

05 JUL 2021

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CIRCULAR

A: Todas las empresas de zonas francas dedicadas a la manufactura de Tabaco y sus Derivados.

ASUNTO: Proyecto de Ley de Finlandia sobre la introducción del empaquetado genérico y prohibición de sabores en el Tabaco.

ANEXO: Proyecto de Ley que modifica la Ley de tabaco de Finlandia.

FECHA: Jueves 01 de julio de 2021

Cortésmente, nos permitimos dirigirnos a ustedes para remitirle en anexo, informaciones importantes suministradas por la Embajada Dominicana en Bélgica, relativas al proyecto de modificación de Ley de Finlandia que introduce el empaquetado genérico y la prohibición de sabores en todos los productos de tabaco, propuesta que entraría en vigor a finales de 2022, como sigue:

En relación al empaquetado, el proyecto de Ley propone “prohibir el uso logotipos, diseños y colores atractivos en los envases al por menor, que en la práctica han promovido las ventas de productos, pero que a menudo han sido difíciles de tratar con la prohibición de comercialización. Todos los paquetes deberán tener el mismo aspecto, con ciertas excepciones que están específicamente permitidas”.

En cuanto a los sabores, de acuerdo con el párrafo 1 del artículo 11, subsección 1 de la Ley del Tabaco, “los cigarrillos o el tabaco de liar con una fragancia o sabor característicos no pueden venderse ni ponerse a disposición de los consumidores de ninguna otra manera”.

En este sentido, nos permitimos exhortarles al análisis minucioso de las informaciones compartidas, a fin de prevenir cualquier efecto negativo sobre las exportaciones dominicanas de tabaco.

Sin otro particular por el momento, les saluda,

Atentamente,

Daniél Liranzo,
Director Ejecutivo
DL/PR/ap



Translation from Finnish
Legally binding only in Finnish and Swedish
Ministry of Social Affairs and Health, Finland

Tobacco Act
(549/2016; amendments up to 1374/2016 included)

Chapter 1 General provisions

Section 1 *Objective of the Act*

- (1) The objective of this Act is to end the use of tobacco products and other nicotine-containing products that are toxic to humans and cause addiction.
- (2) To achieve the objective referred to in subsection 1, this Act lays down measures to prevent people from taking up the use of tobacco products and developing a nicotine addiction, to promote the cessation of the consumption of tobacco products and similar products and to protect the population from exposure to smoke from such products.

Section 2 *Definitions*

For the purposes of this Act:

- 1) *tobacco product* means a product that can be consumed and consists wholly or partly of tobacco (*nicotiana*);
- 2) *smokeless tobacco product* means chewing tobacco, nasal tobacco, tobacco for oral use and other tobacco products not involving a combustion process;
- 3) *tobacco product for smoking* means tobacco products other than a smokeless tobacco product;
- 4) *cigarette* means a roll of tobacco referred to in section 4(1) of the act on excise duty on tobacco products (*laki tupakkaverosta* 1470/1994);
- 5) *cigar* means a roll of tobacco referred to in section 3(1) of the act on excise duty on tobacco products;
- 6) *cigarillo* means a cigar that weighs no more than three grams;
- 7) *roll-your-own tobacco* means tobacco which can be used for making cigarettes by consumers or retail outlets;
- 8) *pipe tobacco* means tobacco that can be consumed via a combustion process and is exclusively intended for use in a pipe;
- 9) *waterpipe tobacco* means a tobacco product that can be exclusively consumed via a waterpipe;
- 10) *chewing tobacco* means a smokeless tobacco product exclusively intended

- for the purpose of chewing;
- 11) *nasal tobacco* means a smokeless tobacco product that can be consumed via the nose;
 - 12) *tobacco for oral use* means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms;
 - 13) *novel tobacco product* means a tobacco product which does not fall into the product categories referred to in paragraphs 4–12 and which has been made available to consumers located in the European Union (EU) after 19 May 2014;
 - 14) *tobacco substitute* means a product which corresponds to tobacco in its intended use but does not contain tobacco;
 - 15) *herbal product for smoking* means a tobacco substitute that is made of plants and intended for consumption via a combustion process;
 - 16) *smoking accessory* means equipment or supplies mainly intended for smoking or the preparation thereof;
 - 17) *tobacco imitation* means a product with a form that closely resembles a tobacco product or smoking accessory but which does not contain tobacco or a substitute thereof;
 - 18) *electronic cigarette* means a product that can be used for inhaling nicotine-containing vapour via a mouth piece, or any component of that product;
 - 19) *nicotine-containing liquid* means a liquid that contains nicotine, is intended for vaporisation by means of an electronic cigarette, does not contain nicotine in excess of 20 milligrams per millilitre and is not intended for a purpose referred to in section 3(1) of the Medicines Act (395/1987);
 - 20) *nicotine-free liquid intended for vaporisation* means a liquid other than nicotine-containing liquid that is intended for vaporisation by means of an electronic cigarette or a similar method;
 - 21) *refill container* means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;
 - 22) *nicotine cartridge* means a replaceable part of an electronic cigarette that contains a nicotine-containing liquid;
 - 23) *ingredient* means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products;
 - 24) *additive* means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging; as regards nicotine containing liquids, additive means a substance, other than nicotine, that is added to a nicotine-containing liquid, a unit packet or to any outside packaging;
 - 25) *characterising flavour or aroma* means a smell or taste other than one of tobacco, resulting from an additive or a combination of additives, which is clearly noticeable in a tobacco product, nicotine-containing liquid or nicotine-free liquid intended for vaporisation before or during its consumption;
 - 26) *emissions* means substances that are released when a tobacco or

- related product is consumed as intended;
- 27) *tar* means the raw anhydrous nicotine-free condensate of smoke;
 - 28) *nicotine* means nicotinic alkaloids;
 - 29) *toxicity* means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;
 - 30) *CMR properties* means the carcinogenic, mutagenic or reprotoxic properties of a tobacco product or any other product referred to in this Act;
 - 31) *unit packet* means the smallest individual packaging of a tobacco product or any other product referred to in this Act that is placed on the market;
 - 32) *outside packaging* means any packaging in which tobacco products or other products referred to in this Act are placed on the market and which includes a unit packet or an aggregation of unit packets; however, the transparent wrappers of unit packets are not regarded as outside packaging;
 - 33) *point of sale* means a customer service point at a sales outlet where tobacco products or nicotine-containing liquids are supplied or sold;
 - 34) *cross-border distance sales* means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in an EU Member State other than the Member State or the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State, if a natural person has his or her place of business in that Member State, or in other cases, if the retail outlet has its statutory seat, central administration, place of business, a branch, any other establishment or an agent in that Member State;
 - 35) *marketing* means advertising, indirect advertising and other promotion efforts as well as tobacco sponsorship;
 - 36) *indirect advertising* means the promotion of a product through the advertising of other commodities by exploiting the established symbol of a product or an altered but identifiable version thereof or by otherwise creating an impression of a particular product;
 - 37) *tobacco sponsorship* means any form of public or private support to an event, activity or individual with the aim or direct or indirect effect of promoting the sales of a tobacco product, tobacco substitute, smoking accessory, tobacco imitation, electronic cigarette or nicotine-containing liquid;
 - 38) *smoking* means the use of tobacco products intended for consumption via a combustion process or other form of heating;
 - 39) *indoor area* means a closed indoor space with ceiling, floor and walls or an area of which it is possible to construct a closed space by installing an additional plane structure and which is intended for living or staying or as a waiting or working area;
 - 40) *smoking area* means a separate space in an indoor area that has been approved by building inspection authorities for smoking purposes;
 - 41) *public event* means a public meeting or public event referred to in

the Assembly Act (530/1999);

42) *housing corporation* means a limited liability company within the scope of application of the Limited Liability Housing Companies Act (1599/2009), a corporation and foundation within the scope of application of the Right-of-Occupancy Housing Act (650/1990), a housing cooperative, a rental building as referred to in section 2 of the Act on Joint Management of Rental Buildings (649/1990) and other rental building stock owned by corporations. (1374/2016)

Section 3

Restrictions on the scope of application

This Act does not apply to medicinal products that have been granted a marketing authorisation referred to in section 21 of the Medicines Act or that are subject to section 2(4) of the Medicines Act, or to products covered by the Narcotics Act (373/2008) or the Medical Devices Act (629/2010).

Chapter 2

Authorities

Section 4

Tasks of the Ministry of Social Affairs and Health

The Ministry of Social Affairs and Health is responsible for the general direction and guidance of compliance with this Act and the provisions issued under it.

Section 5

Tasks of the National Institute for Health and Welfare

The National Institute for Health and Welfare shall monitor and research the impacts of the measures laid down in this Act and of changes in the retail prices of tobacco products on the prevalence of smoking as well as conduct and support research, monitoring and development activities related to reducing the health risks and adverse health effects of smoking. The National Institute for Health and Welfare shall be responsible for national activities to promote the cessation of smoking and shall monitor the market developments concerning electronic cigarettes and refill containers.

Section 6

Tasks of Valvira

The National Supervisory Authority for Welfare and Health (*Valvira*) shall guide regional state administrative agencies and municipalities in carrying out the tasks assigned to them under this Act. Valvira shall supervise:

- 1) compliance with provisions on the ingredients, emissions, fire safety,

- quality and technical features of tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation and herbal products for smoking;
- 2) compliance with provisions on the unit packets of the products referred to in paragraph 1;
 - 3) the marketing of products referred to in this Act throughout the country;
 - 4) compliance with provisions on the verification laboratories referred to in section 85.

Section 7

Tasks of the regional state administrative agency

The regional state administrative agency shall within its territory guide municipalities in implementing this Act and the provisions issued under it. The regional state administrative agency shall also be responsible for regional smoking cessation efforts.

Section 8

Tasks of municipalities

- (1) Within their territories, municipalities shall be responsible for local smoking cessation efforts. Within their territories, municipalities shall supervise:
 - 1) compliance with provisions on the sale or other supply of tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes and nicotine-containing liquids and the related self-monitoring;
 - 2) compliance with provisions on the marketing and display bans laid down in this Act;
 - 3) compliance with provisions on smoking prohibitions and restrictions.
- (2) A municipality has no right to transfer its power to approve the supervision plan referred to in section 84 to a municipal officeholder subordinate to it.
- (3) The activities organised by a municipality pursuant to this Act are subject to the Act on Planning and Government Grants for Social Welfare and Health Care (733/1992), unless otherwise provided by law.

