

Government proposal to Parliament for an Act amending the Tobacco Act

MAIN CONTENT OF THE PROPOSAL

The Proposal proposes amendments to the Tobacco Act. The amendment is required because the sale of nicotine pouches has been liberalised as a result of a change in the interpretation of the Medicines Act.

The Proposal would implement the entry in the Government Programme of Prime Minister Petteri Orpo's Government according to which nicotine pouches will be included in the scope of the Tobacco Act and their sale will be authorised in accordance with the rules set for them to prevent youth use, parallel imports and illicit trafficking, and to combat organised crime. Retail sales are made subject to authorisation, the nicotine limits of the products are aligned with those in use in neighbouring countries, and only flavours aimed at adults will be allowed.

The Proposal proposes to add to the Tobacco Act a definition for a 'smokeless nicotine product' that would cover nicotine pouches and products closely resembling these. Typically, these are snus-like products that do not contain tobacco plant but contain nicotine and which are similar to traditional tobacco for oral use in terms of use and appearance.

A nicotine limit would be laid down for smokeless nicotine products and characterising fragrances or flavours would be prohibited with the exception of menthol, mint, tea, ginger, rosemary and wood flavours. In other respects, it is proposed to regulate smokeless nicotine products in a manner similar to that in which the Tobacco Act regulates tobacco products and nicotine fluids. Health warnings would be required for unit packets of the products and the layout of the packaging would be harmonised. The retail sale of products would be subject to authorisation, wholesale sales would be subject to notification and the distance selling of products would be prohibited. Quantity limits and time limits would be imposed on imports, for example. The products and their sale would be subject to supervisory fees. The use of smokeless nicotine products would be prohibited in the indoor and outdoor areas and playgrounds of kindergartens and pre-primary and basic education institutions and vocational and upper secondary education institutions. The possession and import of all tobacco substitutes would be prohibited for persons under 18 years of age.

The proposed Act is intended to enter into force as soon as possible after the end of the standstill period under the Directive on technical regulations. However, the provisions on the characteristics of a smokeless nicotine product and on unit packets would only come into force at a later date. In addition, the proposed Act contains a number of transitional provisions.

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RATIONALE

1 Background and preparatory work

1.1 Background

In recent years, nicotine pouches have appeared on the market in the EU and the rest of the world. These are products that externally and in their mode of use resemble tobacco for oral use within the meaning of section 2, subsection 12 of the Tobacco Act (549/2016) (hereinafter also referred to as *snus*). Nicotine pouches contain nicotine that is either extracted from tobacco plants or produced synthetically, cellulose, and other ingredients, such as sweeteners. Nicotine pouches do not contain any tobacco plant.

In Finland, the Finnish Medicines Agency (hereinafter 'Fimea') previously classified nicotine pouches as medicinal products. Fimea considered that nicotine pouches meet the definition of a medicinal product based on the pharmacological effect of nicotine. Fimea carried out the classification mainly in the form of product assessment statements submitted to Finnish Customs. The classification as medicinal products meant that nicotine pouches could not be sold in Finland without a marketing authorisation under the Medicines Act (395/1987), and the import of nicotine pouches was additionally restricted under the Medicines Act. Unlike in many other EU countries, nicotine pouches were not sold in Finland, with the exception of products that had been authorised as medicinal products. Despite this, nicotine pouches were imported to Finland in the form of passenger imports and orders from abroad, even though products containing more than 4 milligrams of nicotine were treated as prescription medicines and could not be imported without a prescription. On the basis of Fimea's previous policy, Finnish Customs seized or confiscated any illegally imported nicotine pouches and, if necessary, commenced pre-trial investigations in the case.

On 4 April 2023, Fimea announced that it had changed its interpretation of nicotine pouches and now held that nicotine pouches, for which a marketing authorisation under the Medicines Act has not been granted, do not fall within the scope of the Medicines Act unless they are specifically marketed for a medicinal purpose or it can otherwise be demonstrated that they are typically used similarly to medicinal products. Due to the changed interpretation by Fimea, the provisions of the Tobacco Act and the Chemicals Act (599/2013) now apply to nicotine pouches. Consequently, nicotine pouches can currently be sold in Finland without a retail licence. Legislation also does not impose any direct limits on the nicotine contained in nicotine pouches, for instance.

According to the Government Programme of Prime Minister Petteri Orpo's Government, nicotine pouches will be included in the scope of the Tobacco Act and their sale will be authorised in accordance with the rules set for them to prevent youth use, parallel imports and illicit trafficking, and to combat organised crime. Retail sales are made subject to authorisation, the nicotine limits of the products are aligned with those in use in neighbouring countries, and only flavours aimed at adults will be allowed.

1.2 Preparatory work

The Government Proposal was prepared by the Ministry of Social Affairs and Health. Initially, a draft proposal was prepared in accordance with the official position of the Ministry of Social Affairs and Health, which was sent to a round of comments in the spring of 2023. The Proposal was amended on the basis of the entries in the Government Programme, and a

new round of consultation was held from 13 October to 24 November 2023. The invitation for comments was published via the consultation service lausuntopalvelu.fi, and the invitation for comments was sent to the relevant ministries and other public authorities, wellbeing services counties, municipal environmental health supervision units, public health organisations and representatives of the business community. The feedback from the public consultation is discussed in section 6 below.

The draft Government Proposal was first notified to the European Commission (hereinafter the *Commission*) and other EU Member States on 16 October 2023 in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (the '*TRIS Directive*'). The reference number of the notification in the TRIS database is 2023/0581/FI. No comments or detailed opinions were received on the draft proposal during the standstill period under the TRIS Directive.

The draft Government Proposal was resubmitted in accordance with the procedure under the TRIS Directive on 4 March 2024, after the Proposal had been amended based on the feedback from consultation. The number of that notification is 2024/0117/FI. The Proposal was amended to include, inter alia, amendments to the nicotine limit made immediately prior to the Proposal being submitted, and the amendments were notified in accordance with the procedure under the TRIS Directive. The notification number is not yet known at the time of the Government Proposal being submitted. The notification opens a new standstill period of three months, which should expire in mid-July 2024. However, if the Commission or an EU Member State gives a detailed opinion on the draft Proposal during the standstill period, the standstill period will be extended by three months. The proposed changes to the Proposal may not be adopted before the end of the standstill period.

The draft Government proposal was notified to the World Trade Organisation under the WTO Agreement on Technical Barriers to Trade for the first time on 2 November 2023, a second time on 18 March 2024 and a third time just before the Proposal was submitted. The first notification identifier is G/TBT/N/FIN/85/Rev.1 and the second G/TBT/N/FIN/85/Rev.2. The third notification identifier is not yet known at the time of submission of the Proposal.

The draft Proposal was discussed at the meeting of the Advisory Committee on Local Government Finances and Administration on 5 March 2024.

The Finnish Council of Regulatory Impact Analysis published its opinion on the draft Proposal on 11 March 2024, which is available on the Council's website: <https://vnk.fi/-/nikotiinipusseja-koskeva-esitys-on-hyvin-valmisteltu>.

The documents concerning the Government Proposal are available at valtioneuvosto.fi/hankkeet under the identifier STM029:00/2023.

2 Current situation and its assessment

2.1 Current situation

2.1.1 Legislation

Tobacco Act

According to section 2, subsection 14 of the Tobacco Act, a tobacco substitute means a product which corresponds to tobacco in its intended use but does not contain tobacco. Nicotine pouches meet the definition of a tobacco substitute.

According to section 51 of the Tobacco Act, chewing tobacco, nasal tobacco, and tobacco for oral use may not be sold or otherwise supplied or passed on. Chewing tobacco, nasal tobacco, and tobacco for oral use are defined in section 2, subsections 10 to 12 of the Tobacco Act. As regards tobacco for oral use, i.e. snus, the prohibition on sale laid down in section 51 of the Tobacco Act is based on Article 17 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 (hereinafter the *Tobacco Products Directive*). Sweden is the only EU member state granted an exemption from the prohibition. The exemption was granted in the Swedish Accession Treaty on the condition that Sweden takes all necessary measures to ensure that tobacco for oral use is not placed on the market in other Member States.

Chapter 8 of the Tobacco Act lays down provisions on imports, and section 62 of the Tobacco Act provides that persons under the age of 18 may not import tobacco products or nicotine liquids. In addition, section 63 of the Tobacco Act prohibits the import of chewing tobacco, nasal tobacco, and tobacco for oral use, and the import prohibition also applies to the acquisition and receipt of such tobacco products by post or other similar means from outside Finland. However, there is an exemption from the ban on imports by passengers, which allows private individuals to import a maximum of 1 000 grams of smoke-free tobacco products per calendar day for personal use. Section 66 of the Tobacco Act restricts the import of tobacco products and nicotine liquids from outside the European Economic Area.

Section 74 of the Tobacco Act regulates general smoking bans. The main purpose of smoking bans is to protect other people from exposure to tobacco smoke. However, subsection 3 provides that smoke-free tobacco products may not be used in the indoor and outdoor areas of kindergartens and educational institutions providing pre-school and basic education, vocational education or upper secondary school education, and in playgrounds. The use of smoke-free tobacco products does not cause harm to the health of other people in the same way as smoking, but it has nevertheless been considered justified that the use of smokeless tobacco products should be prohibited, particularly in premises intended for use by children and young people.

The retail sale of tobacco products and nicotine liquids is subject to licence, and section 97 provides for situations in which a retail licence may be revoked. This is the case under section 1, paragraph 3 of the section, if, despite being issued a written warning or receiving a criminal penalty by a municipality or another supervisory authority, the retail licence holder sells or otherwise passes on chewing tobacco, nasal tobacco, or tobacco for oral use in violation of section 51. In addition, anyone who deliberately sells or otherwise passes on for reimbursement chewing tobacco, nasal tobacco, or tobacco intended for oral use in violation of section 51 of the Tobacco Act is to be sentenced to a fine or imprisonment for a maximum of six months for a tobacco sales offence, in accordance with section 109, paragraph 2 of the Tobacco Act.

Under section 118 of the Tobacco Act, persons under the age of 18 may not possess tobacco products or nicotine-containing liquids.

In addition to the Tobacco Act, nicotine pouches are subject to chemicals legislation. Nicotine pouches fall within the scope of Regulation 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (hereinafter the 'CLP Regulation'). Retail packets of nicotine pouches must have labels that are in line with the CLP Regulation and that indicate the hazardous nature of the product based on the classification of the mixture.

The Consumer Safety Act (920/2011) is a general act on the safety of consumer goods and services. According to section 4 of the Consumer Safety Act, this act is of a subsidiary nature: if the special legislation applicable to a product imposes the same or more comprehensive safety standards as the Consumer Safety Act, the Consumer Safety Act does not apply. The Consumer Safety Act does not apply to nicotine pouches because the content requirements and product information requirements for nicotine pouches come from the CLP Regulation.

The World Health Organisation (WHO) Framework Convention on Tobacco Control

Article 5(2)(b) of the WHO Framework Convention on Tobacco Control (Treaty Series 27/2005) requires Parties to adopt and implement effective legislative, executive and administrative measures to develop appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

2.1.2 Practice

In April 2023, Fimea provided a specialist statement to the Supreme Court in a matter regarding smuggling and pharmaceutical crime involving nicotine-containing snus products packed in single-dose sachets, i.e. nicotine pouches. In its decision KKO 2023:77 of October 2023, the Supreme Court held that the nicotine-containing snus product could not be considered a medicinal product as required by section 3 of the Medicines Act, on the basis of its presentation or effects.

The Finnish Safety and Chemicals Agency (hereinafter *Tukes*) monitors compliance with the Chemicals Act. Section 45b of the Chemicals Act provides for the prohibition or restriction of chemicals causing serious harm or danger. Subsection 1 provides that in so far as a chemical is not restricted under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, the Government may, by its decision, restrict or prohibit the manufacture, import, placing on the market or other transfer, export, use or other treatment of a chemical or article containing a chemical for a limited or indefinite period, and may impose restrictions and conditions on operations if the use of the chemical or article containing the chemical is found or can be reasonably estimated to cause serious harm or hazard to human health or the environment. Paragraph 3 provides that if the prevention of harm or hazard referred to in paragraph 1 requires urgent action, Tukes may temporarily impose the necessary prohibitions and restrictions. In such cases, the matter is referred without delay to the Government for decision.

On 14 June 2023, Tukes decided, pursuant to section 45b, subsection 3 of the Chemicals Act, to prohibit the placing on the Finnish market of nicotine pouches containing 20 milligrams or more of nicotine (document register number 6287/00.00.01/2023). The decision is based in particular on the need to protect children and young people from nicotine poisoning. In its decision, Tukes estimated that pouches containing 20 milligrams or more of nicotine could pose a serious risk to babies and young children within the meaning of section 45b of the Chemicals Act. The Government confirmed the decision of Tukes on 21 September 2023.

Since Fimea changed its interpretation of nicotine pouches, advertising of these products online has increased, despite the fact that the marketing of tobacco substitutes is already prohibited under the Tobacco Act currently in force. Advertising is targeted at Finnish consumers, and it is mainly carried out by traders located outside Finland. Imports of nicotine pouches have increased significantly, and products are sold in grocery stores, kiosks and service stations. Products are also sold in establishments where tobacco or other similar products have not traditionally been sold, such as shoe repair shops. According to information in the media, at least some retailers have only offered for sale nicotine pouches with a nicotine content not exceeding a certain limit, e.g. 16 milligrams per gram. On the other hand, according to information received from Tukes, stronger nicotine pouches have also been declared in accordance with the Chemicals Act.

On 5 June 2023, public health organisations published an open letter to traders in the field of retail, in which they argued that nicotine pouches should not be made available via retail sale while the Tobacco Act was being reformed. In their letter, the organisations invoked the toxicity and adverse health effects of nicotine and the fact that the increased availability and sale of nicotine pouches is likely to lead to an increasing number of people developing nicotine addiction at an even younger age, which is difficult to overcome.

In autumn 2023, the Finnish public health organisation Finnish ASH (Action on Smoking and Health) commissioned a survey to investigate the perceptions of Finnish people of nicotine and nicotine pouches (<https://suomenash.fi/tiedotteet/2023/vaesto-huolissaan-nuorten-nikotiinipussien-kaytosta/>). According to the survey, 75 % of Finns are concerned that the use of nicotine pouches is increasing among young people. Overall, 64 % would like to prevent the use of nicotine pouches by tightening legislation, and 16 % are against it. The remaining 20 % were undecided. Almost one in two Finns would ban the sale of nicotine pouches altogether. The survey data was collected in an internet panel using multi-stage stratified sampling, and the number of interviewees was slightly more than 2,000.

The implementation of the Convention on the Rights of the Child (SopS 59 and 60/1991) is monitored by a United Nations Committee, which issued recommendations to Finland on the implementation of the Convention on 2 June 2023. Among other things, the Committee recommends that Finland step up measures to prevent smoking among young people. In addition, the United Nations agency for health, the World Health Organisation (hereinafter 'the WHO'), has stated that it considers flavours to be one of the most important factors in terms of the attractiveness of nicotine pouches for young people.

There is no exact data on the total consumption of nicotine pouches, but consumption is likely to have increased over the past year as the supply of products has increased. The National Institute for Health and Welfare (hereinafter THL) has investigated the use of nicotine pouches as part of the Healthy Finland Survey. Data was collected between September 2022 and March 2023, when the sale of nicotine pouches still required a retail licence under the Medicines Act. According to the survey, 8.1 % of men aged 20 to 64 and 1.9 % of women in

the same age range used nicotine pouches daily or occasionally at the time of the survey. Daily use is rarer (2.5 % for men and 0.5 % for women).

In 2023, the Finnish Student Health and Wellbeing Survey (THL's Statistical Report 48/2023) asked young people about their use of nicotine pouches for the first time. The use of nicotine pouches is more common in boys than in girls. Of boys, 11 % and 3 % of girls in the 8th and 9th grades of basic education, 7 % of boys and 2 % of girls in the 1st and 2nd years of upper secondary school, and 21 % of boys and 8 % of girls in vocational education reported using nicotine pouches occasionally or daily. It should be taken into account that the data from the School Health Promotion Study were collected in grades 4 and 5 of basic education between 1 March and 14 April, and in grades 8 and 9 of basic education and in upper secondary school between 3 April and 12 May, and in vocational education and training institutions between 1 March and 12 May. Thus, the data collection took place partly at a time when the sale of nicotine pouches still required a retail licence under the Medicines Act. It can be assumed that the liberalisation of sales has increased the consumption of nicotine pouches among young people.

In addition, according to the School Health Promotion Study, in 2023 electronic cigarettes were used daily by 7 % of boys in grades 8 and 9 of basic education and 6 % of girls, compared with 3 % for boys and 1 % for girls in 2021. Correspondingly, the product was used daily by 2 % of boys and 3 % of girls in the first and second years of upper secondary school, and by 6 % cent of boys and 7 % of girls in vocational education and training institutions. In addition, it was more common for children in grades 4 and 5 of basic education to try electronic cigarettes, and 7 % of boys and 3 % of girls had tried electronic cigarettes at least once.

In 2023, Finns imported 14.6 million boxes of snus and nicotine pouches to Finland, of which snus accounted for 13.0 million boxes. The volume of imports of snus decreased from 2022, when 14.9 million boxes of snus were imported. However, import volumes cannot be directly compared, as the interview survey included a separate question about the import of nicotine pouches for the first time in 2023. The most snus was imported as passenger imports in 2018, around 18.3 million boxes.

In addition, the illegal distribution and passing on of snus has been becoming more common for some time. The amounts of snus seized by Finnish Customs has increased, but it is not possible to estimate the amount of smuggling on the basis of the seizures. Customs seized a total of 9 104 kilograms of snus in 2021, which was about 2 000 kilograms more than in the previous year and the highest number ever. Larger snus loads were smuggled into the Finnish market mainly from northern Sweden across the land border, but seizures were also made in shipping. Snus sales and smuggling have been largely taken over by professional criminals in Finland.

However, in 2023, much less snus was confiscated than in the previous year. In 2023, the quantity of snus seized was 857 kg and in 2022, 4 460 kg.

2.2 Assessment of the current situation

Nicotine pouches are a new type of nicotine product, and there are so far only few studies on their effects on human health. They have been found to be a potentially less harmful alternative for smokers or users of snus, but some products have been found to have very high

levels of nicotine and tobacco-specific nitrosamines.¹ In addition, the product may attract new users among young people and others who have never used tobacco products.

Nicotine is a stimulating and invigorating substance affecting the central nervous system, which results in strong addiction due to structural changes in the brain. Nicotine is the main addictive substance in cigarettes, snus, and other tobacco products. Nicotine constricts blood vessels, thereby increasing heart rate and blood pressure, and is likely to cause susceptibility to arrhythmias. Nicotine exacerbates cardiovascular diseases, reduces the efficacy of antihypertensive medicines, and increases the risk of vascular thrombosis and type 2 diabetes. There are indications that nicotine contributes to the transformation of cells into cancer cells, increases the division rate of cancer cells, and promotes the development of cancerous tissue.²

Repeated use of nicotine leads to the body quickly becoming accustomed and adapted to it, and the risk of addiction is high. This results in increased tolerance to the effects of nicotine. Tobacco and nicotine addiction is a chronic disease.

Nicotine products are often started at a young age, when the brain is still developing, and the use of nicotine at a young age causes permanent changes in the structure and functioning of the brain. The use of nicotine affects cognitive functions, and the structural and functional changes caused by nicotine result in a long-term lack of attention. In addition, young people experience the short-term positive effects of nicotine more strongly than adults, which may contribute to addiction. Changes in the brain during adolescence partly sustain the nicotine addiction that has already developed and predispose young people to the use of other intoxicating substances. In addition, nicotine has a detrimental effect on mental health in young people, as its use can contribute to the emergence of symptoms of anxiety and depression.³

Nicotine is easily passed through the placenta, and nicotine use during pregnancy has adverse effects on the development of neural cells in the foetus. The study has shown a link between nicotine exposure during pregnancy and adolescent attention deficit hyperactivity disorder (ADHD).⁴ Animal studies show that nicotine is clearly toxic to the foetus and damages the brain and lungs in particular. Preliminary evidence of this has also been obtained in humans.⁵

¹ Mallock N, Schulz T, Malke S, Dreijack N, Laux P, Luch A. Levels of nicotine and tobacco-specific nitrosamines in oral nicotine pouches. *Tobacco Control*. 2024 Mar 1;33(2):193–9. <https://doi.org/10.1136/tc-2022-057280>

² Vähäkangas, Kirsi (2022) Nikotiinin yhteys syöpään (EN: Nicotine's link with cancer) In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. *Tupakka- ja nikotiiniriippuvuus (EN: Tobacco and nicotine addiction)*. Helsinki: Duodecim, 2022, p. 112–113, and National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. Chapter 5. Nicotine. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta (GA): Centers for Disease Control and Prevention (US); 2014. <https://www.ncbi.nlm.nih.gov/books/NBK179276/>

³ For example, Leslie, FM. Unique, long-term effects of nicotine on adolescent brain. *Pharmaceutical Biochemistry and Behavior*. 2020 Oct 1;197:173010. <https://doi.org/10.1016/j.pbb.2020.173010>

⁴ For example, Sourander A., Sucksdorff M., Chudal R., Surcel HM., Hinkka-Yli-Salomäki S., Gyllenberg D., et al. Prenatal Cotinine Levels and ADHD Among Offspring. *Pediatrics*. 2019;e20183144. <https://doi.org/10.1542/peds.2018-3144>

⁵ Vähäkangas, Kirsi (2022) Nikotiinin vaikutukset (EN: Effects of nicotine) In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. *Tupakka- ja nikotiiniriippuvuus (EN: Tobacco and nicotine addiction)*. Helsinki: Duodecim, 2022, p. 111

In adolescence, consumption of alcohol and nicotine products is often linked, and a higher amount of alcohol is consumed when using nicotine and alcohol simultaneously. The use of nicotine products among young people is also clearly linked to experimentation with cannabis.⁶ The risk of nicotine addiction increases as the amount of nicotine increases, but symptoms of nicotine addiction may occur in young people even after minimal use. The earlier nicotine use is started, the more likely it is to continue. Nicotine addiction strongly predicts the continuation of smoking in adulthood.⁷

Nicotine is additionally a highly toxic substance, and its side effects include dizziness, headache, palpitations, nausea, and addiction. Nicotine is similarly toxic regardless of whether it comes from a cigarette, an e-cigarette, or a nicotine pouch. According to harmonised classification at EU level, the estimated acute toxicity of nicotine is 5 mg/kg of body weight when used orally. The number of symptoms of intoxication depends on how much nicotine has been absorbed. This, in turn, varies individually. The lowest level of blood nicotine concentration measured after fatal nicotine poisoning was 1 milligram of nicotine per litre of blood.⁸

As described in section 2.1.2 above, a decision has been taken under section 45b of the Chemicals Act to prohibit the placing on the market of nicotine pouches containing 20 milligrams or more of nicotine. Despite the decision under the Chemicals Act, there may be nicotine pouches with a relatively high nicotine content on the market. The European Food Safety Authority has estimated that the highest dose of nicotine that can be consumed without risk to health is 0.0008 mg/kg of body weight. For an adult weighing 60 kilograms, this would mean 0.048 milligrams of nicotine. Thus, the nicotine dose in a nicotine pouch containing 20 milligrams of nicotine is more than 400 times the amount of nicotine that, based on the above assessment, could be consumed without posing a health hazard.

Nicotine poisoning can be lethal, although estimates vary of the lethal single dose of nicotine when ingested orally. The most frequently mentioned estimate of the fatal dose is 0.5–1 mg/kg of body weight.⁹ Based on this, one nicotine pouch containing 20 milligrams of nicotine could kill a child of up to 40 kg if swallowed. Other estimates suggest that the lethal dose of nicotine when ingested is between 6.5 and 13 mg/kg of body weight.¹⁰ Assuming a lethal dose of

⁶ Cross SJ, Lotfipour S, Leslie, FM. Mechanisms and genetic factors underlying co-use of nicotine and alcohol or other drugs of abuse. *Am J Drug Alcohol Abuse*. 2017 Mar;43(2):171–85 <https://dx.doi.org/10.1080/00952990.2016.1209512>, and Raitasalo K., Karjalainen K., Ollila H., Ruokolainen O., Hakkarainen P. Smoke in the air – Associations between experimentation with cannabis and the use of tobacco and nicotine products among 15–16-year-old school students. *Addictive Behaviors*. 2021 Mar 1;114:106714. <https://doi.org/10.1016/j.addbeh.2020.106714>

⁷ For example, Ruokolainen O., Härkänen T., Lahti J., Haukkala A., Heliövaara M., Rahkonen O. Association between educational level and smoking cessation in an 11-year follow-up study of a national health survey. *Scand J Public Health*. 2021 Mar 1;49(8):951–60. <https://doi.org/10.1177/1403494821993721>

⁸ Vähäkangas, Kirsi (2022): Effects of nicotine. In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. *Tupakka- ja nikotiiniriippuvuus (EN: Tobacco and nicotine addiction)*. Helsinki: Duodecim, 2022, p. 81

⁹ Vähäkangas, Kirsi (2022): Effects of nicotine. In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. *Tupakka- ja nikotiiniriippuvuus (EN: Tobacco and nicotine addiction)*. Helsinki: Duodecim, 2022, p. 81

¹⁰ Bernd Mayer: How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Archives of Toxicology*, 2014, 88th Vol, No. 1,

6.5 mg/kg of body weight, just over three one-gram nicotine pouches with a nicotine content of 20 milligrams per gram could kill a 10 kg child if swallowed. The candy and fruit flavours in nicotine pouches can tempt especially young children to swallow the products, and even a smaller dose could cause serious symptoms of poisoning. In addition, the nicotine content of the pouches is not usually indicated on the packaging of nicotine pouches, so consumers using the product may not know how strong the product is that they are taking.

The Tobacco Act restricts the sale and marketing of tobacco substitutes such as nicotine pouches. For example, in the course of trade activity, they may not be sold or otherwise supplied to a person under the age of 18 (section 53, subsection 2), they may not be marketed (section 68), nor may they or their trademarks be displayed in retail sale (section 71, subsection 1). The Tobacco Act does not however lay down the characteristics of tobacco substitutes, such as how much nicotine or other ingredients may be included in a tobacco substitute. Furthermore, manufacturers or importers of tobacco substitutes are not required to notify the National Supervisory Authority for Welfare and Health (hereinafter *Valvira*) that the product has been placed on the market. Unlike the retail sale of tobacco products and nicotine-containing liquids, the retail sale of tobacco substitutes does not require a retail licence. The Tobacco Act does not require warnings on the health hazards of products on unit packets of tobacco substitutes either, and the presentation of unit packets for tobacco substitutes is not harmonised by law. Tobacco substitutes may be imported without restriction.

Unlike flavourings of tobacco products, flavourings of tobacco substitutes are not subject to regulation. Consequently, nicotine pouches may be flavoured to make them attractive. For example, flavours such as berry, liquorice, energy drink and fruit candy are likely to appeal especially to children and young people, and to reduce the perception of the dangerous nature and health harms of the product. Nicotine pouches also have flavours of various alcoholic beverages, such as whisky, gin long drinks or champagne. Studies have shown that nicotine in itself increases the desire to consume alcohol.¹¹ The interactions between alcohol and nicotine may play a role in the development of addiction, and intoxication may result in the symptoms of nicotine poisoning not being noticed early enough.

It is also worth noting that the flavourings of nicotine pouches constitute the primary flavour of the product and that their purpose is not to mask any unpleasant taste in the product, but to make the product attractive. The flavourings used in nicotine pouches are likely to increase the toxicity of nicotine pouches.¹² Some of the flavourings used in nicotine pouches also enhance nicotine absorption.

Neither the Tobacco Act nor any other law restricts the use of nicotine pouches, so nicotine pouches can at present be used for example in primary schools. The possession of nicotine

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¹¹ Verplaetse TL, McKee SA. An overview of alcohol and tobacco/nicotine interactions in the human laboratory. *Am J Drug Alcohol Abuse*. 2017 Mar;43(2):186–196. <https://dx.doi.org/10.1080/00952990.2016.1189927>

¹² Rinaldi S., Pieper E., Schulz T., Zimmermann R., Luch A., Laux P., Mallock-Ohnesorg N. Oral nicotine pouches with an aftertaste? Part 2: in vitro toxicity in human gingival fibroblasts. *Arch Toxicol*. 2023 Sep;97(9):2343–2356. doi: 10.1007/s00204-023-03554-9. Epub 2023 Jul 23. PMID: 37482550; PMCID: PMC10404181, and Shaikh SB., Tung WC., Pang C., Lucas J., Li D., Rahman I. Flavor Classification/Categorization and Differential Toxicity of Oral Nicotine Pouches (ONPs) in Oral Gingival Epithelial Cells and Bronchial Epithelial Cells. *Toxics*. 2022 Oct 31;10(11):660. <https://doi.org/10.3390/toxics10110660>

pouches or other tobacco substitutes, with the exception of nicotine-containing liquid, is not prohibited for minors under the Tobacco Act. As a result, minors too may possess nicotine pouches, nicotine-free electronic cigarettes, i.e. ‘vapes’, and energy snus.

