

Government proposal to the Parliament for an Act amending the Tobacco Act

MAIN CONTENT OF THE PROPOSAL

The Proposal proposes to amend 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 will 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 licence, nicotine limits in use in neighbouring countries are set for the products, and only flavours for adults are allowed.

The Proposal proposes to add to the Tobacco Act a definition for 'smokeless nicotine products' that would cover nicotine pouches and products closely resembling these. These are products resembling snus products that do not contain tobacco plant, but to which nicotine has been added, and which correspond to traditional tobacco products for oral use in terms of their intended use and appearance.

It is proposed that non-smoking nicotine products be regulated in a manner similar to that laid down in the Tobacco Act for tobacco products and nicotine liquids. Among other things, this would mean imposing a nicotine limit on products and banning the flavours of alcohol and cannabis, as well as flavours that are likely to attract young people. Health warnings would be required for retail packaging of products and the appearance of the packaging would be harmonised. The retail sale of products would be subject to licence, wholesale sale would be subject to declaration, and the distance selling of products would be prohibited. Limitations such as quantitative and temporal restrictions would be imposed on imports. The products and their sale would be subject to supervisory fees. In addition, a ban is proposed on the use of smokeless nicotine products 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.

In addition, the proposal proposes that smokeless tobacco products, such as snus, would be allowed to be imported less than currently as passenger imports.

The proposed Act is intended to enter into force as soon as possible. Restrictions on the characteristics of smoke-free nicotine products and provisions on retail packaging would only enter into force at a later stage. The proposed law furthermore includes a number of transitional provisions.

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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 licence, nicotine limits in use in neighbouring countries are set for the products, and only flavours for adults are 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 modified on the basis of the entries in the Government Programme, and a new round of comments was organised in ###. The feedback from the public consultation is discussed in section 6 below.

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

The draft government proposal has been notified on ### to the European Commission, hereinafter the *Commission*, and to other EU Member States pursuant to 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 (hereinafter the *TRIS Directive*). The notification identifier in the database on draft regulations is ###.

The draft Government Proposal has been notified to the World Trade Organisation in accordance with the WTO Agreement on Technical Barriers to Trade on ###. The notification identifier is ###.

2 Current situation and assessment thereof

2.1 Current situation

2.1.1 Legislation

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 concentration requirements and product information requirements for nicotine pouches come from the CLP Regulation and 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, Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

2.1.2 Practice

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 of the same section provides that, insofar as a chemical is not restricted in the REACH Regulation, the Government may, by its decision, restrict or prohibit for a limited period or until further notice the manufacture, import, placing on the market or otherwise making available, export, use or other similar handling of the chemical or article containing the chemical, and impose operational restrictions and conditions if the use of the chemical or article containing the chemical is found or can be expected 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 was based especially 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 carried out by traders located outside Finland. Imports of nicotine pouches have increased significantly, and products are already on sale 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.

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.

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.

In 2022, Finns imported about 14.9 million boxes of snus to Finland as passenger imports. Imports increased by 116 % compared to 2021, but this increase is largely explained by an increase in travel following the lifting of travel restrictions due to the COVID-19 pandemic. 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 the first half of 2023, much less snus was seized than in previous years. In the first half of 2023, 533 kilograms of snus was seized, whereas the amount was 2 366 kilograms in the first half of 2022 and 5 856 kilograms in the first half of 2021.

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. 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.

Nicotine has acute toxic effects if ingested or when large amounts of it come into contact with the skin or eyes. 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.

Use of nicotine products often starts at a young age, when the brain is still developing. 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 resulting nicotine addiction 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.

Nicotine is easily passed through the placenta, and nicotine use during pregnancy has adverse effects on the development of neural cells in the foetus. Research has shown a link between exposure to nicotine during pregnancy and the development of attention deficit hyperactivity disorder (ADHD) in adolescence. Animal studies show that nicotine is clearly toxic to the foetus and dam-

ages the brain and lungs in particular. Preliminary evidence of this has also been obtained in humans.

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. 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 the use of nicotine is started, the less likely it is that it can be stopped and the more likely it is that its use will continue. Nicotine addiction strongly predicts the continuation of smoking in adulthood.

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.

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 to 1 mg/kg of body weight. Based on this, one nicotine pouch containing 16 milligrams of nicotine could kill a child of 16 to 32 kg in body weight if swallowed. Other estimates suggest that the life-threatening dose of nicotine when ingested would be between 6.5 and 13 mg/kg of body weight. Assuming a lethal dose of 6.5 mg/kg of body weight, four one-gram nicotine pouches with a nicotine concentration of 16 milligrams per gram could kill a child weighing 10 kilograms if swallowed. Flavourings in nicotine pouches can attract especially young children to swallow products, and even a lower dose could cause serious poisoning symptoms. 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.

As described 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. Even after this decision, nicotine pouches with a relatively high nicotine content may still be 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 16 milligrams of nicotine is more than 300 times the amount of nicotine that, based on the above assessment, could be consumed without risk to health.

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 re-

quire 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, the flavours of fruit, mint, liquorice, energy drink, or candy are likely to appeal to children and young people in particular and to reduce the perception of the hazardous nature and health hazards of the product. The characteristic flavours of nicotine pouches also include the flavours of a variety of alcoholic beverages, such as whisky and coke, long drink, or champagne. Studies have shown that nicotine in itself increases the desire to consume alcohol. 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. 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 pouches is not prohibited for minors under the Tobacco Act, so even minors may possess nicotine pouches. Minors are also allowed to import nicotine pouches.