Section 9

Tasks of other authorities

- (1) Finnish Customs shall supervise compliance with the import prohibitions and restrictions laid down in this Act.
- (2) The accreditation unit of the Finnish Safety and Chemicals Agency (*Finnish Accreditation Service, FINAS*) shall assist Valvira in supervising the competence of the verification laboratories referred to in section 85 and the validity of verification methods.

- (3) The Finnish Medicines Agency Fimea shall assist Valvira in the supervision of nicotine-containing liquids.
- (4) The Police shall supervise compliance with the smoking prohibitions and restrictions laid down in this Act at public events.
- (5) Provisions on the monitoring of compliance with smoking prohibitions and restrictions at the workplace are laid down in the Act on Occupational Safety and Health Enforcement and Cooperation on Safety and Health at Workplaces (44/2006).

Chapter 3

Requirements and notifications concerning tobacco products

Section 10

General obligations of manufacturers and importers of tobacco products

- (1) Manufacturers and importers of tobacco products are responsible for ensuring that a tobacco product intended for commercial sale or other supply complies with the applicable provisions.
- (2) The obligation to provide Valvira and the European Commission (*the Commission*) as well as the competent authorities of other EU Member States with the information required in this Chapter lies primarily with the manufacturer, if the manufacturer is established in the European Union. The obligation to provide the information lies primarily with the importer, if the manufacturer is established outside the EU and the importer is established inside the European Union. The obligation to provide the information lies jointly with the manufacturer and the importer if they both are established outside the EU.

Section 11

Prohibited additives and properties

- (1) It is prohibited to sell or otherwise supply to consumers the following:
 - 1) cigarettes or roll-your-own tobacco with a characterising flavour or aroma;
 - 2) tobacco products containing additives that are liable to create the impression that the product has a health benefit or presents reduced health risks compared to other tobacco products;
 - 3) tobacco products containing stimulant compounds or other additives that are liable to create an impression of energy and vitality;
 - 4) tobacco products containing additives that have colouring properties for emissions;
 - 5) tobacco products containing additives that have CMR properties in unburnt form;

- 6) tobacco products for smoking containing additives that facilitate nicotine uptake or the inhalation of smoke;
 - 7) cigarettes or roll-your-own tobacco containing such flavourings in any of their components that allow the modification of the smell, taste or smoke intensity of the product concerned;
 - 8) cigarettes with filters, papers or capsules that contain tobacco or nicotine;
 - 9) tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree.
- (2) To implement EU legislation, maximum content levels may be laid down by decree of the Ministry of Social Affairs and Health for additives in tobacco products or combinations of additives that:
- 1) result in a characterising flavour or aroma in a cigarette or roll-your-own tobacco;
 - 2) amplify the toxic or addictive effect of a tobacco product as referred to in subsection 1(9).

Section 12

Maximum levels of emissions and methods for measuring emissions

- (1) When smoked, a cigarette that is commercially sold or otherwise supplied or commercially manufactured may emit:
- 1) a maximum of 10 milligrams of tar;
 - 2) a maximum of 1 milligram of nicotine;
 - 3) a maximum of 10 milligrams of carbon monoxide.
- (2) The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured and the accuracy of the measurements shall be verified before the product in question is released for retail sale. Further provisions on measurement and verification methods may be issued by decree of the Ministry of Social Affairs and Health.
- (3) To implement EU legislation, provisions may be issued on the following by decree of the Ministry of Social Affairs and Health:
- 1) maximum emission levels for emissions from cigarettes other than tar, nicotine and carbon monoxide emissions;
 - 2) maximum emission levels for emissions from tobacco products other than cigarettes.

Section 13

Fire safety requirements for cigarettes

The burning behaviour of cigarettes shall meet adequate fire safety requirements

regarding self-extinguishing performance. It shall be tested and verified before the product is released for retail sale. Further provisions on methods for testing and verifying burning behaviour may be issued by decree of the Ministry of Social Affairs and Health.

Section 14

Notifications regarding ingredients, emissions and fire safety

- (1) Prior to selling or otherwise supplying a tobacco product to consumers, manufacturers or importers shall submit to Valvira:
- 1) a list of the tar, nicotine and carbon monoxide emissions of the cigarettes that are for sale as well as information about the laboratory that has carried out the measurements and verification;
 - 2) lists with information on cigarette emission levels other than the emissions referred to in paragraph 1 and the methods used for measuring them as well as the emission levels of tobacco products other than cigarettes;
 - 3) information on emission levels other than those referred to in paragraphs 1 and 2, where available;
 - 4) a list, by brand name and type, of all ingredients and quantities thereof used in the manufacture of each tobacco product;
 - 5) for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used in the product and their properties;
 - 6) for cigarettes, test reports and statements by an approved verification laboratory or research institute showing brand-specific compliance with fire safety requirements as well as information about the verification laboratory or research institute.
- (2) The information referred to in subsection 1(2) above shall be provided only if maximum levels for the emissions referred to in the provision have been established under section 12(3).
- (3) Further provisions on the structure of the lists and other documents referred to in subsection 1(1–5) and on the reports on ingredients as well as toxicological and other information to be attached to the lists may be issued by decree of the Ministry of Social Affairs and Health.

Section 15

Notifications of modifications

Manufacturers or importers of a tobacco product shall inform Valvira, if the composition of the product is modified in a way that affects the information provided under section 14. Manufacturers or importers shall submit the modified information to Valvira prior to selling or otherwise supplying the product to consumers.

Section 16

Market research and sales volumes

- (1) With respect to the ingredients and emissions of a tobacco product, manufacturers or importers of a tobacco product shall provide Valvira with the following:
 - 1) available market research and studies on the preferences of various consumer groups;
 - 2) executive summaries of any market surveys the manufacturer or importer carries out when launching new tobacco products.
- (2) Manufacturers or importers shall also annually submit to Valvira the sales volumes of tobacco products by brand name and product type. The sales volumes of cigarettes, cigars and cigarillos shall be reported in sticks and the sales volumes of other tobacco products in kilograms.

Section 17

Studies on primary additives

- (1) If a cigarette or roll-your-own tobacco contains an additive that is included in the priority list of additives referred to in Article 6(1) of Directive 2014/40/EU of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (*Tobacco Products Directive*), the manufacturers or importers of the product shall carry out studies, which shall examine for each additive whether it:
 - 1) contributes to the toxicity or addictiveness of the product concerned, and whether this has the effect of increasing the toxicity or addictiveness of the product concerned to a significant or measurable degree;
 - 2) results in a characterising flavour or aroma;
 - 3) facilitates inhalation or nicotine uptake;
 - 4) leads to the formation of substances that have CMR properties and the quantities thereof, and whether it has the effect of increasing the CMR properties in the product concerned to a significant or measurable degree.
- (2) The studies referred to in subsection 1 shall take into account the intended use of the product concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also examine the interaction of that additive with other ingredients contained in the product concerned.
- (3) Manufacturers or importers using the same additive in their tobacco products may carry out a joint study if they use that additive in their products in a

comparable way.

Section 18

Enhanced reporting obligation

- (1) Manufacturers or importers of cigarettes or roll-your-own tobacco shall establish a report on the results of the studies referred to in section 17. That report shall include an executive summary and a comprehensive overview compiling the available scientific literature on each additive examined and summarising internal data on the effects of the additive.
- (2) Manufacturers or importers shall submit the reports referred to in subsection 1 to the Commission and a copy thereof to Valvira and the competent authorities of those EU Member States where a tobacco product containing the additive examined is placed on the market at the latest 18 months after the additive concerned has been included in the list referred to in section 17(1).
- (3) The Commission and Valvira may also request supplementary information from manufacturers or importers regarding the additive examined. This supplementary information shall form part of the report. The Commission and Valvira may also require these reports to be peer reviewed by an independent scientific body.

Section 19

Derogation for small and medium-sized enterprises

The provisions on the obligations of manufacturers and importers as laid down in sections 17 and 18 shall not apply to small and medium-sized enterprises as referred to in Article 6(5) of the Tobacco Products Directive if a report on that additive is prepared by another manufacturer or importer.

Section 20

Notification of a novel tobacco product

- (1) Manufacturers or importers of tobacco products shall submit a notification to Valvira of any novel tobacco product they intend to sell or otherwise supply to consumers. The notification shall be submitted at the latest six months before the product is placed on the market. The notification shall be accompanied by a detailed description of the product concerned as well as instructions for its use and information on its ingredients and emissions in accordance with section 14.
- (2) Manufacturers or importers shall also, within the same period, provide Valvira with:
 - 1) available scientific studies on the toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;
 - 2) available studies, executive summaries thereof and market research

concerning the product on the preferences of various consumer groups;

- 3) a risk/benefit analysis of the product, its expected effects on the cessation and initiation of tobacco consumption and the predicted consumer perception of the product as well as other available and relevant information about the product.

- (3) Manufacturers or importers shall transmit to Valvira any new or updated information on the studies and other information referred to in subsection 2. Valvira may require manufacturers or importers to carry out additional tests or submit additional information on the product.

Section 21

Method, format and time of submitting information on tobacco products

- (1) The notifications and other information referred to in this Chapter shall be provided to Valvira in electronic form. The same shall apply to information provided to the Commission and the competent authorities of other EU Member States pursuant to section 18.
- (2) When providing the information referred to in this Chapter, manufacturers and importers shall specify which information they consider to constitute a trade or professional secret.
- (3) Further provisions on the method and format of providing the information referred to in sections 14–16 and 18 and on the time of providing the information referred to in sections 16 and 18 may be issued by decree of the Ministry of Social Affairs and Health.

Chapter 4

Requirements and notifications concerning certain other products

Section 22

General obligations of manufacturers and importers of certain other products

- (1) Manufacturers and importers shall ensure that electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation or herbal products for smoking that are intended for commercial sale or other supply comply with the applicable provisions.
- (2) The obligation to provide Valvira and the Commission as well as the competent authorities of other EU Member States with the information required in this Chapter lies primarily with the manufacturer, if the manufacturer is established in the European Union. The obligation to provide the information lies primarily with the importer, if the manufacturer is established outside the EU and the importer is established inside the European Union. The obligation to provide the information lies jointly with the manufacturer and the importer if they both are

established outside the EU.