According to the School Health Promotion Study, the use of electronic cigarettes among children and young people has increased in recent years. In addition, in certain age groups, use among girls is already more common than in boys. The prevalence of electronic cigarettes can be explained by the colourful, nicotine-free ‘vapes’ with different flavours and fragrances, which appeal to young users thanks to their high visibility on social media and vape tricks. Young people’s interest in flavour-containing tobacco substitutes seems to have increased, and learning how to use nicotine-free electronic cigarettes may lower the threshold for use of similar, nicotine-containing products. In addition, children may not always know if the product they are using contains nicotine or not.

It is likely that a large proportion of electronic cigarettes used by young people are purchased outside the official channels, for example via the internet from non-EU countries. These are therefore illegal products. Social media is commonly used for the sale and purchase of electronic cigarettes, and the sellers are often the young people themselves. It is also known that young people have been robbed in connection with electronic cigarette purchases agreed with other young people.

Studies have found that nicotine-free electronic cigarette liquids contain substances harmful to health, such as heavy metals.¹³ For example, lead has been found in quantities many times above the permitted level for drinking water. At least in part, it may be that heavy metals from the metal parts of the device have dissolved in the liquid. Lead has an adverse effect on the central nervous system and causes behavioural disorders and decreased IQ, among other things. In addition, lead has been shown to damage the kidneys as well as the heart and blood vessels. The fact that minors are allowed to possess, for example, nicotine pouches and ‘vapes’ is problematic not only from the point of view of their health, but also from the perspective that those products allow them to practice the use of other products covered by the Tobacco Act.

In educational establishments, the use of ‘vapes’ during the school day has become a problem and the means of intervention are limited. Moreover, the fact that the possession of nicotine-free electronic cigarettes is not prohibited for minors also makes it more difficult to intervene in the possession of nicotine-containing electronic cigarettes, since the staff of the educational establishment may not have the means to determine whether the product contains nicotine or not.

In addition, minors are allowed to import tobacco substitutes, with the exception of nicotine-containing liquid.

Overall, the existing tobacco legislation can be considered insufficient to protect the population, in particular children and young people, against health harms and hazards related to nicotine pouches and other tobacco substitutes. If nicotine pouches remain an unregulated product, there is a risk that their popularity will increase, especially among younger people, and that they will become a new pathway to nicotine addiction. In addition, there are very

¹³ Vivarelli F, Canistro D, Cirillo S, Cardenia V, Rodriguez-Estrada MT, Paolini M, Impairment of testicular function in electronic cigarette (e-cig, e-cigs) exposed rats under low-voltage and nicotine-free conditions, *Life Sciences*. 2019;228, 53–65,. <https://doi.org/10.1016/j.lfs.2019.04.059>

serious health risks associated with the possibility of young children swallowing or sucking on pleasant-tasting nicotine pouches after finding them at home or outside.

Sweden is the only EU country where selling snus is allowed. There are several snus wholesale retailers in operation there, especially near the Finnish border, targeting their products at Finns, and Finnish consumers acquire snus at these wholesalers and sell it illegally in Finland. Sweden produces and sells snus with a high nicotine content, which is particularly popular among Finnish consumers. Its nicotine content is between 16 and 22 milligrams per gram, which is approximately twice the nicotine content of the products popular among Swedish consumers. Finnish consumers typically prefer snus with a high nicotine content, which may lead to passenger imports of particularly strong nicotine pouches into Finland. A Finnish-language Lithuanian online store for example sells nicotine pouches containing up to 150 milligrams of nicotine per gram. Nicotine is better absorbed in the body from nicotine pouches than snus, and a nicotine pouch of just 6 mg raises the level of nicotine in the blood much higher than snus containing 8 mg of nicotine and to almost the same level as a cigarette, for example.¹⁴

It is inconsistent that as a result of the change in the interpretation of Fimea, the sale of chewing tobacco, nasal tobacco, and tobacco for oral use is prohibited under section 51 of the Tobacco Act, while nicotine pouches may be sold in Finland even without a marketing authorisation, even though the health hazards of the products are likely to be equivalent, at least for nicotine. Similarly, nicotine pouches may currently be imported without restrictions, even though the import of chewing tobacco, nasal tobacco, and oral tobacco is prohibited under section 63, with some exceptions. Nicotine pouches and their packaging closely resemble sachet snus and its packaging, and it is not necessarily possible to even distinguish those products on the basis of an external examination. Their method of use is also similar: they are placed inside the upper lip or in another place inside the mouth, from where the nicotine is absorbed into the body through the mucous membranes. The working group for the development of tobacco and nicotine policy set up by the Ministry of Social Affairs and Health in 2022 proposed in its report that nicotine snus, i.e. nicotine pouches, be regulated in the same way as traditional snus.¹⁵

3 Objectives

The Government Programme entries on nicotine pouches are part of a kit of measures aiming to open up the markets and increase competition. In accordance with the Government Programme, the aim of the Proposal is to prevent parallel imports and illicit trafficking and to combat organised crime. The aim of the Proposal is to get Finns who have previously acquired snus through illegal channels to switch to using legally sold nicotine pouches. From this point of view, the regulation must be such that nicotine pouches remain sufficiently attractive as an alternative to snus.

On the other hand, the aim of the Proposal is to prevent the use of nicotine pouches among young people in accordance with the Government Programme. The aim is also to reduce the

¹⁴ The German Federal Institute for Risk Assessment (BfR). Health risk assessment of nicotine pouches. Updated BfR Opinion no. 023/2022, 7 October 2022. <https://dx.doi.org/10.17590/20220204-105615>

¹⁵ Tupakka- ja nikotiinipolitiikan kehittäminen. (EN: Development of tobacco and nicotine policies) Proposals for action by the working group 2023. Reports and memorandums of the Ministry of Social Affairs and Health 2023:5

incidence of life-threatening nicotine poisonings of small children, which can occur if they are able to swallow or suck on nicotine pouches.

The objectives of the Proposal are partly contradictory, as the establishment of nicotine pouches on the Finnish market will inevitably increase the likelihood that products will become a new pathway to nicotine addiction for children and young people, and thus to the use of other tobacco and nicotine products. However, this risk can be reduced by limiting the attractiveness and availability of nicotine pouches.

4 The proposals and their impacts

4.1 Main proposals

The Proposal proposes that a definition of a smokeless nicotine product be added to the Tobacco Act. It would cover not only nicotine pouches but also products that do not contain tobacco plant, but which in terms of their intended use are similar to oral tobacco (snus), chewing tobacco or nasal tobacco.

The nicotine limit for smokeless nicotine products would be set at a maximum of 16.6 milligrams of nicotine per gram of product and characterising fragrances or flavours would be prohibited for smokeless nicotine products, with the exception of menthol, mint, tea, ginger, rosemary and wood flavours.

In other respects, it is proposed to regulate smokeless nicotine products in a manner similar to that in which the Tobacco Act regulates tobacco products and nicotine fluids. This would mean, among other things, that products should be notified to the National Supervisory Authority for Welfare and Health (Valvira) and annual supervisory fees should be paid. Health warnings in Finnish and Swedish would be required for retail packaging and the presentation of the packaging would be harmonised. Retail sales of products would require a license and wholesale would require a notification to be made. The distance selling of products would be prohibited and the import of products would be restricted. Non-business sales of products to persons under 18 years of age would be prohibited. In addition, the possession and import of all tobacco substitutes would be prohibited for persons under 18 years of age.

The main purpose of the smoking bans laid down in the Tobacco Act is to protect other people from exposure to tobacco smoke. The use of smokeless nicotine products does not cause the same health harms to other people as smoking, and therefore it is proposed not to extend all the smoking bans laid down in the Tobacco Act to the use of smokeless nicotine products. However, the Proposal proposes prohibiting the use of smokeless nicotine products in day care centres and educational establishments providing pre-school and basic education, vocational education or upper secondary school education indoors, outdoors and at playgrounds.

The proposed amendments to the Tobacco Act would not affect nicotine pouch products that already have a marketing authorisation in accordance with the Medicines Act or for which a marketing authorisation will subsequently be applied as a medicinal product. Fimea may continue to grant a marketing authorisation under the Medicines Act for a nicotine pouch product that is intended to be used medicinally for the treatment of a known disease, for example for withdrawal from tobacco addiction. The condition is that the product has been found to be appropriate as a medicinal product and the conditions for granting a marketing

authorisation laid down in the Medicines Act are otherwise fulfilled. Nicotine medicinal products that have a marketing authorisation will therefore continue to be subject to pharmaceutical legislation and not to the Tobacco Act and the Chemicals Act.

4.2 Main impacts

4.2.1 Economic impact

General

The proposed amendments would extend the scope of the Tobacco Act to nicotine pouches and other smokeless nicotine products. Since Fimea changed its interpretation on the applicability of the Medicines Act to nicotine pouches in spring 2023, it has been widely known that new legislation on nicotine pouches is being prepared. Due to the change in Fimea's interpretation it has been possible to sell nicotine pouches without a retail licence under the Medicines Act, as a result of which the availability of nicotine pouches has increased sharply. The liberalisation of sales may have shifted the consumption of tobacco products to nicotine pouches to some extent, but it is also likely that new consumption has been created, especially among young people. It is possible that when nicotine pouches become established on the Finnish market as a result of the Proposal, and the uncertainty about future regulation disappears, new nicotine pouch entrepreneurs and new nicotine pouch brands will enter the market and the demand for products will increase and the range may expand compared to the current situation.

At the same time, the Proposal proposes various restrictions on the characteristics, packaging and sale of nicotine pouches and new obligations for manufacturers and importers of the products. The proposed regulation may lead to a reduction in the nicotine pouch market compared to the current situation. The amendment to the Act on Excise Duty on Tobacco effective from the beginning of 2024 may also reduce sales of nicotine pouches. Nicotine pouches have been available for such a short time that accurate information is not available even on the current situation. As the availability of nicotine pouches has increased, some tobacco consumption may already have shifted to nicotine pouches. The proposed regulation is likely to reduce this transition, but due to the weak knowledge base, this assessment contains significant uncertainty. Therefore, only various qualitative assessments can be made or various scenarios can be created on the direction of the impacts of the proposed regulation as a whole.

In any case, the Proposal is one of the measures set out in the Government Programme to open the market and increase competition. The Proposal would firmly establish nicotine pouches and other smokeless nicotine products on the Finnish market. In this way, the aim would be for Finns who have acquired snus from abroad through illegal channels to switch to legally sold nicotine pouches. On this basis, it is considered that the Proposal as a whole will promote business, even though it will simultaneously increase the regulatory burden on undertakings. As a result, the 'One in, one out' principle, as agreed in the Government Programme of Prime Minister Petteri Orpo's Government, does not apply to the Proposal.

Impact on the position of households

Cigarette packets cost more than EUR 10 on average, while the Government's proposal to Parliament for an Act amending the Act on Excise Duty on Tobacco estimates that one packet of nicotine pouches will cost around EUR 7.40–EUR 9.70 after tax increases (see HE 38/2023

vp, p. 8). If smokers switch to nicotine pouches instead of cigarettes and use nicotine pouches at the same rate as cigarettes, they will spend less on the products and have more money for other uses. The Proposal may therefore have a positive impact on the position of households.

In contrast, if the additional costs resulting from the proposed regulation are passed on to product margins, prices will rise and households will not save money. In addition, it is difficult to estimate the comparable quantities of nicotine pouch and cigarette use, as the products differ in both their characteristics and their uses and possibilities. It is therefore difficult to assess how a possible shift in consumption from cigarettes to nicotine pouches would affect household costs. It should also be borne in mind that, at least for the time being, independent data are not available on whether the use of nicotine pouches would actually reduce smoking. It is also possible that smokers will start using nicotine pouches in situations where smoking is prohibited and, despite this, do not quit smoking.

Smoking is clearly more common among low-qualified people. No income group or population group specific data on the consumption of nicotine pouches are available, so it is not possible to directly estimate how the proposed amendments would affect the different income groups.

As a result of the amendments proposed in the Proposal, in future a retail licence would be required for the sale of nicotine pouches and other smokeless tobacco products, and sales between private individuals would be prohibited. In addition, non-business sales of smokeless nicotine products to minors would also be prohibited. The Proposal would therefore have a negative financial impact on the financial situation of persons who have earned income by selling nicotine pouches, for example, to minors.

The toxicity of nicotine to pets is discussed in the context of the effects on the environment below. If, as a result of the changes proposed in the Proposal, the use of nicotine pouches increases and cats and dogs, for example, are increasingly exposed to nicotine, there may be indirect effects on households in the form of veterinary expenses, for example.

The ban on distance selling of smokeless nicotine products would make it harder for people living in remote areas in particular to acquire nicotine pouches. If they want to continue using nicotine pouches, the cost of purchasing the products could be higher in future than at present.

Impact on companies

Nicotine pouches have started to be sold in Finland but no detailed information on the volume of sales is available currently. Companies of different types and sizes appear to be involved. In addition, it is known that nicotine pouches are manufactured by one Finnish company. All the major tobacco companies have their own nicotine pouch brands, but the market shares of the different manufacturers are not known. It is possible that as the requirements for nicotine pouches increase, smaller operators will exit the market and will be replaced by large companies with experience on the similar regulation of tobacco products. At the same time, it may become more difficult for new, small businesses to enter the market.

The proposed changes would affect manufacturers and importers of smokeless nicotine products, as well as retailers and wholesalers. Manufacturers and importers of smokeless nicotine products would incur direct costs, for example, from submitting product notifications, as they would be subject to a fee. In addition, they would need to pay an annual supervisory

fee based on the sales volumes of their products. Costs would also arise from bringing unit packets in line with the proposed regulation.

Under the Waste Act (646/2011), manufacturers and importers of cigarettes must organise the waste management of cigarettes and bear the related costs. There will be savings for manufacturers and importers of cigarettes in so far as the consumption of cigarettes may be replaced by the use of nicotine pouches.

It can be assumed that sales of nicotine pouches would be reduced, at least to some extent, as the Tobacco Act would limit the flavours they may feature. On the other hand, studies have not been carried out in Finland on which flavours are favoured by adult consumers nowadays. It is therefore possible that banning candy flavours, for example, would not significantly reduce sales of nicotine pouches compared to the current level.

Retailers, such as grocery stores and restaurants, would incur costs to apply for a marketing authorisation or to submit a notification of extension of sales, as the municipality charges a fee for these. The fees for marketing authorisation and extension notification vary from one control unit to another, but the largest cities charge around EUR 180–EUR 350 for marketing authorisation processing and around EUR 60–EUR 150 for extension notifications.

The annual supervisory fee for retailers would also increase for some companies if they also sell smokeless nicotine products. As regards the supervisory fee, sellers would be in a different position depending on which products they have previously submitted a notification for under the Tobacco Act. If the seller has previously indicated that they sell only tobacco products or if the seller applies for a completely new authorisation pursuant to the Tobacco Act for smokeless nicotine products, the seller would incur additional costs from the supervisory fee. On the other hand, if the seller has previously announced that it will only sell nicotine liquids, the maximum supervisory fee would remain the same as before.

Administrative costs would also be incurred by the updating of the self-monitoring plan and of the related IT systems. It is therefore possible that some of the current retailers will discontinue the sale of nicotine pouches as a result of the proposed amendments. Just like other tobacco alternatives, smokeless nicotine products may not currently be displayed in retail outlets nor be sold to minors, and therefore, retailers would not incur any additional costs for age-limit controls, for example. Retailers are also responsible for keeping guidelines on the retail sales of the new smokeless nicotine products up to date, as well as for ensuring that the personnel involved in the sale of the products are familiar with the regulations related to the sale. In this respect, administrative work may increase briefly as a result of the new guidelines required and the possible need to arrange training courses for staff. However, immediate direct effects are difficult to assess, as such assessment involves a number of uncertainties, such as the development of the market for smokeless nicotine products as a result of the proposed amendments, changes in consumer purchasing power and economic factors affecting the consumer market.

The supervisory fee would not exceed EUR 500 per point of sale and the cost of the supervisory fees for the various operators would depend on the number of outlets. The smallest operators, such as kiosks and cobblers, typically sell products from only one point of sale. However, in the case of the smallest operators, the administrative burden could still be high in relation to the revenues from the sale of these products, and this may lead to certain operators abandoning the sale of nicotine pouches. Conversely, as far as is known, there are not very many such operators, and the sale of nicotine pouches is not part of their core

business. From the point of view of the Proposal as a whole, the administrative burden or costs of these operators are not expected to be particularly significant.

As a result of the ban on distance selling of smokeless nicotine products, operators that have sold nicotine pouches on the internet would have to change or cease their activity. It is not known how many Finnish companies sell nicotine pouches exclusively or mainly on the internet. A ban on distance selling could reduce competition between companies by potentially eliminating operators completely from the market, which could result in a reduction in the range of products and an increase in the prices of products.

Impact on public finances

The Proposal would consolidate the position of nicotine pouches on the Finnish market, with the aim being to guide snus users to switch to nicotine pouches. If that objective were to be met, the amendment would have a positive impact on public finances in this respect, since, according to the Act on Excise Duty on Manufactured Tobacco (1470/1994) (hereinafter the *Act on Excise Duty on Tobacco*), smokeless nicotine products will be subject to tobacco excise duty from the beginning of 2024. The inclusion of nicotine pouches in tobacco taxation is estimated to increase the revenue from tobacco excise duty on an annual basis by approximately EUR 50 million (see HE 38/2023 vp, p. 8). However, it is also possible that the consumption of nicotine pouches would reduce the consumption of taxable tobacco products, such as cigarettes, thereby reducing the tax revenue-boosting effect.

In addition, if people who currently smoke cigarettes switch to nicotine pouches, for example, public expenditure on the treatment of lung diseases due to smoking is likely to decrease, at least in the long term. Switching to nicotine pouches would also reduce the fire damage associated with smoking. It is possible that not only would such direct costs be reduced, but indirect costs may decrease as well, including loss of inputs of production due to deaths and disability pension claims caused by smoking, as well as labour input losses caused by sickness absences and smoking breaks not covered by statutory breaks. According to estimates by the National Institute for Health and Welfare (THL) in 2020, the direct and indirect social costs of smoking in Finland amounted to approximately EUR 1.0–EUR 1.6 billion.

On the other hand, the use of nicotine pouches is also associated with various health hazards, which can increase healthcare spending and, for example, absences from work. If nicotine pouches becoming established on the Finnish market results in people who have not previously used tobacco or other nicotine products starting to use nicotine pouches, the amendments will have negative effects on public finances in this respect. This is especially the case if nicotine pouches mean that young people become addicted to nicotine and switch to using tobacco and other nicotine products in addition to nicotine pouches. Costs could also be incurred from the treatment of nicotine poisoning.

It should also be borne in mind that the use of a nicotine pouch cannot be said to be unequivocally less harmful than smoking cigarettes, as studies have shown that the nicotine pouch raises the level of nicotine in the blood even higher than a cigarette. On this basis, it can be assumed that if smokers were to switch widely to nicotine pouches, even more public funds could be needed in future to deal with the health harms caused by nicotine. For example, there is clear evidence that nicotine increases the risk of complications after any kind of surgery and

prolongs recovery and hospital stays.¹⁶ In addition, nicotine increases the risk of mental health problems in young people¹⁷, which can have long-term economic effects.

The proposed amendments would increase the work and costs of the authorities supervising the Tobacco Act, in particular the municipalities and the National Supervisory Authority for Welfare and Health (Valvira), as a whole new nicotine-containing product group would be subject to supervision. The municipalities and Valvira could charge control fees to cover the increasing workload of the authorities. However, municipalities would not be able to charge a higher control fee to an operator who already has a retail licence for nicotine-containing liquids or tobacco products and nicotine-containing liquids, and which extends sales to include smokeless nicotine products.

The Regional State Administrative Agencies also play a part in steering the enforcement of the Tobacco Act, but the proposed amendments would not have a major impact on the workload of the Regional State Administrative Agencies.

4.2.2 Impact on the activities of public authorities

The Proposal would increase the work and costs of the authorities supervising the Tobacco Act, in particular municipalities and Valvira, because a whole new group of nicotine-containing products would be subject to supervision. Currently, the municipal authority supervising the Tobacco Act is responsible for ensuring that nicotine pouches, like other tobacco alternatives, are not commercially sold to minors or marketed or displayed in retail outlets. In the future, retail sales of smokeless nicotine products would require a retail licence, and wholesaling would require making a wholesale notification, which would be one of the most significant changes for the municipal supervisory authority. The processing of retail licences and wholesale notifications would require, among other things, that municipalities review and check the legality of self-monitoring plans or their updates of all traders that include nicotine pouches in their selections. This alone can mean going through thousands of self-monitoring plans.

Limiting the flavours of smokeless nicotine products would require guidance for operators both from municipalities and Valvira. In practice, monitoring compliance with flavour restrictions would require organoleptic observations, as flavours can be obtained by different combinations of ingredients and therefore cannot necessarily be deduced from the list of ingredients of the product. Control would be based primarily on notifications from consumers, for example.

The changes proposed in the proposal would increase the work of the authorities. However, the proposal does not propose adding new man-years for the supervisory authorities, and it

¹⁶ Kyrö, Antti; Koljonen, Virve (2022) Tupakoinnin vaikutus leikkauspotilaisiin ja leikkaushoidon tuloksiin. (EN: The effect of smoking on surgical patients and the results of surgery.) In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. Tupakka- ja nikotiiniriippuvuus (EN: Tobacco and nicotine addiction). Helsinki: Duodecim, 2022, 225–228, and Kyrö, Antti; Koljonen, Virve (2022) Tupakoinnista vieroituksen vaikutukset leikkaushoidon tuloksiin. (EN: The effects of giving up smoking on the results of surgical treatment.) In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. Tupakka- ja nikotiiniriippuvuus (EN: Tobacco and nicotine addiction). Helsinki: Duodecim, 2022, 258–259

¹⁷ For example, Leslie, FM. Unique, long-term effects of nicotine on adolescent brain. *Pharmaceutical Biochemistry and Behavior*. 2020 Oct 1;197:173010. <https://doi.org/10.1016/j.pbb.2020.173010>

would be possible to carry out controls and other new tasks within the limits of existing human resources and budgets, as well as the revenue received from control fees.

Nicotine pouches would probably also be sold in sales outlets where there has been no previous marketing authorisation under the Tobacco Act and where there is no experience in selling products referred to in the Tobacco Act or in applying tobacco legislation. For example, in recent years, many restaurants have abandoned marketing authorisations under the Tobacco Act because smoking is now so extensively banned in restaurants. With some exceptions, the proposal does not propose bans on the use of smokeless nicotine products, so it is possible that smokeless nicotine products would also be sold in restaurants, for example. In addition, according to media reports, nicotine pouches have been sold in shoe repair shops, for example. New points of sale would increase the number of tobacco supervision targets and the need to monitor sales and self-monitoring.

The Proposal would also have an impact on Valvira's operations and the information systems needed for it. The licence requirement for the retail sale of nicotine pouches and the requirement to provide wholesale notifications for wholesaling would entail changes to the existing register of marketing authorisations and wholesale notifications for tobacco products and nicotine liquids, electronic forms, and a public version of the register. Maintaining both of these registers is one of Valvira's statutory tasks.

Product notifications under the Tobacco Act are submitted to the Commission's EU Common Entry Gate (EU-CEG). Although the EU-CEG information system is not designed for submitting notifications regarding nicotine pouches, it can also be used for this purpose. However, this would mean that Valvira would have to provide guidance to traders on submitting notifications. Reviewing and supervising product notifications would also be more challenging compared to the monitoring of other products subject to a notification requirement, for instance, because the system does not have automated searches for smokeless nicotine products and these would have to be manually retrieved from the system. Valvira would also need to make changes to the public product notification search service, the maintenance of which is one of Valvira's statutory tasks.

The changes to the information systems provided and used by Valvira and the processing, analysis and publication of the product notifications themselves, the supervision of marketing, and the guidance of municipalities and Regional State Administrative Agencies would require additional resources. Therefore, the bill proposes that Valvira may charge fees from the manufacturer or importer of nicotine pouches to cover at least part of the need for additional resources due to new tasks and updates to the information systems. The supervisory fees are intended to provide Valvira with approximately EUR 180 000 in additional resources for monitoring and controlling the Tobacco Act, which corresponds to approximately two person-years. As the ministry responsible for Valvira's performance management, the Ministry of Social Affairs and Health would allocate a corresponding amount to Valvira in appropriations.

Nicotine pouches and their unit packets are similar in appearance to snus. The similar appearance of the products has posed challenges in monitoring compliance with EU-wide bans on the sale of snus and import regulations. The amendments proposed in the Proposal would not remove these difficulties because the authorities supervising sales and import, i.e. the municipalities and Finnish Customs, would still be required to seek to assess on a case-by-case basis whether a product is a lawful smokeless nicotine product or illegal snus. However, the harmonisation of the layout of unit packets for smokeless nicotine products pursuant to the Proposal could facilitate the distinguishing between products in the supervision of retail sales.

The proposed restrictions on the characteristics of smokeless nicotine products and on passenger imports could contribute to incentivising the smuggling and illicit trade of the products. The introduction of tobacco excise duty on smokeless nicotine products, which has raised the price of nicotine pouches legally sold in Finland, could also encourage smuggling and illicit trade. However, the proposed new quantitative restrictions on passenger imports of smokeless nicotine products should also have the impact of making small-scale illegal imports for commercial purposes within the quantitative limits on passenger imports more difficult.

The proposed ban on the use of smokeless nicotine products in kindergartens and educational establishments, as well as the extension of the ban on possession to all tobacco substitutes, would improve the ability of teachers and others working with people under 18 years of age to address the use in schools of nicotine pouches and snus, as well as nicotine-containing and nicotine-free electronic cigarettes. The similar appearance of snus, energy pouches and nicotine pouches has made it difficult for schools to intervene in the possession and use of tobacco-containing snus, even though it is already prohibited by the law in force. For the same reason, intervention in the use and possession of nicotine-containing electronic cigarettes has been ineffective. The Proposal would simplify the situation and allow intervention in the use of all tobacco substitutes in educational establishments.

Banning the use of nicotine pouches in kindergartens and educational institutions may be relevant from the point of view of workers who use nicotine pouches and are addicted to nicotine. However, the proposed ban on the use of nicotine pouches would not prevent the use of nicotine replacement products referred to in the Medicines Act, which can continue to be used to treat nicotine addiction.

4.2.3 Impact on the environment

Littering caused by smoking and using snus is a major environmental problem. Tobacco butts contain many toxic chemicals that seep into the environment, such as cadmium, arsenic and lead, and when cigarette butts are thrown on the ground, wind and rain transport them to the waterways and toxic chemicals are washed into the aquatic ecosystem.

If nicotine pouches becoming established on the Finnish market results in smokers switching to using nicotine pouches instead of smoking cigarettes, the impact on the environment could be somewhat positive. In contrast, the material used for at least some nicotine pouches contains plastic, so nicotine pouches can also end up as harmful microplastics in the same way as cigarette butts.

Manufacturers and importers of nicotine pouches are not obliged under the Waste Act to organise the waste management of the products nor to bear the related costs. If people who currently use snus switch to nicotine pouches, littering and the resulting problems will probably remain at the same level.

Nicotine is toxic to aquatic organisms and can cause long-term adverse effects in water bodies and water courses.¹⁸ The most abundant litter on Finnish beaches is cigarette butts, and in 2023 nicotine pouches were already among the five most common types of litter found on beaches¹⁹, despite the fact that the sale of nicotine pouches was not liberalised until April

¹⁸ Finnish-language Chemical Safety Card for nicotine, Finnish Institute of Occupational Health, 2024

¹⁹ Helsingin Sanomat 12 February 2024: “Naamaan törröttävät korkit ärsyttävät — Oikeasti niille on hyvä syy” EN: “Bottle caps poking in your face are annoying – There is actually a good reason for them”), <https://www.hs.fi/kotimaa/art-2000010192136.html>, accessed 12 March 2024, and the Finnish

2023. The possible increase in the use of nicotine pouches as a result of the changes proposed in the Proposal can therefore be harmful to water courses and their organisms.

There is limited data on nicotine toxicity to wild mammals. Laboratory studies on nicotine toxicity have been conducted on several mammalian species, in particular rats and mice, and signs of toxicity, cell mutation, reproductive effects and behavioural changes in rodents have been observed. Rodents are often an important part of the food chain, so rodent-eating animals may be potentially exposed to the harmful effects of nicotine.²⁰

The toxicity of nicotine to dogs and cats has been studied more. In dogs and cats, the deadly dose of nicotine has been estimated to be at least 20–100 milligrams.²¹ However, the volume of a lethal dose presumably depends on the weight of the animal. If the changes proposed in the Proposal increase the use of nicotine pouches, pets could be exposed to more nicotine pouches than at present, which would have negative effects on animal health.

4.2.4 Other social effects

Effects on health

As a consequence of the Proposal, legislation would enable a new nicotine product to become established on the Finnish market. This is likely to lead to other nicotine products being sought to be brought to market in the future. New products such as nicotine-containing gummy bears and heated herbal products are already on sale in some EU Member States, for example. The more nicotine products there are on the market, the more likely the health hazards caused by nicotine described in section 2 will be.

