

Proposals and their impacts

1.1 Main proposals

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

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

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

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

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

1.2 Principal impacts

1.2.1 Economic impact

General

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

At the same time, the Proposal proposes various restrictions on the characteristics, packaging and sale of nicotine pouches and new obligations for manufacturers and importers of the products. The proposed regulation may lead to a reduction in the nicotine pouch market compared to the current situation. The amendment to the Act on Excise Duty on Tobacco effective from the beginning of 2024 may also reduce

sales of nicotine pouches. Nicotine pouches have been available for such a short time that accurate information is not available even on the current situation. As the availability of nicotine pouches has increased, some tobacco consumption may already have shifted to nicotine pouches. The proposed regulation is likely to reduce this transition, but due to the weak knowledge base, this assessment contains significant uncertainty. Therefore, only various qualitative assessments can be made or various scenarios can be created on the direction of the impacts of the proposed regulation as a whole.

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

Impact on the position of households

Cigarette packets cost more than EUR 10 on average, while the Government's proposal to Parliament for an Act amending the Act on Excise Duty on Tobacco estimates that one packet of nicotine pouches will cost around EUR 7.40–EUR 9.70 after tax increases (see HE 38/2023 vp, p. 8). If smokers switch to nicotine pouches instead of cigarettes and use nicotine pouches at the same rate as cigarettes, they will spend less on the products and have more money for other uses. The Proposal may therefore have a positive impact on the position of households.

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

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

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

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

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

Impact on companies

Nicotine pouches have started to be sold in Finland but no detailed information on the volume of sales is available currently. Companies of different types and sizes appear to be involved. In addition, it is known that nicotine pouches are manufactured by one Finnish company. All the major tobacco companies have their own nicotine pouch brands, but the market shares of the different manufacturers are not known. It is possible that as the requirements for nicotine pouches increase, smaller operators will exit the market and will be

replaced by large companies with experience on the similar regulation of tobacco products. At the same time, it may become more difficult for new, small businesses to enter the market.

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

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

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

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

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

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

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

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

Impact on public finances

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

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

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

It should also be borne in mind that the use of a nicotine pouch cannot be said to be unequivocally less harmful than smoking cigarettes, as studies have shown that the nicotine pouch raises the level of nicotine in the blood even higher than a cigarette. On this basis, it can be assumed that if smokers were to switch widely to nicotine pouches, even more public funds could be needed in future to deal with the health harms caused by nicotine. There is clear evidence, for example, that nicotine increases the risk of complications after any kind of surgery and prolongs recovery and hospital stays.¹ In addition, nicotine increases the risk of mental health problems in young people², which can have long-term economic effects.

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

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

¹ Kyrö, Antti; Koljonen, Virve (2022) 'The effect of smoking on surgical patients and on the results of surgery' (Finnish: Tupakoinnin vaikutus leikkauspotilaisiin ja leikkaushoidon tuloksiin). In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. 'Tobacco and nicotine addiction' (Finnish: Tupakka- ja nikotiiniriippuvuus). Helsinki: Duodecim, 2022, 225–228 and Kyrö, Antti; Koljonen, Virve (2022) 'The effects of quitting smoking on the results of surgical treatment' (Finnish: Tupakoinnista vieroituksen vaikutukset leikkaushoidon tuloksiin). In the work by Heloma A., Korhonen T., Patja, K., Salminen O., Winell, K. 'Tobacco and nicotine addiction' (Finnish: Tupakka- ja nikotiiniriippuvuus). Helsinki: Duodecim, 2022, 258–259

² For example, Leslie FM. Unique, long-term effects of nicotine on adolescent brain. *Pharmaceutical Biochemistry and Behavior*. 2020 Oct 1;197:173010. <https://doi.org/10.1016/j.pbb.2020.173010>

1.2.2 Impact on the activities of public authorities

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

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

The changes proposed in the proposal would increase the work of the authorities. However, the proposal does not propose adding new man-years for the supervisory authorities, and it would be possible to carry out controls and other new tasks within the limits of existing human resources and budgets, as well as the revenue received from control fees.

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

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

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

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

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

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

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

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

1.2.3 Impact on the environment

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

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

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

Nicotine is toxic to aquatic organisms and can cause long-term adverse effects in watercourses.³ The most abundant litter on Finnish beaches is cigarette butts, and in 2023 nicotine pouches were already among the five most common types of litter found on beaches⁴, despite the fact that the sale of nicotine pouches was not liberalised until April 2023. The possible increase in the use of nicotine pouches as a result of the changes proposed in the Proposal can therefore be harmful to watercourses and their organisms.