Section 23

Requirements for electronic cigarettes and refill containers

- (1) Electronic cigarettes may be sold or otherwise supplied to consumers only if they deliver the nicotine doses at consistent levels under normal conditions of use. Electronic cigarettes and refill containers shall be child- and tamper-proof, be protected against breakage and leakage and have a mechanism that ensures refilling without leakage.
- (2) Further provisions on technical standards for the refill mechanism referred to in subsection 1 and on standards for assessing compliance with the other requirements laid down in subsection 1 may be issued by decree of the Ministry of Social Affairs and Health.

Section 24

Requirements for nicotine-containing liquids

(1374/2016)

- (1) Nicotine-containing liquids intended for use in electronic cigarettes may only be sold or otherwise supplied to consumers:
 - 1) in refill containers, disposable electronic cigarettes or single use nicotine cartridges;
 - 2) if the liquid does not have characteristics or contain additives that are prohibited in tobacco products under section 11(1)(1–6);
 - 3) if only ingredients of high purity are used in the manufacture of the liquid;
 - 4) if, except for nicotine, only ingredients are used in the liquid that do not pose a risk to human health in heated or unheated form.
- (2) Nicotine-containing liquids may not contain ingredients for which no prior notification has been submitted in accordance with section 26. This does not apply to traces that are technically unavoidable during manufacture.
- (3) The volume of a refill container shall not exceed 10 millilitres, and the volume of the tank of an electronic cigarette or a single use cartridge shall not exceed 2 millilitres.
- (4) Further provisions on assessing compliance with the requirements laid down in subsections 1 and 2 may be issued by decree of the Ministry of Social Affairs and Health.

Section 25

Requirements for nicotine-free liquids intended for vaporisation

The provisions laid down in section 24(1)(2–4) shall also apply to nicotine-free

liquids intended for vaporisation.

Section 26

Prior notification of electronic cigarettes and refill containers

(1) Manufacturers or importers of electronic cigarettes or refill containers shall submit a notification to Valvira of any such products they intend to sell or otherwise supply to consumers. The notification shall be submitted at the latest six months before the product is placed on the market. Similarly, a notification shall be submitted for each substantial modification of the product prior to selling or otherwise supplying the product to consumers.

(2) The notification shall contain:

- 1) the name and contact details of the manufacturer, a responsible legal or natural person within the EU and the importer into the EU;
- 2) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- 3) toxicological data regarding the product's ingredients and emissions, including when heated, taking into account in particular their effects on the health of consumers when inhaled and any addictive effect;
- 4) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
- 5) a description of the components of the product;
- 6) a description of the production process and a declaration that the production process ensures conformity with the requirements of this Act;
- 7) a declaration that the manufacturer or importer bears full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

Section 27

Market research on and sales volumes of electronic cigarettes and refill containers

Manufacturers or importers of electronic cigarettes or refill containers shall annually submit to Valvira:

- 1) comprehensive data on sales volumes, by brand name and type of the product;
- 2) information on the preferences of various consumer groups;
- 3) information on the modes of sale of the products;
- 4) executive summaries of any market surveys carried out in respect of matters referred to in paragraphs 1–3 above, including an English translation thereof.

Section 28

Monitoring of adverse effects and corrective action

(1) Manufacturers, importers and distributors of electronic cigarettes or refill

containers shall establish and maintain a system for collecting information about the suspected adverse effects on human health of electronic cigarettes and refill containers. Manufacturers, importers and distributors shall provide Valvira with the information from the system.

- (2) Should any of the operators referred to in subsection 1 consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe and are not of good quality or are otherwise not in conformity with this Act and the provisions issued under it, that operator shall immediately take the corrective action necessary to bring the product concerned into conformity with the applicable provisions, to withdraw or to recall it. In such cases, the operator shall also immediately inform Valvira and the market surveillance authorities of the EU Member States in which the product is made available or is intended to be made available. When informing the authorities, it shall also give details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

Section 29

Notifications of the ingredients of herbal products for smoking

- (1) Manufacturers and importers of herbal products for smoking shall submit to Valvira a list of all ingredients, and quantities thereof, that are used in the manufacture of such products by brand name and type prior to selling or otherwise supplying the products to consumers.
- (2) Manufacturers or importers shall inform Valvira, if the composition of the product is modified in a way that affects the information provided pursuant to subsection 1. Manufacturers or importers shall submit the modified information to Valvira prior to selling or otherwise supplying the product to consumers.

Section 30

Method, format and time of submitting information on certain other products

- (1) The notifications and other information referred to in this Chapter shall be provided to Valvira in electronic form.
- (2) When providing the information referred to in this Chapter, manufacturers and importers shall specify which information they consider to constitute a trade or professional secret.
- (3) Further provisions on the method and format of providing the information referred to in sections 26 and 27 and on the time of providing the information referred to in sections 27 and 28(1) may be issued by decree of the Ministry of Social Affairs and Health.

Chapter 5 Unit packets

Section 31

General provision on unit packets

Tobacco products, electronic cigarettes, refill containers and herbal products for smoking as well as nicotine-containing liquids and nicotine-free liquids intended for vaporisation may be sold and otherwise supplied to consumers only in unit packets that comply with this Act and the provisions issued under it as well as with relevant EU legislation. However, cigars may be supplied individually if they are labelled in accordance with section 32(1)(1).

Section 32

Mandatory labelling of unit packets of tobacco products (1374/2016)

(1) The unit packets of tobacco products must carry:

- 1) text warnings in Finnish and in Swedish of the adverse health effects of tobacco products; the unit packets of tobacco products for smoking must also carry picture warnings of the adverse health effects of tobacco products as well as an information message about the harmfulness of tobacco smoke and smoking cessation information in Finnish and Swedish;
- 2) a unique identifier to ensure the traceability of the unit packet and a tamper- proof security feature, composed of visible and invisible elements.

(2) Further provisions on the following may be given by decree of the Ministry of Social Affairs and Health:

- 1) the text, illustrations, font and font size, colour, framing, surface area, position, rotation, affixation, protection against breakage and other properties of the labelling referred to in subsection 1(1);
- 2) the position and marking of the unique identifier referred to in subsection 1(2), the information that can be determined via the unique identifier as well as which information shall form part of the unique identifier and which shall be electronically accessible by means of a link to the unique identifier;
- 3) the position of the security feature referred to in subsection 1(2) and its marking on the packet as well as the technical standards for the security feature and their possible rotation.

Section 33

Labelling elements prohibited in tobacco products and their unit packets

The labelling of tobacco products and their unit packets shall not:

- 1) promote the product or encourage its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
- 2) include any information about the nicotine, tar or carbon monoxide content of the product;
- 3) suggest that the product is less harmful than others or aims to reduce the effect of some harmful components of smoke;
- 4) suggest that the product has vitalising, energetic, healing, rejuvenating, natural or organic properties or that its use has other health or lifestyle benefits;
- 5) refer to taste, smell, any flavourings or other additives or the absence thereof;
- 6) resemble a food or a cosmetic product;
- 7) suggest that the product has environmental advantages;
- 8) suggest that the product is fire safe or otherwise create an impression that the product is not dangerous or that it has a reduced fire risk compared to other similar products.

Section 34

Minimum size of unit packets of tobacco products

- (1) The minimum size of a unit packet of a tobacco product shall be 20 cigarettes, 30 g of roll-your-own or pipe tobacco, or 10 cigarillos.
- (2) Except for cigars, tobacco products may not be sold or otherwise supplied to consumers in unit packets that contain smaller packets or that can be divided into smaller packets.
- (3) To implement EU legislation, provisions on the minimum dimensions of the unit packets of tobacco products may be issued by decree of the Ministry of Social Affairs and Health.

Section 35

Shape, material and opening mechanism of the unit packets of certain tobacco products

- (1) Unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch.
- (2) A unit packet of cigarettes shall consist of carton or soft material. It shall not have an opening that can be re-closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. If a unit packet has a

flip- top lid or a hinged lid, the lid shall be hinged only at the back of the unit packet.

Section 36

Labelling of unit packets of electronic cigarettes and refill containers

(1) Unit packets of electronic cigarettes and refill containers shall include:

- 1) a list of ingredients contained in the product in descending order of the weight;
- 2) an indication of the nicotine content of the product and the delivery per dose;
- 3) the manufacturer's batch number;
- 4) a recommendation to keep the product out of reach of children;
- 5) health warnings in Finnish and in Swedish;
- 6) a leaflet with information on the product and its use and the necessary contact details.

(2) Subsections 1(1), (2) and (5) shall not apply to electronic cigarettes that are not pre-filled with a nicotine-containing liquid.

(3) Electronic cigarettes, refill containers or unit packets thereof shall not include any of the prohibited labelling elements referred to in section 33. This shall not apply to information on the nicotine content, delivery per dose and flavourings.

(4) Further provisions on the text, font and font size, colour, surface area, position and other properties of the health warning referred to in subsection 1(5) as well as on the information to be included in the leaflet referred to in subsection 1(6) may be issued by decree of the Ministry of Social Affairs and Health.

Section 37

Labelling of electronic cigarettes and refill containers

Provisions on the labelling of electronic cigarettes that are pre-filled with nicotine-containing liquid and of refill containers are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Section 38

Labelling of unit packets of nicotine-free liquid intended for vaporisation

Sections 36(1)(1) and 36(3) above also apply to nicotine-free liquids intended for vaporisation and the unit packets thereof.

Section 39

Labelling of unit packets of herbal products for smoking

- (1) Unit packets of herbal products for smoking shall include warnings in Finnish and in Swedish on the adverse health effects of the product. Further provisions on the text, font and font size, colour, surface area, position and other properties of the health warnings may be issued by decree of the Ministry of Social Affairs and Health.
- (2) Herbal products for smoking or unit packets thereof shall not include any of the prohibited labelling elements referred to in section 33(1–4) or (6), and the product or its unit packet shall not state that the product is free of additives or flavourings.