In 2021, 5 % of young people aged 14 to 20 used snus daily, and the use rates have increased for several years despite the fact that actual smoking has decreased significantly among young people. The extent to which young people use nicotine pouches is not yet known. However, the increasing use of snus suggests that nicotine pouches are also likely to be of interest to young people. According to Nordic experiences, the use of nicotine pouches has increased among young people, such that in Sweden for example 18 % of girls aged 16 to 29 used nicotine-containing snus in 2022. Recently, experimentation with electronic cigarettes and similar products has also become more common among young people in educational institutions. A variety of flavoured nicotine-containing or nicotine-free liquids are used in the devices. Young people's interest in flavoured tobacco substitutes seems to have increased.

Overall, existing legislation can be considered insufficient to protect the population, particularly children and young people, from the harms and health hazards associated with nicotine pouches. 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 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 into the body from nicotine pouches than from snus, and a six milligram nicotine pouch raises the level of nicotine in the blood clearly higher than snus and to almost the same level as smoking a cigarette.

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 (Development of tobacco and nicotine policy: Proposals for action by the working group 2023. Reports and Memorandums of the Ministry of Social Affairs and Health 2023:5) that nicotine snuff, that is, nicotine pouches, should be regulated in the same way as traditional snus.

Under the current Tobacco Act, a total of 1 000 grams of snus and other non-smoking tobacco products may be imported as passenger imports for personal use, which is quite a lot. It must be presumed that at least some of the snus imported by passengers will be illegally passed on to other users.

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 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 mitigated by for example limiting the nicotine content, attractiveness, and availability of nicotine pouches.

4 Proposals and their impacts

4.1 Main proposals

The Proposal proposes that a definition of a smokeless nicotine product is 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 chewing tobacco or nasal tobacco.

The nicotine limit for smokeless nicotine products would be set at a maximum of 20 milligrams of nicotine per gram of product, in addition to which the flavours of alcohol and cannabis, as well as flavours likely to attract young people, would be prohibited in smokeless nicotine products. More detailed provisions on flavours that are likely to attract young people could be laid down in a decree issued by the Ministry of Social Affairs and Health.

In other respects, it is proposed that smokeless nicotine products be regulated largely in a manner similar to what is laid down in the Tobacco Act on tobacco products and nicotine-containing liquids. This would mean, among other things, that products should be declared to Valvira and subjected to annual supervisory fees. Health warnings in Finnish and Swedish would be required for retail packaging, and the appearance of the packaging would be harmonised. Retail sales of products would be subjected to authorisation and wholesale to declaration. The distance selling of products would be prohibited, and the import of products would be restricted. The possession of products would be prohibited for persons under 18 years of age, and non-commercial sales to persons under 18 years of age would be prohibited as well.

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 similar health hazards to people as smoking does, which is why it is proposed not to extend the smoking bans laid down in the Tobacco Act to cover the use of smokeless nicotine products. The Proposal does however propose prohibiting the use of smokeless nicotine products 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 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 is subsequently applied for as a medicinal product. Fimea may continue to grant marketing authorisations upon application 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 to help with weaning from tobacco addiction. The precondition is that the product has been found to be appropriate as a medicinal product and that the conditions for granting a marketing authorisation laid down in the Medicines Act are otherwise fulfilled. Medicinal nicotine products subject to marketing authorisation will therefore continue to be subject to pharmaceutical legislation instead of the Tobacco Act and the Chemicals Act.

In the future, a total of 500 grams of smokeless tobacco products, such as snus, could be imported as passenger imports per calendar day instead of the current 1 000 grams per calendar day.

4.2 Principal impacts

4.2.1 Economic impacts

General

The proposed amendments would extend the scope of the Tobacco Act to cover nicotine pouches and other smokeless nicotine products in a more comprehensive manner. Since Fimea changed its interpretation on the applicability of the Medicines Act to nicotine pouches in the spring of 2023, it has been known that new legislation on nicotine pouches is being prepared. It is possible that when the Proposal consolidates nicotine pouches on the Finnish market and uncertainty about future regulation disappears, new nicotine pouch entrepreneurs and new nicotine pouch brands will enter the market, and the demand for products will grow.

In contrast, the Proposal includes various restrictions on the characteristics, packaging, and sale of nicotine pouches, as well as new kinds of obligations for the manufacturers and importers of such products. The proposed regulation may lead to a contraction of the nicotine pouch market. Nicotine pouches have only been freely available for such a short time that no accurate situational data exists even for the current situation. As such, only different qualitative estimates can be made or different alternative developments be predicted concerning the direction in which the proposed regulation as a whole will ultimately move things.

Impacts on the position of households

A packet of cigarettes costs more than EUR 10 on average, while a packet of nicotine pouches currently costs between EUR 5 and EUR 7, based on data from the Ministry of Finance, or around EUR 7.4 to 9.7 after the planned tax increases. If smokers switch to using 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 available for other uses. The Proposal may therefore have a positive impact on the position of households. However, if the additional costs resulting from the proposed regulation are passed on to product margins, prices will rise and there will be no savings for households.