It is possible that some current users of tobacco products will switch to using nicotine pouches instead of smoking cigarettes or using snus, for example. In addition to nicotine, smoking also causes tar and carbon monoxide to enter the body, which the nicotine pouches do not contain according to current knowledge. In this respect, health hazards can be reduced compared to smoking cigarettes.

In contrast, a nicotine pouch raises the level of nicotine in the blood more than a cigarette. This is why nicotine-induced health harms may even increase compared to today. In addition, it is possible that the increased use of nicotine pouches will not reduce smoking or e-cigarette use, but that the total use of various tobacco and nicotine-containing products increases instead. There are indications of this in other Nordic countries, and this would lead to health harms increasing from the current level. The higher the levels of nicotine in the body, the stronger the nicotine addiction becomes, and authorised nicotine replacement therapy products may no longer be sufficient on their own for nicotine weaning.

Environment Institute's beach litter monitoring

²⁰ Beutel, M.W.; Harmon, T.C.; Novotny, T.E.; Mock, J.; Gilmore, M.E.; Hart, S.C.; Traina, S.; Duttagupta, S.; Brooks, A.; Jerde, C.L.; et al.: A Review of Environmental Pollution from the Use and Disposal of Cigarettes and Electronic Cigarettes: Contaminants, Sources, and Impacts, p. 12, Sustainability 2021, 13, 12994, and therein referred Cardoso, L.S.; Estrela, F.N.; Chagas, T.Q.; Da Silva, W.A.M.; Costa, D.R.D.O.; Pereira, I.; Vaz, B.G.; Rodrigues, A.S.D.L.; Malafaia, G. The exposure to water with cigarette residue changes the anti-predator response in female Swiss albino mice. Environ. Sci. Pollut. Res. 2018, 25, 8592–8607

²¹ Nicole C. Hackendahl, DVM, and Colin W. Sereda, DVM: The dangers of nicotine ingestion in dogs ASPCA Pro Veterinary Medicine Toxicology Brief, p. 220, March 2004, and references therein

There is no research data available on the health harms caused by the use of snus compared with the health harms caused by the use of nicotine pouches, but the harms presumably depend on how much nicotine the products contain.

Unlike cigarettes, nicotine pouches can be used quite discreetly and for long periods at a time. Several pouches can also be used at the same time. In addition, even after the proposed changes, use of nicotine pouches would be permitted in most places where smoking is prohibited. It is therefore possible that, if the use of cigarettes is replaced by nicotine pouches, nicotine exposure, and consequently nicotine addiction and other health harms caused by nicotine, will increase compared with the present.

The Proposal proposes regulation that is estimated to make nicotine pouches less attractive than at present at least for people who do not smoke or use snus. The restriction of flavours and the labelling and harmonisation of packaging would be expected to have such effects, for example. There is scientific evidence that the harmonisation of packaging for tobacco products reduces the attractiveness of the product and increases the visibility of warning labels.²² As far as nicotine pouches are concerned, there are no known studies investigating how the warning labels or the harmonised appearance of the packaging affect the attractiveness of the product. However, it is assumed that the effects are similar for nicotine pouches.

The proposed nicotine limit of 16.6 milligrams of nicotine per gram of product and limiting the maximum dose unit size to one gram would mean that a nicotine pouch weighing one gram could not contain more than 16.6 milligrams of nicotine. The Proposal would therefore result in the strength of nicotine pouches on the Finnish market being lower in the future than today. This can be estimated to have positive effects on human health, since, as stated above, nicotine has a number of adverse health effects, and the more nicotine is used, the greater these harmful effects will be.

In addition, the Proposal does not seek to prohibit additives in smokeless nicotine products that increase nicotine absorption. Thus, for example, it would continue to not be possible to clearly determine how much nicotine is absorbed from the nicotine content of a nicotine pouch, and nicotine could be absorbed in different ways from two products containing the same amount of nicotine depending on the amount of additives that increase nicotine absorption.

A ban on distance selling of smokeless nicotine products would reduce access to nicotine pouches for people living in more remote areas. This could have positive effects on their health. In contrast, it is also possible that when shopping in the future, such persons would acquire more nicotine pouches at a time, which means the use of nicotine pouches would not decrease. In any event, it should be borne in mind that the Proposal would not restrict the ordering of authorised nicotine pouches from pharmacies' online stores.

²² Moodie C., Hoek J., Hammond D., et al. Plain tobacco packaging: progress, challenges, learning and opportunities. *Tobacco Control* 2022;31:263–271 and the World Health Organisation. Plain packaging of tobacco products: evidence, design and implementation. Geneva: World Health Organisation 2016

Impact on children and young people

The use of nicotine pouches is more common in certain groups of young people than in others. According to the School Health Promotion study, daily use occurred among 4 % of boys in grades 8 and 9 of basic education and 5 % of boys in vocational education and training. Currently, 11 % of boys and 3 % of girls in grades 8 and 9 of basic education, 7 % of boys and 2 % of girls in the first and second year of upper secondary school, and 21 % of boys and 8 % of girls in vocational education and training reported using nicotine pouches daily or occasionally. It is worth noting that the School Health Promotion study was conducted in 2023, at the same time as Fimea changed its interpretation of the applicability of the Medicines Act to nicotine pouches. It can be assumed that youth use of nicotine pouches has increased to some extent since the completion of the School Health Promotion study.

The Proposal proposes changes designed to reduce the attractiveness of nicotine pouches compared to the current state. It can be estimated that the restriction of flavours, warning markings and harmonisation of the appearance of packaging can, at least to some extent, reduce the attractiveness of the products, especially among children and young people. In this way, youth use of the products and the life-threatening nicotine poisoning of young children could be affected. However, flavours such as menthol and mint would continue to be permitted in smokeless nicotine products, although the current Tobacco Products Directive prohibits characterising fragrances and flavours including menthol and mint in certain tobacco products, above all because they had been found to appeal to young people in particular. The flavours of menthol and mint in nicotine pouches can also be expected to be of interest to children and adolescents.

The proposed nicotine limit of 16.6 milligrams of nicotine per gram of product is quite high and may be life-threatening, especially for young children. As mentioned above, estimates of how lethal nicotine is vary. However, according to some estimates, one nicotine pouch containing 16.6 milligrams of nicotine could, if swallowed, kill a child weighing just over 30 kg.

By requiring a license for the retail sale of smokeless nicotine products, the supervisory authorities would be aware of the retailers, which would make it possible to control more effectively that the products are not sold to minors. The use of smokeless nicotine products by youths would probably be reduced by prohibiting the sale of products to minors, also in a non-commercial context, and making the violation of the ban punishable as a tobacco sales offence.

Bans on the use of smokeless nicotine products are proposed to protect children and adolescents, in particular. Smokeless nicotine products should not be used, for example, in school yards, which could contribute to reducing the use of products among minors. However, bans on use alone are not enough to prevent youth use, as electronic cigarettes have recently become a problem in schools, despite the fact that their use is not allowed in school areas. However, the proposed bans on the use of smokeless nicotine products, as well as the proposed extension of the ban on possession for young people under the age of 18, would improve the ability of personnel at educational institutions and other adults to intervene in youth use of tobacco substitutes. Furthermore, a ban on the use of smokeless nicotine products in playgrounds could, at least to some extent, reduce the presence of toxic nicotine pouches in areas specifically intended for young children. This would reduce the risk of life-threatening nicotine poisoning.

Exposure to nicotine and tobacco smoke during pregnancy and while breastfeeding is detrimental to the child's development. When a mother smokes, the levels of nicotine and carbon monoxide in the blood of the foetus are about 15 % higher than the mother's. Maternal smoking during pregnancy has been found to cause significant foetal harm, including a higher risk of miscarriage. There is also an increase in cot death and many long-term harms to the health of the child. There is clear evidence of nicotine causing foetal harm in animals, but there are currently insufficient epidemiological studies in humans.²³

In 2022, 7.5 % of all pregnant people smoked during pregnancy. Smoking during pregnancy is more common in younger age groups; 29 % of pregnant people who are under 20 years of age smoke during pregnancy. The use of nicotine pouches among young women may increase with the stabilisation of the nicotine pouch market, which may lead to an increase in their use even during pregnancy. Pregnant smokers may also switch to nicotine pouches assuming they are less harmful than cigarettes. However, the proposed amendments are intended to reduce the appeal of nicotine pouches and thus also protect unborn children from the harmful effects of nicotine use during pregnancy.

Impact on gender equality

In 2020, 7 % of men aged 20–64 and 1 % of women of the same age used snus on a daily basis.²⁴ In 2021, 2 % of girls aged 14–20 and 7 % of boys used snus daily. The use of snus in Finland is much more common in men and boys than in women and girls. In addition, according to the Healthy Finland study, nicotine addiction is most common among men of low socio-economic status.

According to the Healthy Finland study, 8.1 % of men aged 20 to 64 and 1.9 % of women of the same age use nicotine pouches daily or occasionally. In addition, according to the School Health Survey, the use of nicotine pouches is clearly more common among boys than girls. It can therefore be estimated that the impact of the Proposal would be more significant on men and boys than on women and girls.

However, in Sweden, the use of nicotine pouches is even more common in some age groups among girls than boys, and the use of snus has also become more common among Swedish girls. In Sweden, snus has been developed for years to attract women as well, and there are indications of this in the product development of nicotine pouches as well. The changes proposed in the Proposal, which would reduce the attractiveness of nicotine pouches, could therefore potentially prevent the development that nicotine pouches would become a trend product specifically among girls. This appears to already partly be the case in respect of 'vapes'.

Impact on crime prevention

²³ Tikkanen M. Tupakointi ja raskaus. (EN: Smoking and Pregnancy) The medical journal Duodecim. 2008;124(11):1224–9, and the National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. Chapter 9. Reproductive outcomes. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta (GA): Centers for Disease Control and Prevention (US); 2014. <https://www.ncbi.nlm.nih.gov/books/NBK179276/>

²⁴ Tobacco statistics 2021, Terveyden ja hyvinvoinnin tilastoraportti 40/2022 (EN: Statistical report on health and wellbeing)

The sale of snus is prohibited and punishable as a tobacco sales offence, the importation of the product is restricted, and unlawful importation is punishable as a smuggling offence. Despite this, snus is imported and sold in Finland, as there are few resources to enforce such prohibitions and restrictions. If the proposed amendments in the Proposal result in smokeless nicotine products becoming established on the Finnish market, demand for snus in Finland may decrease, with the result that snus-related smuggling and other offences are expected to decrease. There are already indications of this, because, as stated in section 2.1.2, seizures of snus have clearly decreased during the period when nicotine pouches have been freely marketed in Finland. However, it is possible that the more stringent provisions of the Proposal regarding the sale and properties of smokeless nicotine products will reduce demand for nicotine pouches and increase demand for snus, in which case the Proposal would not have a positive impact on crime prevention.

The amendment to the Act on Excise Duty on Tobacco in respect of smokeless nicotine products is likely to have synergies with the amendments put forward in the present Government Proposal. The amendments to the Act on Excise Duty on Tobacco may have a negative impact on the Government Programme's objective of combatting grey imports, illicit trade and organised crime. However, the amendment to the Act on Excise Duty on Tobacco has set the tax level at a moderate level in the early stages, with the aim of redirecting consumption to domestic taxable sales.

Impact on fundamental and human rights

According to section 7 of the Constitution, everyone has the right to life, and section 19, subsection 3 lays down the obligation of the public authorities to promote the health of the population. The Proposal would implement everyone's right to life and would support the health of the population, especially of minors, by laying down various requirements, prohibitions and restrictions on nicotine pouches and other smokeless nicotine products. The amendments would make nicotine pouches less attractive than at present and raise public awareness of the health harms caused by nicotine. It can be estimated that the proposed amendments would have a positive impact on human health and thus on the realisation of section 7 of the Constitution, when comparing the proposed regulation with the current situation where nicotine pouches are subject to little regulation.

In contrast, the proposal would cause a new nicotine product to become established on the Finnish market. The proposal marks a significant change in Finland's present tobacco policy, which, in accordance with section 1 of the Tobacco Act, aims to end the use of tobacco products and other nicotine-containing products containing substances that are toxic to humans and cause addiction. Especially in the long term, this could have negative consequences on the implementation of section 7 of the Constitution.

5 Alternative methods of implementation

5.1 Alternatives and their impacts

Alternatives to the amendments proposed in the Proposal include, firstly, that nicotine pouches and other smokeless nicotine products would not be subject to any new regulation. This would mean that a novel nicotine product, which causes addiction and other health harms and hazards that would be subject to much less stringent regulation than other products covered by the Tobacco Act, would remain on the market. Maintaining the current state of affairs would mean, for example, that nicotine pouches could continue to be sold without a

retail licence and there would be no clear legal limits on the nicotine content of the products. In addition, nicotine pouches would continue to be allowed to contain flavours that may attract children and young people in particular. This option cannot be considered justified from the perspective of protection of public health, since nicotine is a toxic and highly addictive substance, the use of which damages health in many different ways.

The draft Proposal, which was submitted for consultation in spring 2023, proposed that smokeless nicotine products should be regulated in the same way as snus, chewing tobacco and nasal tobacco. This would have meant a prohibition on the sale, other transfer and supply of smokeless nicotine products and a ban on import, with the exception of certain restrictions. Infringement of the sales ban would have been punishable as a tobacco sales offence and could have led to the withdrawal of a retail licence under the Tobacco Act. These proposals could have restored the situation with regard to legislation to much the same as that which existed before the change in Fimea's interpretation in respect of nicotine pouches: the sale of nicotine pouches would not have been allowed at all, unless the product was covered by a marketing authorisation under the Medicines Act, and the import of the products would have been allowed only to a limited extent.

The solutions under this option would have been likely to significantly reduce the risk of life-threatening nicotine poisoning in young children and counteract the development that nicotine pouches would become a new pathway to nicotine addiction for children and young people. However, not all public health risks could have been eliminated by this alternative, as strict regulation could have encouraged the illegal import of products. Additionally, the regulation described above could not have been used to ensure nicotine pouches remain a sufficiently attractive alternative to snus, as part of the aim to combat snus-related crime.

In practice, the above-mentioned alternatives were not considered in the preparation of the Proposal, because the Government Programme has stated that the sale of nicotine pouches will continue to be allowed, but that the retail sale of the products will be subject to authorisation, the nicotine content of the products will be limited and the flavours allowed in the products will be restricted. Limiting the nicotine content and flavours of smokeless nicotine products are key issues for which different options have been assessed within the framework conditions set by the entries in the Government Programme.

According to the Government Programme, only flavours intended for adults will be permitted in nicotine pouches, and different ways of achieving this have been considered in the preparation of the Proposal. The draft Proposal submitted for consultation proposed that a smokeless nicotine product should not contain alcohol or cannabis flavours, nor flavours that are likely to attract young people, and that further provisions on flavours likely to appeal to young people could be laid down by decree of the Ministry of Social Affairs and Health. Following the consultation, such a solution was found to be unworkable, since regulation based on a negative list of prohibited substances would have become open to interpretation and it would have been difficult or even impossible to enforce it.

Another alternative to the regulation proposed in the Proposal would have been to ban all characterising fragrances and flavours of smokeless nicotine products in the same way as they are prohibited for cigarettes, roll-your-own tobacco and heated tobacco products, nicotine-containing liquids and nicotine-free liquids for vaporisation. The advantage of this option would have been that all flavours appealing to children and young people would have been comprehensively banned. However, this option was not chosen because it was estimated to

excessively restrict the flavours available for nicotine pouches and hinder the achievement of the objective of making nicotine pouches a sufficiently attractive alternative to snus.

According to the Government Programme, nicotine pouches will be subject to nicotine limits that are in use in neighbouring countries. So far, Iceland is the only Nordic country to have laid down a nicotine limit for nicotine pouches, which is 20 milligrams of nicotine per gram of product. During the preparation of the Proposal, consideration was given to various nicotine limits and their impact on preventing illegal imports of snus and on protecting public health, in particular the health of children and young people. Laying down a nicotine limit of, for example, 4 milligrams per gram of product would have been fairly effective in protecting young children from nicotine poisoning and reducing other health harms caused by nicotine. However, users of snus would not necessarily find such a product so attractive that they would like to switch to it instead of snus. By weighing up the different options for the Proposal, it was decided that the proposed nicotine limit, i.e. 16.6 milligrams of nicotine per gram of product, provides the best balance in terms of the objectives of the proposal.

5.2 Legislation and other means in place in other countries

Nicotine pouches are available on the market in several EU and EEA countries, but regulation of the products has not yet been harmonised at the EU level. Depending on the Member State, nicotine pouches are subject to tobacco legislation, chemicals legislation, food legislation, pharmaceutical legislation, or general product safety legislation, for example.

On 20 May 2021, the European Commission submitted a report on the application of the Tobacco Products Directive as referred to in Article 28 of the Tobacco Products Directive. The report addressed in particular elements requiring review or adaptation to scientific and technical developments, including the development of internationally agreed rules and standards on tobacco products and related products. In the report, the Commission identified a number of possible amendment needs to the existing Tobacco Products Directive. Areas of development identified by the Commission included taking into account novel and emerging tobacco and nicotine products and improving the flexibility of regulation to address rapid product development. The report specifically mentions that snus-like products, such as nicotine pouches, have been placed on the market to circumvent the ban on snus in place in the EU.

Updating the Tobacco Products Directive is part of the implementation of the EU's Beating Cancer Plan 2021–2025. There are no official estimates of the timetable for the preparation of the update of the Tobacco Products Directive yet, but at best it will take several years for it to progress to national legislation, and it is not possible to wait for this preparation in view of the public health harms caused by nicotine pouches.

In the Nordic countries other than Finland, nicotine pouches have not been considered to be medicinal products. They may be on the market, but they are subject to varying degrees of regulation. In Sweden, nicotine-free nicotine products are subject to a separate law, “lag (2022:1257) om tobaksfria nikotinprodukter”. It provides, inter alia, for an age limit of 18 years, prior declaration of products, the characteristics of products, declaration of sale, fees for supervision, restriction of advertising, and health warnings on unit packets. So far, no nicotine limit has been laid down for these products in Sweden but a report was published in March 2024, proposing that the nicotine content of products should not exceed 12 milligrams per gram of product. The report also points out that the acidity of the product has a significant impact on how much nicotine is absorbed from the product and that even a small increase in

pH will result in a sharp increase in the amount of free nicotine. In addition, the report proposes that the minimum size of the unit packet of the product be set at 20 doses.²⁵

In Sweden, 29 % of men aged between 17 and 29 and 13 % of women of the same age used snus daily in 2021. For nicotine-containing snus, the figures were 12 % for men and 13 % for women. In addition, these products were used occasionally by 8–10 % of men and women in the same age group. In 2022, 22 % of Swedish ninth-graders had tried nicotine pouches at some point (23 % of boys and 22 % of girls). The corresponding proportion for students in the second year of upper secondary school was 40 % (39 % of boys and 42 % of girls). In upper secondary school, 22 % of boys and girls had used nicotine pouches in the last 30 days. The use of nicotine pouches had become more common in both student groups since 2021. Of boys, 23 % had not used any tobacco or nicotine products before trying nicotine pouches, while the corresponding percentages for girls were 32 % (year 9) and 37 % (upper secondary school). At the same time, the use of traditional cigarettes also increased among young Swedes: in 2021, 17 % of Swedish upper secondary school pupils smoked cigarettes, and in 2022 the share had risen to 20 %. The use of e-cigarettes has also risen, especially among young girls. In 2021, 2 % of girls aged 16–29 used e-cigarettes, and in 2022 the share was 8 %. According to reports in Swedish media, the use of strong nicotine snus in schools has risen sharply, and students have vomited during the school day due to the use of nicotine.²⁶

In Denmark, nicotine pouches fall within the scope of the Tobacco Act and are regulated as tobacco substitutes. It follows, inter alia, that the retail packaging of nicotine pouches must carry health warnings and a tax is imposed on nicotine pouches. There is currently no legal limit on the nicotine content of the products. On 14 November 2023, the Danish Government published an agreement on a prevention plan for tobacco, nicotine and alcohol. Under the plan, Denmark intends to increase the price of nicotine pouches to the same level as tobacco products, ban characterising fragrances and flavours of nicotine pouches, with the exception of menthol flavour, lay down a nicotine limit for nicotine content in nicotine pouches that corresponds to the nicotine content of cigarettes, and provide for harmonised product packaging for all nicotine products used as psychoactive drugs.

In Denmark, electronic cigarettes and nicotine pouches were the most popular nicotine products among young people in 2022, with 18.2 % of 15–17-year-olds using them. Nearly 30.4 % of 15–17-year-old Danes use at least one tobacco or nicotine product.

In Norway, the placing on the market of nicotine pouches is subject to authorisation by regulatory authorities. Despite applications being submitted, no nicotine pouch has so far been approved by the authorities and none should therefore be on the market. In practice, however, there are nicotine pouches on the Norwegian market, to which, according to the manufacturer, a small quantity of tobacco plant has been added and whose brands are the same as for those products sold in other countries in the form of nicotine pouches. As a result, the products have been placed on the market as snus, the sale of which is authorised in Norway. In Norway, the regulation on uniform packaging also applies to snus. There is no limit on the nicotine content of the products.

In Norway, 27 % of 25–34-year-olds used snus in 2022. The number has doubled since 2012. Daily use of snus among young women has increased: 12 % of women aged between 16 and

²⁵ En trygg uppväxt utan nicotine, alkohol och lustgas, SOU 2024:23

²⁶ ‘Kräkkaos på skola i Robertsfors – rektorn varnar för starkt snus: “Har exploderat”’, <https://www.svt.se/nyheter/lokalt/vasterbotten/krakkaos-pa-skola-i-robertsfors-rektorn-varnar-for-starkt-snus-har-exploderat--ws0lc5>, accessed 28 March 2024

24 used snus in 2021 and 16 % in 2022. Over the same period, daily use of snus by women aged between 25 and 34 increased from 17 % to 22 %. The proportion of men in the same age groups who used snus daily was 29 % and 32 % in 2022.

In Iceland, provisions on nicotine pouches were added to the legislation on electronic cigarettes in 2022. The products are subject to, for example, a ban on advertising, an age limit of 18 years, and a ban on use in places where children and young people are present. Among other things, the law allows the prohibition of characteristic flavours in nicotine pouches, but so far no such regulation has been adopted. Products may not contain more than 20 milligrams of nicotine per gram of product. The restriction is based on the nicotine limit set for nicotine-containing fluids. However, a study is currently being conducted on lowering the nicotine limit of nicotine pouches, as the use of nicotine pouches has increased sharply over the past two years, especially among young people. In 2022, 30 % of men aged 18–34 and 16 % of women of the same age used nicotine pouches, compared with 20 % and 12 % respectively in 2020. The use of nicotine pouches among men in this age group has thus increased by 50 % in only two years and by a third for women. Almost 40 % of young Icelandic men aged between 18 and 24 used nicotine pouches in 2022.

Nordic statistics show that the use of nicotine pouches and snus has increased steeply in recent years, especially among youths and young adults. Nicotine pouches have also been tried by young people who have not previously tried or used other tobacco or nicotine-containing products. The increased use of snus and nicotine pouches among young people, at least in Sweden, has not reduced smoking or electronic cigarette use, and smoking and the use of electronic cigarettes have also increased in recent years. The number of young people using nicotine pouches has increased in many other countries too, but use is particularly high in the Nordic countries. This is considered to be due to the fact that the product closely resembles tobacco-containing snus, which has traditionally been used in the Nordic countries in particular.

In Estonia, experimentation with snus has increased over the past four years among 11–15-year-olds, especially girls. In 2022, nearly 20 % of girls in that age group had tried snus, compared with around 7 % in 2018. For boys, too, experimentation had increased over the same period, but the increase was more moderate, being about 4 percentage points. The above figures include the use of both snus and nicotine pouches. There is no limit on the nicotine content of nicotine pouches in Estonia.

Belgium is the first EU country to ban nicotine and cannabinoid pouches. The ban entered into force in October 2023 and aims to prevent the health harms caused by the use of these novel products, the use of such products among young people, and the potential negative effects they may have on combating smoking.

In the Netherlands, nicotine pouches with a nicotine content exceeding 0.035 mg are considered a dangerous and harmful food product and they are therefore prohibited. The Dutch government has planned a full ban on nicotine pouches in the Tobacco Act in the same way as for snus. Nicotine pouches are also not to be used in places where smoking is prohibited.

In Germany, too, nicotine pouches are considered to be food products and their sale is in practice prohibited because of the nicotine contained in the products.

In Czechia, nicotine pouches are largely regulated in the same way as tobacco and electronic cigarette products. The regulation of the characteristics of nicotine pouches and unit packets, such as the nicotine content, ingredients, and size of the nicotine pouch, as well as the size of the unit packets and the information and health warnings contained therein, is modelled on tobacco and electronic cigarette legislation. In Czechia, a nicotine pouch may not contain more than 12 milligrams of nicotine. Products must also be declared in the EU-CEG information system similarly to tobacco and electronic cigarette products. The sale of nicotine pouches is limited to certain retail outlets and nicotine pouches may not be sold to persons under the age of 18.

Latvia has recently adopted a legislative amendment on nicotine pouches, which sets the nicotine limit for nicotine pouches at 4 milligrams. In other ways too, the regulation is similar to that for tobacco products and e-cigarettes, including, for example, product notifications and health warnings, size restrictions for nicotine pouches and their packaging, restrictions on distance selling, marketing and display bans, and prohibitions on the use of products in educational establishments. The use of characterising fragrances and flavours in nicotine pouches is prohibited and there is also a specific ban on additives that contribute to nicotine absorption. In addition, the age limit for all products covered by the Latvian tobacco legislation, including nicotine pouches, has been raised from 18 to 20 years by the same amendment.

As far as is known, other EU Member States do not have legal limits on the nicotine contents of nicotine pouches. The product is not yet on the market in all Member States, and Italy for example has banned the entry into the market of individual nicotine pouch products on the basis of hazard analyses. However, legislative proposals are currently under preparation in some Member States, seeking to set limits on the nicotine contents of nicotine pouches. Lithuania, for example, has been preparing a bill to limit the nicotine content to 4 milligrams, but the draft bill has so far not progressed. Hungary, in turn, is preparing a draft law proposing to limit the nicotine content of nicotine pouches to 17 milligrams. Austria is also preparing a legislative amendment to propose a restriction of 16.5 milligrams on the nicotine content of nicotine pouches.

Sales of nicotine pouches doubled between 2020 and 2021 in Denmark, Czechia, Slovakia, Croatia and the UK.

Nicotine pouches are also on the market outside the EU. Nicotine pouches entered the UK market in 2019 and their use in adults aged 18 and over increased between 2020 and 2021, but remains very low (0.3 %). The use of nicotine pouches in the UK is largely concentrated in younger and middle-aged men who use other nicotine products and have a history of smoking. The UK intends to ban nicotine pouches for minors. In the United States, 11 % of 13–20-year-olds had occasionally used nicotine pouches in 2021. In Australia and New Zealand, nicotine pouches are considered to be tobacco-like products and their sales are prohibited.

Overall, it can be said that nicotine pouches are reaching or have already reached the market even in countries where there is no strong tradition of using snus. The fact that cannabidiol is added to nicotine pouches in some countries may have contributed to this development. Internationally, too, nicotine pouches are seen as a product endangering tobacco policy objectives, as evidenced, for example, by the fact that the issue is also being discussed at EU and WHO level. The WHO has in fact stated that all necessary means should be used to minimise the availability, attractiveness and uptake of nicotine pouches among young people. In addition, non-medicinal nicotine pouches should be regulated in the same way as products

that correspond to nicotine pouches in appearance, content and manner of use. In many countries, including in the EU, measures are being taken to prevent the harms caused by nicotine pouches. It is expected that the regulation of nicotine pouches will increase in the future and possibly be harmonised in the EU.