Section 40

Derogation concerning warning labels in international traffic

The provisions of sections 32(1)(1), 36(1)(5) and 39(1) concerning the use of Finnish and Swedish in warning labels shall not apply to tobacco products, electronic cigarettes, refill containers and herbal products for smoking that are sold on board a vessel or aircraft in commercial international traffic or in a tax-free shop at an airport.

Chapter 6

Traceability of tobacco products

Section 41

Recording

- (1) All economic operators involved in the trade of tobacco products, except the retailer, shall record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. Recorded data shall not be modified or deleted.
- (2) All economic operators engaged in the supply chain of tobacco products shall maintain complete and accurate records of all relevant transactions.
- (3) Manufacturers of tobacco products shall provide the economic operators referred to in subsection 1 with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility set out in section 42.

Section 42

Data storage facility

- (1) Manufacturers and importers of tobacco products shall conclude with an

independent third party a data storage contract in which the third party undertakes to host a data storage facility for all data that are relevant for traceability. The data storage facility shall be physically located on the territory of the EU. The suitability of the third party and the data storage contract shall be approved by the Commission.

- (2) The activities of the third party referred to in subsection 1 above shall be monitored by an external auditor, who is proposed and paid by the tobacco product manufacturer and approved by the Commission. The external auditor shall submit an annual report to the Commission and Finnish Customs, assessing in particular any irregularities in relation to access.
- (3) The external auditor referred to in subsection 2 as well as the Commission, Finnish Customs and the competent authorities of other EU Member States shall have full access to the data storage facilities. In duly justified cases the Commission or Finnish Customs may grant manufacturers or importers access to the stored data.
- (4) Separate provisions shall govern the protection of trade and professional secrets and the protection of personal data.

Section 43

Further provisions on traceability

Further provisions on the following may be given by decree of the Ministry of Social Affairs and Health:

- 1) technical standards for the establishment and operation of the tracing system, including the marking with a unique identifier as referred to in section 32(1)(2), the recording, transmitting, processing and storing of data and access to stored data;
- 2) technical standards for ensuring that the systems used for the unique identifier referred to in section 32(1)(2) and the related functions are fully compatible with each other across the EU;
- 3) the key contents of the data storage contracts referred to in section 42, such as duration, renewability, regular monitoring, evaluation, expertise required and the definition of confidentiality.

Chapter 7 Sales and other supply

Section 44 *Retail licence*

- (1) Tobacco products and nicotine-containing liquids may only be sold or otherwise supplied under a retail licence that is specific to the sales outlet and licence holder and granted by the municipality where the sales outlet is located. However, the licence for retail sale on a means of transport moving across several municipalities is granted by the licence applicant's municipality of residence.
- (2) A retail licence may be granted for a fixed period if the operation is meant to continue for a fixed period. A fixed-term licence may be granted for a maximum of one year at a time.

Section 45 *Preconditions for and impediments to granting a retail licence*

- (1) A retail licence referred to in section 44 is granted by the municipality on application. The preconditions for granting the licence are that the applicant is an adult and presents an acceptable self-monitoring plan as referred to in section 54 and that there are no impediments to granting the licence arising from subsections 2 and 3. However, a retail licence cannot be granted if the activities specified in the application would clearly be in violation of this Act or if the sales outlet cannot be monitored by the municipality.
- (2) A retail licence may not be granted to an applicant whose retail licence, which was granted pursuant to this Act or the Tobacco Act (693/1976), hereinafter referred to as the *old Tobacco Act*, has been permanently cancelled during the previous two years.
- (3) A retail licence may not be granted to an outlet that is located:
 - 1) in the indoor areas of a day-care centre or a family day care home or in the outdoor areas of a day-care centre;
 - 2) in indoor or outdoor areas intended for children under the age of 18 at institutions providing care under the Child Welfare Act (417/2007) or the Mental Health Act (1116/1990);
 - 3) in the indoor areas or student accommodation of educational institutions providing basic, vocational or upper secondary education or in the outdoor areas used by such institutions.

Section 46

Form and content of the retail licence application

- (1) The application for a retail licence shall be submitted in writing. The application shall include:
- 1) the applicant's name or business name and contact details in Finland, personal or business identity code, and the address of the outlet that will sell the products;
 - 2) information specifying the products that the licence application concerns;
 - 3) a self-monitoring plan;
 - 4) information specifying the number and location of points of sale at the sales outlet;
 - 5) information specifying the placement of tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes and nicotine-containing liquids at the point of sale.
- (2) Further provisions on the content of the licence application may be given by decree of the Ministry of Social Affairs and Health.

Section 47

Display of the retail licence

The retail licence shall be kept on display to customers at the point of sale. Further provisions on the size, layout and display of the licence may be issued by decree of the Ministry of Social Affairs and Health.

Section 48

Notification of the retail sale of nicotine-containing liquids

- (1) An operator holding a tobacco product retail licence that has been granted under the old Tobacco Act may also sell nicotine-containing liquids at the same sales outlet after submitting a written notification on the matter to the municipality that has granted the licence and providing the municipality with an updated version of the information specified in section 46(1).
- (2) After receiving the notification referred to in subsection 1, the municipality shall send to the applicant an acknowledgement of receipt without delay.

Section 49

Notifications concerning the retail licence

The holder of a retail licence shall inform the municipality of any changes in the information it has provided in the application referred to in section 46 or in the notification referred to in section 48 and of terminating sales. The municipality shall inform Valvira of granting and cancelling licences, changes concerning licences,

sales violations and the termination of sales.

Section 50

Wholesale notification

- (1) Anyone who has submitted a written notification to the municipality where the sales outlet is located may engage in the wholesale of tobacco products and nicotine-containing liquids. The notification shall include the information referred to in section 46(1). A similar notification shall be made before making any significant changes to the activities or when terminating the activities.
- (2) After receiving the notification referred to in subsection 1, the municipality shall send to the applicant an acknowledgement of receipt without delay.
- (3) The municipality shall inform Valvira of the notifications referred to in subsection 1.

Section 51

Prohibition on the sale of certain smokeless tobacco products (1374/2016)

Chewing tobacco, nasal tobacco and tobacco for oral use may not be sold or otherwise supplied or passed on.

Section 52

Prohibition on the sale of certain nicotine-containing liquids

Nicotine-containing liquids that are intended for vaporisation via an electronic cigarette and contain nicotine in excess of 20 milligrams per millilitre or are intended for a purpose referred to in section 3(1) of the Medicines Act may not be sold or otherwise supplied.

Section 53

Prohibition on the sale to minors

- (1) Tobacco products and nicotine-containing liquids may not be sold or otherwise supplied or passed on to persons under the age of 18.
- (2) Tobacco substitutes, smoking accessories and electronic cigarettes may not be commercially sold or otherwise supplied to persons under the age of 18.
- (3) A clearly noticeable sign regarding the age limits for sales shall be displayed at the points of sale of products referred to in subsections 1 and 2. Further provisions on the content of the sign may be issued by decree of the Ministry of Social Affairs and Health.

Section 54

Self-monitoring plan

An economic operator selling tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes or nicotine-containing liquids shall, at their own expense, draw up and implement a self-monitoring plan for complying with the prohibitions laid down in sections 53(1) and (2). Further provisions on the preparation, content and implementation of a self-monitoring plan may be issued by decree of the Ministry of Social Affairs and Health.

Section 55

Continuous supervision of purchase situations

A salesperson shall be present at the point of sale so that he or she can continuously supervise the purchase of tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes and nicotine-containing liquids.

Section 56

Minimum age of salespersons

A person engaged in the commercial sale of tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes or nicotine-containing liquids shall be at least 18 years of age. However, a person younger than that may sell the above-mentioned products, if they are sold under the supervision of a person who has attained the age of 18.

Section 57

Ban on automatic vending machines

Tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes or nicotine-containing liquids shall not be sold or otherwise supplied from automatic vending machines.

Section 58

Ban on distance sales

The cross-border distance sales of tobacco products, electronic cigarettes and nicotine-containing liquids are prohibited. Furthermore, an economic operator established in Finland shall not sell or otherwise supply the mentioned products to consumers using a means of distance communication as referred to in Chapter 6, section 7(2) of the Consumer Protection Act (38/1978).

Section 59

Ban on sale at customs auction

Tobacco products, herbal products for smoking, electronic cigarettes and

nicotine-containing liquids shall not be sold at customs auction.

Section 60

Restrictions on wholesaling

- (1) Tobacco products may only be sold at wholesale for retail purposes to wholesalers that have submitted the notification referred to in section 50 and to those who hold:
 - 1) a retail licence as referred to in section 44 and have submitted a notification of selling tobacco products under section 46(1)(2) or section 49;
 - 2) a retail licence granted under the old Tobacco Act.
- (2) Nicotine-containing liquids may only be sold at wholesale to wholesalers that have submitted the notification referred to in section 50 for retail purposes and to those who hold:
 - 1) a retail licence as referred to in section 44 and have submitted a notification of selling nicotine-containing liquids under section 46(1)(2) or section 49;
 - 2) a retail licence granted under the old Tobacco Act and have submitted a notification referred to in section 48.
- (3) Tobacco products or nicotine-containing liquids may not be sold at wholesale in places referred to in section 45(3).
- (4) In addition, tobacco products and nicotine-containing liquids may be sold at wholesale to retailers who do not need a retail license referred to in this Act, and to wholesalers who are not subject to the information obligation laid down by this Act.
(1374/2016)

Chapter 8

Import

Section 61

Definition of border in import

(1374/2016)

The provisions on import laid down in section 63 and 65 also apply to import as referred to in section 18(2) of the Act on Derogations Concerning the Province of Åland from the Provisions of the Value Added Tax and Excise Duty Legislation (1266/1996).

Section 62

Ban on import by minors

Persons under the age of 18 shall not import tobacco products or nicotine-containing liquids.

Section 63

Ban on the import of certain smokeless tobacco products
(1374/2016)

- (1) The import of chewing tobacco, nasal tobacco and tobacco for oral use is prohibited. The import ban also applies to the acquisition and reception of such tobacco products by mail or other comparable means from countries outside Finland.
- (2) Notwithstanding the provisions of subsection 1, private persons may import for their personal use a maximum of 1,000 grams of tobacco products referred to in subsection 1 within a calendar day.
- (3) The import ban referred to in subsection 1 above shall not apply to products held in closed sales or storage facilities on board vessels or aircraft operating in international traffic.