Smoking is clearly more common among low-qualified people. No income or population-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 sections.

The Proposal proposes that, in the future, snus and other smokeless tobacco products could be imported into Finland as passenger imports in smaller quantities than at present. Snus imported into Finland may not be sold further in Finland, but some individuals who imported snus have nonetheless earned income by selling snus on the black market. Lowering the limit for passenger imports would reduce the chances of doing so, which could reduce the income of persons operating in this way. However, snus ends up in Finland primarily through illegal imports, on which the proposed amendments would not have any direct effect.

Impacts on enterprises

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

The proposed amendments would impact manufacturers and importers of smokeless nicotine products, as well as retailers and wholesalers. Manufacturers and importers of smokeless nicotine products would incur direct costs in the form of, inter alia, product declaration submissions, as such declarations would be subject to fees. In addition, an annual supervisory fee would become payable, which would be based on the sales volumes of the products. Costs would also arise from efforts to bring retail packaging into 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 insofar as the consumption of cigarettes may be replaced by the use of nicotine pouches.

It can be assumed that product sales would be reduced, at least to some extent, as the Tobacco Act would limit the flavours they may feature. However, it has not been studied in Finland which flavours are favoured by adult consumers today. It is therefore possible that banning candy flavours, for example, would not significantly reduce the sales of nicotine pouches compared to the current situation.

Retailers would incur costs when applying for marketing authorisations, for which the municipalities will charge fees. The annual supervisory fee for retailers would also increase for some enterprises if smokeless nicotine products were also available for sale. As regards the supervisory fee, sellers would be placed in different positions depending on which products they have previously declared for sale under the Tobacco Act. If a seller has previously declared selling only tobacco products, or if a seller applied for a completely new licence under the Tobacco Act for smokeless nicotine products, the supervisory fee would incur additional costs for the seller. If a seller has previously declared only selling nicotine-containing 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 its related information 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. Smokeless nicotine products, like other tobacco substitutes, may not be displayed at retail outlets or sold to minors even at present, so retailers would not incur any new costs for things such as age limit controls.

As a result of the ban on distance selling of smokeless nicotine products, operators who have been selling nicotine pouches on the internet would have to alter or cease their activities. It is not known how many Finnish companies there are that sell nicotine pouches exclusively or mainly on the internet.

Effects on public finances

The Proposal proposes amendments to steer snus users to start using nicotine pouches instead. If this objective is met, the change will have positive impacts on public finances in this respect, as the Government intends to propose that tobacco tax be levied on smokeless nicotine products. Moreover, if people who currently smoke cigarettes switch to using nicotine pouches, public spending on the treatment of tobacco-related illnesses 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 are such direct costs reduced, but indirect costs may be reduced as well, including input losses

caused by smoking deaths and disability pensions, as well as labour input losses caused by sickness absences and tobacco breaks not covered by statutory breaks. According to THL's estimate, the direct and indirect costs of smoking in Finland amounted to approximately EUR 1.3 billion in 2020.

However, the use of nicotine pouches is also associated with various health hazards, which can increase healthcare spending and, for example, absences from work. If the establishment of nicotine pouches on the Finnish market results in nicotine pouches starting to be used by people who have not previously used tobacco or other nicotine products, the amendment will have negative effects on public finances in this respect.

It should also be borne in mind that the use of a nicotine pouch cannot be said to be unequivocally less harmful than smoking a cigarette, as studies have shown that nicotine pouches raise the level of nicotine in the blood even higher than cigarettes do. On this basis, it can be assumed that if smokers start using nicotine pouches on a large scale, even more public funds may be needed to treat nicotine-related health hazards in the future. There is clear evidence, for example, that nicotine increases the risk of complications following all surgeries and prolongs recovery times and hospital stays. In addition, nicotine increases the risk of mental health problems in young people, which can have long-term economic effects.

4.2.2 Impacts on the activities of public authorities

The Proposal proposes that a decree of the Ministry of Social Affairs and Health could be issued to lay down more detailed provisions on flavours that are likely to attract young people. This would require continuous work in the Ministry to monitor the flavours available on the market and determining which ones could be considered attractive to young people. It should be assumed that the list of prohibited flavours would need updating frequently, at least at the initial stage. In addition to an amendment, each update would require issuing a declaration under the TRIS Directive to the Commission and the other EU Member States, including a waiting period specified in that Directive, which means that reacting to new flavours entering the market that could attract young people would, in principle, be rather slow. The restrictions on flavours and their associated ambiguity would additionally burden the authorities supervising the Tobacco Act and possibly the courts as well.

The Proposal would increase the work and expenses spent by the authorities supervising the Tobacco Act, municipalities and Valvira in particular, as a whole new nicotine-containing product group would then become subject to supervision. The municipal authorities supervising the Tobacco Act are currently responsible for ensuring that nicotine pouches or other tobacco substitutes are not sold to minors in trade or marketed or displayed at retail outlets. In the future, the retail sales of smokeless nicotine products would require a retail licence, and wholesale sales would require issuing a wholesale declaration, which would be one of the most significant changes for the municipal supervisory authorities. The processing of retail licences and wholesale declarations would require, among other things, that municipalities review and check the legality of self-monitoring plans or their updates from all traders who take nicotine pouches into their selections. This alone can mean going through thousands of self-monitoring plans.