6 Feedback from consultation

6.1 Feedback received during the consultation round

A total of 60 comments were received on the draft Proposal. Comments were submitted by the Ministry of Justice, the Ministry of Finance, the Ministry of Education and Culture, the Poison Information Centre, the Finnish National Agency for Education, the Finnish National Institute for Health and Welfare (THL), Finnish Customs, the Finnish Safety and Chemicals Agency (Tukes), Valvira, the wellbeing services county of South Karelia, the wellbeing services county of South Ostrobothnia, the wellbeing services county of Kainuu, the wellbeing services county of Kanta-Häme, the wellbeing services county of Western Uusimaa, the wellbeing services county of Pirkanmaa, the wellbeing services county of Päijät-Häme, the wellbeing services county of Satakunta, the wellbeing services county of Southwest Finland, the Regional State Administrative Agency for Southern Finland, Espoo Region Environmental Health Services, the Environmental Health Unit of the City of Helsinki Urban Environment Division, the City of Kotka, the City of Kuopio, the City of Pori, the City of Porvoo, Siilinjärvi Municipality Environmental Health Services, City of Tampere Environment Health Services, Ylivieska local government environmental health co-management area, the Finnish Allergy, Skin and Asthma Federation, the DAT Doctors Against Tobacco network, EHYT Finnish Association for Substance Abuse Prevention, Filha Finnish Lung Health Association, the Organisation for Respiratory Health in Finland, Liikennepalvelukauppiat ry, the trade association for service stations and the transport services sector, the Finnish Hospitality Association MaRa, the Finnish Grocery Trade Association, the Tobacco-Free Finland 2030 Network, SOSTE Finnish Federation for Social Affairs and Health, Finnish ASH (Action on Smoking and Health), Association of Finnish Local and Regional Authorities, the Finnish Medical Association, the Finnish Heart Association, the Finnish Cancer Association, the Finnish Association of Public Health Nurses STHL, the Tobacco Industries' Federation, Vapers Finland ry, Auralaki Ky, British American Tobacco Denmark A/S and British American Tobacco Finland Oy, Haypp Group, High Voltage Group Oy, Hit Factor/Viestintäilme Oy, Imperial Brands Finland Oy, JNTL Consumer Health (Finland) Oy, Nordic Nicotine Pouches Alliance, Philip Morris Finland Oy, R-Kioski Oy, Valo SWE Oy, Wellgio Medical Oy Ltd, and one private individual. In addition, the Ministry of the Interior, the Ministry of Economic Affairs and Employment, the Ministry of the Environment, Fimea and the Government of Åland said that they had no opinion on the draft Proposal.

Most of the respondents providing comments were very critical of the draft Proposal. As such, the proposal to include nicotine pouches more comprehensively within the scope of the Tobacco Act was considered worthwhile. However, the majority of the authorities and public health organisations considered the proposed regulation to be insufficient to prevent the health harms caused by nicotine pouches, and a full ban on nicotine pouches was seen as a better alternative to the proposed regulation. In contrast, the representatives of the tobacco and nicotine pouch industry considered the proposed regulation to involve too many restrictions on their trade.

While the definition of a smokeless nicotine product proposed in the Proposal was supported by the respondents, some comments suggested that the definition should cover a wider range

of nicotine products than proposed. However, some representatives of the tobacco and nicotine pouch industry felt that the definition was too broad and did not meet its purpose. Valvira commented that the definition should be clarified to cover all nicotine-containing tobacco substitutes, regardless of whether nicotine is added to the product or whether the product already contains nicotine. Additionally, in its response, the Ministry of Finance proposed that in the further preparation of the Proposal, an explicit mention be added to the effect that the definition of smokeless nicotine products would also cover liquid products.

Many responses commented on the proposed new section 25a, which would provide for the maximum nicotine content of smokeless nicotine products and limit the flavours of smokeless nicotine products. Almost all authorities and public health organisations considered the nicotine limit proposed in the draft Proposal, 20 milligrams of nicotine per gram of product, to be clearly too high, given the risk of acute poisoning and the risk of nicotine addiction. For example, the Poison Information Centre stated that the maximum nicotine content should be set at approximately 4–8 milligrams of nicotine per gram of product. According to the opinion of the National Institute for Health and Welfare, one nicotine pouch should be permitted to contain no more than 8 milligrams of nicotine. In its opinion, the Finnish Safety and Chemicals Agency (Tukes) also considered that the limit for the maximum nicotine content should be set at well below 20 milligrams per gram in order to adequately control the serious health hazards posed by nicotine.

Some of the respondents suggested that the law should also limit the amount of nicotine contained in one nicotine pouch. This could be achieved by setting a maximum limit for nicotine level per pouch or by limiting the size of nicotine pouches. In addition, some comments indicated that the minimum size of the nicotine pouch should also be laid down.

The draft Proposal submitted for consultation proposed that a smokeless nicotine product should not contain alcohol or cannabis flavours, nor flavours that are likely to attract young people, and that further provisions on flavours likely to appeal to young people could be laid down by decree of the Ministry of Social Affairs and Health. Several respondents commented on that proposal by stating that regulation based on a negative list of prohibited substances would become open to interpretation and that it would be difficult or even impossible to enforce it. It was also pointed out that virtually all flavours, including menthol, can be attractive to children and young people. Indeed, many public authorities and public health organisations argued that, in order to protect the health of children and young people in particular, all characterising fragrances and flavours should be banned from smokeless nicotine products. In addition, the Ministry of Justice stated that there would be stronger grounds for the power to issue decrees to be allotted to the Government instead of the Ministry of Social Affairs and Health.

Representatives of the tobacco and nicotine pouch industry also considered the proposal to limit the flavours of nicotine pouches to be unsuccessful. The proposed restrictions on flavours were also considered excessive and were seen as increasing the risk of smokers not wishing to switch to potentially less harmful products. According to the comments, in order to avoid ambiguities, the flavours allowed in smokeless nicotine products should be clearly regulated at the level of the law. The flavours mentioned by the representatives of the tobacco and nicotine pouch industry included menthol, apple and various citrus fruit and berry flavours.

The draft Proposal that was submitted for consultation proposed that a smokeless nicotine product should not contain additives that increase nicotine absorption. The exception would be

additives used to create the menthol flavour in the product. Several authorities and public health organisations stated that the flavour of menthol should also be banned in smokeless nicotine products. Meanwhile, representatives of the tobacco and nicotine pouch industry pointed out in their comments that in practice nicotine pouches always contain additives that increase nicotine absorption and that banning such additives would reduce the quality of the products. Instead, it was proposed to set a maximum pH limit for smokeless nicotine products. In addition, some comments suggested prohibiting additives that have CMR properties in unburnt form from smokeless nicotine products, as well as smokeless nicotine products containing additives in quantities that significantly or measurably increase the toxic or addictive effects or the CMR properties of the product at the stage of use.

The proposals concerning unit packets of smokeless nicotine products divided the interested parties submitting responses: public authorities and public health organisations largely supported the harmonisation of the design of unit packets of smokeless nicotine products, while representatives of the tobacco and nicotine pouch industry considered the proposal to be unnecessarily strict and contrary to the objectives of the proposal. In addition, some of the comments pointed out that the Tobacco Act should provide for a maximum and minimum size of unit packets for nicotine pouches.

In its response, TUKES pointed out that the proposals on labelling in the draft Proposal are partly overlapping and contradictory in respect of the CLP Regulation and that the proposals on product notifications and sales volume declarations overlap with the national regulation of the Chemicals Act. In addition, some comments from public health organisations suggested laying down that unit packets of smokeless nicotine products should be child-resistant. In its comment, Tukes pointed out that the provisions of the CLP Regulation on child-resistant fastenings are suitable for the unit packets of nicotine pouches where the nicotine content of the product is at least 16.7 milligrams per gram.

The responses showed considerable support for making the retail sale of smokeless nicotine products subject to authorisation and for the proposed bans on the use of smokeless nicotine products.

The proposals on control fees received criticism from respondents. The Proposal proposes that, in addition to the sale of smokeless nicotine products, one single control fee could also cover the sale of nicotine-containing liquids, and if nicotine-containing liquids are already for sale, smokeless nicotine products could be sold without an additional control fee. The public authorities and public health organisations argued that regulation could lead to nicotine-containing liquids used in electronic cigarettes being available for sale more widely than at present. In contrast, representatives of the tobacco and nicotine pouch industry opposed the extension of the control fee regulation to smokeless nicotine products.

The proposal to ban distance sales of smokeless nicotine products was largely supported. The draft Proposal that was submitted for consultation proposed that the ban on distance selling of smokeless nicotine products should take effect six months after the entry into force of the proposed Act. However, in their responses the Nordic Nicotine Pouches Alliance, the Finnish Grocery Trade Association, the Tobacco Industries' Federation and British American Tobacco Denmark A/S and British American Tobacco Finland Oy took the view that distance sales of smokeless nicotine products should be prohibited without a six-month transitional period.

While the draft Proposal that was submitted for consultation proposed no changes to the age limits for products covered by the Tobacco Act, several authorities and public health

organisations proposed in their comments that the age limit for products covered by the Tobacco Act should be increased from the current 18 to 20 years. In addition, some of the comments pointed out that the prohibition on possession by minors should be extended to, for example, energy snus and nicotine-free ‘vapes’.

The proposal has been modified on the basis of the feedback from consultation. The nicotine limit laid down for smokeless nicotine would be 16.6 milligrams of nicotine per gram of product. The minimum weight of a dose unit of a smokeless nicotine product, such as a nicotine pouch, would be set at 0.5 g and the maximum weight at 1 g. The regulation on flavour restrictions has been modified to ban characterising fragrances and flavours in smokeless nicotine products with the exception of menthol, mint, tea, ginger, rosemary and wood flavours. In addition, additives with CMR properties would be banned from products, but additives that increase nicotine absorption would not be banned. A minimum packaging size would be laid down for unit packets. There would be no transitional period for the prohibition of distance selling. In addition, the possession and import of all tobacco substitutes would be prohibited for persons under 18 years of age. The extension of the prohibition of possession would therefore apply not only to smokeless nicotine products, but also, for example, to ‘vapes’, which have recently become a problem, especially in educational establishments.

On the basis of the comment of the Ministry of Justice, the grounds for tobacco sales offences in section 109 and for smoking offences in section 113 have been supplemented in the further preparation of the Proposal. On the basis of the comment of the Ministry of Finance, the section on the economic impact of the Proposal and the detailed grounds for section 2 have been specified.

No changes have been made to the proposed nicotine limit for smokeless nicotine products on the basis of feedback. As indicated in section 5.1, the proposed nicotine limit is best assessed in a balanced manner with regard to the objectives of the proposal.

Tukes’ remarks on the overlapping of the proposed regulation in the Tobacco Act with the requirements of the Chemicals Act should be reviewed again at the time of possible amendments to the Chemicals Act. In any case, Tukes should control smokeless nicotine products to the extent that the Chemicals Act applies to them. Furthermore, the Proposal will not look to raise the age limit for products covered by the Tobacco Act to 20 years, since the proposed amendments are primarily intended to respond to novel nicotine products that have come to the market unexpectedly.

A separate summary of the feedback from consultation has been prepared and published on the project website.

6.2 Statement of the Finnish Council of Regulatory Impact Analysis

In its opinion, the Council considered that the draft Proposal submitted to it for evaluation was a well-prepared package and satisfactorily met the requirements of the Impact Assessment Guide for legislative drafting. According to the opinion of the Council, the draft Proposal provided a good understanding of the background and problems of the matter. The effects of the amendments had been discussed closely and widely and the health risks and harms associated with the use of nicotine pouches had been described openly in the draft. The Council had only a few additional suggestions for the Proposal: the Council considered that the draft Proposal should include references to the studies used and that the total costs and

administrative burden for undertakings should be clarified. The Council also pointed out that impacts on animals could be taken into account as part of the environmental impact.

The development areas outlined in the Council's opinion have been taken into account in the further preparation of the Proposal.

7 Provision-specific rationale

Section 2 Definitions. It is proposed to add a new paragraph 14a to this section to define smokeless nicotine products. A smokeless nicotine product would refer to a tobacco substitute which in respect of its intended use corresponds to a tobacco product referred to in paragraphs 10 to 12, i.e. chewing tobacco, nasal tobacco or tobacco for oral use, and which contains nicotine. Smokeless nicotine products would therefore not count as tobacco products, but as tobacco substitutes containing nicotine.

Therefore, in order to meet the definition of a smokeless nicotine product, a product would first of all need to be a tobacco substitute, i.e. a product which in terms of its intended use corresponds to a tobacco product, but which does not contain tobacco. Secondly, meeting the definition of a smokeless nicotine product would require the product, in respect of its intended use, to correspond specifically to chewing tobacco, nasal tobacco, or tobacco for oral use. Nicotine pouches would be considered smokeless nicotine products within the meaning of the Proposal. For example, a tobacco substitute which in respect of its intended use corresponds to a cigarette or cigar would not meet the proposed definition.

Although the main focus of the proposed regulation is nicotine pouches, in order to prevent circumvention of the regulations, it is important that the definition covers not only nicotine pouches but also products closely resembling these. The regulation would therefore not only be limited to nicotine pouches, since, like snus, it is likely to also be possible to sell a similar tobacco substitute not only as pouches but also in loose form. In addition, the definition would also cover tobacco substitutes similar to chewing tobacco and nasal tobacco in terms of their intended use, even though such products are not yet known to be on the market. If such products were excluded, it would be easy to circumvent the regulation by claiming, for example, that the product does not correspond to snus but to chewing tobacco or nasal tobacco in terms of its intended use.

Thirdly, the definition of a smokeless nicotine product would include the presence of nicotine. The nicotine could be synthetic or natural and could be added to the product, for example, in powder format, as particles, paste, or as a combination of these. In contrast, products such as 'energy snus', which is a tobacco substitute not containing nicotine, would not meet the definition of a smokeless nicotine product.

It is not ruled out that a liquid product may also meet the definition of a smokeless nicotine product. However, the definition would only be met if the liquid tobacco substitute contained nicotine and corresponded specifically to chewing tobacco, nasal tobacco or tobacco for oral use in terms of its intended use.

Although Fimea no longer treats nicotine pouches mainly as medicinal products based on their pharmacological effect, an individual nicotine pouch product may continue to be classified as a medicinal product under section 3, subsection 1 of the Medicines Act if medicinal claims are made for the product. In this case, the product is subject to pharmaceutical legislation instead

of other product legislation under the priority provision in section 3, subsection 3 of the Medicines Act.

It is proposed that paragraph 25 of the section be amended so that the definition of a characterising fragrance or flavour would also cover a fragrance or flavour other than that of tobacco of a smokeless nicotine product that is clearly noticeable before or during use of the product and is the result of an additive or a combination of additives.

It is also proposed to amend paragraph 33 of the section, which defines point of sale. The definition of a point of sale would in future also cover a customer service counter in a retail outlet from which smokeless nicotine products are handed over or sold.

Section 6 *Duties of Valvira.* It is proposed that paragraph 1 of the section is amended so that Valvira's duties would also include the monitoring of compliance with the provisions on the ingredients, emissions, fire safety, quality, and technical characteristics of smokeless nicotine products.

Section 8 *Functions of municipalities* It is proposed that the introductory part of subsection 1 of the section be amended so that the municipality would, in cooperation with the wellbeing services county, be responsible for local activities to stop the use not only of tobacco products but also of other nicotine-containing products.

Section 22 *General obligations of the manufacturer and importer of certain other products.* It is proposed that subsection 1 of the section is amended so that the manufacturer and importer of a smokeless nicotine product would also be responsible for ensuring that the product intended for sale or other release in trade complies with the relevant provisions and regulations.

Section 25a *Requirements for smokeless nicotine products.* It is proposed to add a new section 25a to the Tobacco Act, which would lay down requirements for smokeless nicotine products. According to subsection 1, paragraph 1, a smokeless nicotine product containing more than 16.6 milligrams of nicotine per gram of product may not be sold or otherwise made available to the consumer. The weight of the product would also include the weight of the pouch, because nicotine gets absorbed into the pouch from the nicotine mixture, and if the weight of the pouch were not included in the weight of the product, regulation could be circumvented by adding nicotine to the pouch material.

According to subsection 1, paragraph 2, a smokeless nicotine product with a characterising fragrance or flavour may not be sold or otherwise handed over to the consumer. According to the proposed paragraph 25 of section 2, 'characterising fragrance or flavour' refers to a fragrance or flavour other than tobacco, resulting from an additive or a combination of additives, which is clearly noticeable in a tobacco product, nicotine-containing liquid, nicotine-free liquid for vaporisation or smokeless nicotine product before or during use. The starting point would therefore be that a smokeless nicotine product should only taste like a non-flavoured tobacco product, such as conventional snus.

However, it would also be laid down that a smokeless nicotine product would be allowed to taste like menthol, mint, tea, ginger, rosemary or wood. This would constitute an exception to the prohibition of characterising fragrances or flavours. Menthol and mint are the main flavours in nicotine pouches, and they would continue to be allowed. The other flavours that would remain permissible are not considered to specifically appeal to minors. Tea flavour

would refer to the flavour of unflavoured tea from the tea bush, such as black or green tea. Wood flavour would refer to the flavour of the woody parts of a tree such as pine or cedar, i.e. the flavours of the actual wood material. However, the flavours of leaves, needles, flowers, fruits, berries, seeds, cones, roots, burrs or sap would not be allowed.

Under subsection 2 of the section, a smokeless nicotine product may not be sold or otherwise handed over to the consumer in the form of a ready-to-use dose unit weighing less than 0.5 grams or more than 1 gram. The dose unit could be, for example, a nicotine pouch or a pellet resembling chewing tobacco in which the single dose intended for use by the consumer is pre-packed. By laying down the minimum size of the dose unit, it would be possible to ensure that in future too there will be no very small and inconspicuous nicotine pouches on the market, which, for example, could be easily swallowed by young children. The regulation on maximum size would, in turn, limit the maximum quantity of nicotine that a single dose unit, such as a nicotine pouch, could contain. A smokeless nicotine product would be allowed to contain no more than 16.6 milligrams of nicotine per gram of product, so that in a single dose unit of up to 1 gram, nicotine should not exceed 16.6 milligrams.

In subsection 3 it is proposed to lay down that the provisions of section 11, subsection 1, paragraphs 2, 3, 5, 7 and 9 also apply to smokeless nicotine products. Certain additives that are prohibited from tobacco products would therefore also be prohibited for smokeless nicotine products. This would mean, first, that smokeless nicotine products could not contain additives that are likely to create the impression that the product has health effects or poses a lower health risk than other tobacco products. Products containing stimulants or other additives that are likely to create an impression of energy and vitality would also be prohibited. In this respect, the regulation would be in line with that of Sweden. For example, smokeless nicotine products containing vitamins, caffeine, or taurine would be banned.

Additives with CMR properties in unburnt form would be prohibited. According to section 2, paragraph 30, CMR properties refer to the properties of the components of a tobacco product or other product referred to in the Tobacco Act that are carcinogenic, mutagenic or toxic for reproduction. Products containing additives in such quantities as to significantly or measurably increase the toxic or addictive effects or CMR properties of the product at the stage of use would also be prohibited.

Smokeless nicotine products any part of which contains flavourings that can alter the fragrance or taste of the product would be prohibited. For example, nicotine pouches containing flavour capsules that consumers can pop on their own could not be sold.

Section 29a *Declarations of smokeless nicotine products.* It is proposed that a new section 29a be added to the Tobacco Act, which would regulate the product declarations required for smokeless nicotine products. Product declarations would enable Valvira to monitor the product and its properties.

Under subsection 1, the manufacturer or importer of a smokeless nicotine product should inform Valvira in advance of any product it intends to sell or otherwise supply to consumers. A significant change to a product, such as any change affecting the user's body, should also be declared before the product is sold or otherwise supplied to consumers.

Under section 26, subsection 1 of the Tobacco Act, electronic cigarettes, refill containers, and nicotine-free liquids intended for vaporisation must be declared at least six months before the product is placed on the market. The requirement to declare six months in advance is based on

the Tobacco Products Directive, and no similar proposal is made for smokeless nicotine products. It would be sufficient to submit the declaration prior to the product being placed on the market.

Subsection 2 of the section would lay down provisions on the information that the declaration to be submitted under subsection 1 should contain. The proposed information would be essentially the same as the information that the manufacturer or importer is required under section 26, subsection 2 to provide on e-cigarettes, refill containers, and nicotine-free liquids intended for vaporisation. In paragraph 2 of the subsection, the product type would refer to whether the product in question is a nicotine pouch or a tobacco substitute corresponding in use to chewing tobacco or something else.

According to paragraph 5 of the subsection, the declaration should contain information stating that the manufacturer or importer bears full responsibility for the quality and safety of the product when it is placed on the market and when it is used under normal or reasonably foreseeable conditions. Such a declaration is important from the point of view of consumer legal protections, despite the fact that the provisions on liability under the Product Liability Act (694/1990) and the Consumer Protection Act apply to nicotine pouches and other smokeless nicotine products and their sale in any case. With this declaration, the manufacturer or importer would confirm that it is responsible if the use of the product causes health hazards or other issues. The Tobacco Act would not provide for further provisions on the content and conditions of the liability, as it would be determined by other legislation. The general premise would however be that the trader could not rely on its ignorance of the characteristics of the product, on the warning label on the product, or on conscious risk-taking by the consumer in order to avoid liability, for example.

Section 29b *Sales volumes of smokeless nicotine products.* The section would be new, specifying that the manufacturer or importer of a smokeless nicotine product would need to provide Valvira annually with information on the sales volumes of the products. The sales volume data would be necessary for Valvira, which would use them to levy an annual supervisory fee from manufacturers and importers of the products in accordance with section 91 of the Tobacco Act.

Section 30 *The manner, model, and timing of the submission of certain information on other products.* It is proposed that subsection 3 of the section be amended so that more detailed provisions on the manner and model of submitting declarations for smokeless nicotine products could also be issued by decree of the Ministry of Social Affairs and Health.

Section 31 *General provision on unit packets.* It is proposed to amend the section so that in the future, smokeless nicotine products could also be sold and otherwise passed on to consumers only in unit packets in accordance with the Tobacco Act and the provisions issued under it and the relevant EU legislation. Smokeless nicotine products could thus not be passed on as loose units, but there should always be a unit packet which would need to meet certain requirements. This could ensure that the consumer who acquires the product is properly informed about the product.

Section 34 *Minimum packaging size for tobacco products and smokeless nicotine products.* The title and subsections 1 and 2 of the section would be amended to include smokeless nicotine products. According to subsection 1, the minimum size of the unit packet of a smokeless nicotine product would be 20 dose units and 30 grams of loose product. Dose unit would refer to a nicotine pouch, for example. Boxes of nicotine pouches already typically

contain at least 20 nicotine pouches, so the proposal would not in practice mean a change from the current situation. The proposed minimum packaging size of 30 grams for a product sold as loose product would correspond to the minimum packaging size for roll-your-own and pipe tobacco. The provision on minimum size could prevent small and inexpensive unit packets likely to attract young people in particular.

In addition, subsection 2 provides that smokeless nicotine products should not be sold or otherwise handed over to consumers in unit packets containing smaller packages or which can be divided into smaller packages. In this respect, too, the aim of the regulation is to prevent the attractiveness of products, especially from the perspective of young people.

Subsection 3 would remain the same.

Section 39a *Markings on unit packets of smokeless nicotine products.* The section would be new, laying down, on the one hand, what markings would be required on the unit packets of smokeless nicotine products and, on the other hand, what markings would be permitted and prohibited on the packaging.

Subsection 1 of the section would lay down provisions on labelling that would be mandatory on unit packets. The unit packets of smokeless nicotine products would require essentially the same markings as the unit packets of electronic cigarettes and nicotine-containing liquids. First, a list of the ingredients contained in the product, in descending order of weight, would be required for the unit packets of smokeless nicotine products. The packaging should therefore indicate all the ingredients that the product contains. In this way, the consumer would be able to know all the ingredients that end up in the body from the product.

The unit packet should indicate the nicotine content and dosage of the product. Thus, first of all, the packet should specify the amount of nicotine contained in the product as milligrams of nicotine per gram of product. In addition, dosage should be indicated, meaning the amount of nicotine contained in, for example, one nicotine pouch. In the case of a product in loose form, the packaging should indicate how many grams the manufacturer thinks a single dose contains.

The unit packet should bear the batch number of the manufacturer. The batch number would make it possible to determine the place and time of manufacture of the product, and it could additionally be used to identify the products, for example in case recalls are required.

The unit packet would need to contain a recommendation to keep the product out of reach of children. These are toxic and addictive products that should not end up in the hands of children.

Unit packets should contain health warnings in Finnish and Swedish. In this respect, the regulation would correspond to the provisions on unit packets of tobacco products, e-cigarettes, and nicotine-containing liquids.

Subsection 2 would apply to labels which are prohibited on the unit packets of smokeless nicotine products. With the exception of paragraphs 2, 5, and 8, the provisions of section 33 would also apply to unit packets of smokeless nicotine products. This would mean that the labelling of the unit packets of smokeless nicotine products should not promote the sale or encourage the consumption of the product by giving a false impression of the characteristics, health effects, risks, or emissions of the product, suggest that the product is less harmful than

other products, or that the product seeks to reduce the impact of some harmful components of smoke, suggest that the product improves or enhances vitality and energy, or has healing, rejuvenating, natural, or organic properties, or that its use has other health or lifestyle benefits, resemble a food or cosmetic product, and imply that the product has environmental benefits.

Subsection 3 would concern the harmonisation of unit packets for smokeless nicotine products, and the proposed regulation largely corresponds to the provisions of section 32, subsection 3 of the Tobacco Act on the harmonisation of the labelling of unit packets for tobacco products, for example. According to the subsection, the unit packet of a smokeless nicotine product would be allowed to show the product name and group of the product, the name and contact details of the manufacturer or importer, and the size, flavour, and bar code of the product, but the unit packet labelling may not distinguish it from other packets of smokeless nicotine products or promote the sale of the product. This would limit the information to the information that is necessary for identifying and distinguishing a product from other similar products, enabling the consumer to contact the manufacturer or importer of the product if necessary. The information under the proposed subsection 3 concerns the minimum information that a consumer using the product can be expected to need. Product group information would refer to information on whether a smokeless nicotine product is a nicotine pouch or another type of smokeless nicotine product, for example.

In the case of the trade name of the manufacturer or importer, it would be allowed to present the trade name entered in the company's or other operator's business information system. In addition, the contact details of the manufacturer or importer could be provided. Information on, for example, the company's social media channels could not be considered permitted contact information.

The packaging could indicate the size of the product packaging, such as how many nicotine pouches the package contains. However, labelling such as 'Isompi pakkaus' ('Bigger pack') or 'Uusi pakkauskoko' ('New pack size') would not be allowed.

The packaging could indicate the flavour of the product. However, this information should not be presented in an advertising manner.

In addition, a bar code could be displayed on the packaging. However, it would be contrary to the marketing ban if consumers were to be able to read the barcode with their own devices in such a way that would make available product slogans or any other advertising elements or such information that should not be provided on the packaging of the product under the proposed section. Furthermore, the barcode should not form an image, figure, or symbol resembling something else than a barcode.

All the information referred to in subsection 3 should be provided in such a way that the unit packet cannot by its markings be distinguished from other unit packets of smokeless nicotine products and where the labelling does not promote the sale of the product. This would mean that the labelling should not in any way attract the consumer's attention and that the labelling should be identical in appearance on all retail packaging of the product group, irrespective of the brand.

According to subsection 4, the unit packet of a smokeless nicotine product should not bear markings other than those which are mandatory or permitted on unit packets pursuant to subsections 1 to 3. Any labelling not mandatory under subsection 1 or permitted under subsections 2 or 3 would therefore be unambiguously prohibited. However, the exception

would be labelling required by other legislation. For example, the CLP Regulation gives rise to certain requirements for unit packets of smokeless nicotine products, and the proposed regulations under the Tobacco Act would not interfere with this labelling. If the product contains at least 2.5 milligrams per gram but less than 16.7 milligrams per gram of nicotine, the packaging must carry the exclamation mark health hazard symbol and the hazard statement 'Harmful if swallowed'.

Furthermore, according to Article 35 of the CLP Regulation, the packaging of a chemical supplied to the general public must not attract or arouse the curiosity of children or mislead consumers. The presentation or design of the packaging may not be similar to that used for foodstuff, animal feed or medicinal or cosmetic products. The same article also provides that the packaging of a hazardous chemical must be designed, constructed and fastened in such a way that its contents cannot escape at any time. Packaging fitted with replaceable fastening devices must be capable of being reclosed without the contents escaping.

Subsection 4 would include a mandate to the Ministry of Social Affairs and Health to issue decrees.

Section 39b *Other appearance elements of unit packets of smokeless nicotine products.* The section would be new and would lay down requirements for the uniform presentation and appearance of the unit packets of smokeless nicotine products with regard to matters other than labelling. The regulation would correspond to the provisions on the presentation and appearance of unit packets of tobacco products, e-cigarettes, and nicotine-containing liquids. According to subsection 1, a unit packet of a smokeless nicotine product should not be distinguishable in shape, colour, material, or other appearance element from other unit packets of smokeless nicotine products, and the presentation of the unit packet should not promote the sale of the product.

Subsection 2 would include a mandate to the Ministry of Social Affairs and Health to issue decrees.

Section 39c *The appearance of smokeless nicotine products.* The section would be new and would relate to the appearance of the smokeless nicotine product itself, while the proposed sections 39a and 39b would regulate the appearance of the unit packet of the product. While harmonising the presentation and appearance of unit packets, it would also be justified to harmonise the appearance of the product itself, as otherwise there would be a risk that marketing efforts for example would shift from the packaging to the product itself.

Under subsection 1 of the section, a smokeless nicotine product should not be distinguished by its shape, colour, surface or other appearance from other smokeless nicotine products of the same product group, nor must its appearance be used to promote the sale of the product. The aim of the regulation is to ensure that smokeless nicotine products are not stained with attractive colours; for example, that nicotine pouches are not made heart-shaped and that no glitter is added to nicotine pouches. The product group would mean nicotine pouches, snus substitutes sold as loose product and other possible smokeless nicotine products, among others.