Section 64

Ban on the import of certain nicotine-containing liquids

- (1) Private persons may not import nicotine-containing liquids that are intended for vaporisation via an electronic cigarette and that contain nicotine in excess of 20 milligrams per millilitre or are intended for a purpose referred to in section 3(1) of the Medicines Act. The import ban also applies to the acquisition and reception of such liquids by mail or other comparable means from countries outside Finland.
- (2) Notwithstanding the provisions of subsection 1, private persons may import for their personal use a maximum of 10 millilitres of such liquids.

Section 65

Ban on the import of products acquired using means of distance communication

Private persons shall not acquire or receive from an economic operator tobacco products, electronic cigarettes or nicotine-containing liquids by mail, freight or other comparable means from countries outside Finland.

Section 66

Time limits for imports by travellers

- (1) A person resident in Finland who arrives in Finland from outside the European Economic Area by means other than air transport and whose journey has lasted no more than 24 hours may not import tobacco products or nicotine-containing liquids.
- (2) A person resident outside the European Economic Area who arrives in Finland from outside the European Economic Area by means other than air transport and whose stay in Finland is not a transit journey and lasts no more than three days may not import tobacco products or nicotine-containing liquids.
- (3) Notwithstanding the provisions of subsection 1, a person may import tobacco products and nicotine-containing liquids if it is apparent that they were acquired before the person left Finland. Notwithstanding the provisions of subsection 2, a person may import said products if it is apparent that they are intended for his or her personal use during the stay in Finland.

Section 67

Quantitative restrictions on import by travellers

- (1) Private persons may import:
 - 1) tobacco products whose unit packet labelling differ from that laid down in section 32(1)(1) a maximum amount of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of roll-your-own or pipe tobacco;
 - 2) nicotine-containing liquids in electronic cigarettes or refill containers whose unit packet labelling differ from that laid down in section 36(1)(5) a maximum amount of 10 millilitres;
 - 3) herbal products for smoking whose unit packet labelling differ from that laid down in section 39(1) a maximum amount of 200 pre-rolled units and 250 grams of loose product.
- (2) Private persons may import the products referred to in subsection 1 only for their own use.

Chapter 9

Bans on marketing and display

Section 68

Marketing ban

The marketing of tobacco products, tobacco substitutes, smoking accessories, tobacco imitations, electronic cigarettes or nicotine-containing liquids is prohibited.

Section 69

Derogations from the marketing ban

(1) The provisions of section 68 shall not apply to:

- 1) marketing in publications which are printed and published outside the EU and are not principally intended for the EU market and whose main purpose is not the marketing of a tobacco product, tobacco substitute, smoking accessory, tobacco imitation, electronic cigarette or nicotine-containing liquid;
- 2) the marketing of individual smoking accessories, other than new accessories, that are considered collector's items, if the brand names of the products are not visible in the marketing;
- 3) product information provided by product manufacturers or importers to parties engaged in the sale of the product.

(2) The product information referred to in subsection 1(3) above includes information on the product's price, composition, properties, manufacturing, health risks and adverse health effects, country of origin and unit packet. A picture of the product or its unit packet may be provided as product information only when accompanied by other product information. No other pictures may be included in product information. The contents of product information shall provide a party engaged in selling the product with comprehensive and accurate information about the product and its properties.

Section 70

Ban on price rebates

An economic operator shall not offer or pay a rebate on the price of tobacco products, tobacco substitutes, smoking accessories, tobacco imitations, electronic cigarettes or nicotine-containing liquids which is based on the purchase of the mentioned products or other consumer goods and services.

Section 71

Display ban

- (1) It is prohibited to display tobacco products, tobacco substitutes, electronic cigarettes, nicotine-containing liquids and the trademarks thereof in the retail sale of tobacco products, tobacco substitutes, electronic cigarettes and nicotine-containing liquids.
- (2) The display ban laid down in subsection 1 above does not apply to sales outlets which have a separate entrance and which sell almost exclusively the products referred to in this Act, provided that the products and their trademarks are not visible from outside the sales outlet.
- (3) The provisions of subsection 1 do not apply to sales on board a vessel engaged in international maritime transport.

Section 72

Catalogue and list

Notwithstanding the provisions of sections 68 and 71, a retailer may show purchasers at their request a printed catalogue presenting the products or unit packets thereof on sale at the sales outlet. At the purchaser's request, a retailer may also give to a purchaser a printed list of said products and their prices. Further provisions on the format, content and layout of the catalogue and list may be issued by decree of the Ministry of Social Affairs and Health.

Chapter 10

Smoking bans and restrictions

Section 73

Application of smoking bans

The provisions laid down in this Chapter regarding smoking and tobacco smoke also apply to the consumption of herbal products for smoking and the use of electronic cigarettes as well as the resulting smoke, vapour and particles.

Section 74

General smoking bans

(1) Smoking is prohibited:

- 1) in the indoor areas of buildings, vehicles or similar places that are accessible to the public or employees or accessible to customers for the purpose of providing commercial or public services;
- 2) in shelters, auditoriums and other spectator areas at public events organised outdoors or other facilities that are directly intended for following the event and where participants stay in one place;
- 3) in the outdoor areas of day-care centres or institutions providing pre-primary, basic, vocational or upper secondary education.

(2) Smoking is also prohibited in private vehicles with anyone under the age of 15 present in the vehicle. The prohibition does not apply to living areas inside vehicles.

(3) Smokeless tobacco products may not be consumed in the indoor or outdoor areas of day-care centres or institutions providing pre-primary, basic, vocational or upper secondary education.

Section 75

Derogations from general smoking bans

(1) Notwithstanding the provisions of section 74(1)(1) above, smoking is allowed in:

- 1) the home or private vehicle of a customer, employee, economic operator or self-employed person and any other indoor areas that are in the exclusive use of persons belonging to the same family and others living in the same household; however, this does not apply to the indoor areas of family day care homes when family day care is provided in the premises;
- 2) a maximum of one out of ten rooms for customer accommodation in a hotel or other tourist accommodation establishment or, depending on the number of rooms, in a maximum of three rooms;
- 3) the indoor areas of a restaurant on board a vessel used in international maritime transport when the serving area is not larger than 50 square metres or in larger establishments no more than 50 per cent of the area.

(2) The proprietors of indoor premises who allow smoking in the indoor areas referred to in subsection 1(2) or (3) or in outdoor areas under their control shall ensure that employees in the indoor areas are not exposed to tobacco smoke and that tobacco smoke cannot enter areas where smoking is prohibited.

Section 76

Smoking area

(1) In the indoor areas referred to in section 74(1)(1) above, smoking may be allowed in a separate smoking area that has been approved for smoking purposes under the Land Use and Building Act (132/1999). In such cases, it shall be ensured that tobacco smoke cannot enter areas where smoking is prohibited. Smoking areas shall not be located in connection with indoor areas that are mainly used by persons under the age of 18.

(2) Apart from work that is necessary for maintaining order, fire and rescue services and work that is necessary for ensuring safety, working is prohibited in smoking areas. The smoking area may be cleaned only after it has been carefully aired.

(3) Further provisions on technical requirements concerning the structural and functional properties of smoking areas may be issued by government decree.

Section 77

Smoking area in a restaurant

(1) If a smoking area referred to in section 76 is established in a restaurant, it must be reasonably large in proportion to the size and seating capacity of the business premises. It is prohibited to serve or consume food and drink in the smoking area.

- (2) An economic operator shall draw up a self-monitoring plan describing how the functionality of the smoking area is to be ensured and how the conditions and order in the smoking area can be supervised from outside the area.
- (3) Further provisions on the minimum and maximum surface area of the smoking area and on the proportion of the surface area to the size or seating capacity of the restaurant's serving area may be issued by government decree.

Section 78

Smoking bans in housing corporations

- (1) Smoking is prohibited in the shared and public indoor areas of housing corporations.
- (2) A housing corporation may prohibit smoking in shared outdoor areas under its control near the entrances and air inlets of the building, in children's play areas and on shared balconies.

Section 79

Imposition of smoking bans in housing corporations (1374/2016)

- (1) A housing corporation may submit an application requesting the municipality to impose a ban that forbids smoking on the balconies of individual apartments in a building belonging to the housing corporation, in the outdoor areas to which the apartments have access, and inside apartments. The occupants of the apartments referred to in the application shall be heard before submitting the application.
- (2) The municipality shall impose a smoking ban on the areas referred to in the application if, due to structural or other conditions, tobacco smoke may other than occasionally spread from the area in question to another balcony, to an outdoor area belonging to another apartment or inside another apartment. Smoking may be prohibited inside an apartment only if the spreading of smoke cannot be reasonably prevented by repairing or altering the structures and the occupant of the apartment has been, prior to the ban, given an opportunity to take measures to prevent the smoke from spreading. The prohibition of smoking inside an apartment does not apply to the use of electronic cigarettes.
- (3) The municipality shall withdraw the smoking ban upon the housing corporation's request if there no longer are grounds for the ban due to changed circumstances. The ban may also be withdrawn upon the occupant's application if the housing corporation does not apply for withdrawal of the ban despite significant changes in the circumstances. Further provisions on how to submit an application for a smoking ban or its withdrawal and on how to record the hearing organised by the housing corporation in the application may be issued by government decree.

(4) The hearing referred to in section 1 above is regarded as carried out if the housing corporation informs the occupants of the apartments mentioned in the application of the grounds for the application not later than two weeks before making a decision, and by the same date gives them instructions for transmitting their comments. The information shall be submitted:

- 1) in case of a person occupying the apartment on the basis of a proprietary right, to the postal address known to the housing corporation, or to the email address or other telecommunication address that the occupant has submitted to the housing corporation; and
- 2) in case of a person occupying the apartment on the basis of a lease, on the commonly used notice board of the housing corporation or by delivering the information to the apartment.

Section 80

'No smoking' signs

The proprietors of indoor or outdoor areas and organisers of public events shall put up signs indicating areas where smoking is prohibited under section 74(1) and where smoking is allowed under sections 76 and 77. The content of the signs shall be unambiguous, and the size and location of the signs shall be such that they are easily visible to those who enter or spend time in the premises.

Section 81

Enforcement of smoking bans

Any person who violates a smoking ban referred to in section 74 and does not stop smoking despite being asked to do so may be removed from the premises by the proprietor or his or her representative, unless such removal can be considered unreasonable.