Nicotine pouches would probably also be placed for sale at points of sale that have not possessed a previous marketing authorisation under the Tobacco Act and have no experience in selling products regulated by the Tobacco Act or in applying tobacco legislation. Many restaurants for example have in the recent years given up pursuing marketing authorisations under the Tobacco Act because

smoking is now 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. According to media reports, nicotine pouches have also been sold in shoe repair shops, for example. New sales outlets would increase the number of tobacco control targets and the need to monitor sales and self-monitoring.

The Proposal would also have an impact on the operations of Valvira and the information systems needed for it. The requirement for authorisation for the retail sale of nicotine pouches and the requirement to submit a declaration for wholesale would require changes to the existing register of marketing authorisations and wholesale declarations for tobacco products and nicotine-containing liquids, its electronic forms, and the public version of the register. Maintaining both registers is one of Valvira's statutory tasks.

Product declarations under the Tobacco Act are submitted to the Commission's EU Common Entry Gate (hereinafter EU-CEG). The EU-CEG information system is not designed for declaring nicotine pouches, but it can be used for this purpose as well. This would however require Valvira to provide guidance for traders in submitting such declarations. Reviewing product declarations and monitoring declarations would also be more challenging in comparison to the monitoring of other products to be declared, as the system does not have automated searches for smokeless nicotine products for example, so any declarations for such would have to be manually searched from within the system. Valvira would need to make changes to the public search service for product declarations as well, the maintenance of which is one of Valvira's statutory tasks.

Making changes to the information systems provided and used by Valvira and the processing, analysis, and publication of the product declarations itself, the supervision of marketing, and the steering of municipalities and regional state administrative agencies would require additional resources. It is therefore proposed that Valvira may charge fees from the manufacturers or importers of nicotine pouches to cover at least part of the need for additional resources resulting from the new tasks and updates to be made to the information systems. The supervisory fees are planned to provide Valvira with an additional monetary resource of approximately EUR 180,000 for monitoring and controlling the Tobacco Act, which corresponds to approximately two man-years. As the ministry responsible for the performance management of Valvira, 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 uniform appearance of the products has posed challenges in monitoring compliance with EU-wide bans on the sales and imports of snus. The amendments proposed would not remove these difficulties, as the authorities supervising sales and imports would continue to seek to assess whether the product in question is a legitimate smokeless nicotine product or illegal snus product on a case-by-case basis. However, harmonisation of the appearances of unit packets for smokeless nicotine products could make it easier to distinguish products from each other in the supervision of retail sales.

The proposal to ban the use of smokeless nicotine products in kindergartens and educational establishments and the proposal for a ban on possession would improve opportunities for teachers and other people working with children under the age of 18 to tackle the use of nicotine pouches and snus in schools. The similar appearance of the products has made it difficult for schools to intervene in the possession and use of tobacco snus in practice, even though this is already prohibited under the current legislation. The Proposal would simplify the situation and allow educational institutions to intervene in the use of both products.

Banning the use of nicotine pouches in kindergartens and educational institutions may also be relevant from the point of view of employees who use nicotine pouches and are addicted to nicotine. The proposed ban on the use of nicotine pouches would however 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 Impacts on the environment

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

If the establishment of nicotine pouches on the Finnish market results in smokers switching to nicotine pouches instead of smoking cigarettes, the impact on the environment may be somewhat positive. However, at least some nicotine pouches contain plastic, which means that microplastics that are harmful to the environment can also end up in the environment from used nicotine pouches. In addition, manufacturers and importers of nicotine pouches are not obligated under the Waste Act to organise the waste management of their products and 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.

4.2.4 Other social impacts

Impacts on health

With the Proposal, legislation would be used to establish a new nicotine product on the Finnish market. This is likely to lead to efforts to bring other novel nicotine products to the market in the future. Such new products, like nicotine-containing heated herbal products are already on sale, for example in some EU Member States. The more nicotine products there are on the market, the more likely are the health hazards caused by nicotine, as described in section 2.

It is possible that some current smokers will switch to nicotine pouches instead of smoking cigarettes for example. Smoking cigarettes introduces not only nicotine but also tar and carbon monoxide into the body, which are substances not known to be contained in nicotine pouches. In this respect, the health hazards can be reduced as compared to smoking. In contrast, using a nicotine pouch raises the level of nicotine in the blood higher than smoking a cigarette. As a result, the health hazards caused by nicotine can 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 the total use rates of various tobacco and nicotine products increase instead. There are indications of this in other Nordic countries, and this would lead to a further increase in health hazards.

Unlike cigarettes, nicotine pouches can be used quite unnoticed and for long periods of time. It is also possible to use several pouches at one time. It is therefore possible that if the use of cigarettes is replaced by the use of nicotine pouches, nicotine exposure, and the following nicotine addiction and other health hazards caused by nicotine, will increase compared to current levels.

If the weight of one nicotine pouch is assumed to be 1 gram, the nicotine limit proposed in the Proposal – a maximum of 20 milligrams of nicotine per gram of product – corresponds to the nicotine limit decided under section 45b of the Chemicals Act, i.e. a maximum of 20 milligrams of nicotine per pouch. However, it is also possible to make nicotine pouches bigger than this, in which case the amount of nicotine contained in one pouch can increase compared to how high it may be today. Due to the harmful nature of nicotine, this would have negative effects on human health.