Subsection 2 would include a mandate to the Ministry of Social Affairs and Health to issue decrees.

Section 40 *Exemption to warning labelling in international traffic.* Section 40 of the Tobacco Act provides for an exemption to warning labelling in foreign traffic. It is proposed to amend the introductory paragraph of the section so that it also mentions the provisions of the proposed section 39a, subsection 1, paragraph 5 on the use of the Finnish and Swedish languages in warning labels for smokeless nicotine products.

Section 44 *Subjecting retail sales to licence.* It is proposed that subsection 1 of the section is amended so that the retail licence requirement would also apply to smokeless nicotine products. Like tobacco products and nicotine-containing liquids, smokeless nicotine products could only be sold and otherwise passed on in retail only based on a retail licence specific to the place of sale or licence holder and granted by the municipality in which the place of sale is located. The licence for retail sale on a mobile means of transport, such as a mobile grocery shop, would however be granted by the municipality of residence of the applicant.

Section 48 *Declaring nicotine-containing liquids and smokeless nicotine products for retail sale.* It is proposed to amend the title and subsection 1 of the section so that the regulation would also cover smokeless nicotine products. A person who holds a retail licence for tobacco products issued under the old Tobacco Act (693/1976) could also sell smokeless nicotine products at the same point of sale after having submitted a written declaration to the municipality that granted the licence and having provided the municipality with an update of the information referred to in section 46, subsection 1. Such notification may be subject to a fee. If the operator has a retail licence for tobacco products issued under the current Tobacco Act, and they want to also sell smokeless nicotine products, they should notify the municipality of any change in the information provided in the previous licence application. Such a notice concerning a change of licence information would be free of charge. It is a separate issue that the introduction of smokeless nicotine products for retail could increase the annual supervisory fee charged by the municipality for some retailers.

Section 50 *Requiring a declaration for wholesale.* It is proposed that subsection 1 of the section be amended so that the wholesale of smokeless nicotine products would be subject to declaration in the same way as the wholesale of tobacco products and nicotine-containing liquids. The declaration would need to be made in advance to the municipality where the point of sale is located, and it should provide the information referred to in section 46, subsection 1. A similar declaration should also be issued before the activity is substantially changed and when the activity is terminated.

Section 52a *Ban on the sale of products for flavouring tobacco products and smokeless nicotine products.* The section and its title would be extended to smokeless nicotine products. A product intended to produce a fragrance or flavour that is characteristic of a smokeless nicotine product could not be sold or otherwise passed on to consumers. The purpose of the proposed regulation is to avoid circumventing the ban on flavours that attract young people, for example by means of 'flavour cards' intended to be placed inside nicotine pouch packets. Although it is not proposed to ban all characterising fragrances or flavours in smokeless nicotine products and, for example, the flavours of menthol and mint will continue to be allowed, it would still be justified to ban products intended for the flavouring of smokeless nicotine products in the same way as for tobacco products. Otherwise, an attempt could be made to circumvent the existing regulation by claiming that a menthol-flavoured flavour card is not intended for flavouring a tobacco product but a smokeless nicotine product, for example.

Section 53 *Prohibition of selling to minors.* It is proposed that subsection 1 is amended so that smokeless nicotine products could also not be sold or otherwise passed on or conveyed to minors. The provision would apply not only in the course of trade, but also to other sales and other transfers. Conveying would have the same meaning as in the context of the distribution of alcoholic beverages in connection with the reform of the provisions on alcohol offences (Government Proposal 84/2008). Conveying in this Government Proposal means any activity of a person to acquire alcoholic beverages on behalf of another person and transfer it to the person commissioning the activity. The acquisition is preceded by a prior request or assignment. The Proposal also included in the definition of conveying the supply of illegal alcoholic beverages from a seller or other supplier to a buyer and the finding of a buyer for an illegal lot. However, the mere communication of general information on where illegal alcoholic beverages would be available was not considered to be conveying.

Under subsection 2, the sale of tobacco substitutes other than smokeless nicotine products to minors would remain prohibited only in the course of trade.

Section 58 *Prohibition of distance sales.* It is proposed that the section is amended so that it would apply to smokeless nicotine products similarly as it does to tobacco products, e-cigarettes, nicotine-containing liquids, and plant-based products intended for smoking. Cross-border distance sales are defined in section 2, paragraph 34. The prohibition of cross-border distance selling would not only mean that traders established abroad would not be allowed to sell smokeless nicotine products to Finnish consumers, but also that Finnish traders would not be allowed to sell their products to foreign consumers.

In addition, the section would also prohibit traders established in Finland from selling and otherwise supplying smokeless nicotine products to consumers by means of distance communication referred to in chapter 6, section 7, subsection 2 of the Consumer Protection Act (38/1978), such as a computer network or telephone.

A violation of the prohibition on distance selling would not be punishable, but municipalities could prohibit such activities and increase the effectiveness of the prohibition by imposing a penalty payment. In addition, a breach of the prohibition on distance selling would justify the withdrawal of the retail licence.

Section 59 *Prohibition of sales through customs auctions.* It is proposed to that the section is amended so that the prohibition on selling by means of customs auctions would apply to smokeless nicotine products as it applies to tobacco products, e-cigarettes, nicotine-containing liquids, and plant-based products intended for smoking.

Section 60 *Wholesale restrictions.* Under section 60, subsection 2, paragraph 1 currently in force, nicotine-containing liquids may only be sold wholesale to wholesale distributors who have issued the declaration specified in section 50 for resale purposes, and to those possessing a retail licence specified in section 44 and who have declared selling nicotine-containing liquids pursuant to section 46, subsection 1, paragraph 2; or section 49. The section would be extended to apply to smokeless nicotine products as well.

Subsection 3 of the section would be amended so that smokeless nicotine products could also not be sold wholesale in the places referred to in section 45, subsection 3, including in the interior and outdoor areas of kindergartens or educational institutions providing basic education.

Subsection 4 of the section would be amended to allow the wholesale of smokeless nicotine products to retailers who do not need a retail licence under the Tobacco Act and to wholesalers who are not subject to the declaration obligation under this Act. Wholesalers may have customers who are not subject to Finnish legislation and who are therefore not obligated to obtain a retail licence under the Tobacco Act. Such operators include vessels sailing under the flags of other countries.

Section 62 *Prohibition on imports by minors.* It is proposed to amend the section so that it would apply to all tobacco substitutes. Nicotine-containing liquids would no longer be mentioned separately in the provision, as they are also considered tobacco substitutes. The import ban would be in line with the proposed extension of the prohibition on possession by minors and necessary to protect the health of minors.

Section 65 *Prohibition of imports of products obtained by means of distance communication.* It is proposed to amend the section so that private individuals would not be allowed to obtain or receive smokeless nicotine products from a trader by post, transport of goods, or other similar means from outside Finland. While the Proposal proposes a ban on cross-border distance selling of smokeless nicotine products, it would still be practically difficult for Finnish authorities to intervene in the violation of the ban if the operator is foreign, and especially if the operator is established outside the EU. The proposed ban on imports under section 65 could more effectively address the ordering of nicotine pouches and other smokeless nicotine products from abroad.

Section 66 *Time limits for passenger imports.* It is proposed to amend the section to include smokeless nicotine products. This is a special regulation for imports from outside the European Economic Area, which applies in addition to other restrictions on imports when the import takes place from outside the European Economic Area.

Section 67 *Quantitative limits on passenger imports.* A new paragraph 4 is proposed to be added to subsection 1. Under this paragraph, private individuals would not be allowed to import more than 1 000 grams of smokeless nicotine products, the unit packets of which carry labelling that deviates from the provisions of section 39a, subsection 1, paragraph 5. This restriction is necessary to protect public health and would apply to products whose unit packets do not contain warning labels in Finnish and Swedish in accordance with Finnish tobacco legislation.

An amendment related to the technicalities of legislative drafting would be made to subsection 1, paragraph 3 of the section as a result of the addition of the new paragraph 4.

Section 74 *General smoking bans.* It is proposed that subsection 3 of the section is amended so that in the future, smokeless nicotine products could not be used in the indoor or outdoor areas of kindergartens or institutions providing pre-primary or basic education, vocational training, or upper secondary school education, or in playgrounds. The proposed amendment aims to protect children from observational learning related to smoking and use of other nicotine products and to protect them against life-threatening nicotine poisonings that may result from ingesting nicotine pouches.

Section 80 *Smoking ban signage.* A new subsection 2 is proposed to be added. According to the current section, the holder of an indoor or outdoor area and the organiser of a public event must display signs indicating the smoking ban referred to in section 74, subsection 1 and the space reserved for smoking referred to in sections 76 and 77. Under the currently valid section

74, subsection 3, smokeless tobacco products may not be used in the indoor or outdoor spaces of kindergartens, educational institutes providing pre-primary or basic education, vocational training, or upper secondary school education, or in playgrounds, but the current Tobacco Act does not require the holder of the space to display signs indicating the prohibition on the use of smokeless tobacco products. Therefore, the new subsection 2 of section 80 would provide that the provisions of subsection 1 on the smoking ban would also apply to the prohibition on the use of smokeless tobacco products and smokeless nicotine products laid down in section 74, subsection 3. In this way, bans on smokeless tobacco products and smokeless nicotine products would also become more clearly known to people, which could contribute to improving compliance.

Section 81 *Enforcement of smoking bans.* The current section provides that if a person violates the smoking ban referred to in section 74 and does not stop smoking despite being asked to do so, the holder of the place or their representative may remove the person from the premises, unless such removal can be regarded as unreasonable. It is proposed to amend the section so that it also covers situations where someone violates the prohibition on the use of smokeless tobacco products or smokeless nicotine products laid down in section 74, subsection 3. It would also be specified that the section refers specifically to the prohibitions on smoking laid down in section 74, subsection 1, and not to the prohibition on smoking laid down in section 74, subsection 2, which applies to private vehicles when persons under 15 years of age are present.

Section 90 *Fees for the processing of applications and declarations.* Under the Proposal, paragraph 1 of subsection 1 of the section would be amended so that the municipality would also charge a fee for the notification of an amendment to the retail licence in relation to the extension of retail sales to new product groups. The fee would therefore be levied, for example, if a retail licence has been granted for the retail sale of tobacco products and the sale is to be extended to nicotine-containing liquids or smokeless nicotine products, or to both of these product groups.

Under the Proposal, paragraph 2 of subsection 1 of the section would be amended so that the municipality would also levy a fee in accordance with its approved tariff when the notification referred to in section 48 is made for smokeless nicotine products.

It is proposed that paragraph 3 of subsection 3 is amended so that Valvira could also charge the manufacturer or importer a fee for the receipt, storage, processing, analysis, and publication of information provided under the proposed sections 29a and 29b, as well as for any measures relating thereto. Section 90, subsection 5 would also apply to smokeless nicotine products, according to which the product may not be placed on the market until the fee referred to in paragraph 3 of subsection 3 has been paid.

Section 91 *Supervisory fees under the Tobacco Act.* According to subsection 2 of the current section, the maximum supervisory fee charged by municipalities is EUR 500 per point of sale. However, if an operator has declared the retail sale or wholesale of both tobacco products and nicotine-containing liquids in accordance with section 46, subsection 1, paragraph 2 or section 50, subsection 1, or has declared the retail sale of nicotine-containing liquids as referred to in section 48, the supervisory fee is charged at most double. It is proposed to add a mention in the subsection that the provisions on nicotine-containing liquids therein would also apply to smokeless nicotine products. This would mean that if a seller has already declared selling tobacco products and nicotine-containing liquids, the maximum fee would remain at EUR 1 000, even if the seller also declared placing for sale smokeless nicotine products. If the seller

has declared only selling tobacco products, the supervisory fee would be increased to EUR 1 000 if the seller were also to declare selling smokeless nicotine products. If the seller has declared only selling nicotine-containing liquids, the fee would remain at EUR 500 even if the seller were to declare also starting to sell smokeless nicotine-containing liquids.

Subsection 4 of the section would be amended so that Valvira would also collect an annual supervisory fee from manufacturers and importers of smokeless nicotine products to cover the costs arising from monitoring compliance with the Tobacco Act. The supervisory fee would be based on the sales volumes that the manufacturer or importer has declared to Valvira in the previous calendar year pursuant to the proposed section 29b. It is proposed to add two new paragraphs to subsection 4 and to make an amendment related to the technicalities of legislative drafting to paragraph 5 as a result of the addition of the new paragraphs. According to the new paragraph 6, the supervisory fee for smokeless nicotine products sold in dosing units, such as nicotine pouches, would be EUR 0.001 per unit. This would be equivalent to the supervisory fee for one cigarette. The new paragraph 7 would provide that other smokeless nicotine products would be subject to a supervisory fee of EUR 1.7 per kilogram, which is the same amount as for example for roll-your-own tobacco.

Subsection 5 would also apply to smokeless nicotine products, according to which the supervisory fee is between EUR 300 and EUR 70 000 per manufacturer or importer.

Section 94 *Storage and publication of product control information.* It is proposed to amend subsection 2 so that Valvira would also need to place the information on smokeless nicotine products received under section 29a on a website accessible to the public, with the exception of trade secrets, where the information could only be searched for as individual inquiries using the name of the product or the name, company number, or registration number of the registered entity.

It is proposed to amend subsection 3 so that the name of the natural person referred to in section 29a, subsection 2, paragraph 1 should also be made publicly available as such when information is made available in accordance with section 94, subsection 2.

Section 97 *Revocation of retail licence.* It is proposed that the section be amended to cover smokeless nicotine products more extensively than now. Chapter 5 of the Tobacco Act also proposes to lay down requirements for unit packets of smokeless nicotine products, and section 97, subsection 1, paragraph 1 is proposed to be amended to allow revoking a retail sale licence if the unit packets are in breach of the provisions of chapter 5. This would cover not only situations where the packaging does not bear the required warning labels, but also situations where the presentation and appearance of the packaging is not uniform as proposed.

It is proposed that paragraph 2 of subsection 1 is amended so that the retail licence could be revoked if the holder of the retail licence fails to declare the sale of smokeless nicotine products in violation of section 48 or any relevant information referred to in section 49.

In addition, for section 58, it is proposed that the sale and other supply of smokeless nicotine products to consumers by means of distance communication is prohibited, and section 97, subsection 1, paragraph 6 would be amended so that the infringement of the prohibition on distance selling would also justify the withdrawal of the retail sales licence.

It should also be noted that, since smokeless nicotine products are tobacco substitutes, some of the other grounds for withdrawal of retail licences laid down in section 97, subsection 1 may

also apply to smokeless nicotine products. A retail licence may also be revoked if smokeless nicotine products are sold to persons under the age of 18 or from automatic vending machines, or if they are marketed or displayed in connection with retail sales.

Section 100 *Ban on sales.* It is proposed to amend the introductory paragraph and paragraph 3 of subsection 1 so that Valvira could prohibit the sale and other distribution of smokeless nicotine products if the manufacturer or importer has not provided Valvira with the information referred to in section 29a or 29b in the prescribed manner, within the prescribed period, or using the prescribed model, or if the information provided is incorrect.

In addition, it is proposed to amend subsection 1, paragraph 4 so that a sales ban could also be imposed if the manufacturer or importer has failed to pay Valvira the fee referred to in section 91, subsection 4, i.e. a control fee based on the sales volumes of the product. The amendment would enhance Valvira's ability to intervene in situations where the manufacturer or importer has not paid a control fee.

Section 109 *Criminal offence involving the sale of tobacco.* It is proposed that the section is amended so that the elements that constitute a tobacco sales offence would be extended to cover illegal activities related to smokeless nicotine products as well. According to paragraph 1, a person who, in breach of section 53, subsection 1, intentionally sells or otherwise hands over for compensation or otherwise supplies smokeless nicotine products to persons under the age of 18 should also be convicted of a criminal offence involving the sale of tobacco.

Paragraph 2 of this section would remain unchanged.

According to paragraph 3, a person who intentionally sells or otherwise transfers in the course of trade smokeless nicotine products without a retail licence in violation of section 44, or without submitting a notification of the retail sale of smokeless nicotine products as referred to in section 48, should also be convicted of a tobacco sales offence.

According to paragraph 4, a person who, in violation of section 60, intentionally sells or otherwise transfers in wholesale sales smokeless nicotine products to operators other than those referred to in said section, should also be convicted of a tobacco sales offence.

Nicotine pouches are toxic and highly addictive products that are harmful to the health of children and young people in particular. It would therefore be justified that their sale to minors, as proposed above, should be punishable not only in the course of business but also between private individuals. It would also be justified to penalise their transfer in the course of trade without a retail licence or a required notification and their transfer in wholesale sales to an operator other than those mentioned in section 60. Due to the harmful nature of nicotine pouches and other smokeless nicotine products, pressing social reasons require the criminalisation of the above-mentioned acts.

The above-mentioned acts would only be punishable when undertaken intentionally. The penalty for a tobacco sales offence would continue to be a fine or a maximum of four months' imprisonment. In the case of products that cause addiction and other health hazards and, depending on their nicotine content, may even be life-threatening, an infringement provision that threatens a fine only cannot be considered sufficient.

Section 113 *Smoking violation.* It is proposed that subsection 2 of the section is amended so that the elements constituting a smoking offence would be extended to cover the use of

smokeless nicotine products as well in violation of section 74, subsection 3. The provision would additionally be updated by mentioning playgrounds, which were added to section 74, subsection 3 by amendment 283/2022.

The proposed changes would be required by a pressing social need. Section 74, subsection 3 of the Tobacco Act protects children and young people, including very young children, from model learning related to the use of tobacco and other nicotine products and from life-threatening nicotine poisoning. In order to protect the health of children and young people, it would be important that the use of a smokeless nicotine product in, for example, the outdoor areas of a kindergarten or school or in a playground, could also be addressed by means of criminal law if necessary.

Section 117 *Outer packaging.* It is proposed that the section is amended so that the provisions of the Tobacco Act on the unit packets of smokeless nicotine products would also apply to the possible outer packaging of the products. According to section 2, paragraph 32 of the Tobacco Act, outer packaging means packaging in which tobacco products or other products referred to in the Tobacco Act are placed on the market and which contains a unit packet or several unit packets. However, the outer packaging does not refer to the transparent wrapping of the retail packaging. When the regulation on retail packaging would also apply to outer packaging, warning labels for example could not be hidden by selling unit packets in cartons.

Section 118 *Prohibition on possession.* It is proposed to amend the section so that in future, a person under the age of 18 would not be allowed to possess any tobacco substitutes. Nicotine-containing liquids would no longer be mentioned separately in the section because they are included in tobacco substitutes. The ban on possession would therefore be extended to, inter alia, nicotine pouches and other smokeless nicotine products, nicotine-free ‘vapes’, herbal cigarettes and energy snus.

A violation of the prohibition on possession is not proposed to be treated as a criminal offence, but, as a result of the prohibition on possession, bringing any smokeless nicotine products into certain educational establishments would be prohibited directly pursuant to section 29, subsection 2 of the Basic Education Act (628/1998), section 40, subsection 2 of the Act on General Upper Secondary Education (714/2018), and section 80, subsection 2 of the Act on Vocational Education and Training (531/2017). In addition, under section 36d, subsection 1 of the Basic Education Act, section 45, subsection 1 of the Act on General Upper Secondary Education, and section 89, subsection 1 of the Act on Vocational Education and Training, a principal or a school teacher would be able to confiscate smokeless nicotine products from a pupil or student. In addition, under section 65, subsection 4 of the Child Welfare Act (417/2007), products which, according to section 118 of the Tobacco Act, cannot be held by a person under 18 years of age may be confiscated from the child by an establishment.

In addition, the extension of the prohibition on possession would support decision-making by entities involved with children and young people, such as sports clubs, in order to prevent nicotine addiction in minors.

Section 119 *Disposal.* The section would be amended to include smokeless nicotine products.

8 Regulation at the level of secondary legislation

Sections 39a to 39c of the proposed Act would include granting new powers to issue decrees to the Ministry of Social Affairs and Health concerning the provisioning for the details of the labelling and other appearance details of the unit packets of smokeless nicotine products. Due to its technical and detailed nature, it would be justified for the more detailed regulation on standardisation of unit packets to be issued by decree rather than an act. It would be appropriate to extend the provisions of the Decree of the Ministry of Social Affairs and Health on the labelling and other appearance elements of tobacco products and similar products and their unit packets (591/2016) to include the retail packets of smokeless nicotine products. For example, regulation on the harmonisation of unit packets for smokeless nicotine products could be modelled on Norway, which has harmonised unit packets for snus.

9 Entry into force

It is proposed that the Act enter into force as soon as possible after the end of the standstill period under the TRIS Directive. The current situation involves risks that pose a threat to public health and to the health of children and young people in particular.

However, it is proposed that section 25a on the characteristics of smokeless nicotine products, section 34 on the minimum size of unit packets and section 39a, subsection 1 on mandatory labelling of unit packets would enter into force six months after the entry into force of the proposed law. The nicotine content of nicotine pouches is already restricted under section 45b of the Chemicals Act, and the decision is valid until further notice. During the proposed six months, operators would be able to sell the remainder of their stocks of products containing more than 16.6 milligrams of nicotine per gram, flavours that are due to be banned and the packaging of which does not bear any warning labels for nicotine.

It is proposed that sections 39a, subsection 2 to 4, 39b, and 39c on the harmonisation of smokeless nicotine products and their unit packets enter into force one year after the entry into force of the proposed Act. This would give manufacturers and importers sufficient time to adapt their packaging to the new regulation. One year after the entry into force of the proposed Act, no packaging or products that do not comply with the proposed regulation should be sold or otherwise passed on to consumers regardless of when the products were manufactured. The obligation to make visible signs banning the use of smokeless nicotine products under section 80, subsection 2 would also take effect one year after the entry into force of the proposed Act.

The provisions of section 65 would not apply to smokeless nicotine products purchased before the entry into force of the proposed Act. A private individual who, for example, ordered nicotine pouches from a foreign online store before the entry into force of the proposed Act would not be in breach of section 65 when receiving the products, even if they were to arrive in Finland only after the Act enters into force.

The proposed Act contains a number of transitional provisions. For smokeless nicotine products being sold or otherwise passed on to consumers in Finland when the proposed Act enters into force, the declaration of section 29a should be submitted within six months of the entry into force of the proposed Act. The information on sales volumes under section 29b should be provided to Valvira for the first time during the calendar year following the entry into force of the proposed Act.

Transitional periods are also proposed for the regulation on the requirement of authorisation for retail sales and the declaration requirement for wholesale. A trader who, upon the entry into force of the proposed Act, sells or otherwise passes on smokeless nicotine products in retail and within three months of the entry into force of the proposed Act and submits to the municipality an application for authorisation for the retail sale of smokeless nicotine products referred to in section 46, or who issues the declaration for the retail sale of smokeless nicotine products referred to in section 48, would be allowed to sell or otherwise pass on smokeless nicotine products in retail for a period of one year after the entry into force of the proposed Act, without prejudice to section 44, subsection 1.

A trader who, upon the entry into force of the proposed Act, sells or otherwise transfers smokeless nicotine products in wholesale sales and within three months of the entry into force of the proposed Act, submits a notification to the municipality of the wholesale sale of smokeless nicotine products provided for in section 50, may, without prejudice to section 50, sell smokeless nicotine products on a wholesale basis for a period of one year after the entry into force of the proposed Act. The provisions of the introductory paragraph to section 60, subsection 2 notwithstanding, it would be allowed in wholesale sales to sell and otherwise transfer for retail smokeless nicotine products for a period of three months after the entry into force of the proposed Act, and, the provisions of paragraph 1 of the subsection notwithstanding, for a period of one year after the entry into force of this Act if the buyer is able to prove that the application or notification referred to in that paragraph has been submitted.

10 Implementation and monitoring

The use of nicotine pouches is monitored with surveys conducted by THL and others. The monitoring of passenger imports is used to provide information on the import of snus by travellers, and the frequency of seizures by Customs is used to monitor illegal imports of snus. The above data sources can be used to retroactively assess the impact of the proposed regulation on the use of nicotine pouches and, for example, on the legal and illegal import of snus. In the monitoring, special attention is paid to nicotine poisoning caused by nicotine pouches and other smokeless nicotine products, especially in children. Conclusions will be drawn on the basis of the monitoring which will be considered separately as necessary to update the regulation.

However, the assessment is hampered by the fact that nicotine pouches have only been freely available on the market for a very short time, and the current situation has therefore not yet stabilised. In addition, nicotine pouches have recently been included in the scope of the Act on Excise Duty on Tobacco, and this may have implications for product demand. Therefore, it is not possible to retrospectively assess precisely the changes in demand for nicotine pouches, for example, that have been caused specifically by the amendments proposed in this Government proposal.

11 Relationship to the Constitution and legislative process

11.1 General

For nearly four decades, tobacco legislation has been aimed at reducing the significant health-related and economic harms caused by the use of tobacco products and other nicotine products. From the perspective of the Constitution, tobacco legislation is unquestionably linked to section 19, subsection 3 of the Constitution, according to which public authorities

shall guarantee, as provided in more detail by law, adequate social, health, and medical services for everyone, and promote the health of the population. Against this background, on several occasions in the past, consideration has been given to whether there are acceptable grounds for restricting other fundamental rights. However, the Constitutional Law Committee has stated that the legislator's margin of discretion in tobacco legislation is wide, and that the general social interest in the cessation of use of tobacco products is quite pressing, so there is no justification or real need for justifying individual restrictions in order to safeguard a certain fundamental right (PeVL 7/2022 vp, p. 2).

The Proposal proposes regulating smokeless nicotine products in a manner essentially similar to tobacco products and nicotine-containing liquids under the current Tobacco Act. Therefore, the previous positions of the Constitutional Law Committee on the Tobacco Act are relevant to the proposed regulation.

11.2 Personal liberty

According to section 7, subsection 1 of the Constitution, everyone has the right to personal liberty. Personal liberty is a universal right which protects not only physical freedom but also the freedom of will and self-determination (e.g. government proposal HE 309/1993 vp and Constitutional Law Committee statement PeVL 6/2014 vp). The Constitutional Law Committee has considered smoking bans to be relevant to a person's right to self-determination and thus to personal freedoms protected by section 7, subsection 1 of the Constitution (PeVL 7/2022 vp, p. 3 and PeVL 17/2016 vp, p. 3). However, the Constitutional Law Committee has stated that the regulation of smoking bans also implements the task of promoting the health of the population assigned to the public authorities in section 19, subsection 3 of the Constitution (PeVL 7/2022 vp, p. 3).

The Proposal proposes to ban the use of smokeless nicotine products in kindergartens and educational institutions providing pre-school and basic education, vocational education, or upper secondary school education, and in playgrounds. The proposal affects a person's right to self-determination and thus the personal liberty protected under section 7, subsection 1 of the Constitution. The proposed ban however aims to protect children and adolescents from the learning of habits by imitation and life-threatening nicotine poisonings related to the use of tobacco and nicotine products in such indoor and outdoor areas that are occupied by children and adolescents in particular. The Proposal therefore has a legitimate objective and would fulfil the obligation of the public authorities to promote the health of the population, as laid down in section 19, subsection 3 of the Constitution.

The proposed ban on the use of smokeless nicotine products is necessary in order to achieve the above objectives and otherwise complies with the proportionality requirement and does not go beyond what is justified taking into consideration the weight of the interests underlying the proposed ban in relation to the legal priority being restricted. Neither can the use of nicotine pouches or other smokeless nicotine products in kindergartens, educational institutions, or playgrounds be considered part of the core domain of personal liberty.

The Proposal proposes that minors should not possess or import any tobacco substitutes. Age restrictions on possession and imports may be regarded as a type of restrictions of a person's right to self-determination, in addition to which they are relevant in respect of equality as provided for in section 6 of the Constitution. However, the proposed restrictions are supported by strong health policy arguments, as they would specifically protect children and young people, who are particularly vulnerable to the harmful effects of tobacco and nicotine

products, from the health harms caused by the products. At the same time, children and young people would be prevented from using tobacco substitutes as practice for the use of other products referred to in the Tobacco Act. The proposed prohibitions therefore have legitimate grounds and would promote the health of the population in accordance with section 19, subsection 3 of the Constitution.

According to the Proposal, a violation of the prohibition on possession would continue to not be a punishable offence. In its statement PeVL 21/2010 vp on the old Tobacco Act (693/1976), the Constitutional Law Committee considered that this kind of purely symbolic legislation, the violation of which will not be sanctioned, should be avoided. However, the key practical importance of the prohibition on possession is, above all, linked to the fact that it makes it possible for all tobacco substitutes to be confiscated from students during the school day under legislation on educational establishments. The extension of the prohibition on possession would also be relevant for child welfare institutions.

11.3 Freedom of speech

According to section 12, subsection 1 of the Constitution, everyone enjoys freedom of expression. Commercial communications fall within the scope of the freedom of expression provision, but they are not considered to be at the core of freedom of expression. That is why the Constitutional Law Committee has considered that commercial communications can be subject to more extensive restrictions than the core area of freedom of expression. However, the Committee's policy is that regulations of advertising and marketing must also meet the general requirements of a law restricting a fundamental right (PeVL 7/2022 vp, p. 3-4, PeVL 21/2010 vp, p. 3/II, PeVL 3/2010 vp, p. 2/I, and PeVL 54/2006 vp, p. 2/I).