Section 82

Notifications by authorities

- (1) Labour protection authorities, municipalities and, where necessary, the police shall notify the licensing authority specified in the Alcohol Act (1143/1994) of any violations of the provisions concerning smoking areas, and the building control authority of any violations of the provisions concerning the construction and maintenance of smoking areas as well as repairs and alterations to smoking areas.
- (2) The licensing authority under the Alcohol Act shall notify the labour protection authority and the municipality of any violations of provisions concerning smoking areas and smoking outdoors that it has observed. The labour protection authority and the municipal supervisory authority shall notify each other of any violations of

the provision referred to above.

Chapter 11 Direction and supervision

Section 83 *Supervision programme* (1374/2016)

- (1) To guide and coordinate the implementation of this Act, Valvira shall draw up a national supervision programme for the Tobacco Act (*supervision programme*).
- (2) The supervision programme shall be revised as necessary. The shared objectives for environmental health care set by the national supervision programme for environmental health care shall be taken into account in the supervision programme for the Tobacco Act.

Section 84 *Supervision plan*

- (1) Each municipality shall draw up and adopt a supervision plan for the Tobacco Act (*supervision plan*) for regular supervision of compliance with this Act. The supervision shall be of a high quality and based on risks as well as prevent adverse effects on health.
- (2) The supervision plan shall take into account the supervision programme in accordance with local needs. The supervision plan shall be revised as necessary.
- (3) Regional state administrative agencies shall evaluate the supervision plans and their implementation within their respective territories.

Section 85 *Approval of a verification laboratory*

- (1) The emission measurements referred to in section 12 shall be verified and the burning behaviour of cigarettes referred to in section 13 demonstrated by a laboratory which is approved and monitored by Valvira. The laboratory shall not be owned or controlled by the manufacturer or importer of a tobacco product. Valvira shall maintain and update a list of approved laboratories and communicate it to the Commission.
- (2) Laboratories shall submit their applications for approval to Valvira. Valvira approves a laboratory if the laboratory presents, attached to its application, a

certificate indicating that the Finnish Accreditation Service (FINAS) has ascertained that the laboratory meets the international requirements concerning the proficiency of verification laboratories and that its field of competence includes the methods referred to in sections 12 and 13. The laboratory shall inform Valvira of any changes concerning the grounds for its approval.

- (3) A laboratory is considered approved without a separate decision, if it provides Valvira with a certificate indicating that it has been approved by an authority of another EU Member State and states the grounds on which the laboratory and its verification methods have been approved.
- (4) Further provisions on the laboratories referred to in this section, their approval, the accreditation procedure required for the approval, the implementation of supervision and the notifications to be submitted to Valvira and the Commission may be issued by decree of the Ministry of Social Affairs and Health.

Section 86

Inspection and sampling rights

- (1) To supervise compliance with this Act and the provisions issued under it, Valvira and municipalities have the right to:
 - 1) inspect the facilities and operations of establishments for manufacturing, packaging, storing and selling the products referred to in this Act and of the verification laboratories as well as any documents necessary for supervision;
 - 2) take and receive for examination free samples of products referred to in this Act from the manufacturer, importer and seller of the product in question.
- (2) An inspection referred to in subsection 1 may not be carried out in premises intended for permanent accommodation unless it is necessary for investigating the matters subject to inspection and there are reasonable grounds to suspect a tobacco sales offence under section 109 or a tobacco marketing offence under section 111.
- (3) An inspection of a dwelling in relation to the smoking bans and restrictions laid down in Chapter 10 of this Act is subject to section 46 of the Health Protection Act (763/1994).
- (4) In other respects, the inspections under this Act are subject to the provisions of section 39 of the Administrative Procedure Act (434/2003).
- (5) If the samples referred to in subsection 1(2) are not provided within the time allowed, Valvira or the municipality may issue a notice of a conditional fine to enforce the obligation. The decision on ordering a conditional fine to be paid is made by an Administrative Court on the application of the authority issuing the

notice of a conditional fine. However, a notice of a conditional fine may not be issued if there is reason to suspect the party in question of an offence and the material requested is related to a matter subject to suspicion of an offence.

Section 87

Right of access to information

- (1) Valvira and municipalities have the right to obtain information that is necessary for investigating violations of this Act and the provisions issued under it from manufacturers, importers and sellers of the products referred to in this Act as well as from other authorities, free of charge and confidentiality provisions notwithstanding.
- (2) If the information referred to in subsection 1 is not provided within the time allowed, Valvira or the municipality may issue a notice of a conditional fine to enforce the obligation. The decision on ordering a conditional fine to be paid is made by an Administrative Court on the application of the authority issuing the notice of a conditional fine. However, a notice of a conditional fine may not be issued if there is reason to suspect the party in question of an offence and the material requested is related to a matter subject to suspicion of an offence.
- (3) Upon request, municipalities and regional state administrative agencies have the obligation to provide Valvira with information on inspections and other supervisory measures, supervisory personnel, fees and other information on supervision, free of charge, for the purposes of guiding, monitoring and reporting on the supervision under this Act as well as for compiling related statistics. The information shall be submitted in the manner specified by Valvira.

Section 88

Disclosure of information

Notwithstanding confidentiality provisions, Valvira or municipalities may disclose to another supervisory authority information on business or professional secrets that it has obtained when supervising compliance with this Act or when performing tasks relating to supervision, if the information is necessary for performing the supervisory task assigned by law to the authority in question. Information may also be disclosed to foreign bodies and inspectors as required by EU legislation or other international obligations binding on Finland if the legislation or agreement in question so requires.

Section 89

Executive assistance

Valvira and municipalities have the right to receive executive assistance from other authorities in order to supervise compliance with this Act and the provisions issued under it and to enforce decisions issued under this Act.

Section 90

Fees for processing applications and notifications

- (1) The municipality charges a fee for the following tasks based on the rates it has approved:
 - 1) processing an application for a retail licence referred to in section 44;
 - 2) processing a notification concerning the retail sale of a nicotine-containing liquid as referred to in section 48;
 - 3) processing a wholesale notification referred to in section 50;
 - 4) processing an application for a smoking ban referred to in section 79.
- (2) The fees charged by municipalities for performing the tasks referred to in subsection 1 shall not exceed the total costs incurred in performing the task.
- (3) Valvira may charge a fee from manufacturers or importers for the following tasks:
 - 1) examining whether a tobacco product contains properties or additives prohibited by section 11;
 - 2) verifying the measurements of tar, nicotine and carbon monoxide yields of cigarettes;
 - 3) receiving, storing, handling, analysing and publishing the information submitted to the authority under sections 14–16, 18, 20 and 26–29 and for related measures;
 - 4) peer reviews referred to in section 18(3).
- (4) Provisions on the amount of the fee referred to in subsection 3 are laid down by the Act on Criteria for Charges Payable to the State (150/1992).

Section 91

Fees for supervision of compliance with the Tobacco Act

- (1) The municipality charges an annual supervision fee, which is based on the rate the authority has approved and specific to the point of sale, from those who hold a retail licence referred to in section 44 or granted under the old Tobacco Act and from those who have submitted a wholesale notification referred to in section 50 of this Act.
- (2) The supervision fee shall not exceed EUR 500 per point of sale. If an operator has submitted a notification for the retail sale or wholesale of both tobacco products and nicotine-containing liquids in accordance with section 46(1)(2) or section 50(1) or has submitted a notification of the retail sale of nicotine-containing liquids as referred to in section 48, the maximum amount charged shall be twice the amount of the supervision fee.

- (3) The municipality charges a supervision fee for the year in question for all retail licences that are valid and activities that are being carried out under a wholesale notification on 1 January. If a retail licence is granted or a wholesale notification is submitted during the course of the year or an activity is pursued for less than a year, the municipality may collect a supervision fee that is proportional to the duration of the activity.

Section 92

Recovery of and interest on fees

- (1) The fees laid down in this Act are directly distrainable. Provisions on their recovery are laid down in the Act on the Enforcement of Taxes and Charges (706/2007).
- (2) If the payment is overdue, an interest for late payment shall be paid in accordance with section 4(1) of the Interest Act (633/1982). The due date may be at the earliest two weeks after the delivery of the service on which the fee is based. Instead of interest for late payment, the authority may charge a penalty of five euros for late payment if the amount of the interest for late payment is lower than that.

Section 93

Reimbursement of costs to municipalities

The State shall reimburse the costs incurred by municipalities for such tobacco control inspections, sampling, research and studies that are laid down in this Act to be tasks of Valvira but have been carried out by a municipality as executive assistance.

Section 94

Storing and publishing product control information

- (1) Valvira shall store all information provided to it under sections 14–16 and 18 electronically and in such a way that the Commission and the competent authorities of other EU Member States have access to the information. Valvira shall also make all information received pursuant to section 20 available to the Commission. Furthermore, Valvira shall, upon request, make all information received pursuant to sections 26–28 available to the Commission and the competent authorities of other EU Member States.
- (2) With the exception of business and professional secrets, Valvira shall make the information received under section 14(1)(1–4) and sections 15, 18, 26 and 29 publicly available on a website where information can be searched only through individual searches using as search criterion the name of the product or the name or business identity code of the registered operator.
- (3) By way of derogation from the provisions of section 16(3) of the Act on the

Openness of Government Activities (621/1999), the name of a natural person referred to in section 26(2)(1) of this Act shall be made public in an unaltered form when information is made available in accordance with subsection 2 of this section. The information referred to in section 26(2) shall be stored permanently.

- (4) Further provisions on the format for making available the information referred to in subsection 2 may be issued by decree of the Ministry of Social Affairs and Health.