The Proposal proposes regulation that can be estimated to make nicotine pouches less attractive than they are now, at least for people who do not smoke or use snus. Such impacts could be expected, for example, through the restriction of flavours and the hazard labelling and harmonisation of packaging. 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. As far as nicotine pouches are concerned, it has not yet been studied how warning labels or the harmonised presentation of the packaging are perceived to affect the attractiveness of the product. It can however be assumed that the effects are similar for nicotine pouches as well.

Impacts on children and young people

The Proposal proposes amendments aimed at reducing the attractiveness of nicotine pouches compared to the current situation. It can be estimated that the restriction of flavours, the placement of warning labels, and the harmonisation of the appearance of packaging can reduce the attractiveness of products, at least to some extent and especially among children and young people. In this way, use of the products by youths and the occurrence of life-threatening nicotine poisoning of young children could be regulated. In contrast, the proposed nicotine limit of 20 milligrams of nicotine per gram of product is quite high and may be life-threatening, especially for young children.

By requiring authorisation for the retail sale of smokeless nicotine products, retailers would become known to supervisory authorities, which would make it possible to more effectively control that products are not sold to minors. The use of smokeless nicotine products by young people could probably also be reduced by prohibiting the sale of products to minors outside of the course of trade as well, and by making violations of the prohibition punishable as tobacco sales offences.

The bans on the use of smokeless nicotine products are proposed to protect children and adolescents in particular. The use of smokeless nicotine products would be prohibited for example in school yards, which could contribute to reducing the use of the products among minors. However, bans alone are not enough to prevent youth use, as e-cigarettes have recently become a problem in schools, despite the fact that their use is not allowed in school areas. The proposed bans on the use of smokeless nicotine products, as well as the proposed ban on possession for persons under 18, would still improve the ability of school employees and other adults to intervene in the use of smokeless nicotine products by young people. In addition, a ban for playgrounds could, at least to some extent, prevent toxic nicotine pouches from ending up into areas specifically intended for young children. This could reduce the risk of life-threatening nicotine poisoning.

Impacts on gender equality

In 2020, 7 % of men aged 20 to 64 and 1 % of women of the same age used snus on a daily basis (Tobacco statistics 2021. Statistical report on health and wellbeing 40/2022). In 2021, 2 % of girls and 7 % of boys aged 14 to 20 used snus daily. The use of snus is thus much more common in men and boys than in women and girls.

According to the Healthy Finland survey, 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 in boys than in girls. It can therefore be estimated that the Proposal would impact men and boys more than women and girls.

However, in Sweden the use of nicotine pouches is even more common among girls than boys in some age groups, 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 amendments proposed to reduce the attractiveness of nicotine pouches could therefore potentially prevent the development where nicotine pouches become a trend product specifically among girls.

Impacts on crime prevention

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 result in the establishment of smokeless nicotine products on the Finnish market, demand for snus in Finland may decrease, with the related result that snus-related smuggling and other crime also decrease. There are already indications of this, given that seizures of snus have decreased significantly during the free sale of nicotine pouches in Finland. In contrast, it is possible that the restrictions proposed to 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.

Halving the import limit for snus and other smokeless tobacco products may result in fewer illegal sales of snus in Finland. However, it is possible that while legal passenger imports of snus decrease, illegal imports will increase. This effect is countered by efforts to ensure that the use of nicotine pouches would replace the use and demand of snus.

Impacts on fundamental and human rights

According to section 7 of the Constitution of Finland (731/1999), everyone has the right to life, and section 19, subsection 3 stipulates that the public authorities are obligated to promote the health of the population. The Proposal would support everyone's right to life and the health of the population, especially minors, by imposing various prohibitions and restrictions on nicotine pouches and other smokeless nicotine products. The amendments would make nicotine pouches less attractive than now and raise public awareness of the health hazards 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.

However, the Proposal would establish a new nicotine product on the Finnish market. The Proposal marks a significant change in Finland's tobacco policy so far, which aims to stop the use of tobacco products containing substances toxic to humans and addictive tobacco products and other nicotine-containing products in accordance with section 1 of the Tobacco Act. This may have negative consequences for the achievement of section 7 of the Constitution, especially in the long term.

5 Alternative methods of implementation

5.1 Alternatives and their impacts

According to the Government Programme, only flavours intended for adults are allowed in nicotine pouches. Different ways of achieving this have been considered during the preparation of the Proposal. One option would have been to prohibit characteristic fragrances and flavours in smokeless nicotine-containing products, similarly to cigarettes, roll-your-own tobacco, heated tobacco products, and nicotine-containing liquids. 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.

As a second option, it was considered that provisions would be laid down in the Tobacco Act or pursuant to it that would specify which flavours are considered intended for adults. The advantage of this option would have been clarity: the permitted flavours would have been explicitly listed and all other flavours would have been banned. However, this option was not chosen in order to maintain the premise that all flavours are allowed by default and that prohibited flavours are regulated separately.

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. Setting the nicotine limit to, for example, 4 milligrams per pouch or gram of product would have been rather effective in protecting young children from nicotine poisoning and reducing other health hazards caused by nicotine, but users of snus would not necessarily find such a product attractive enough to start using it. Based on the weighing of the different options, it was concluded for the Proposal that the proposed nicotine limit, i.e. 20 milligrams of nicotine per gram of product, is best balanced 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.