The Proposal proposes that the unit packets of smokeless nicotine products should contain health warnings in Finnish and Swedish. The Constitutional Law Committee has assessed the relationship between the freedom of expression and mandatory warning labels when discussing the Government Proposal to amend the Alcohol Act (HE 232/2006 vp and PeVL 54/2006 vp). In view of the toxicity of nicotine and its adverse health effects, it can be considered that the proposed obligation to include health warnings on the unit packet of a smokeless nicotine product is based on acceptable grounds, in particular from the point of view of promoting public health, and that the obligation is not unreasonable from the point of view of freedom of expression for the trader.

The above comments of the Constitutional Law Committee are also relevant to the proposal to harmonise the unit packets of smokeless nicotine products. There should be no elements not permitted by law on the packaging for retail sale, and the manner in which labelling is presented would be strictly regulated. The Proposal is therefore relevant for the freedom of expression of manufacturers and importers of products as intended in the Tobacco Act. The same applies to the proposal to harmonise the appearance of smokeless nicotine products by law.

The aim of the proposed regulation is to prevent retail packaging or the product itself from being used as a marketing tool. Due to the health-related and economic disadvantages caused by the use of nicotine products, society has a strong reason to seek to prevent the use of these products and to support their cessation. Studies have shown that the harmonisation of retail packages of tobacco products has reduced the attractiveness of packaging, the start of smoking among young people, and the overall smoking rate in other countries. As far as nicotine pouches are concerned, this has apparently not yet been studied, but it can be assumed that the

effects would be similar in impact. A further aim is to not mislead the consumer by means of attractive packaging in terms of the harmful health effects of the product. The proposed regulation is therefore required by a pressing social need and would fulfil the right to life laid down in section 7 of the Constitution and the obligation of the public authorities to promote the health of the population, as laid down in section 19, subsection 3 of the Constitution.

The effect of the harmonisation of retail packaging may be limited to some extent by the fact that products covered by the Tobacco Act or their trademarks may not be displayed in connection with retail sales. As a rule, consumers cannot see the unit packets, for example in grocery stores, if they are not themselves buying the products referred to in the Tobacco Act. However, retail packets do appear, for example, on social media and as litter on the ground, so the advertising elements they contain can nonetheless attract new users. In addition, it is essential that the user of a product referred to in the Tobacco Act is not subjected to any marketing efforts, not even through the packaging or the product itself.

From the point of view of freedom of speech, it is essential that product packaging constitutes part of marketing, and that any marketing efforts for products referred to in the Tobacco Act are prohibited under the Tobacco Act already in force. Thus, none of the elements that promote the sale of products, either on the packaging or in the product itself, are currently permitted, but it is often difficult to intervene in them in practice. The current situation also creates inequalities between operators, as operators use packaging to push the limits of the marketing ban, but the authorities have the resources to intervene only in the most flagrant breaches of the marketing ban. The proposed regulation would thus simplify the situation from the point of view of manufacturers and importers as well as the supervisory authorities, and it would also improve equality between different traders.

When considering the Government proposal on the harmonisation of unit packets of tobacco products, refill containers and nicotine-containing liquids (HE 141/2021 vp), the Constitutional Law Committee drew attention to the fact that the requirement to extend the harmonisation of unit packets for tobacco products to the catalogue referred to in section 72 of the Tobacco Act is incompatible with the freedom of speech guaranteed in section 12 of the Constitution. The Constitutional Law Committee considered that the legislative proposal could only be dealt with in the ordinary legislative order if the Committee's constitutional comment on the information to be included in the catalogue referred to in section 72 of the Tobacco Act is duly taken into account (PeVL 7/2022 vp). As a result of the statement of the Constitutional Law Committee, a mention was added to section 72 of the Tobacco Act specifying that product trademarks may be displayed in the catalogue. The display ban laid down in the Tobacco Act already applies widely to smokeless nicotine products and other tobacco substitutes, and section 72 is also applicable to these products. The proposal for the harmonisation of unit packets of smokeless nicotine products is therefore not considered to be in conflict with the freedom of speech guaranteed in section 12 of the Constitution.

11.4 Protection of property

According to section 15, subsection 1 of the Constitution, everyone's property is protected. Protection of property includes not only the power to control and use property, but also the power to govern it. Protection of property also includes intangible property rights, such as trade marks (see e.g. PeVL 17/2011 vp and PeVL 21/2010 vp). The Constitutional Law Committee has stated that the regulation on harmonising the appearance of tobacco products, refill containers, and nicotine-containing liquids and their unit packets is relevant for the protection of property under section 15 of the Constitution (PeVL 7/2022 vp).

The Proposal proposes that unit packets of smokeless nicotine products be harmonised under the Tobacco Act. The permissible appearance of the products themselves would also be regulated by law. The proposals are relevant for the protection of property of manufacturers and importers of smokeless nicotine products, since the unit packets and the products may have been protected by different types of trade marks, such as word marks, figurative marks, or figurative marks containing word elements.

According to the Proposal, the presentation of packaging should be harmonised such that no logos or other designs could be displayed on the packaging, even if they were protected by trademarks. For example, the colour of the packaging would also be standardised. The proposals would completely prohibit the presentation of figurative marks and figurative marks containing word elements on packaging. The proposed regulation would therefore constitute a restriction on the right of trademark proprietors to exploit that property in their business operations. However, the proposed regulation is considered to be required by a pressing social need and it fulfils the requirement on right to life laid down in section 7 of the Constitution and the obligation of the public authorities to promote the health of the population as laid down in section 19, subsection 3 of the Constitution.

However, from the point of view of the proportionality of the proposed regulation, it is significant that the product name could continue to be displayed on packaging. The proposed regulation would therefore not completely prevent the use of trademarks on packaging, and it would continue to be possible to distinguish between different products by means of a brand name printed on the packaging. No-one other than the proprietor of a trademark could continue to use a mark that can be confused with the trademark as an emblem of their product, and the proprietor of the trademark would be entitled to rely on their exclusive right against all their competitors. Registration of a trademark does not however give rise to an unlimited right to use the trademark, but trademark rights may be limited in order to protect the public interest and public health.

On the basis of the above considerations, the proposal considers that the proposed regulation on the harmonisation of smokeless nicotine products and their packaging is presented on acceptable grounds and is required by a pressing social need. Moreover, the regulation does not target the core of the protection of property, and the restrictions do not go beyond what is justified by the importance of the social interest underpinning the regulation.

Freedom of contract is not expressly enshrined in the Constitution, but freedom of contract is nevertheless protected to a certain extent by the provision on protection of property (see e.g. HE 309/1993 vp and PeVL 16/2007 vp).

The proposal proposes prohibiting the sale of smokeless nicotine products to minors in the course of trade as well as elsewhere. This constitutes a certain degree of restriction of the freedom of contract. However, there would be very strong public health grounds for this restriction, linked to the protection of the life and health of minors. Moreover, the proposed regulation cannot be regarded as unreasonable in terms of the protection of property or the freedom of contract.

11.5 Right to work and freedom to conduct a business

According to section 18, subsection 1 of the Constitution, everyone has the right, as provided by the law, to earn their livelihood by the employment, occupation, or commercial activity of their choice. In its statement practice, the Constitutional Law Committee has considered the

freedom to conduct a business to be the primary rule, but has also considered it possible to make business activities subject to authorisation in exceptional cases. However, the requirement for a licence must always be laid down by law, which must meet the requirements of precision and definition required of a law restricting a fundamental right (e.g. PeVL 69/2014 vp, p. 2). The mere provision of a declaration obligation has not been considered problematic from the point of view of the freedom to conduct a business if the authority is not required to make a decision as a result of the declaration (PeVL PeVL 10/2012 vp, p. 4-5 and PeVL 54/2002 vp, p. 3), or if the failure to declare has not constituted a prohibition on the exercise of the activity (PeVL 16/2009 vp, p. 3).

The Proposal proposes that the retail sale of smokeless nicotine products be made subject to authorisation and wholesale sales subject to notification, which entails a restriction on the freedom of sellers of smokeless nicotine products to conduct business. However, the restriction can be considered to be justified by the fact that the products contain nicotine, which causes addiction and other serious hazards to health. In addition, the products can even cause life-threatening nicotine poisoning, especially in young children. The proposals concerning the licencing requirement of retail sales and the declaration requirement for wholesale thus have acceptable objectives, and they would fulfil the obligation of the public authorities to promote public health, as laid down in section 19, subsection 3 of the Constitution.

The precise and defined provisions of the Tobacco Act in force concerning the requirement for a licence for retail sales and the requirement for notification for wholesale sales would apply to smokeless nicotine products. Municipalities would not make decisions on the basis of the wholesale notification, but failing to submit a notification would result in a ban on carrying on operations. There are reasonable grounds for such a restriction, taking into account the fact that these products are addictive and harmful to health, meaning that all wholesalers should be known to the supervisory authorities.

In connection with the regulation of business activities, the Constitutional Law Committee has consistently considered the effects of revocation of a retail licence to be more severe than the refusal of a requested retail licence. The Committee has therefore considered it necessary for the proportionality of the regulation to tie the possibility of revocation of a retail licence to serious or material infringements or omissions, and to the eventuality that any notices or warnings given to the licensee have not led to the correction of the deficiencies that have emerged in connection with the operation (PeVL 13/2014 vp).

The Proposal proposes that a retail licence under the Tobacco Act could be revoked for a retailer of smokeless nicotine products if the licensee were to violate certain prohibitions laid down in the Tobacco Act or failed to comply with certain requirements of the Tobacco Act. These are new types of nicotine products which are harmful to health and additionally misleadingly reminiscent of snus, the sale of which is prohibited. The possibility of revocation of a retail licence would therefore contribute to promoting public health in accordance with section 19, subsection 3 of the Constitution. In accordance with the Constitutional Law Committee's statement practice, revocation of a licence would always require a warning from a municipality or other supervisory authority or a criminal penalty, such as a conviction for an offence relating to the sale of tobacco. In all cases, the licence could only be revoked permanently if the licence had first been revoked for a limited period of time and the licensee nevertheless had continued or repeated the illegal activity. A further condition would be that the unlawfulness of the conduct should not be regarded as negligible.

The Proposal would prohibit distance sales of smokeless nicotine products, which would mean interference with the freedom to conduct business of traders selling smokeless nicotine products via the internet, for example. However, there is an acceptable justification for restricting the freedom to conduct business, taking into account that in distance selling the seller is unable to continuously monitor the purchase situation, as required by section 55 of the current Tobacco Act. A ban on distance selling is therefore necessary, in particular to prevent minors from obtaining nicotine pouches or other smokeless nicotine products. In addition, because of the marketing ban, under the Tobacco Act in force, nicotine pouches or other tobacco substitutes may not be presented in mail order catalogues or online stores, for example. It is therefore already practically impossible to carry out distance selling so that the activities would not be contrary to the provisions of the Tobacco Act, and the explicit prohibition of distance selling would clarify the matter.

11.6 Supervisory fees

According to a well-established definition, a tax is a financial contribution which is not compensation or consideration for benefits or services provided by the public authorities to the person liable for payment and which is characterised by the financing of state expenditure (see HE 1/1998 vp). Under section 121, subsection 3 of the Constitution, municipalities have the right of taxation. Legislation lays down provisions on the grounds of tax liability and the determination of taxes and on the legal protection of the taxpayer.

The Proposal proposes that municipalities should collect annual supervisory fees from sellers of smokeless nicotine products as well. Like the supervisory fees for tobacco products and nicotine-containing liquids, the proposed supervisory fee would be a tax in nature. The grounds for tax liability would be a licence for the retail sale of products or a declaration for wholesale. The basis for determining the amount of tax would be the number of points of sale. Provisions on legal protection are laid down in section 106 on appeals.

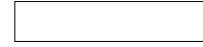
According to section 81, subsection 1 of the Constitution, state taxation is governed by an act containing provisions on the basis of tax liability and tax amounts and on the legal protection of the taxpayer.

According to the Proposal, Valvira would charge manufacturers and importers of smokeless nicotine products an annual supervisory fee based on the sales volumes of the products, which would generally be used to cover the costs of monitoring compliance with the Tobacco Act. From the point of view of constitutional law, the supervisory fee would be a tax which, as explained above, must be laid down by law. According to the Proposal, the Tobacco Act would provide for an obligation to pay the supervisory fee, the criteria for the amount of the control fee, and the legal protection of the person liable for the control fee.

On the basis of the above, it is considered that the proposal can be processed in the course of ordinary legislative procedure.

Resolution

Based on the foregoing, the following Government Proposal is submitted to Parliament for approval:



Act

amending the Tobacco Act

In accordance with the decision of Parliament the following sections of the Tobacco Act (549/2016) are *amended*: section 2, paragraphs 25 and 33; section 6, paragraph 1; section 8, introduction to subsection 1; section 22, subsection 1; section 30, subsection 3; sections 31 and 34; introduction to section 40; section 44, subsection 1; the title and subsection 1 of section 48; section 50, subsection 1; section 52a; section 53, subsection 1; sections 58 and 59; section 60, subsection 2, paragraph 1 and subsections 3 and 4; sections 62, 65 and 66; section 67, subsection 1, paragraph 3; section 74, subsection 3; section 81; section 90, subsection 1, paragraphs 1 and 2, and paragraph 3 of subsection 3; section 91, subsection 2 and introduction and paragraph 5 of subsection 4; section 94, subsections 2 and 3; section 97, subsection 1, paragraphs 1, 2 and 6; section 100, introduction and paragraphs 3 and 4 of subsection 1; section 109; section 113, subsection 2; and sections 117, 118 and 119;

of these, as the introduction to subsection 1 of section 8 is laid down in Act 547/2022; the introduction to section 40 is laid down in Act 136/2022; sections 52a, 58 and 65; subsection 3 of section 74; introduction and paragraph 5 of subsection 4 of section 91; subsection 3 of section 94; and section 117 are laid down in Act 283/2022; subsection 4 of section 60; subsection 1, paragraphs 1, 2 and 6 of section 97; and section 109 are laid down in Act 1374/2016; subsection 2 of section 94 is laid down in Act 701/2018; introduction and paragraphs 3 and 4 of subsection 1 of section 100 are laid down in Act 262/2022; and section 119 is laid down in Act 248/2019; and

to section 2, as partially set out in Acts 248/2019, 1170/2022, and 212/2023, a new paragraph 14a, to the Act new sections 25a, 29a, 29b, and 39a to 39c, to subsection 1 of section 67, as partially set out in Act 283/2022, a new paragraph 4, to section 80 a new subsection 2, and to subsection 4 of section 91, as set out in Act 283/2022, new sections 6 and 7 are *added* as follows:

Section 2

Definitions

For the purposes of this Act:

14a) *smokeless nicotine product* refers to a tobacco substitute which in respect of its intended use corresponds to a tobacco product referred to in paragraphs 10 to 12, and which contains nicotine;

25) *characterising fragrance or flavour* refers to a fragrance or flavour other than tobacco, resulting from an additive or a combination of additives, which is clearly noticeable in a tobacco product, nicotine-containing liquid, nicotine-free liquid for vaporisation or smokeless nicotine product before or during use of the product;

33) *point of sale* refers to a customer service counter in a retail outlet from which tobacco products, nicotine-containing liquids or smokeless nicotine products are made available or sold;

Section 6

Duties of Valvira

The National Supervisory Authority for Welfare and Health (*Valvira*) directs the Regional State Administrative Agencies and municipalities in the performance of their duties under this Act. Valvira supervises:

1) compliance with the provisions on the ingredients, emissions, fire safety, quality, and technical characteristics of tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation, plant-based products for smoking, and smokeless nicotine products;

Section 8

Functions of municipalities

A municipality would, in cooperation with the wellbeing services county, be responsible for local activities to stop smoking and the use of other nicotine-containing products. In its area, the municipality shall supervise:

Section 22

General obligations of the manufacturer and importer of certain other products

The manufacturer and importer are responsible for ensuring that electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids for vaporisation, plant-based products for smoking, or smokeless nicotine products comply with the relevant provisions and regulations.

Section 25a

Requirements for smokeless nicotine products

It is prohibited to sell or transfer to consumers a smokeless nicotine product with:

1) a nicotine content of more than 16.6 milligrams per gram of product;
2) a characterising fragrance or flavour; however, a smokeless nicotine product may taste of menthol, mint, tea, ginger, rosemary or wood.

A smokeless nicotine product may not be sold or otherwise handed over to the consumer in the form of a ready-to-use dose unit weighing less than 0.5 grams or more than 1 gram.

The provisions of section 11, subsection 1, paragraphs 2, 3, 5, 7 and 9, concerning tobacco products also apply to smokeless nicotine products.

Section 29a

Declaring smokeless nicotine products

The manufacturer or importer of a smokeless nicotine product must inform Valvira in advance of the product it intends to sell or otherwise pass on to consumers. Similarly, any significant changes to products must also be declared before the product is sold or otherwise passed on to consumers.

The declaration referred to in subsection 1 above must contain:

- 1) the name and contact details of the manufacturer, the legal or natural person responsible for the product in the EU, and the importer of the product into the EU;
- 2) a list of all the ingredients contained in the product sorted by brand and type, and the quantities of ingredients;
- 3) toxicological data on the ingredients and emissions of the product, considering in particular their addictive effect;
- 4) information on the dosage and absorption of nicotine when the product is used under normal or reasonably foreseeable conditions;
- 5) information stating that the manufacturer or importer bears full responsibility for the quality and safety of the product when it is placed on the market and when it is used under normal or reasonably foreseeable conditions.

Section 29b

Sales volumes of smokeless nicotine products

Each year, the manufacturer or importer of a smokeless nicotine product must provide Valvira with information on the sales volumes of smokeless nicotine products by brand and type.

Section 30

Method, model, and timing of the submission of information for certain other products

Further provisions on the manner and model for the submission of the information referred to in sections 26, 27, 29a, and 29b, and on the timing of the submission of the information referred to in section 27; 28, subsection 1; and 29b may be issued by decree of the Ministry of Social Affairs and Health.

Section 31

General provision on unit packets

Tobacco products, electronic cigarettes, refill containers, plant-based products for smoking, nicotine-containing liquids, nicotine-free liquids for vaporisation, and smokeless nicotine products may be sold and otherwise passed on to consumers only in retail packaging that is in accordance with this Act and the provisions adopted pursuant to it and the relevant EU legislation. Cigars may however be passed on individually if they are labelled in accordance with section 32, subsection 1, paragraph 1.

Section 34

Minimum packaging size for tobacco products and smokeless nicotine products

The minimum size of the unit packet of a tobacco product is 20 cigarettes, 30 grams of roll-your-own or pipe tobacco or 10 cigarillos. The minimum size of the unit packet of a smokeless nicotine product is 20 dose units and 30 grams of loose product.

Tobacco products or smokeless nicotine products, with the exception of cigars, may not be sold or otherwise handed over to consumers in a unit packet containing smaller packages or which can be divided into smaller packages.

The minimum dimensions of the unit packet of a tobacco product may be laid down by decree of the Ministry of Social Affairs and Health for the implementation of EU legislation.

Section 39a

Labelling of unit packets of smokeless nicotine products

The unit packet of a smokeless nicotine product must bear:

- 1) a list of the ingredients contained in the product in descending order of weight;
- 2) an indication of the nicotine content and dosage of the product;
- 3) the manufacturer's batch number;
- 4) a recommendation to keep the product out of reach of children;
- 5) Finnish and Swedish-language health warnings.

The provisions of section 33 also apply to unit packets of a smokeless nicotine product, with the exception of paragraphs 2, 5 and 8 of that section.

The unit packet of a smokeless nicotine product may display the product name and group of products, the trade name and contact details of the manufacturer or importer, and the size, flavour and bar code of the product in such a way that the unit packet cannot by its labelling be distinguished from other unit packets of smokeless nicotine products and where the labelling does not promote the sale of the product.

Unless otherwise provided elsewhere by law, the unit packets of smokeless nicotine products may not bear any markings other than those which are mandatory or permitted on unit packets pursuant to subsections 1 to 3.

Further provisions may be laid down by decree of the Ministry of Social Affairs and Health on:

- 1) the texts, font type and size, colour, surface area, placement, and other specifications concerning the health warning referred to in subsection 1, paragraph 5;
- 2) the font type and size, colour, surface, placement, and other specifications concerning the labelling referred to in subsection 3; derogations from the uniformity requirement laid down in subsection 3 in respect of the specifications concerning labelling may also be given by decree of the Ministry of Social Affairs and Health, if the exemption is minor and does not promote the sale of the product.

Section 39b

Other appearance elements of the unit packets of smokeless nicotine products

A unit packet of a smokeless nicotine product may not differ in form, colour, material, or other presentation element from other retail packets of smokeless nicotine products, nor may the presentation of the unit packet contribute to the sale of the product.

More detailed provisions on the authorised shape, colour, material, and other appearance elements of unit packets of smokeless nicotine products may be issued by decree of the Ministry of Social Affairs and Health. Derogations from the uniformity requirement laid down in subsection 1 may also be given by decree of the Ministry of Social Affairs and Health in respect of the presentation of a unit pack, if the exemption is minor and does not promote the sale of the product.

Section 39c

Appearance of smokeless nicotine products

A smokeless nicotine product may not be distinguished by its shape, colour, surface or other appearance from other smokeless nicotine products of the same product group, nor must its appearance be used to promote the sale of the product.

More detailed provisions on the permitted form, colour, surface, and other appearance elements of smokeless nicotine products may be issued by decree of the Ministry of Social Affairs and Health. A decree of the Ministry of Social Affairs and Health may also provide for exceptions to the requirement of uniformity laid down in subsection 1 with regard to the appearance of a smokeless nicotine product if the derogation is minor and does not promote the sale of the product.

Section 40

Exemption to warning labelling in international traffic

The provisions of paragraph 1 of subsection 1 of section 32, paragraph 5 of subsection 1 of section 36, subsection 1 of section 39, and paragraph 5 of subsection 1 of section 39a on the use of Finnish and Swedish-language in warning labels do not apply to the sale of tobacco products, electronic cigarettes, refill containers, plant-based products for smoking, and smokeless nicotine products:

Section 44

Licence requirements for retail sales

Tobacco products, nicotine-containing liquids, and smokeless nicotine products may only be sold or passed on in retail on the basis of a place and holder-specific retail licence granted by the municipality where the place of sale is located. Licences for retail operations on mobile means of transport is however granted by the municipality of residence of the applicant.

Section 48

Declaration of the retail sale of nicotine-containing liquids and smokeless nicotine products

The holder of a retail licence for tobacco products issued under the old Tobacco Act may also sell nicotine-containing liquids and smokeless nicotine products at the same point of sale after having issued a written notification to the municipality that granted the licence and after providing the municipality with an update of the information referred to in section subsection 1 of section 46.

Section 50

Declaration requirement for wholesale

Wholesale of tobacco products, nicotine-containing liquids, and smokeless nicotine products may be carried out by an operator that has issued a written declaration to the municipality where the place of sale is located. The declaration must contain the information referred to in subsection 1 of section 46. A similar declaration must be made before the activity is substantially changed and when the activity is terminated.

Section 52a

Ban on the sale of products intended for flavouring tobacco products and smokeless nicotine products

No product may be sold or otherwise passed on to the consumer for the purpose of creating a characteristic fragrance or flavour in a tobacco product or a smokeless nicotine product.

Section 53

Prohibition of selling to minors

Tobacco products, nicotine-containing liquids, and smokeless nicotine products may not be sold or otherwise passed on or conveyed to persons under the age of 18.

Section 58

Prohibition of distance selling

Cross-border distance sales of tobacco products, electronic cigarettes, nicotine-containing liquids, plant-based products for smoking, and smokeless nicotine products are prohibited. A trader established in Finland may additionally not sell or otherwise pass on such products to the consumer using a means of distance communication in the sense of chapter 6, section 7, subsection 2 of the Consumer Protection Act (38/1978).

Section 59

Prohibition of sale by customs auction

Tobacco products, plant-based products for smoking, electronic cigarettes, nicotine-containing liquids, and smokeless nicotine products may not be sold at a customs auction.

Section 60

Wholesale restrictions

Nicotine-containing liquids may only be sold wholesale to wholesale distributors that have issued the declaration referred to in section 50 for resale purposes and to those who have:

1) a retail licence referred to in section 44 and issued a declaration of selling nicotine-containing liquids pursuant to section 46, subsection 1, paragraph 2, or section 49; the provisions of this subsection on nicotine-containing liquids also apply to smokeless nicotine products;

Tobacco products, nicotine-containing liquids, or smokeless nicotine products may not be sold on a wholesale basis in the places referred to in section 45, subsection 3.

Tobacco products, nicotine-containing liquids, and smokeless nicotine products may furthermore be sold on a wholesale basis to retailers who do not need a retail licence under this Act and to wholesalers who are not subject to the declaration obligation under this Act.

Section 62

Prohibition on imports by minors

A person under the age of 18 may not import a tobacco product or tobacco substitute.

Section 65

Prohibition of importation of products obtained by means of distance communication

Private individuals may not obtain or receive from traders tobacco products, electronic cigarettes, nicotine-containing liquids, plant-based products for smoking, or smokeless nicotine products by post, transport of goods, or other similar means from outside Finland.

Section 66

Time limits for passenger imports

A person residing in Finland who arrives in the country from outside the European Economic Area other than by air and whose journey has lasted up to 24 hours is not allowed to import tobacco products, nicotine-containing liquids, or smokeless nicotine products into the country.

A person residing outside the European Economic Area who arrives in the country from outside the European Economic Area other than by air, and whose non-transit-related stay in Finland does not exceed three days, may not import tobacco products, nicotine-containing liquids, or smokeless nicotine products into the country.

The provisions of subsection 1 notwithstanding, a person may import tobacco products, nicotine-containing liquids, and smokeless nicotine products if it is evident that they were acquired before leaving the country. The provisions of subsection 2 notwithstanding, a person may import said products if it is evident that they are intended for their personal use for the duration of their stay in the country.

Section 67

Quantitative limits on passenger imports

Private individuals are not allowed to import:

3) more than 200 units of ready-rolled and 250 grams in loose form of herbal products for smoking, the unit packet labelling of which deviates from that provided for in section 39, subsection 1;

4) more than 1 000 grams of smokeless nicotine products, the unit packet labelling of which deviates from that provided for in section 39a, subsection 1, paragraph 5.

Section 74

General smoking bans

Smokeless tobacco products and smokeless nicotine products must not be used in the indoor or outdoor areas of kindergartens and educational institutions providing pre-school and basic education, vocational education or upper secondary school education, or in playgrounds.

Section 80

Smoking ban signage

The provisions of subsection 1 on smoking bans also apply to the prohibition on the use of smokeless tobacco and smokeless nicotine products laid down in section 74, subsection 3.

Section 81

Enforcement of smoking bans

A person violating the smoking ban referred to in section 74, subsection 1 and not stopping smoking despite being asked to do so, the holder of the place or their representative may remove the person from the premises, unless such removal can be regarded as unreasonable. The provisions above on smoking bans also apply to the prohibition on the use of smokeless tobacco and smokeless nicotine products laid down in section 74, subsection 3.

Section 90

Fees for processing applications and notifications

Municipalities collect fees according to their approved rates for:

1) processing an application for a retail licence referred to in section 44; the fee is also levied on the notification of an amendment to the retail licence in respect of the extension of retail sales to new product groups;

2) the processing of a notification concerning the retail sale of nicotine-containing liquids or smokeless nicotine products referred to in section 48;

Valvira may charge the manufacturer or importer a fee for:

3) the receipt, storage, processing, analysis, and publication of information submitted to the agency pursuant to sections 14 to 16, 18, 20, 26 to 29, 29a, and 29b, and for measures related thereto;

Section 91

Supervisory fees of the Tobacco Act

A supervisory fee may not exceed EUR 500 per point of sale. However, if an operator has declared the retail sale or wholesale of both tobacco products and nicotine-containing liquids in accordance with section 46, subsection 1, paragraph 2 or section 50, subsection 1, or has declared the retail sale of nicotine-containing liquids as referred to in section 48, the supervisory fee is charged at most double. The provisions of this subsection above on nicotine-containing liquids also apply to smokeless nicotine products.

In order to cover the costs of monitoring this Act, Valvira charges an annual supervisory fee to manufacturers and importers of tobacco products, nicotine-containing liquids, nicotine-free liquids intended for vaporisation, and smokeless nicotine products. The supervisory fee is calculated on the basis of the sold quantities declared by the manufacturer or importer to Valvira in the previous calendar year pursuant to sections 16, 27, and 29b:

- 5) nicotine-containing liquids and nicotine-free liquids for vaporisation: EUR 0.01 per millilitre;
6) smokeless nicotine products sold in portion units: EUR 0.001 per piece;
7) other smokeless nicotine products: EUR 1.7 per kilogram.