Section 95

Register of retail licences and wholesale notifications

(1374/2016)

- (1) For the purpose of processing, supervising and compiling statistics of the licence and notification matters referred to in this Act, Valvira and local authorities shall keep a register of economic operators:
- 1) who have been granted a licence referred to in section 44 or who have applied for such a licence;
 - 2) who have submitted a notification referred to in sections 48–50.
- (2) Valvira is responsible for ensuring that the register's data processing system functions. The information to be registered shall include:
- 1) the applicant's or notifier's name, business name and contact details in Finland, personal or business identity code, and the address of the outlet selling the products;
 - 2) licence or notification number, information on the activities and self-monitoring carried out under the licence or notification, information on violations of this Act and the provisions and prohibitions issued under it and of any consequences of such violations as well as information on any inspections carried out by authorities and their outcomes;
 - 3) other information necessary for processing, supervising and compiling statistics of licence and notification matters.
- (3) By way of derogation from the provisions of section 16(3) of the Act on the Openness of Government Activities, the name of the licence holder and notifier, the licence and notification number and the address and contact details intended for public use may be made publicly available in the register in unaltered form, allowing information to be searched only through individual searches using as search criterion the licence holder's or notifier's name, business identity code, licence or notification number or the name of the sales outlet. Information concerning economic operators shall be stored in the register for five years after the termination of sales or cancellation of a retail licence.

Chapter 12
Prohibitions and cancellation of a retail licence

Section 96
Prohibitions issued by a municipality

If a municipality performing its supervisory duties observes within its territory activities that violate this Act or the provisions issued under it, the municipality may prohibit such activities.

Section 97
Cancellation of a retail licence
(1374/2016)

- (1) A municipality may cancel a retail licence referred to in section 44 or granted under the old Tobacco Act for a fixed period of at least one week and not more six months, if the holder of the retail licence despite a written warning or a criminal sanction issued by the municipality or other supervisory authority:
- 1) sells or otherwise supplies tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation or herbal products for smoking whose unit packets do not comply with the provisions of Chapter 5;
 - 2) fails to provide relevant information concerning sales of nicotine-containing liquids, in violation of the provisions laid down in section 48, or relevant information referred to in section 49;
 - 3) sells or otherwise supplies chewing tobacco, nasal tobacco and tobacco for oral use in breach of section 51;
 - 4) sells or otherwise supplies tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes or nicotine-containing liquids to persons under the age of 18 in violation of section 53 or allows a person under the age of 18 to sell or otherwise supply the mentioned products in violation of section 56;
 - 5) sells or otherwise supplies tobacco products, tobacco substitutes, smoking accessories, electronic cigarettes or nicotine-containing liquids from an automatic vending machine in violation of section 57;
 - 6) sells or otherwise supplies tobacco products, electronic cigarettes or nicotine-containing liquids to consumers using a means of distance communication in violation of section 58;
 - 7) markets tobacco products, tobacco substitutes, smoking accessories, tobacco imitations, electronic cigarettes or nicotine-containing liquids in violation of section 68;
 - 8) displays tobacco products, tobacco substitutes, electronic cigarettes, nicotine-containing liquids or their trademarks at the sales outlet in violation of section 71.
- (2) A municipality may permanently cancel a retail licence, if the holder of the

retail licence continues or resumes the illegal activity referred to in subsection 1 despite the temporary cancellation of the licence and if the act cannot be considered minor.

Section 98

Reporting sales violations to the municipality

If the police become aware of any violations of this Act that may constitute grounds for cancelling a retail licence, they shall report them to the municipality that has issued the licence. The municipality shall also be informed of any measures taken by the police in the matter.

Section 99

Marketing prohibition

If a tobacco product, tobacco substitute, smoking accessory, tobacco imitation, electronic cigarette or nicotine-containing liquid is being marketed in violation of section 68 and the practice is not limited to the territory of one municipality, Valvira may prohibit the party commissioning or executing the marketing activity as well as those employed by them from continuing and resuming the non-compliant activity.

Section 100

Sales prohibition

- (1) Valvira may prohibit the sale or other supply of a tobacco product, electronic cigarette, nicotine-containing liquid, nicotine-free liquid intended for vaporisation and herbal product for smoking, if:
- 1) the tobacco product includes additives or properties prohibited under section 11;
 - 2) the emissions of the tobacco product have not been measured as required by section 12 or verified in a laboratory that has been approved in accordance with section 85 or if the emissions exceed the maximum levels laid down in section 12 or under it;
 - 3) the burning behaviour of a cigarette does not meet the requirements laid down in section 13 or under it, or if the burning behaviour has not been tested and verified in accordance with section 13 or by a laboratory that has been approved in accordance with section 85;
 - 4) an electronic cigarette or refill container does not meet the requirements laid down in section 23 or under it or in section 24(3);
 - 5) a nicotine-containing liquid does not meet the requirements laid down in section 24 or under it, or a nicotine-free liquid intended for vaporisation does not meet the requirements laid down in section 25;
 - 6) the manufacturer, importer or distributor of an electronic cigarette or refill container has not established or maintained a system for monitoring adverse effects as referred to in section 28(1) or refuses to provide Valvira with

- information from the monitoring system;
- 7) the manufacturer, importer or distributor of an electronic cigarette or refill container has not in a situation referred to in section 28(2) taken the corrective action referred to in the provision or has not submitted the notification referred to in the provision;
 - 8) the manufacturer or importer has failed to provide Valvira with the information referred to in sections 14–16, 18, 20, 26, 27 or 29 in the manner, time or format prescribed or if the information submitted is incorrect;
 - 9) the manufacturer or importer has failed to pay the fee referred to in section 90(3) to Valvira;
 - 10) the unit packet of a tobacco product does not comply with sections 32–35 or provisions issued under them, an electronic cigarette or refill container or a unit packet thereof does not comply with section 36 or provisions issued under it, the unit packet of a nicotine-free liquid intended for vaporisation does not comply with section 38 or the unit packet of a herbal product for smoking does not comply with section 39 or provisions issued under it.
- (2) Valvira shall notify to the Commission any sales prohibition that has been imposed under subsection 1(1) because the tobacco product does not comply with section 11(1)(1) or (9).
- (3) Valvira may also prohibit a tobacco product from being sold and otherwise supplied to consumers while it considers the preconditions for approving a verification laboratory responsible for verifying the product in accordance with section 85 or the preconditions for cancelling the approval in accordance with section 104, if the authority has reasonable grounds to suspect the correctness of the information concerning the laboratory or the appropriateness of the laboratory's activities. When imposing a sales prohibition, it shall be taken into account whether it is possible for the manufacturer or importer to use another approved laboratory to fulfil the obligations laid down in this Act while the matter is being processed.
- (4) Valvira shall cancel a sales prohibition immediately after grounds for it no longer exist.

Section 101

Withdrawal from the market

In matters referred to in sections 99 and 100, Valvira may require the manufacturer or importer to withdraw the product from the market within a time limit set by Valvira and at the manufacturer's or importer's own expense. Valvira shall cancel the market withdrawal obligation immediately after grounds for it no longer exist.

Section 102

Temporary prohibition

- (1) If the non-compliant practice referred to in section 99 or 100 is of such nature or significance that its continuation or resumption must be urgently prevented, Valvira may issue a temporary prohibition before reaching a final decision on the matter. The temporary prohibition takes effect immediately, and it may be cancelled before the final decision.
- (2) If Valvira ascertains or has reasonable grounds to believe that specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, could present a serious risk to human health despite complying with the requirements of this Act and EU legislation, Valvira may temporarily prohibit the product from being sold or otherwise supplied to consumers. Valvira shall immediately inform the Commission and the competent authorities of other EU Member States of the temporary prohibition and the grounds for it. Final decision on the matter is reached when the Commission has notified whether it considers the prohibition justified.

Section 103

Rectification

When deciding on a prohibition referred to in section 99, 100 or 102 or on a market withdrawal referred to in section 101, Valvira may require the party receiving the prohibition or order to rectify the incorrect or misleading information within the time limit and in the manner determined by the authority, if it is considered necessary due to the apparent adverse effects of the non-compliant practice.

Section 104

Suspending the operations and withdrawing the approval of a verification laboratory

- (1) Valvira may suspend the operations of a verification laboratory referred to in section 85 for a fixed period or withdraw the approval of the laboratory if:
 - 1) the Finnish Accreditation Service (FINAS) ascertains that the laboratory does not meet the requirements for its competency or for the validity of its verification methods; or
 - 2) Valvira has received substantiated information from the authority of another Member State or some other body that the laboratory or the verification methods do not meet the requirements set for their approval or validity or that the measurements reported by the laboratory cannot be considered reliable.
- (2) Valvira may also suspend the operations of a laboratory for a fixed period if the authority has, in a matter that is essential to the operations, reasonable grounds to suspect the correctness of information concerning the laboratory or

the appropriateness of its activities and the warnings issued to the laboratory have not led to those deficiencies being addressed.

Section 105

Notice of a conditional fine and notice of enforced compliance

- (1) To enforce a prohibition or an order issued under the provisions of this Act, Valvira or a municipality may issue a notice of a conditional fine or a notice of enforced compliance, which means that a measure that has not been implemented within the time limit set will be carried out at the defaulter's expense.
- (2) Upon the application of the party issuing a notice of a conditional fine or a notice of enforced compliance, the Market Court shall decide whether to order the conditional fine to be paid or enforced compliance to be implemented as imposed by Valvira or a municipality in a matter referred to in section 107. Provisions on appealing against such notice of a conditional fine and notice of enforced compliance are laid down in section 107.
- (3) In other respects, notices of a conditional fine and notices of enforced compliance are subject to the provisions of the act on notice of a conditional fine (*uhkasakkolaki* 1113/1990).

Chapter 13

Appeals

Section 106

Appeals against the decisions of Valvira and municipalities

- (1) Unless otherwise provided in subsection 4 or section 107, decisions made under this Act may be appealed against by lodging an appeal in an Administrative Court in accordance with the provisions of the Administrative Judicial Procedure Act (586/1996).
- (2) Appeal against a decision of an Administrative Court may only be lodged if the Supreme Administrative Court has granted leave to appeal.
- (3) Subject to the provisions of subsection 2, Valvira may appeal against a decision of an Administrative Court, if the matter concerns:
 - 1) the prohibition of the sale or other supply of a tobacco product under section 100(1)(1);
 - 2) the prohibition of the sale or other supply of an electronic cigarette or refill container under section 100(1)(4);
 - 3) the prohibition of the sale or other supply of a nicotine-containing liquid or

a nicotine-free liquid intended for vaporisation under section 100(1)(5).

- (4) Provisions on appeal against decisions concerning the supervision plan referred to in section 84 or the fees referred to in sections 90 and 91 are laid down in the Local Government Act (410/2015).