Nicotine pouches have not been considered medicinal products in other Nordic countries. 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, there is no nicotine limit in place for products in Sweden, but this is under consideration. At the same time, the possibility of restricting flavours in nicotine pouches is being investigated.

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 %.

In Denmark, nicotine pouches fall within the scope of the Tobacco Act and they are regulated as tobacco substitutes. It follows, inter alia, that the retail packaging of nicotine pouches is subject to the placement of health warnings and a tax is imposed on nicotine pouches. There is no limit on the nicotine content of the products. In Denmark, e-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. 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 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.

In Iceland, the use of nicotine pouches has increased sharply over the past two years, especially among young people: in 2022, 30 % of men aged between 18 and 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 has not reduced smoking or the use of electronic cigarettes, at least in Sweden, but their use has 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 can be attributed to the fact that the product closely resembles traditional snus, which has been traditionally 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 do not differentiate between the use of snus containing tobacco and nicotine pouches. There is no limit on the nicotine content of nicotine pouches in Estonia.

Belgium is the first EU country planning to ban pouches containing nicotine and cannabinoids. The ban will enter into force in October 2023 and aims to prevent the health damage caused by the use of these new products, the use of such products among young people, and the potential negative effects they may have on reducing 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 total ban on nicotine pouches similar to that of snus. Nicotine pouches could also not be used in places where smoking is prohibited.

In the Czech Republic, nicotine pouches are regulated largely in a similar manner as tobacco and e-cigarette products. The characteristics of nicotine pouches and retail packages, such as the nicotine content, ingredients, and size of the nicotine pouch, as well as the size of the retail packets and the

information and health warnings contained therein, are regulated in accordance with a model provided by tobacco and e-cigarette legislation. In the Czech Republic, nicotine pouches may not contain more than 12 milligrams of nicotine. Products must also be declared in the EU-CEG information system similarly to tobacco and e-cigarette products. The sale of nicotine pouches is also limited to certain places of sale, and nicotine pouches may not be sold to persons under the age of eighteen.

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. Latvia for example is processing a legislative proposal on nicotine pouches setting a nicotine content limit of 4 mg. The legislative proposal also introduces general provisions for nicotine pouches similar to those for tobacco products and e-cigarettes, including for example product declarations, health warnings, restrictions on the sizes of nicotine pouches and their packaging, age limits for sales, restrictions on distance selling, marketing and display bans, and a ban on the use of products in the areas of educational establishments. The legislative proposal has already passed two of the three required consideration rounds. Lithuania has also been preparing a draft law introducing a 4 milligram nicotine limit, but the proposal has so far not progressed. Hungary is in the process of preparing a draft law proposing a restriction of 17 milligrams on the nicotine contents of nicotine pouches.

The use of nicotine pouches in adults aged 18 or over in the UK increased between 2020 and 2021, but remains very low (0.3 %). 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.

6 Feedback from consultation

To be added later.

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 terms of its intended use corresponds to the tobacco products referred to in paragraphs 10 to 12, i.e. chewing tobacco, nasal tobacco, and tobacco for oral use, and to which nicotine has been added. 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 should not therefore be limited to nicotine pouches, because, like snus, it is also possible to sell tobacco substitutes similar to it not only in sachets but also in loose form. It is also justified that the definition should also cover tobacco substitutes which in terms of their use correspond to chewing tobacco and nasal tobacco, even though such products, at least as far as is known, are not yet 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 addition of nicotine to the product. 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.

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.

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 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 of the section, a smokeless nicotine product could contain a maximum of 20 milligrams of nicotine per gram of product. How much nicotine a single nicotine pouch could contain would thus depend on the weight of the pouch. 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 2 of the section, a smokeless nicotine product could not feature the flavour of alcohol or cannabis or flavours that are likely to attract young people. It is clear that the latter would include at least the flavours of sweets, desserts, fruits, and berries, and the flavours of alcohol and cannabis would additionally be mentioned separately in the provision. Attractiveness should be assessed from the point of view of which flavours typically appeal to young people. For example, sweet and sour flavours would be included here, as would flavours that aim for shock value or funniness.

It is proposed to provide in subsection 3 that the provisions of section 11, subsection 1, paragraphs 2, 3, 6 and 7 apply also 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.

Smokeless nicotine products could not contain additives that contribute to nicotine absorption. For example, additives that increase the pH of a product would be prohibited, because the more alkaline a product is, the more nicotine is absorbed from the product and into the mucous membranes of the mouth. However, an exception to this would be additives to create the taste of menthol in the product.

Smokeless nicotine products containing flavourings that can alter the smell 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.

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

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 a statement 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 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 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 social media channels, for example, could not be considered as 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. Fur-

thermore, 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 retail packets of smokeless nicotine products, and the proposed regulation to the Tobacco Act would not interfere with this labelling.

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 could not be distinguished by its shape, colour, surface, or other appearance element from other smokeless nicotine products, and its appearance should not 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, that, for example, nicotine pouches are not made heart-shaped, that no glitter is added to nicotine pouches, and that no other similar efforts are made to increase their attractiveness.