Section 94

Storage and publication of product control information

With the exception of trade secrets, Valvira places the information obtained under section 14, subsection 1, paragraphs 1 to 4, and sections 15, 18, 26, 29, 29a, and 29b on a website accessible to the public, where information can only be searched as individual queries using the name of the product or the name of the registered or the business register and company code of the registered.

By way of derogation from section 16, subsection 3 of the Act on the Openness of Government Activities (621/1999), the name of the natural person referred to in section 26, subsection 2, paragraph 1 and section 29a, subsection 2, paragraph 1 of this Act is made public as such when information is made available in accordance with subsection 2 of this section.

Section 97

Revocation of a retail licence

A municipal authority may revoke a retail licence referred to in section 44 or issued under the old Tobacco Act for a period of at least one week and not more than six months, if the holder of the retail licence, in spite of receiving a written warning from a municipality or other supervisory authority or a criminal penalty:

1) sells or otherwise passes on tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids for vaporisation, plant-based products for smoking, or smokeless nicotine products, the unit packets of which do not comply with the provisions of chapter 5;

2) fails to declare the sale of nicotine-containing liquids or smokeless nicotine products in violation of section 48 or essential information referred to in section 49;

6) sells or otherwise makes available tobacco products, electronic cigarettes, nicotine-containing liquids or smokeless nicotine products to the consumer by means of distance communication in violation of section 58;

Section 100

Ban on sales

Valvira may prohibit the sale and other passing on of tobacco products, electronic cigarettes, nicotine-containing liquids, nicotine-free liquids for vaporisation, plant-based products for smoking, and smokeless nicotine products, if:

3) the manufacturer or importer has not provided Valvira with the information referred to in sections 14 to 16, 18, 20, 26, 27, 29, 29a, or 29b in the prescribed manner, within the prescribed time period, or using the prescribed model, or if the information provided is not correct;

4) the manufacturer or importer has failed to pay Valvira the fee referred to in section 90, subsection 3 or section 91, subsection 4.

Section 109

Tobacco sales offence

Any party which deliberately,

1) in violation of section 53, subsection 1, sells or otherwise passes on or conveys for consideration a tobacco product, nicotine-containing liquid, or smokeless nicotine product to a person under the age of 18,

2) in violation of section 51, sells or otherwise passes on or conveys for consideration chewing tobacco, nasal tobacco, or tobacco intended for oral use,

3) in the course of trade or otherwise sells or otherwise passes on tobacco products, nicotine-containing liquids, or smokeless nicotine products without a retail licence in violation of section 44 or without declaring the retail sale of nicotine-containing liquids or smokeless nicotine products pursuant to section 48, or

4) in violation of section 60, in wholesale sells or otherwise passes on tobacco products, nicotine-containing liquids, or smokeless nicotine products to an operator other than the one referred to in the said section,

is sentenced to a fine or imprisonment of up to six months for an *offence relating to the sale of tobacco*.

Section 113

Smoking offence

The provisions on smoking in subsection 1 also apply to the smoking of plant-based products intended for smoking and the use of electronic cigarettes and the use of smokeless tobacco products and smokeless nicotine products in violation of section 74, subsection 3 in the indoor and outdoor areas of a kindergarten or educational institution providing preliminary or basic education, vocational education or upper secondary school education, and on playgrounds.

Section 117

Outer packaging

The provisions of this Act on the unit packets of tobacco products, plant-based products for smoking, electronic cigarettes, refill containers, nicotine-free liquids for vaporisation, and smokeless nicotine products also apply to any outer packaging of the products, with the exception of section 32, subsection 1, paragraph 2, sections 34 and 35, and chapter 6.

Section 118

Prohibition of possession

A person under the age of 18 may not possess a tobacco product or tobacco substitute.

Section 119

Disposal

An official with the right to arrest may demonstrably dispose of or arrange the disposal of such a tobacco product, plant-based product for smoking, electronic cigarette, nicotine-containing liquid, or smokeless nicotine product that may be confiscated if there is reason to believe that it will be declared lost and which has no significant sale or use value.

This Act enters into force on [] [] 20[]. However, section 25a, section 34 and subsection 1 of section 39a of this Act enter into force six months after the entry into force of this Act and subsections 2 to 4 of section 39a, sections 39b and 39c, and subsection 2 of section 80 enter into force one year after the entry into force of this Act.

The provisions of section 65 do not apply to smokeless nicotine products acquired before the entry into force of this Act.

Smokeless nicotine products sold or otherwise passed on to consumers in Finland upon the entry into force of this Act must be declared pursuant to section 29a within six months of the entry into force of this Act. The manufacturer or importer of a smokeless nicotine product must submit the information referred to in section 29b to Valvira for the first time in the calendar year following the entry into force of this Act.

A trader who, upon the entry into force of this Act, sells or otherwise passes on smokeless nicotine products in retail and within three months of the entry into force of this Act submits to the municipality an application for a licence for the retail sale of smokeless nicotine products referred to in section 46, or declares the retail sale of smokeless nicotine products referred to in section 48, may, subsection 1 of section 44 notwithstanding, sell or otherwise pass on smokeless nicotine products in retail for a period of one year after the entry into force of this Act.

A trader who, upon the entry into force of this Act, sells or otherwise transfers smokeless nicotine products in wholesale sales and within three months of the entry into force of this Act, submits a notification to the municipality of the wholesale sale of smokeless nicotine products provided for in section 50, may, without prejudice to section 50, sell smokeless nicotine products on a wholesale basis for a period of one year after the entry into force of the proposed Act. The provisions of the introductory paragraph to subsection 2 of section 60 notwithstanding, a trader may sell or otherwise supply for resale smokeless nicotine products for a period of three months from the entry into force of this Act, and, paragraph 1 of that subsection notwithstanding, for a period of one year after the entry into force of this Act, if the buyer can prove that they have submitted the application or notification referred to in that paragraph.

Helsinki, 18 April 2024

Prime Minister

Petteri Orpo

Minister of Social Security Sanni Grahn-Laasonen



Act

amending the Tobacco Act

In accordance with the decision of Parliament the following sections of the Tobacco Act (549/2016) are *amended*: section 2, paragraphs 25 and 33; section 6, paragraph 1; section 8, introduction to subsection 1; section 22, subsection 1; section 30, subsection 3; sections 31 and 34; introduction to section 40; section 44, subsection 1; the title and subsection 1 of section 48; section 50, subsection 1; section 52a; section 53, subsection 1; sections 58 and 59; section 60, subsection 2, paragraph 1 and subsections 3 and 4; sections 62, 65 and 66; section 67, subsection 1, paragraph 3; section 74, subsection 3; section 81; section 90, subsection 1, paragraphs 1 and 2, and paragraph 3 of subsection 3; section 91, subsection 2 and introduction and paragraph 5 of subsection 4; section 94, subsections 2 and 3; section 97, subsection 1, paragraphs 1, 2 and 6; section 100, introduction and paragraphs 3 and 4 of subsection 1; section 109; section 113, subsection 2; and sections 117, 118 and 119;

of these, as the introduction to subsection 1 of section 8 is laid down in Act 547/2022; the introduction to section 40 is laid down in Act 136/2022; sections 52a, 58 and 65; subsection 3 of section 74; introduction and paragraph 5 of subsection 4 of section 91; subsection 3 of section 94; and section 117 are laid down in Act 283/2022; subsection 4 of section 60; subsection 1, paragraphs 1, 2 and 6 of section 97; and section 109 are laid down in Act 1374/2016; subsection 2 of section 94 is laid down in Act 701/2018; introduction and paragraphs 3 and 4 of subsection 1 of section 100 are laid down in Act 262/2022; and section 119 is laid down in Act 248/2019; and

the following are *added*: to section 2, as partially set out in Acts 248/2019, 1170/2022, and 212/2023, a new paragraph 14a; to the Act new sections 25a, 29a, 29b, and 39a to 39c; to subsection 1 of section 67, as partially set out in Act 283/2022, a new paragraph 4; to section 80 a new subsection 2; and to subsection 4 of section 91, as set out in Act 283/2022, new sections 6 and 7 as follows:

Existing Act

Proposal

Section 2

Section 2

Definitions

Definitions

For the purposes of this Act:

For the purposes of this Act:

 14a) **smokeless nicotine product** refers to a tobacco substitute which in respect of its intended use corresponds to a tobacco product referred to in paragraphs 10 to 12, and which contains nicotine;

 25) *characterising fragrance or flavour*

Existing Act

refers to a fragrance or flavour other than 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 for vaporisation before or during use of the product;

33) *point of sale* refers to a customer service counter in a retail outlet from which tobacco products or nicotine-containing liquids are made available or sold;

Section 6

Duties of Valvira

The National Supervisory Authority for Welfare and Health (*Valvira*) directs the Regional State Administrative Agencies and municipalities in the performance of their duties under this Act. Valvira supervises:

1) compliance with the provisions on the ingredients, emissions, fire safety, quality and technical characteristics of tobacco products, electronic cigarettes, refill containers, nicotine liquids for vaporisation, and herbal products for smoking;

2) compliance with the provisions on unit packets of products referred to in paragraph 1;

3) the marketing of products referred to in this Act throughout the country;

4) compliance with the provisions on verification laboratories referred to in section 85.

Section 8

Functions of municipalities

Municipalities shall manage local activities to stop smoking in their respective areas in

Proposal

25) *characterising fragrance or flavour* refers to a fragrance or flavour other than tobacco, resulting from an additive or a combination of additives, which is clearly noticeable in a tobacco product, nicotine-containing liquid, nicotine-free liquid for vaporisation *or smokeless nicotine product* before or during use of the product;

33) *point of sale* refers to a customer service counter in a retail outlet from which smokeless nicotine products, nicotine-containing liquids *or smokeless nicotine products* are made available or sold;

Section 6

Duties of Valvira

The National Supervisory Authority for Welfare and Health (*Valvira*) directs the Regional State Administrative Agencies and municipalities in the performance of their duties under this Act. Valvira supervises:

1) compliance with the provisions on the ingredients, emissions, fire safety, quality and technical characteristics of tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation, herbal products for smoking *and smokeless nicotine products*;

2) compliance with the provisions on unit packets of products referred to in paragraph 1;

3) the marketing of products referred to in this Act throughout the country;

4) compliance with the provisions on verification laboratories referred to in section 85.

Section 8

Functions of municipalities

Municipalities shall manage local activities to stop smoking *and the use of other*

Existing Act

collaboration with the wellbeing services counties. In its area, the municipality shall supervise:

1) compliance with the provisions on the sale and other transfer of tobacco products, tobacco substitutes, smoking equipment, electronic cigarettes and nicotine-containing liquids, as well as on self-monitoring;

2) compliance with the provisions on marketing and display bans laid down in this Act;

3) compliance with the provisions on smoking bans and restrictions.

The municipality does not have the right to transfer the powers of approval of the supervisory plan referred to in section 84 to an official under its authority.

Section 22

General obligations of the manufacturer and importer of certain other products

The manufacturer and importer are responsible for ensuring that electronic cigarettes, refill tanks, nicotine-containing liquids, nicotine-free liquids for vaporisation or herbal products for smoking intended for sale or other transfer in the course of trade, comply with the relevant provisions and regulations.

The obligation to provide Valvira and the EU Commission and the competent authorities of other EU Member States with the information required under this chapter is primarily incumbent on the manufacturer, if the manufacturer is established in the European Union. The obligation to provide information lies primarily with the importer if the manufacturer is established outside the EU and the importer is established in the European Union. The obligation to provide information lies jointly with the manufacturer and the importer if both the manufacturer and the importer are established outside the EU.

Proposal

nicotine-containing products in their respective areas in collaboration with the wellbeing services counties. In its area, the municipality shall supervise:

1) compliance with the provisions on the sale and other transfer of tobacco products, tobacco substitutes, smoking equipment, electronic cigarettes and nicotine-containing liquids, as well as on self-monitoring;

2) compliance with the provisions on marketing and display bans laid down in this Act;

3) compliance with the provisions on smoking bans and restrictions.

The municipality does not have the right to transfer the powers of approval of the supervisory plan referred to in section 84 to an official under its authority.

Section 22

General obligations of the manufacturer and importer of certain other products

The manufacturer and importer are responsible for ensuring that electronic cigarettes, refill tanks, nicotine-containing liquids, nicotine-free liquids for vaporisation, herbal products for smoking *or smokeless nicotine products* intended for sale or other transfer in the course of trade, comply with the relevant provisions and regulations.

The obligation to provide Valvira and the EU Commission and the competent authorities of other EU Member States with the information required under this chapter is primarily incumbent on the manufacturer, if the manufacturer is established in the European Union. The obligation to provide information lies primarily with the importer if the manufacturer is established outside the EU and the importer is established in the European Union. The obligation to provide information lies jointly with the manufacturer and the importer if both the manufacturer and the importer are established outside the EU.

Section 25a

Requirements for smokeless nicotine products

It is prohibited to sell or transfer to consumers a smokeless nicotine product with:

- 1) a nicotine content of more than 16.6 milligrams per gram of product;*
- 2) a characterising fragrance or flavour; however, a smokeless nicotine product may taste of menthol, mint, tea, ginger, rosemary or wood.*

A smokeless nicotine product may not be sold or otherwise handed over to the consumer in the form of a ready-to-use dose unit weighing less than 0.5 grams or more than 1 gram.

The provisions of section 11, subsection 1, paragraphs 2, 3, 5, 7 and 9, concerning tobacco products also apply to smokeless nicotine products.

Section 29a

Declaring smokeless nicotine products

The manufacturer or importer of a smokeless nicotine product must inform Valvira in advance of the product it intends to sell or otherwise pass on to consumers. Similarly, any significant changes to products must also be declared before the product is sold or otherwise passed on to consumers.

The declaration referred to in subsection 1 above must contain:

- 1) the name and contact details of the manufacturer, the legal or natural person responsible for the product in the EU, and the importer of the product into the EU;*
- 2) a list of all the ingredients contained in the product sorted by brand and type, and the quantities of ingredients;*
- 3) toxicological data on the ingredients and emissions of the product, considering in particular their addictive effect;*
- 4) information on the dosage and*

Existing Act

Proposal

absorption of nicotine when the product is used under normal or reasonably foreseeable conditions;

5) information stating that the manufacturer or importer bears full responsibility for the quality and safety of the product when it is placed on the market and when it is used under normal or reasonably foreseeable conditions.

Section 29b

Sales volumes of smokeless nicotine products

Each year, the manufacturer or importer of a smokeless nicotine product must provide Valvira with information on the sales volumes of smokeless nicotine products by brand and type.

Section 30

Method, model, and timing of the submission of information for certain other products

Notifications and other information referred to in this chapter shall be submitted to Valvira in electronic format.

When submitting the information referred to in this chapter, the manufacturer and importer shall indicate which information it considers to be confidential business information.

Further provisions may be issued by decree of the Ministry of Social Affairs and Health on the manner and form of the transmission of the information referred to in sections 26 and 27 and on the timing of the transmission of the information referred to in section 27 and subsection 1 of section 28.

Section 31

General provision on unit packets

Tobacco products, electronic cigarettes, refill containers and herbal products for

Section 30

Method, model, and timing of the submission of information for certain other products

Notifications and other information referred to in this chapter shall be submitted to Valvira in electronic format.

When submitting the information referred to in this chapter, the manufacturer and importer shall indicate which information it considers to be confidential business information.

Further provisions may be issued by decree of the Ministry of Social Affairs and Health on the manner and form of the submission of the information referred to in sections 26, 27, 29a, and 29b, and on the timing of the submission of the information referred to in section 27, subsection 1 of section 28, and section 29b.

Section 31

General provision on unit packets

Tobacco products, electronic cigarettes, refill containers, herbal products for

Existing Act

smoking, as well as nicotine-containing liquids and nicotine-free liquids for vaporisation may only be sold and otherwise made available to consumers in unit packets that are in compliance with this Act and the provisions adopted pursuant to it and the relevant EU legislation. Cigars may however be supplied individually if they are labelled in accordance with section 32, subsection 1, paragraph 1.

Section 34

Minimum packaging size for tobacco products

The minimum size of the unit packet of a tobacco product is 20 cigarettes, 30 grams of roll-your-own or pipe tobacco or 10 cigarillos.

Tobacco products, with the exception of cigars, may not be sold or otherwise made available to consumers in a unit packet containing smaller packets or which can be divided into smaller packets.

The minimum dimensions of the unit packet of a tobacco product may be laid down by decree of the Ministry of Social Affairs and Health for the implementation of EU legislation.

Proposal

smoking, nicotine-containing liquids, nicotine-free liquids for vaporisation *and smokeless nicotine products* may only be sold and otherwise made available to consumers in unit packets that are in compliance with this Act and the provisions adopted pursuant to it and the relevant EU legislation. Cigars may however be passed on individually if they are labelled in accordance with section 32, subsection 1, paragraph 1.

Section 34

*Minimum packet size for tobacco products and **smokeless nicotine products***

The minimum size of the unit packet of a tobacco product is 20 cigarettes, 30 grams of roll-your-own or pipe tobacco or 10 cigarillos. *The minimum size of the unit packet of a smokeless nicotine product is 20 dose units and 30 grams of loose product.*

Tobacco products or *smokeless nicotine products*, with the exception of cigars, may not be sold or otherwise made available to consumers in a unit packet containing smaller packets or which can be divided into smaller packets.

The minimum dimensions of the unit packet of a tobacco product may be laid down by decree of the Ministry of Social Affairs and Health for the implementation of EU legislation.

Section 39a

*Labelling of unit packets of **smokeless nicotine products***

The unit packet of a smokeless nicotine product must bear:

- 1) a list of the ingredients contained in the product in descending order of weight;*
- 2) an indication of the nicotine content and dosage of the product;*
- 3) the manufacturer's batch number;*
- 4) a recommendation to keep the product*

Existing Act

Proposal

out of reach of children;

5) Finnish and Swedish-language health warnings.

The provisions of section 33 also apply to unit packets of a smokeless nicotine product, with the exception of paragraphs 2, 5 and 8 of that section.

The unit packet of a smokeless nicotine product may display the product name and group of products, the trade name and contact details of the manufacturer or importer, and the size, flavour and bar code of the product in such a way that the unit packet cannot by its labelling be distinguished from other unit packets of smokeless nicotine products and where the labelling does not promote the sale of the product.

Unless otherwise provided elsewhere by law, the unit packets of smokeless nicotine products may not bear any markings other than those which are mandatory or permitted on unit packets pursuant to subsections 1 to 3.

Further provisions may be laid down by decree of the Ministry of Social Affairs and Health on:

1) the texts, font type and size, colour, surface area, placement, and other specifications concerning the health warning referred to in subsection 1, paragraph 5;

2) the font type and size, colour, surface, placement, and other specifications concerning the labelling referred to in subsection 3; derogations from the uniformity requirement laid down in subsection 3 in respect of the specifications concerning labelling may also be given by decree of the Ministry of Social Affairs and Health, if the exemption is minor and does not promote the sale of the product.

Section 39b

Other appearance elements of the unit packets of smokeless nicotine products

A unit packet of a smokeless nicotine

Existing Act

Proposal

product may not differ in form, colour, material, or other presentation element from other retail packets of smokeless nicotine products, nor may the presentation of the unit packet contribute to the sale of the product.

More detailed provisions on the authorised shape, colour, material, and other appearance elements of unit packets of smokeless nicotine products may be issued by decree of the Ministry of Social Affairs and Health. Derogations from the uniformity requirement laid down in subsection 1 may also be given by decree of the Ministry of Social Affairs and Health in respect of the presentation of a unit pack, if the exemption is minor and does not promote the sale of the product.

Section 39c

Appearance of smokeless nicotine products

A smokeless nicotine product may not be distinguished by its shape, colour, surface or other appearance from other smokeless nicotine products of the same product group, nor must its appearance be used to promote the sale of the product.

More detailed provisions on the permitted form, colour, surface, and other appearance elements of smokeless nicotine products may be issued by decree of the Ministry of Social Affairs and Health. A decree of the Ministry of Social Affairs and Health may also provide for exceptions to the requirement of uniformity laid down in subsection 1 with regard to the appearance of a smokeless nicotine product if the derogation is minor and does not promote the sale of the product.

Section 40

Exemption to warning labelling in international traffic

The provisions of section 32, subsection 1, paragraph 1; section 36, subsection 1, paragraph 5; and section 39, subsection 1 on

Section 40

Exemption to warning labelling in international traffic

The provisions of section 32, subsection 1, paragraph 1; section 36, subsection 1, paragraph 5; section 39, subsection 1, and

Existing Act

the use of Finnish and Swedish in warning labels do not apply to the sale of tobacco products, electronic cigarettes, refill containers and herbal products for smoking:

- 1) on a vessel or aircraft used in commercial international traffic;
- 2) in a duty-free airport shop if the products are sold to passengers travelling abroad to take with them abroad.

Section 44

Licence requirements for retail sales

Tobacco products and nicotine-containing liquids may be sold or otherwise made available in retail only on the basis of a point of sale-specific and licensee-specific retail licence granted by the municipality where the point of sale is located. Licences for retail trade on a mobile means of transport are however granted by the municipality of residence of the applicant.

A retail licence may be granted for a limited period of time in the case of fixed-term operations. A fixed-term licence may be granted for not more than one year at a time.

Section 48

Notification of the retail sale of nicotine-containing liquids

The holder of a retail licence for tobacco products granted under the old Tobacco Act may also sell nicotine-containing liquids at the same point of sale after having made a written notification to the municipality that granted the licence and after having provided the municipality with an update to the information referred to in section 46, subsection 1.

Proposal

section 39a, subsection 1, paragraph 5 on the use of Finnish and Swedish in warning labels do not apply to the sale of tobacco products, electronic cigarettes, refill container, herbal products for smoking *and smokeless nicotine products*:

- 1) on a vessel or aircraft used in commercial international traffic;
- 2) in a duty-free airport shop if the products are sold to passengers travelling abroad to take with them abroad.

Section 44

Licence requirements for retail sales

Tobacco products, nicotine-containing liquids *and smokeless nicotine products* may be sold or otherwise made available in retail only on the basis of a point of sale-specific and licensee-specific retail licence granted by the municipality where the point of sale is located. Licences for retail operations on mobile means of transport is however granted by the municipality of residence of the applicant.

A retail licence may be granted for a limited period of time in the case of fixed-term operations. A fixed-term licence may be granted for not more than one year at a time.

Section 48

*Notification of the retail sale of nicotine-containing liquids **and smokeless nicotine products***

The holder of a retail licence for tobacco products granted under the old Tobacco Act may also sell nicotine-containing liquids *and smokeless nicotine products* at the same point of sale after having made a written notification to the municipality that granted the licence and after having provided the municipality with an update to the

Existing Act

Upon receipt of the notification referred to in subsection 1, the municipality shall send the notifier an acknowledgement of receipt without delay.

Section 50

Declaration requirement for wholesale

Wholesale sales of tobacco products and nicotine-containing liquids may be carried out by a party who has submitted a written notification to the municipality where the point of sale is located. The declaration must contain the information referred to in subsection 1 of section 46. A similar declaration must be made before the activity is substantially changed and when the activity is terminated.

Upon receipt of the notification referred to in subsection 1, the municipality shall send the notifier an acknowledgement of receipt without delay.

The municipality shall notify Valvira of the notifications referred to in subsection 1.

Section 52a

Ban on the sale of products intended to add flavours to tobacco products

It shall not be permitted to sell or otherwise make available to consumers a product which is intended to produce a characterising fragrance or flavour for the tobacco product.

Section 53

Prohibition of selling to minors

Tobacco products and nicotine-containing liquids may not be sold or otherwise supplied or conveyed to persons under the age of 18.

Tobacco substitutes, smoking equipment

Proposal

information referred to in section 46, subsection 1.

Upon receipt of the notification referred to in subsection 1, the municipality shall send the notifier an acknowledgement of receipt without delay.

Section 50

Declaration requirement for wholesale

Wholesale sales of tobacco products, nicotine-containing liquids *and smokeless nicotine products* may be carried out by a party who has submitted a written notification to the municipality where the point of sale is located. The declaration must contain the information referred to in subsection 1 of section 46. A similar declaration must be made before the activity is substantially changed and when the activity is terminated.

Upon receipt of the notification referred to in subsection 1, the municipality shall send the notifier an acknowledgement of receipt without delay.

The municipality shall notify Valvira of the notifications referred to in subsection 1.

Section 52a

*Ban on the sale of products intended to add flavours to tobacco products and **smokeless nicotine products***

No product may be sold or otherwise made available to the consumer for the purpose of producing a characterising fragrance or flavour in a tobacco product *or smokeless nicotine product*.

Section 53

Prohibition of selling to minors

Tobacco products, nicotine-containing liquids *and smokeless nicotine products* may not be sold or otherwise supplied or conveyed to persons under the age of 18.

Existing Act

and electronic cigarettes may not be sold or otherwise made available in trade to persons under the age of 18.

The point of sale of the products referred to in subsections 1 and 2 shall have a notice indicating the age limits of sales, which must be clearly displayed to customers. Further provisions on the content of the notice may be issued by decree of the Ministry of Social Affairs and Health.

Section 58

Prohibition of distance selling

Cross-border distance selling of tobacco products, e-cigarettes, nicotine liquids and herbal products for smoking is prohibited. Additionally, a trader established in Finland may not sell or otherwise make available such products to the consumer using distance communication as referred to in chapter 6, section 7, subsection 2 of the Consumer Protection Act (38/1978).

Section 59

Prohibition of sale by customs auction

Tobacco products, herbal products for smoking, electronic cigarettes and nicotine-containing liquids may not be sold through a customs auction.

Section 60

Wholesale restrictions

Tobacco products may be sold wholesale for resale only to wholesale distributors who have submitted the notification referred to in section 50 and have the identification codes referred to in Articles 15 and 17 of the EU Commission's Traceability Regulation, and for retail trade only to parties who hold the relevant identification codes and:

Proposal

Tobacco substitutes, smoking equipment and electronic cigarettes may not be sold or otherwise made available in trade to persons under the age of 18.

The point of sale of the products referred to in subsections 1 and 2 shall have a notice indicating the age limits of sales, which must be clearly displayed to customers. Further provisions on the content of the notice may be issued by decree of the Ministry of Social Affairs and Health.

Section 58

Prohibition of distance selling

Cross-border distance selling of tobacco products, electronic cigarettes, nicotine-containing liquids, herbal products for smoking *and smokeless nicotine products* is prohibited. A trader established in Finland may additionally not sell or otherwise pass on such products to the consumer using a means of distance communication in the sense of chapter 6, section 7, subsection 2 of the Consumer Protection Act (38/1978).

Section 59

Prohibition of sale by customs auction

Tobacco products, herbal products for smoking, electronic cigarettes, nicotine-containing liquids *and smokeless nicotine products* may not be sold through a customs auction.

Section 60

Wholesale restrictions

Tobacco products may be sold wholesale for resale only to wholesale distributors who have submitted the notification referred to in section 50 and have the identification codes referred to in Articles 15 and 17 of the EU Commission's Traceability Regulation, and for retail trade only to parties who hold the relevant identification codes and:

Existing Act

1) a retail licence referred to in section 44 and who have declared that they sell tobacco products pursuant to section 46, subsection 1, paragraph 2, or section 49;

2) a retail licence granted under the old Tobacco Act.

Nicotine-containing liquids may only be sold wholesale to wholesale distributors that have issued the declaration referred to in section 50 for resale purposes and to those who have:

1) a retail licence referred to in section 44 and issued a declaration of selling nicotine-containing liquids pursuant to section 46, subsection 1, paragraph 2, or section 49;

2) a retail licence granted under the old Tobacco Act and who have submitted the notification referred to in section 48.

Tobacco products or nicotine-containing liquids may not be sold wholesale in the places referred to in section 45, subsection 3.

In addition, tobacco products and nicotine-containing liquids may be sold on a wholesale basis to a retailer who does not require a retail licence under this Act and to a wholesaler who is not subject to the notification obligation under this Act.

Wholesalers have the right to obtain from Valvira the information necessary to ensure their obligations laid down in subsections 1 and 2 concerning retail licence holders and traders who have filed a wholesale notification, and to process this information.

Section 62

Prohibition on imports by minors

A person under the age of 18 may not import tobacco products or nicotine-containing liquids.

Proposal

1) a retail licence referred to in section 44 and who have declared that they sell tobacco products pursuant to section 46, subsection 1, paragraph 2, or section 49;

2) a retail licence granted under the old Tobacco Act.

Nicotine-containing liquids may only be sold wholesale to wholesale distributors that have issued the declaration referred to in section 50 for resale purposes and to those who have:

1) a retail licence referred to in section 44 and issued a declaration of selling nicotine-containing liquids pursuant to section 46, subsection 1, paragraph 2, or section 49; *the provisions of this subsection on nicotine-containing liquids also apply to smokeless nicotine products;*

2) a retail licence granted under the old Tobacco Act and who have submitted the notification referred to in section 48.

Tobacco products, nicotine-containing liquids *or smokeless nicotine products* may not be sold wholesale in the places referred to in section 45, subsection 3.

In addition, tobacco products, nicotine-containing liquids *or smokeless nicotine products* may be sold on a wholesale basis to a retailer who does not require a retail licence under this Act and to a wholesaler who is not subject to the notification obligation under this Act.

