

Government proposal to Parliament for an Act amending the Tobacco Act

4 Proposals and their impacts

4.1 Main proposals

The Proposal proposes that a definition of a smokeless nicotine product be added to the Tobacco Act. It would cover not only nicotine pouches but also products that do not contain tobacco 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, and the smokeless nicotine products would be prohibited from having alcohol or cannabis flavouring, as well as flavours likely to attract young people. A decree of the Ministry of Social Affairs and Health could provide more detailed provisions on flavours that are likely to attract young people.

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

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

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

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

4.2 Principal impacts

4.2.1 Economic impact

General

The proposed amendments would extend the scope of the Tobacco Act to nicotine pouches and other smokeless nicotine products. Since Fimea changed its interpretation on the applicability of the Medicines Act to nicotine pouches in spring 2023, it has been widely known that new legislation on nicotine pouches is being prepared. It is possible that when the proposal causes nicotine pouches to become established on the Finnish market and the uncertainty about future regulation dissipates, new nicotine pouch entrepreneurs and new nicotine pouch brands will enter the market and the demand for products will increase compared to the present demand.

At the same time, the Proposal proposes various restrictions on the characteristics, packaging and sale of nicotine pouches and new obligations for manufacturers and importers of the products. The proposed regulation may lead to a reduction in the nicotine pouch market compared to the current situation. Nicotine pouches have been available for such a short time that accurate information is not available even on the current situation. Therefore, only various qualitative assessments can be made on the direction of the impacts of the proposed regulation as a whole, or various scenarios can be identified.

Impacts on the position of households

Cigarette packets cost more than EUR 10 on average, while one packet of nicotine pouches currently costs between EUR 5 and EUR 7, based on data from the Ministry of Finance, and after the planned tax increases, around EUR 7.40–9.70. If smokers switch to nicotine pouches instead of cigarettes and use nicotine pouches at the same rate as cigarettes, they will spend less on the products and have more money for other uses. The Proposal may therefore have a positive impact on the position of households. On the other hand, 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. Since income- or population-specific data on consumption of nicotine pouches is not available, it is not possible to directly assess how the proposed changes will affect different income groups.

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

Impact on companies

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

The proposed changes would affect manufacturers and importers of smokeless nicotine products, as well as retailers and wholesalers. Manufacturers and importers of smokeless nicotine products would incur direct costs, for example, from submitting product notifications, as they would be subject to a fee. In addition, they would need to pay an annual supervisory fee based on the sales volumes of their products. Costs would also arise from bringing unit packets in line with the proposed regulation.

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

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

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

Administrative costs would also be incurred by the updating of the self-monitoring plan and of the related IT systems. It is therefore possible that some of the current retailers will discontinue the sale of nicotine pouches as a result of the proposed amendments. Just like other tobacco alternatives, smokeless nicotine products may not currently be displayed in retail outlets nor be sold to minors, and therefore, retailers would not incur any additional costs for age-limit controls, for example.

As a result of the ban on distance selling of smokeless nicotine products, operators that have sold nicotine pouches on the internet would have to change or cease their activity. It is not known how many Finnish companies sell nicotine pouches exclusively or mainly on the internet.

Effects on public finances

The Proposal proposes amendments that aim to steer snus users to switch to nicotine pouches. If this objective is met, the amendments will have a positive impact 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 nicotine pouches, public spending on treatment of tobacco-related diseases 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, in addition to these reductions in direct costs, indirect costs, such as production input losses caused by smoking-related deaths and going on disability pension, as well as labour input losses caused by sickness leave and smoking breaks, which are, not included in statutory breaks, could also decrease. The Finnish Institute for Health and Welfare (THL) estimates that in 2020, the direct and indirect costs of smoking in Finland amounted to approximately EUR 1.3 billion.

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

It should also be borne in mind that the use of a nicotine pouch cannot be said to be unequivocally less harmful than smoking cigarettes, as studies have shown that the nicotine pouch raises the level of nicotine in the blood even higher than a cigarette. On this basis, it can be assumed that if smokers move widely to nicotine pouches, 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 after any kind of surgery and prolongs recovery 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 Impact on the activities of public authorities

The Proposal proposes that a decree of the Ministry of Social Affairs and Health could 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 on the market and determining which ones can be considered attractive to young people. It is assumed that, at least initially, the list of prohibited flavours should be updated frequently. Each update would require, in addition to the amendment to the decree, a notification under the TRIS Directive to the Commission and the other EU member states with a waiting period in accordance with the Directive, which means that the response to new flavours entering the market that could attract young people would, in principle, be rather slow. In addition, the restrictions on flavours and the associated ambiguity would burden the authorities supervising the Tobacco Act and possibly also the courts.