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. Regulatory authorities have in practice considered that such declarations may be subject to fees. 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. Even if it is not proposed to ban characteristic fragrances or flavours in smokeless nicotine products, but rather to restrict flavours differently, it would still be justified to ban flavouring products in the same way as for tobacco products, as existing regulations could otherwise be circumvented.

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 to sales and other transfers in the course of trade but also outside of it. 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 ac-

tivity. 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 to include smokeless nicotine products. This would be necessary to protect the health of minors and consistent with the proposed ban on the possession of smokeless nicotine products by persons under the age of 18.

Section 63 *Prohibition on imports of certain smokeless tobacco products.* It is proposed to amend subsection 2 so that the quantitative limits for passenger imports of smokeless tobacco products laid down therein would be lowered from 1 000 g to 500 grams per day. In the future, a private individual would thus be allowed to bring in a maximum of 500 grams of snus, chewing tobacco, and nasal tobacco to the country for personal use in one calendar day.

The quantitative limits for imports of smokeless nicotine products would be laid down in section 67.

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 the paragraph, private individuals would not be allowed to import more than 500 grams of smokeless nicotine products whose unit packets are labelled differently than what is provided for in section 39a, subsection 1, paragraph 5. The restriction would apply to products whose unit packets do not contain warning labelling 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.* It is proposed that paragraph 2 of subsection 1 of the section is amended so that the municipality could also charge a fee in accordance with the charge it has approved when the declaration referred to in section 48 has been 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 placing smokeless nicotine-containing liquids for sale.

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.

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. These are toxic and highly addictive products, the sale of which to minors should be punishable not only in the course of business but also in transactions taking place between private individuals.

Paragraph 2 of this section would remain unchanged.

According to paragraph 3, a person who deliberately 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 in violation of section 48 should be convicted of a tobacco sales offence.

According to paragraph 4, a person who deliberately sells or otherwise distributes tobacco products, nicotine-containing liquids, or smokeless nicotine products in wholesale in violation of section 60 to operators other than ones referred to in that section should be convicted of a tobacco sales offence.

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.

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 the future, persons under the age of 18 could not possess smokeless nicotine products, which are toxic and cause addiction. A violation of the prohibition on possession is not proposed to be treated as a criminal offence, but, as a result of the ban on possession, bringing smokeless nicotine products into certain educational institutions 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 Train-

ing (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 could take possession of smokeless nicotine products possessed by a student. The ban also supports decision making of entities dealing with children and young people, such as sports clubs, 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

Section 25a of the proposed Act would include granting a new power to issue decrees to the Ministry of Social Affairs and Health, according to which a decree of the Ministry of Social Affairs and Health could provide more detailed provisions on flavours that are likely to attract young people. This is a technical regulation at the decree level, and, because of its level of detail, it is suitable for adoption by ministerial decree. The adoption of a ministerial decree would also make it possible to react more quickly to new flavours entering the market if necessary.

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.

9 Entry into force

It is proposed that the Act enter into force as soon as possible. The current state of affairs poses risks that pose a threat to public health and, in particular, to the health of children and young people.

However, it is proposed that section 25a on the characteristics of smokeless nicotine products, section 39a, subsection 1 on mandatory labelling of unit packets, section 58 on the prohibition of distance selling, and section 65 on imports of products obtained by distance communication enter into force six months after the entry into force of the proposed Act. The nicotine content of nicotine pouches has already been restricted under section 45b of the Chemicals Act, and the decision is valid until further notice. Within the proposed six-month period, operators would be able to sell out their stocks of products that are in breach of the proposed sections 25a and 39, subsection 1. In addition, regulations on flavour restrictions and labelling that have to be declared under the TRIS Directive could be prepared during this period.

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 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 passes on smokeless nicotine products in wholesale would be required to submit the declaration referred to in section 50 within three months of the entry into force of the proposed Act. The provisions of the introductory paragraph of section 60, subsection 2 notwithstanding, it would be allowed in wholesale to sell and otherwise pass on 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 could prove that the application or declaration 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.

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 are coming into the scope of the Act on Tobacco Tax, which may have an impact on product demand. Therefore, it is not possible to make precise estimates on what changes in the demand for e.g. nicotine pouches are due to the changes proposed in this 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 would not be allowed to possess or import smokeless nicotine products. Age restrictions on possession and imports may be regarded as restrictions of a type of a person's right to self-determination, in addition to which they are relevant in respect of the equality principle provided for in section 6 of the Constitution. However, the proposed restrictions are supported by strong health policy arguments, as they would protect children and young people especially, who are particularly vulnerable to the harmful effects of smokeless nicotine products, from the health hazards caused by such products. The proposed prohibition is therefore justified and

would contribute to 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 central practical importance of the ban on possession is primarily linked to the fact that, for example, legislation on educational institutions allows the seizure of smokeless nicotine products from students during the school day.

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 health hazards caused by nicotine, it can be considered that the proposed obligation to place health warning labels on the unit packets of smokeless nicotine products is acceptable, in particular from the point of view of the promotion of public health, and that the obligation is not unreasonable from the point of view of the freedom of expression of traders.

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. The proposed regulation is therefore required by a pressing social need and would fulfil the obligation of the public authorities to promote public health, 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). Due to the opinion 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 should also be harmonised by 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 pro-

tected 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. For example, the presentation of figurative marks and figurative marks containing words or letters on packaging would be completely prohibited. The proposed regulation would therefore constitute a restriction on the right of the trademark proprietors to exploit that property in their commercial activities.