Section 107

Appeals in market law cases

- (1) The following decisions may not be challenged by an appeal:

- 1) a prohibition decision or other decision issued by Valvira or a municipality with regard to marketing that does not comply with section 68 or a unit packet of tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation or herbal products for smoking that does not comply with the provisions of Chapter 5;
- 2) a notice of a conditional fine or notice of enforced compliance concerning a decision referred to in paragraph 1.

- (2) A party to whom Valvira has issued a decision referred to in subsection 1 or a notice of a conditional fine or notice of enforced compliance referred to in subsection 1 may refer the matter to the Market Court by submitting an application within 30 days of the service of notice of the decision.

- (3) A party to whom a municipality has issued a decision referred to in subsection 1 or a notice of a conditional fine or notice of enforced compliance referred to in subsection 1 may refer the matter to Valvira by submitting an application within 14 days of the service of notice of the decision. Valvira's decision may be further referred to the Market Court as laid down in subsection 2.

Section 108

Enforcement of a decision irrespective of appeal

- (1) The decisions of administrative authorities as referred to in this Act can be enforced irrespective of appeal. However, the appeal authority has the right to prohibit or suspend the enforcement of the decision pending a final decision on the appeal.
- (2) The provisions of subsection 1 shall not apply to a ban issued under section 79.

Chapter 14
Penal
provisions

Section 109
Tobacco sales offence
(1374/2016)

(1) Any person who intentionally

- 1) sells or otherwise in return for payment supplies or passes on a tobacco product or nicotine-containing liquid to a person under the age of 18 in violation of section 53(1);
- 2) sells or otherwise in return for payment supplies or passes on chewing tobacco, nasal tobacco or tobacco for oral use in violation of section 51;
- 3) commercially sells or otherwise supplies tobacco products or nicotine-containing liquids without a retail licence in violation of section 44 or without submitting a notification of the retail sale of nicotine-containing liquids as referred to in section 48; or
- 4) in wholesale, sells or otherwise supplies, contrary to section 60, tobacco products or nicotine-containing liquids to operators other than those referred to in the said section;

shall be sentenced for a *tobacco sales offence* to a fine or to imprisonment for a maximum of six months.

Section 110
Tobacco marketing violation

(1) A party commissioning or implementing a marketing action and their employees who intentionally

- 1) market a tobacco product, tobacco substitute, smoking accessory, tobacco imitation, electronic cigarette or nicotine-containing liquid in violation of section 68; or
- 2) display tobacco products, tobacco substitutes, electronic cigarettes, nicotine-containing liquids or the trademarks thereof at the sales outlet in violation of section 71;

shall be sentenced for a *tobacco marketing violation* to a fine.

Section 111
Tobacco marketing offence

A party commissioning or implementing a marketing action and their employees who intentionally market a tobacco product, tobacco substitute, smoking accessory,

tobacco imitation, electronic cigarette or nicotine-containing liquid contrary to section 68 in such a way that the marketing, with due consideration to the method of its implementation, the age or size of its target group or the financial benefit gained from the action, is aggravated also when assessed as a whole, shall be sentenced for a *tobacco marketing offence* to a fine or to imprisonment for a maximum of two years.

Section 112
Hearing Valvira

Before bringing charges for a tobacco marketing violation referred to in section 110 and a tobacco marketing offence referred to in section 111, the prosecutor shall reserve Valvira an opportunity to give a statement. When hearing a case dealing with such a matter, the court shall reserve Valvira an opportunity to be heard.

Section 113
Smoking violation

- (1) A person who intentionally and despite an objection from the proprietor of a means of public transport, indoor areas or outdoor areas, or their representative, or an organiser of a public event or a person acting as a steward in such an event, or a supervisory authority continues to smoke in indoor or outdoor areas where smoking is prohibited under section 74(1), shall be sentenced for a *smoking violation* to a fine.
- (2) The provisions of subsection 1 concerning smoking also apply to smoking a herbal product for smoking, using an electronic cigarette and using a smokeless tobacco product in violation of section 74(3) in the indoor and outdoor areas of a day-care centre or institution providing pre-primary, basic, vocational or upper secondary education.

Section 114
Failure to take protective measures against exposure to tobacco smoke

- (1) The proprietor of a means of public transport, indoor areas or outdoor areas, or their representative, or an organiser of a public event who intentionally or through gross negligence:
 - 1) allows smoking in indoor or outdoor areas where it is prohibited, in violation of section 74(1); or
 - 2) allows working in a smoking area in violation of section 76(2) or allows food or drink to be served or consumed in a smoking area in violation of section 77(1);

shall, unless the failure is deemed to be petty or a more severe penalty has been provided elsewhere in law for the act, be sentenced for *failure to take protective measures against exposure to tobacco smoke* to a fine.

(2) The provisions of subsection 1 concerning smoking also apply to smoking a herbal product for smoking and using an electronic cigarette.

Section 115

Reference to the Criminal Code

Provisions on the penalty for smuggling and petty smuggling are laid down in Chapter 46, sections 4 and 5 of the Criminal Code of Finland (39/1889).

Section 116

Waiver of punishment in certain cases

Any person who violates a prohibition or other order referred to in this Act and enforced with a notice of a conditional fine, may be exempted from a penalty for the same act.

Chapter 15

Miscellaneous provisions

Section 117

Outside packaging

The provisions of this Act on the unit packets of tobacco products, herbal products for smoking, electronic cigarettes or refill containers also apply to any outside packaging with the exception of section 32(1)(2), sections 34 and 35 and Chapter 6.

Section 118

Prohibition on possession

Persons under the age of 18 may not possess tobacco products or nicotine-containing liquids.

Section 119

Disposal

Public officials with the power of arrest may verifiably dispose of a tobacco product, herbal product for smoking, electronic cigarette or nicotine-containing liquid and its packaging, or have it disposed of, if the product can be seized, because there is reason to assume that it will be declared forfeit, and it has no significant sales or use value.

Chapter 16
Entry into force

Section 120
Entry into force

- (1) This Act enters into force on 15 August 2016.
- (2) This Act repeals the old Tobacco Act (693/1976).
- (3) If provisions elsewhere in the law refer to the old Tobacco Act, this Act applies instead.
- (4) Section 11(1)(1) of this Act applies to products referred to in Article 7(14) of the Tobacco Products Directive from 20 May 2020.
- (5) The prohibition on characterising flavours and aromas laid down in section 25 of this Act applies to nicotine-free liquids intended for vaporisation from 1 January 2017.
- (6) Section 32(1)(2) and Chapter 6 of this Act apply to the unit packets of cigarettes and roll-your-own tobacco from 20 May 2019 and to the unit packets of other tobacco products from 20 May 2024. Before these dates, the identifiability and traceability of unit packets shall be subject to the provisions in force at the time of the entry into force of this Act.
- (7) The following provisions apply from July 2017: the provisions of section 58 on the cross-border distance sales of electronic cigarettes and nicotine-containing liquids and the provisions of section 65 on banning the import of products acquired using means of distance communication.
(835/2016)
- (8) Sections 70 and 79 of this Act apply from 1 January 2017.
- (9) Section 71 of this Act applies to products mentioned in the provision other than tobacco products from 1 January 2017 if the product does not carry the trademark of a tobacco product. However, the provisions of this subsection do not apply to nicotine-containing liquids and electronic cigarettes that are pre-filled with a nicotine-containing liquid.
- (10) Section 106(3) of this Act will remain in force until 20 May 2026. The provisions in force at the time of the entry into force of this Act apply to appeals against administrative decisions that were issued before the entry into force of this Act, unless otherwise provided in the entry-into-force provision of the Act amending sections 21 and 35 of the Tobacco Act (1043/2015).

Section 121

Transitional provision on notifications

(1374/2016)

- (1) For tobacco products, electronic cigarettes, refill containers and herbal products for smoking that have been legally sold or otherwise supplied to consumers in Finland by 20 May 2016, the notifications and other information referred to in sections 14, 26 and 29 shall be submitted by 20 November 2016.
- (2) For tobacco products, electronic cigarettes, refill containers and herbal products for smoking that have been sold or otherwise supplied to consumers in Finland after 20 May 2016 but before 15 August 2016, the notifications and other information referred to in sections 14, 26 and 29 shall be submitted by 1 March 2017.

Section 122

Transitional provisions on unit packets

- (3) Tobacco products for smoking may be sold or otherwise supplied to consumers in unit packets that comply with the provisions that were in force at the time of the entry into force of this Act until 20 May 2017, if the products have been manufactured or released for free circulation before 20 May 2016.
- (4) Electronic cigarettes that have not been pre-filled with a nicotine-containing liquid and whose unit packets do not comply with section 36 and the provisions issued under it may be sold and otherwise supplied to consumers until 20 May 2017 notwithstanding the mentioned provisions, if the products have been manufactured or released for free circulation before 20 November 2016.
- (5) Herbal products for smoking whose unit packets do not comply with section 39 and the provisions issued under it may be sold and otherwise supplied to consumers until 20 May 2017 notwithstanding the mentioned provisions, if the products have been manufactured or released for free circulation before 20 May 2016.
- (6) Nicotine-free liquids intended for vaporisation whose unit packets do not comply with section 38 may be sold and otherwise supplied to consumers notwithstanding the mentioned provisions until the end of 2016.

Section 123

Transitional provisions on retailing and wholesaling

- (1) Upon the entry into force of this Act, the retail licences granted under the old Tobacco Act will remain in force. However, after the year 2016 no such activities may be continued under such a licence for which a licence may not be granted under the present Act.

(2) The wholesale activities referred to in section 50 of this Act may be continued until the end of 2016 without submitting the notification referred to in the section in question, if the wholesale activities were started before the entry into force of this Act.

Section 124

Transitional provision on certain smokeless tobacco products (1374/2016)

Notwithstanding section 51, chewing tobacco and nasal tobacco may be sold and otherwise supplied by retail until 20 May 2017.

Section 125

Transitional provision on smoking areas

Smoking may be allowed without the approval referred to in section 76(1) in a room intended for smoking or in part of facilities or a space as referred to in section 13(1) of the old Tobacco Act until 20 May 2018.

Section 126

Transitional provision on supervision fees

A local authority may charge the supervision fees referred to in section 91 from 1 January 2017. Before that the provisions of section 25a (2) and (3) apply to supervision fees.