article 10).
- 7. Visibility at points of sale (*cf.* the second paragraph of Article 11).
- 8. Restrictions on the authorised use of nicotine products and electronic cigarettes (cf. Article 12).
- 9. Notifications to the Housing and Construction Authority (*cf.* Article 14).
- 10. Obligation to provide information, site inspections and seizure (*cf.* Article 15).
- 11. Product contents and safety and obligation to rectify irregularities (cf. Article 16).
- 12. Information on sales and consumer behaviour (cf. Article 17).

The minister may issue a regulation determining the monetary amounts of administrative fines to be imposed for violations of individual provisions of this Act within the framework set out in the fourth paragraph of this Article.

Where the monetary amounts of fines have not been determined in regulations, then when fines are determined, consideration shall be given to matters including the severity of the violation, how long it has lasted and whether repeated violations have taken place.

Administrative fines shall be imposed irrespective of whether violations are committed on purpose or through negligence. Administrative fines imposed on natural persons may range from ISK 10,000 to ISK 10,000,000. Administrative fines imposed on legal persons may range from ISK 25,000 to ISK 25,000,000.

The due date for the payment of administrative fines shall be 30 days after the decision to impose the fine was taken. If an administrative fine remains unpaid 15 days after the due date, then arrears interest shall be paid on the fine as from the due date. Decisions by the Housing and Construction Authority on administrative fines are enforceable in law, and the fines shall go to the Treasury following deduction of the cost of their imposition and collection. The imposition of arrears interest, and calculation of the interest, shall be in accordance with the Interest and Indexation Act.]<sup>1)</sup>

Act No. 56/2022, Article 22.

# [Article 20 c *Referral to the police.*

The Housing and Construction Authority may refer violations to the police.

If an alleged violation of this Act is punishable by both administrative fines and sanctions, the Housing and Construction Authority shall assess whether or not the matter is to be referred to the police or concluded by an administrative fine imposed by the authority. In the event of a major violation, the Housing and Construction Authority shall refer it to the police. Violations shall be regarded as major if the action is carried out in a particularly reprehensible manner or under circumstances which substantially enhance the criminality of the offence. Furthermore, the Housing and Construction Authority may, at any stage of the proceedings, refer a case involving violation of this Act for a criminal investigation. Consistency shall be observed in the resolution of comparable cases.

Referrals from the Housing and Construction Authority shall be accompanied by copies of the data on which the suspicion of violation is based. The provisions of Sections IV–VII of the Administrative Procedure Act shall not apply to decisions by the Housing and Construction Authority to refer cases to the police.

The Housing and Construction Authority may provide the police and the prosecuting authority with information and data that the authority has gathered and that are connected with the violations mentioned in the second paragraph of this Article. The Housing and Construction Authority may take part in measures taken by the police regarding the investigation of the violations mentioned in the second paragraph of this Article.

The police and the prosecuting authority may provide the Housing and Construction Authority with information and data that have been gathered and that are connected with the violations mentioned in the second paragraph of this Article. The police may take part in measures taken by the Housing and Construction Authority regarding the investigation of the violations mentioned in the second paragraph of this Article.

If a prosecutor considers there are insufficient grounds for bringing a court case concerning alleged criminal activity which is also punishable by administrative sanctions, he or she may send the matter back to the Housing and Construction Authority for processing and resolution.]<sup>1)</sup>

Act No. 56/2022, Article 22.

Article 21 *Commencement.* 

This Act shall take effect on 1 March 2019.

Article 22
Amendments to other Acts of law.

Interim provisions.

I.

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.

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

# [II.

Without prejudice to Article 14, manufacturers and importers of nicotine products that have been placed on the market prior to 1 June 2022 can send a notification of a market placement of the products to the monitoring authority until 1 September 2022.]<sup>1)</sup> *Act No. 56/2022, Article 25.* 

[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.]