The aim of the harmonisation regulation is to reduce the attractiveness of products and their packaging and thereby reduce the uptake of smokeless nicotine products, especially among young people. Studies have shown that legislation on the harmonisation of unit packets for tobacco products has had such effects in other countries. A further aim is to not mislead the consumer by means of attractive packaging in terms of the harmful health effects of the product.

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. The proposed regulation is therefore required by a pressing social need and implements the right to life laid down in section 7 of the Constitution and the obligation of the public authorities to promote public health 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 weighty public health grounds for the restriction, in particular as regards the protection 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 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 to make the retail sale of smokeless nicotine products subject to licence and wholesale sales subject to declaration, which constitutes a restriction on the freedom of operators to conduct a 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 licencing for retail sales and the requirement to declare for wholesale would be applicable to smokeless nicotine products. Municipalities would not make decisions on the basis of the wholesale declaration, but failing to declare would result in a prohibition on carrying out the activity. 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 from a retailer of smokeless nicotine products if the licensee violated 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.

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

By decision of Parliament,

paragraph 1 of section 6, subsection 1 of section 22, subsection 3 of section 30, section 31, the introductory paragraph to section 40, subsection 1 of section 44, the title and subsection 1 of section 48, subsection 1 of section 50, section 52a, subsection 1 of section 53, sections 58 and 59, paragraph 1 of subsection 2 and subsections 3 and 4 of section 60, section 62, subsection 2 of section 63, sections 65 and 66, paragraph 3 of subsection 1 of section 67, subsection 3 of section 74, section 81, paragraph 2 of subsection 1 and paragraph 3 of subsection 3 of section 90, subsection 2 and the introductory paragraph and paragraph 5 of subsection 4, subsections 2 and 3 of section 90, subsections 2 and 3 of section 94, paragraphs 1, 2, and 6 of subsection 1 of section 97, the introductory paragraph and paragraph 3 of subsection 1 of section 100, section 109, subsection 2 of section 113, and sections 117, 118, 119 of the Tobacco Act (549/20),

as the introductory paragraph of section 40 is amended in Act 136/2022; as sections 52a, 58, 65, and subsection 3 of section 74, the introductory paragraph and paragraph 5 of subsection 4 of section 91, subsection 3 of section 94, and section 117 are amended in Act 283/2022; subsection 4 of section 60, subsection 2 of section 63, paragraphs 1, 2, and 6 of subsection 1 of section 97, and section 109 are amended in Act 1374/2016; subsection 2 of section 94 is amended in Act 701/2018; the introductory paragraph to subsection 1 of section 100 and section 3 are amended in Act 262/2022; and section 119 are amended in Act 248/2019; are *amended* 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* means a tobacco substitute that in respect of its intended use corresponds to the tobacco products referred to in paragraphs 10 to 12 and to which nicotine has been added;

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 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

A smokeless nicotine product may contain no more than 20 milligrams of nicotine per gram of product.

A smokeless nicotine product may not have the flavour of alcohol or cannabis or a flavour that is likely to attract young people.

The provisions of paragraphs 2, 3, 6, and 7 of subsection 1 of section 11 also apply to smokeless nicotine products. However, the provisions of this subsection above on the application of paragraph 6 of subsection 1 of section 11 to smokeless nicotine products do not apply to additives creating the taste of menthol in the products.

More detailed provisions on flavours that are likely to attract young people may be laid down by a decree of the Ministry of Social Affairs and Health.

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 effects;
- 4) information on the dosage and absorption of nicotine when the product is used under normal or reasonably foreseeable conditions;
- 5) a statement that the manufacturer or importer bears full responsibility for the quality and safety of the product when it is placed on the market and 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 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.

With the exception of paragraphs 2, 5, and 8, the provisions of section 33 also apply to unit packets of smokeless nicotine products.

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;
- 3) 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 must not differ in shape, colour, surface, or other appearance element from other smokeless nicotine products, and the appearance elements must not 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

No tobacco products, nicotine-containing liquids, or smokeless nicotine products may be imported by a person under 18 years of age.

Section 63

Prohibition on imports of certain smokeless tobacco products

The provisions of subsection 1 notwithstanding, a private individual may import a maximum of 500 grams of the tobacco products referred to in subsection 1 per calendar day for their own personal use.

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 bulk of plant-based products intended for smoking, the labelling of which differs from that provided for in section 39, subsection 1;

4) more than 500 grams of smokeless nicotine products whose unit packet labelling differs 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:

2) the processing of a declaration 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 passes on 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;

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, nicotine-containing liquid or smokeless nicotine product.

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 the day of the month in the year 20 . However, section 25a, subsection 1 of section 39a, and sections 58 and 65 of this Act will 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 will enter into force one year after 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 passes on smokeless nicotine products in wholesale must submit the declaration referred to in section 50 within three months of the entry into force of this Act. The provisions of the introductory paragraph of section 60, subsection 2 notwithstanding, it is permissible in wholesale to sell and otherwise pass on smokeless nicotine products for resale for a period of three months from the entry into force of this Act, and, paragraph 1 of this 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 declaration referred to in that paragraph.