The Proposal would increase the work and costs of the authorities supervising the Tobacco Act, in particular municipalities and Valvira, because a whole new group of nicotine-containing products would be subject to supervision. Currently, the municipal authority supervising the Tobacco Act is responsible for ensuring that nicotine pouches, like other tobacco alternatives, are not commercially sold to minors or marketed or displayed in retail outlets. In the future, retail sales of smokeless nicotine products would require a retail licence, and wholesaling would require making a wholesale no-

tification, which would be one of the most significant changes for the municipal supervisory authority. The processing of retail licences and wholesale notifications would require, among other things, that municipalities review and check the legality of self-monitoring plans or their updates of all traders that include nicotine pouches in their selections. This alone can mean going through thousands of self-monitoring plans.

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

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

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

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

Nicotine pouches and their unit packets are similar in appearance to snus. The similar appearance of the products has posed challenges in monitoring compliance with EU-wide bans on the sale of snus and import regulations. The changes proposed in the Proposal would not remove these difficulties, as the authorities supervising sales and imports should continue to seek to assess, on a case-by-case basis, whether a legitimate smokeless nicotine product or illegal snus is in question. However, the

harmonisation of the presentation of unit packets for smokeless nicotine products pursuant to the Proposal could facilitate the distinguishing of the products in the supervision of retail sales.

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

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

4.2.3 Impact on the environment

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

If nicotine pouches becoming established on the Finnish market results in smokers switching to using nicotine pouches instead of smoking cigarettes, the impact on the environment could be somewhat positive. On the other hand, at least some nicotine pouches seem to contain plastic, which means that harmful microplastics can also end up in the environment from the nicotine pouches. In addition, manufacturers and importers of nicotine pouches are not obliged under the Waste Act to organise the waste management of the products nor to bear the related costs. If people who currently use snus switch to nicotine pouches, littering and the resulting problems will probably remain at the same level.

4.2.4 Other social effects

Effects on health

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

It is possible that some of the current smokers will switch to nicotine pouches instead of smoking cigarettes, for example. In addition to nicotine, smoking also causes tar and carbon monoxide to enter the body, which the nicotine pouches do not contain according to current knowledge. In this re-

spect, health hazards can be reduced compared to smoking cigarettes. In contrast, a nicotine pouch raises the level of nicotine in the blood more than a cigarette. As a result, the health hazards caused by nicotine can even increase from the present. In addition, it is possible that the increased use of nicotine pouches will not reduce smoking or e-cigarette use, with the aggregate use of various tobacco and nicotine products increasing instead. There are indications of this in other Nordic countries, and this would lead to health hazards increasing from the current level.

Unlike cigarettes, nicotine pouches can be used quite discreetly and for long periods at a time. Several pouches can also be used at the same time. It is therefore possible that, if the use of cigarettes is replaced by nicotine pouches, nicotine exposure, as well as nicotine addiction and other health hazards caused by nicotine, will increase compared with the present.

If the weight of one nicotine pouch is assumed to be 1 gram, the nicotine limit proposed in the proposal, i.e. 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 larger than this, and the amount of nicotine contained in one pouch can increase compared with how high it is permitted to be today. Due to the harmful nature of nicotine, this would have negative effects on human health.

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

Effects on children and young people

The Proposal proposes changes designed to reduce the attractiveness of nicotine pouches compared to the current state. It can be estimated that the restriction of flavours, warning markings and harmonisation of the appearance of packaging can, at least to some extent, reduce the attractiveness of the products, especially among children and young people. In this way, youth use of the products and the life-threatening nicotine poisoning of young children could be affected. On the other hand, 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 a license for the retail sale of smokeless nicotine products, the supervisory authorities would be aware of the retailers, which would make it possible to control more effectively that the products are not sold to minors. The use of smokeless nicotine products by youths would probably be reduced by prohibiting the sale of products to minors, also in a non-commercial context, and making the violation of the ban punishable as a tobacco sales offence.

Bans on the use of smokeless nicotine products are proposed to protect children and adolescents, in particular. Smokeless nicotine products should not be used, for example, in school yards, which could contribute to reducing the use of products among minors. On the other hand, bans alone are not enough to prevent youth use, as e-cigarettes have recently become a problem in schools, despite the fact that they are not allowed to be used on school premises. However, the proposed bans on the

use of smokeless nicotine products, as well as the proposed ban on possession of smokeless nicotine products for people under 18 years of age, would improve the ability of employees of educational establishments and other adults to intervene in youth use of smokeless nicotine products. In addition, a ban on use at playgrounds could reduce, at least to some extent, the occurrence of toxic nicotine pouches in areas specifically intended for young children. This would reduce the risk of life-threatening nicotine poisoning.

Impact on gender equality

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

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

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

Effects on crime prevention

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

Halving the import limit for snus and other smokeless tobacco products could result in less illegal sales of snus in Finland. However, it is possible that while legal passenger imports of snus decrease, illegal imports will increase. The aim is to counter this effect by the fact that use of nicotine pouches would replace use of and demand for 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 obliged to promote the health of the population. The Proposal would promote everyone's right to life and would support the health of the population, especially minors, by imposing various prohibitions and restrictions on nicotine pouches and other smokeless nicotine products. The changes would make nicotine pouches less attractive than they are today and would 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.

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