Wholesalers have the right to obtain from Valvira the information necessary to ensure their obligations laid down in subsections 1 and 2 concerning retail licence holders and traders who have filed a wholesale notification, and to process this information.

Section 62

Prohibition on imports by minors

A person under the age of 18 may not import a tobacco product or *tobacco substitute*.

Existing Act

Proposal

Section 65

Section 65

*Prohibition of importation of products
obtained by means of distance
communication*

*Prohibition of importation of products
obtained by means of distance
communication*

A private person may not purchase or receive from a trader tobacco products, electronic cigarettes, nicotine-containing liquids or herbal products intended for smoking by mail, transport of goods or other similar means from outside Finland.

Private individuals may not obtain or receive from traders tobacco products, electronic cigarettes, nicotine-containing liquids, herbal products for smoking or *smokeless nicotine products* by post, transport of goods, or other similar means from outside Finland.

Section 66

Section 66

Time limits for passenger imports

Time limits for passenger imports

A person residing in Finland who enters the country from outside the European Economic Area other than by air and whose journey has lasted no more than 24 hours may not import tobacco products or nicotine-containing liquids.

A person residing in Finland who enters the country from outside the European Economic Area other than by air and whose journey has lasted no more than 24 hours may not import tobacco products, nicotine-containing liquids or *smokeless nicotine products*.

A person residing outside the European Economic Area who enters the country from outside the European Economic Area other than by air and whose non-transit stay in Finland lasts no more than three days may not import tobacco products or nicotine-containing liquids.

A person residing outside the European Economic Area who enters the country from outside the European Economic Area other than by air and whose non-transit stay in Finland lasts no more than three days may not import tobacco products, nicotine-containing liquids or *smokeless nicotine products*.

The provisions of subsection 1 notwithstanding, a person may import tobacco products and nicotine-containing liquids if it is evident that they were acquired before leaving the country. The provisions of subsection 2 notwithstanding, a person may import said products if it is evident that they are intended for their personal use for the duration of their stay in the country.

The provisions of subsection 1 notwithstanding, a person may import tobacco products, nicotine-containing liquids and *smokeless nicotine products* if it is evident that they were acquired before leaving the country. The provisions of subsection 2 notwithstanding, a person may import said products if it is evident that they are intended for their personal use for the duration of their stay in the country.

Section 67

Section 67

Quantitative limits on passenger imports

Quantitative limits on passenger imports

Private individuals are not allowed to import:

Private individuals are not allowed to import:

Existing Act

1) tobacco products, the unit packet labelling of which deviates from that provided for in section 32, subsection 1, paragraph 1, by more than 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of roll-your-own, pipe or waterpipe tobacco, or other tobacco product by more than 200 dose units or 250 grams in loose form;

2) more than 10 millilitres of nicotine-containing liquid in an electronic cigarette or refill container whose unit packet labelling deviates from that laid down in section 36, subsection 1, paragraph 5;

3) more than 200 units of ready-rolled and 250 grams of loose product of herbal products intended for smoking, the unit packet labelling of which deviates from that provided for in section 39, subsection 1;

A private individual may not import the products referred to in subsection 1 except for their own use.

Section 74

General smoking bans

Smoking is not allowed:

1) in the indoor areas of a building, means of transport or other similar place, which are available to the public or to employees, or for the provision of services provided in the course of trade or for the provision of public services for use by customers;

2) in the shelters or stands of public events held outdoors, or in other facilities intended for viewing the event, where the participants remain in one place;

3) in the outdoor areas of kindergartens and educational institutions providing pre-school and basic education, vocational education or upper secondary school education;

4) in playgrounds for which a safety

Proposal

1) tobacco products, the unit packet labelling of which deviates from that provided for in section 32, subsection 1, paragraph 1, by more than 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of roll-your-own, pipe or waterpipe tobacco, or other tobacco product by more than 200 dose units or 250 grams in loose form;

2) more than 10 millilitres of nicotine-containing liquid in an electronic cigarette or refill container whose unit packet labelling deviates from that laid down in section 36, subsection 1, paragraph 5;

3) more than 200 units of ready-rolled and 250 grams of loose product of plant-based products intended for smoking, the unit packet labelling of which deviates from that provided for in section 39, subsection 1;

4) *more than 1 000 grams of smokeless nicotine products, the unit packet labelling of which deviates from that provided for in section 39a, subsection 1, paragraph 5.*

A private individual may not import the products referred to in subsection 1 except for their own use.

Section 74

General smoking bans

Smoking is not allowed:

1) in the indoor areas of a building, means of transport or other similar place, which are available to the public or to employees, or for the provision of services provided in the course of trade or for the provision of public services for use by customers;

2) in the shelters or stands of public events held outdoors, or in other facilities intended for viewing the event, where the participants remain in one place;

3) in the outdoor areas of kindergartens and educational institutions providing pre-school and basic education, vocational education or upper secondary school education;

4) in playgrounds for which a safety

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document in accordance with section 7 of the Consumer Safety Act (920/2011) must be drawn up;

5) in the outdoor areas of institutions providing care under the Child Welfare Act or the Mental Health Act intended for persons under the age of 18;

6) at a public beach from the beginning of May until the end of September; a public beach means a beach where the municipal health protection authority expects a significant number of people to swim and which is subject to notification in accordance with section 13, subsection 1, paragraph 2 of the Health Protection Act (763/1994).

In addition, smoking is not allowed inside a private vehicle when persons under the age of 15 are present in the vehicle. The prohibition does not apply to living spaces on board vehicles.

Smokeless tobacco products may not be used in the indoor or outdoor areas of kindergartens and educational institutions providing pre-school and basic education, vocational education or upper secondary school education, or in playgrounds.

Section 80

Smoking ban signage

The holder of the indoor or outdoor area and the organiser of the public event shall display signs indicating the smoking ban referred to in section 74, subsection 1 and the space for smoking referred to in sections 76 and 77. The signs shall be unambiguous in terms of their content and their size and placement shall be such that they are easily visible to those entering and occupying the premises.

Section 81

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document in accordance with section 7 of the Consumer Safety Act (920/2011) must be drawn up;

5) in the outdoor areas of institutions providing care under the Child Welfare Act or the Mental Health Act intended for persons under the age of 18;

6) at a public beach from the beginning of May until the end of September; a public beach means a beach where the municipal health protection authority expects a significant number of people to swim and which is subject to notification in accordance with section 13, subsection 1, paragraph 2 of the Health Protection Act (763/1994).

In addition, smoking is not allowed inside a private vehicle when persons under the age of 15 are present in the vehicle. The prohibition does not apply to living spaces on board vehicles.

Smokeless tobacco products *and smokeless nicotine products* may not be used in the indoor or outdoor areas of kindergartens and educational institutions providing pre-school and basic education, vocational education or upper secondary school education, or in playgrounds.

Section 80

Smoking ban signage

The holder of the indoor or outdoor area and the organiser of the public event shall display signs indicating the smoking ban referred to in section 74, subsection 1 and the space for smoking referred to in sections 76 and 77. The signs shall be unambiguous in terms of their content and their size and placement shall be such that they are easily visible to those entering and occupying the premises.

The provisions of subsection 1 on smoking bans also apply to the prohibition on the use of smokeless tobacco and smokeless nicotine products laid down in section 74, subsection 3.

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Enforcement of smoking bans

Enforcement of smoking bans

In the event that someone violates the smoking ban referred to in section 74 and, despite requests, does not stop smoking, the holder of the location or their representative may remove the person from the location, unless the removal can be considered unreasonable.

In the event that someone violates the smoking ban referred to in section 74, *subsection 1*, and, despite requests, does not stop smoking, the holder of the location or their representative may remove the person from the location, unless the removal can be considered unreasonable. *The provisions above on smoking bans also apply to the prohibition on the use of smokeless tobacco and smokeless nicotine products laid down in section 74, subsection 3.*

Section 90

Section 90

Fees for processing applications and notifications

Fees for processing applications and notifications

Municipalities collect fees according to their approved rates for:

- 1) processing an application for a retail licence referred to in section 44;
- 2) the processing of a notification concerning the retail sale of nicotine-containing liquid referred to in section 48;

3) the processing of a wholesale sales notification referred to in section 50;

4) the processing of an application for a smoking ban referred to in section 79.

The municipality shall determine the fees it collects for its services referred to in subsection 1 in such a way that they do not exceed the total cost of producing the service.

Valvira may charge the manufacturer or importer a fee for:

- 1) examining whether the tobacco product has characteristics or additives prohibited under section 11;
- 2) verifying the measurements of the amounts of tar, nicotine and carbon monoxide that are produced when smoking a cigarette;
- 3) the reception, storage, processing,

Municipalities collect fees according to their approved rates for:

- 1) processing an application for a retail licence referred to in section 44; *the fee is also levied on the notification of an amendment to the retail licence in respect of the extension of retail sales to new product groups;*
- 2) the processing of a notification concerning the retail sale of nicotine-containing liquids *or smokeless nicotine products* referred to in section 48;

3) the processing of a wholesale sales notification referred to in section 50;

4) the processing of an application for a smoking ban referred to in section 79.

The municipality shall determine the fees it collects for its services referred to in subsection 1 in such a way that they do not exceed the total cost of producing the service.

Valvira may charge the manufacturer or importer a fee for:

- 1) examining whether the tobacco product has characteristics or additives prohibited under section 11;
- 2) verifying the measurements of the amounts of tar, nicotine and carbon monoxide that are produced when smoking a

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analysis and publication of data submitted to the Authority pursuant to sections 14–16, 18, 20 and 26–29 and related measures;

4) peer reviews referred to in section 18, subsection 3.

The amount of the fee referred to in subsection 3 is laid down in the Act on Criteria for Charges Payable to the State (150/1992).

The product may not be placed on the market until the fee referred to in subsection 3, paragraph 3 has been paid.

Section 91

Supervision fees of the Tobacco Act

The municipality shall levy an annual supervisory fee per point of sale according to the tariff it has approved, from a party who holds a retail licence referred to in section 44 or granted under the old Tobacco Act and from a party who has submitted a wholesale notification referred to in section 50 of this Act.

A supervisory fee may not exceed EUR 500 per point of sale. However, if an operator has declared the retail sale or wholesale of both tobacco products and nicotine-containing liquids in accordance with section 46, subsection 1, paragraph 2 or section 50, subsection 1, or has declared the retail sale of nicotine-containing liquids as referred to in section 48, the supervisory fee is charged at most double.

The municipality shall levy a supervisory fee for retail licences and activities carried out on the basis of a wholesale distribution notification in force on 1 January for the year in question. If a retail licence is granted or a wholesale notification is made in the middle of a year or the activity is carried out for a period of less than a year, the municipality

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cigarette;

3) the reception, storage, processing, analysis and publication of data submitted to the Authority pursuant to sections 14–16, 18, 20, 26–29, 29a, and 29b, and for measures related thereto;

4) peer reviews referred to in section 18, subsection 3.

The amount of the fee referred to in subsection 3 is laid down in the Act on Criteria for Charges Payable to the State (150/1992).

The product shall not be placed on the market until the fee referred to in subsection 3, paragraph 3 has been paid.

Section 91

Supervisory fees of the Tobacco Act

The municipality shall levy an annual supervisory fee per point of sale according to the tariff it has approved, from a party who holds a retail licence referred to in section 44 or granted under the old Tobacco Act and from a party who has submitted a wholesale notification referred to in section 50 of this Act.

A supervisory fee may not exceed EUR 500 per point of sale. However, if an operator has declared the retail sale or wholesale of both tobacco products and nicotine-containing liquids in accordance with section 46, subsection 1, paragraph 2 or section 50, subsection 1, or has declared the retail sale of nicotine-containing liquids as referred to in section 48, the supervisory fee is charged at most double. *The provisions of this subsection above on nicotine-containing liquids also apply to smokeless nicotine products.*

The municipality shall levy a supervisory fee for retail licences and activities carried out on the basis of a wholesale distribution notification in force on 1 January for the year in question. If a retail licence is granted or a wholesale notification is made in the middle of a year or the activity is carried out for a period of less than a year, the municipality

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may charge a supervisory fee on a pro rata basis for the duration of the activity.

In order to cover the costs of enforcing this law, Valvira annually collects a supervision fee from manufacturers and importers of tobacco products, nicotine-containing liquids and nicotine-free liquids intended for vaporisation. The supervision fee is based on the sales volumes notified to Valvira by the manufacturer or importer during the previous calendar year pursuant to sections 16 and 27:

- 1) cigarettes: EUR 0,001 per piece;
- 2) cigars: EUR 0,02 per piece;
- 3) cigarillos: EUR 0,001 per piece;
- 4) tobacco products other than those referred to in paragraphs 1–3: EUR 1,7/kg;
- 5) nicotine-containing liquids and nicotine-free liquids for vaporisation: EUR 0.01 per millilitre.

However, the control fee referred to in paragraph 4 shall not be less than EUR 300 and shall not exceed EUR 70 000 per manufacturer or importer.

Section 94

Storage and publication of product control information

Valvira shall store the information received under sections 14–16 and 18 by electronic means so that the Commission and the competent authorities of other EU Member States have access to it. Valvira shall forward the information received under section 20 to the Commission. In addition, upon request, Valvira shall provide the Commission and the competent authority of another EU Member State with the information received pursuant to sections 26–28.

With the exception of confidential business information, Valvira shall place the information obtained under section 14,

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may charge a supervisory fee on a pro rata basis for the duration of the activity.

In order to cover the costs of supervision under this Act, Valvira charges an annual supervisory fee to manufacturers and importers of tobacco products, nicotine-containing liquids, nicotine-free liquids intended for vaporisation *and smokeless nicotine products*. The supervisory fee is based on the sales volumes notified to Valvira by the manufacturer or importer in the previous calendar year pursuant to sections 16, 27, *and 29b*:

- 1) cigarettes: EUR 0,001 per piece;
- 2) cigars: EUR 0,02 per piece;
- 3) cigarillos: EUR 0,001 per piece;
- 4) tobacco products other than those referred to in paragraphs 1–3: EUR 1.7/kg;
- 5) nicotine-containing liquids and nicotine-free liquids for vaporisation: EUR 0.01 per millilitre;
- 6) *smokeless nicotine products sold in portion units: EUR 0.001 per piece;*
- 7) *other smokeless nicotine products: EUR 1.7 per kilogram.*

However, the supervisory fee referred to in paragraph 4 is less than EUR 300 and not more than EUR 70 000 per manufacturer or importer.

Section 94

Storage and publication of product control information

Valvira shall store the information received under sections 14–16 and 18 by electronic means so that the Commission and the competent authorities of other EU Member States have access to it. Valvira shall forward the information received under section 20 to the Commission. In addition, upon request, Valvira shall provide the Commission and the competent authority of another EU Member State with the information received pursuant to sections 26–28.

With the exception of confidential business information, Valvira shall place the information obtained under section 14,

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subsection 1, paragraphs 1 to 4, and sections 15, 18, 26 and 29 on a website accessible to the public, where information can only be searched as individual queries using the name of the product or the name or business ID of the registered party.

By derogation from section 16, subsection 3 of the Act on the Openness of Government Activities (621/1999), the name of the natural person referred to in section 26, subsection 2, paragraph 1 of this Act must be made public as is when information is made available in accordance with subsection 2 of this section.

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

Section 97

Revocation of a retail licence

A municipal authority may revoke a retail licence referred to in section 44 or issued under the old Tobacco Act for a period of at least one week and not more than six months, if the holder of the retail licence, in spite of receiving a written warning from a municipality or other supervisory authority or a criminal penalty:

1) sells or otherwise makes available tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation or plant-based products intended for smoking, the unit packets of which do not comply with the provisions of chapter 5;

2) fails to notify, in violation of section 48, the sale of nicotine-containing liquids or essential information referred to in section 49;

3) in violation of section 51, sells or otherwise makes available chewing tobacco, nasal tobacco or tobacco for oral use;

4) in violation of section 53, sells or otherwise makes available tobacco products, tobacco substitutes, smoking equipment,

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subsection 1, paragraphs 1 to 4, and sections 15, 18, 26, 29, 29a and 29b on a website accessible to the public, where information can only be searched as individual queries using the name of the product or the name or business ID of the registered party.

By derogation from section 16, subsection 3 of the Act on the Openness of Government Activities (621/1999), the name of the natural person referred to in section 26, subsection 2, paragraph 1 and section 29a, subsection 2, paragraph 1 of this Act must be made public as is when information is made available in accordance with subsection 2 of this section.

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

Section 97

Revocation of a retail licence

A municipal authority may revoke a retail licence referred to in section 44 or issued under the old Tobacco Act for a period of at least one week and not more than six months, if the holder of the retail licence, in spite of receiving a written warning from a municipality or other supervisory authority or a criminal penalty:

1) sells or otherwise makes available tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, nicotine-free liquids intended for vaporisation, plant-based products intended for smoking or *smokeless nicotine products*, the unit packets of which do not comply with the provisions of chapter 5;

2) fails to notify, in violation of section 48, the sale of nicotine-containing liquids or *smokeless nicotine products*, or essential information referred to in section 49;

3) in violation of section 51, sells or otherwise makes available chewing tobacco, nasal tobacco or tobacco for oral use;

4) in violation of section 53, sells or otherwise makes available tobacco products, tobacco substitutes, smoking equipment,

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electronic cigarettes or nicotine-containing liquids to a person under the age of 18 or, in violation of section 56, permits a person under the age of 18 to sell or otherwise make available such products;

5) in violation of section 57, sells or otherwise makes available tobacco products, tobacco substitutes, smoking equipment, electronic cigarettes or nicotine-containing liquids from an automatic vending machine;

6) in violation of section 58, sells or otherwise makes available tobacco products, electronic cigarettes or nicotine-containing liquids to consumers by means of distance communication;

7) in violation of section 68, markets tobacco products, tobacco substitutes, smoking equipment, imitation tobacco, electronic cigarettes or nicotine-containing liquids;

8) in violation of section 71, displays at the point of sale tobacco products, tobacco substitutes, electronic cigarettes, nicotine-containing liquids or smoking equipment intended for the heating of tobacco products, or the trade marks of such products.

A municipality may withdraw a retail licence permanently if, despite the temporary suspension of the licence, the holder of the retail licence continues or resumes the unlawful activities referred to in subsection 1 and the action cannot not be regarded as minor.

Section 100

Ban on sales

Valvira may prohibit the sale and other supply of tobacco products, electronic cigarettes, nicotine-containing liquids, nicotine-free liquids for vaporisation and plant-based products for smoking if:

1) the manufacturer, importer or distributor of an electronic cigarette or refill container has not established or maintained a monitoring system for harmful effects

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electronic cigarettes or nicotine-containing liquids to a person under the age of 18 or, in violation of section 56, permits a person under the age of 18 to sell or otherwise make available such products;

5) in violation of section 57, sells or otherwise makes available tobacco products, tobacco substitutes, smoking equipment, electronic cigarettes or nicotine-containing liquids from an automatic vending machine;

6) in violation of section 58, sells or otherwise makes available tobacco products, electronic cigarettes, nicotine-containing liquids *or smokeless nicotine products* to consumers by means of distance communication;

7) in violation of section 68, markets tobacco products, tobacco substitutes, smoking equipment, imitation tobacco, electronic cigarettes or nicotine-containing liquids;

8) in violation of section 71, displays at the point of sale tobacco products, tobacco substitutes, electronic cigarettes, nicotine-containing liquids or smoking equipment intended for the heating of tobacco products, or the trade marks of such products.

A municipality may withdraw a retail licence permanently if, despite the temporary suspension of the licence, the holder of the retail licence continues or resumes the unlawful activities referred to in subsection 1 and the action cannot not be regarded as minor.

Section 100

Ban on sales

Valvira may prohibit the sale and other supply of tobacco products, electronic cigarettes, nicotine-containing liquids, nicotine-free liquids for vaporisation, herbal products for smoking *and smokeless nicotine products* if:

1) the manufacturer, importer or distributor of an electronic cigarette or refill container has not established or maintained a monitoring system for harmful effects

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referred to in section 28, subsection 1, or refuses to submit the information in the monitoring system to Valvira;

2) the manufacturer, importer or distributor of an electronic cigarette or refill container in a situation referred to in section 28, subsection 2, has not taken the corrective measures referred to in the provision or has failed to make the notification referred to in the provision;

3) the manufacturer or importer has not submitted the information referred to in sections 14 to 16, 18, 20, 26, 27 or 29 to Valvira in the prescribed manner, within the prescribed time period, or using the prescribed model, or if the information provided is not correct;

4) the manufacturer or importer has failed to pay Valvira the fee referred to in section 90, subsection 3.

Valvira shall notify the Commission of any prohibition imposed under section 18 of the Market Surveillance Act based on a tobacco product being in violation of section 11, subsection 1, paragraphs 1 or 9 of this Act.

Valvira may also prohibit the sale and other supply of a tobacco product to consumers when considering the conditions for the approval of a verification laboratory responsible for verifying the tobacco product in accordance with section 85 or the conditions for withdrawing approval in accordance with section 104, if the Authority has reasonable doubts about the accuracy of the information concerning the laboratory or the proper functioning of the laboratory. When ordering a sales ban, account shall be taken of whether the manufacturer or importer has the opportunity to use another approved laboratory in order to fulfil the obligations referred to in this Act while the matter is being considered.

Valvira must withdraw the sales ban as soon as there is no longer a reason for the ban.

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referred to in section 28, subsection 1, or refuses to submit the information in the monitoring system to Valvira;

2) the manufacturer, importer or distributor of an electronic cigarette or refill container in a situation referred to in section 28, subsection 2, has not taken the corrective measures referred to in the provision or has failed to make the notification referred to in the provision;

3) the manufacturer or importer has not submitted the information referred to in sections 14 to 16, 18, 20, 26, 27, 29, 29a or 29b to Valvira in the prescribed manner, within the prescribed time period, or using the prescribed model, or if the information provided is not correct;

4) the manufacturer or importer has failed to pay Valvira the fee referred to in section 90, subsection 3 or section 91, subsection 4.

Valvira shall notify the Commission of any prohibition imposed under section 18 of the Market Surveillance Act based on a tobacco product being in violation of section 11, subsection 1, paragraphs 1 or 9 of this Act.

Valvira may also prohibit the sale and other supply of a tobacco product to consumers when considering the conditions for the approval of a verification laboratory responsible for verifying the tobacco product in accordance with section 85 or the conditions for withdrawing approval in accordance with section 104, if the Authority has reasonable doubts about the accuracy of the information concerning the laboratory or the proper functioning of the laboratory. When ordering a sales ban, account shall be taken of whether the manufacturer or importer has the opportunity to use another approved laboratory in order to fulfil the obligations referred to in this Act while the matter is being considered.

Valvira must withdraw the sales ban as soon as there is no longer a reason for the ban.

Section 109

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Proposal

Tobacco sales offence

Tobacco sales offence

Any party which deliberately,
1), in violation of section 53, subsection 1, sells or otherwise makes available in return for consideration a tobacco product or nicotine-containing liquid to a person under the age of 18;
2) in violation of section 51, sells or otherwise supplies or conveys in return for consideration chewing tobacco, nasal tobacco or tobacco for oral use,
3) sells or otherwise makes available in trade tobacco products or nicotine-containing liquids without a retail licence in violation of section 44 or without submitting the notification of the retail sale of nicotine-containing liquids referred to in section 48; or
4) in violation of section 60, in wholesale sales sells or otherwise makes available tobacco products or nicotine-containing liquid to an operator other than the one referred to in the said section;
shall be sentenced to a fine or imprisonment of up to six months for an *offence relating to the sale of tobacco*.

Any party which deliberately,
1) in violation of section 53, subsection 1, sells or otherwise supplies or conveys in return for consideration a tobacco product, nicotine-containing liquid *or smokeless nicotine product* to a person under the age of 18,
2) in violation of section 51, sells or otherwise passes on or conveys for consideration chewing tobacco, nasal tobacco, or tobacco intended for oral use,
3) sells or otherwise makes available in trade tobacco products or nicotine-containing liquids *or smokeless nicotine products* without a retail licence in violation of section 44 or without submitting the notification of the retail sale of nicotine-containing liquids *or smokeless nicotine products* referred to in section 48; or
4) in violation of section 60, in wholesale sales sells or otherwise makes available tobacco products, nicotine-containing liquid *or smokeless nicotine products* to an operator other than the one referred to in the said section,
is sentenced to a fine or imprisonment of up to six months for an *offence relating to the sale of tobacco*.

Section 113

Section 113

Smoking offence

Smoking offence

A party who intentionally, despite the warning of the holder of a means of transport, indoor or outdoor area or their representative, or the organiser of a public event or the security guard at such public event, or the supervisory authority, continues to smoke in an indoor or outdoor area where smoking is prohibited under section 74,

A party who intentionally, despite the warning of the holder of a means of transport, indoor or outdoor area or their representative, or the organiser of a public event or the security guard at such public event, or the supervisory authority, continues to smoke in an indoor or outdoor area where smoking is prohibited under section 74,

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subsection 1, shall be sentenced to a fine for a *smoking offence*.

The provisions on smoking in subsection 1 shall also apply to the smoking of a herbal product for smoking, the use of electronic cigarettes and the use of a smokeless tobacco product in the indoor and outdoor spaces of a kindergarten or an educational institution providing pre-school and basic education, vocational education or upper secondary education in violation of section 74, subsection 3.

Section 117

Outer packaging

The provisions of this Act on the retail packaging of a tobacco product, herbal product intended for smoking, electronic cigarette, refill container, or nicotine-free liquid intended for vaporisation shall also apply to the product's outer packaging, if any, with the exception of section 32, subsection 1, paragraph 2, sections 34 and 35 and chapter 6.

Section 118

Prohibition of possession

A person under the age of 18 may not have in their possession a tobacco product or nicotine-containing liquid.

Section 119

Disposal

An official with the power of arrest may demonstrably dispose of or arrange for the disposal of such a tobacco product, herbal product for smoking, electronic cigarette or nicotine-containing liquid with outside

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subsection 1, shall be sentenced to a fine for a *smoking offence*.

The provisions on smoking in subsection 1 shall also apply to the smoking of a herbal product for smoking, the use of electronic cigarettes, the use of a smokeless tobacco product and the use of a *smokeless nicotine product* in the indoor and outdoor spaces of a kindergarten or an educational institution providing pre-school and basic education, vocational education or upper secondary education in violation of section 74, subsection 3.

Section 117

Outer packaging

The provisions of this Act on the unit packets of tobacco products, herbal products for smoking, electronic cigarettes, refill containers, nicotine-free liquids for vaporisation *and smokeless nicotine products* shall also apply to any outside packaging of the products, with the exception of section 32, subsection 1, paragraph 2, sections 34 and 35, and chapter 6.

Section 118

Prohibition of possession

A person under the age of 18 may not have in their possession a tobacco product or *tobacco substitute*.

Section 119

Disposal

An official with the power of arrest may demonstrably dispose of or arrange for the disposal of such a tobacco product, herbal product for smoking, electronic cigarette, nicotine-containing liquid *or smokeless*

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packaging that may be confiscated if there is reason to believe that it will be declared lost and which has no significant commercial value or value for use.

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nicotine product with outside packaging that may be confiscated if there is reason to believe that it will be declared lost and which has no significant commercial value or value for use.

This Act enters into force on [] [] 20[]. However, section 25a, section 34 and subsection 1 of section 39a of this Act enter into force six months after the entry into force of this Act and subsections 2 to 4 of section 39a, sections 39b and 39c, and subsection 2 of section 80 enter into force one year after the entry into force of this Act.

The provisions of section 65 do not apply to smokeless nicotine products acquired before the entry into force of this Act.

Smokeless nicotine products sold or otherwise passed on to consumers in Finland upon the entry into force of this Act must be declared pursuant to section 29a within six months of the entry into force of this Act. The manufacturer or importer of a smokeless nicotine product must submit the information referred to in section 29b to Valvira for the first time in the calendar year following the entry into force of this Act.

A trader who, upon the entry into force of this Act, sells or otherwise passes on smokeless nicotine products in retail and within three months of the entry into force of this Act submits to the municipality an application for a licence for the retail sale of smokeless nicotine products referred to in section 46, or declares the retail sale of smokeless nicotine products referred to in section 48, may, subsection 1 of section 44 notwithstanding, sell or otherwise pass on smokeless nicotine products in retail for a period of one year after the entry into force of this Act.

A trader who, upon the entry into force of this Act, sells or otherwise transfers smokeless nicotine products in wholesale sales and within three months of the entry into force of this Act, submits a notification to the municipality of the wholesale sale of smokeless nicotine products provided for in section 50, may, without prejudice to section

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50, sell smokeless nicotine products on a wholesale basis for a period of one year after the entry into force of the proposed Act. The provisions of the introductory paragraph to subsection 2 of section 60 notwithstanding, a trader may sell or otherwise supply for resale smokeless nicotine products for a period of three months from the entry into force of this Act, and, paragraph 1 of that subsection notwithstanding, for a period of one year after the entry into force of this Act, if the buyer can prove that they have submitted the application or notification referred to in that paragraph.