There is limited data on nicotine toxicity to wild mammals. Laboratory studies on nicotine toxicity have been conducted on several mammalian species, in particular rats and mice, and signs of toxicity, cell mutation,

³ Finnish-language Chemical Safety Card for nicotine, Finnish Institute of Occupational Health, 2024

⁴ Helsingin Sanomat 12 February 2024: 'Bottle caps poking in your face are annoying – There is actually a good reason for them' (Finnish: Naamaan törröttävät korkit ärsyttävät — Oikeasti niille on hyvä syy), <https://www.hs.fi/kotimaa/art-2000010192136.html>, accessed 12 March 2024, and the Finnish Environment Institute's beach litter monitoring

reproductive effects and behavioural changes in rodents have been observed. Rodents are often an important part of the food chain, so rodent-eating animals may be potentially exposed to the harmful effects of nicotine.⁵

The toxicity of nicotine to dogs and cats has been studied more. In dogs and cats, the deadly dose of nicotine has been estimated to be at least 20–100 milligrams.⁶ However, presumably the weight of the animal determines how much nicotine is lethal. If the changes proposed in the Proposal increase the use of nicotine pouches, pets could be exposed to more nicotine pouches than at present, which would have negative effects on animal health.

1.2.4 Other social effects

Effects on health

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

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

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

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

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

The Proposal proposes regulation that is estimated to make nicotine pouches less attractive than at present at least for people who do not smoke or use snus. The restriction of flavours and the labelling and harmonisation of packaging would be expected to have such effects, for example. There is scientific evidence that the harmonisation of packaging for tobacco products reduces the attractiveness of the product and increases the visibility of warning labels.⁷ As far as nicotine pouches are concerned, there are no known

⁵ Beutel, M.W.; Harmon, T.C.; Novotny, T.E.; Mock, J.; Gilmore, M.E.; Hart, S.C.; Traina, S.; Duttgupta, S.; Brooks, A.; Jerde, C.L.; et al.: A Review of Environmental Pollution from the Use and Disposal of Cigarettes and Electronic Cigarettes: Contaminants, Sources, and Impacts, p. 12, Sustainability 2021, 13, 12994, with reference to Cardoso, L.S.; Estrela, F.N.; Chagas, T.Q.; Da Silva, W.A.M.; Costa, D.R.D.O.; Pereira, I.; Vaz, B.G.; Rodrigues, A.S.D.L.; Malafaia, G. The exposure to water with cigarette residue changes the anti-predator response in female Swiss albino mice. Environ. Sci. Pollut. Res. 2018, 25, 8592–8607

⁶ Nicole C. Hackendahl, DVM, and Colin W. Sereda, DVM: The dangers of nicotine ingestion in dogs ASPCA Pro Veterinary Medicine Toxicology Brief, p. 220, March 2004, and references therein

⁷ Moodie C, Hoek J, Hammond D, et al. Plain tobacco packaging: progress, challenges, learning and opportunities. Tobacco Control 2022;31:263–271 and the World Health Organization. Plain packaging of tobacco products: evidence,

studies investigating how the warning labels or the harmonised appearance of the packaging affect the attractiveness of the product. However, it is assumed that the effects are similar for nicotine pouches.

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

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

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

Impact on children and young people

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

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

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

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

Bans on the use of smokeless nicotine products are proposed to protect children and adolescents, in particular. Smokeless nicotine products should not be used, for example, in school yards, which could contribute to reducing the use of products among minors. However, bans on use alone are not enough to

design and implementation. Geneva: World Health Organisation 2016

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

Exposure to nicotine and tobacco smoke during pregnancy and while breastfeeding is detrimental to the child's development. When a mother smokes, the levels of nicotine and carbon monoxide in the blood of the foetus are about 15 % higher than the mother's. Maternal smoking during pregnancy has been found to cause significant foetal harm, including a higher risk of miscarriage. There is also an increase in cot death and many long-term harms to the health of the child. There is clear evidence of nicotine causing foetal harm in animals, but there are currently insufficient epidemiological studies in humans.⁸

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

Impact on gender equality

In 2020, 7% of men aged 20–64 and 1% of women of the same age used snus on a daily basis.⁹ In 2021, 2 % of girls aged 14–20 and 7 % of boys used snus daily. The use of snus in Finland is much more common in men and boys than in women and girls. In addition, according to the Healthy Finland study, nicotine addiction is most common among men of low socio-economic status.

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

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

Impact on crime prevention

The sale of snus is prohibited and punishable as a tobacco sales offence, the importation of the product is restricted, and unlawful importation is punishable as a smuggling offence. Despite this, snus is imported and sold in Finland, as there are few resources to enforce such prohibitions and restrictions. If the proposed amendments in the Proposal result in smokeless nicotine products becoming established on the Finnish market, demand for snus in Finland may decrease, with the result that snus-related smuggling and other offences are expected to decrease. There are already indications of this, because, as stated in section 2.1.2,

⁸ Tikkanen M. 'Smoking and Pregnancy' (Finnish: Tupakointi ja raskaus). The medical journal Duodecim. 2008;124(11):1224-9 and the National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health. Chapter 9. Reproductive outcomes. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta (GA): Centers for Disease Control and Prevention (US); 2014. <https://www.ncbi.nlm.nih.gov/books/NBK179276/>

⁹ Tobacco Statistics 2021, 'Statistical report on health and well-being' (Finnish: Terveysten ja hyvinvoinnin tilastoraportti) 40/2022

seizures of snus have clearly decreased during the period when nicotine pouches have been freely marketed in Finland. However, it is possible that the more stringent provisions of the Proposal regarding the sale and properties of smokeless nicotine products will reduce demand for nicotine pouches and increase demand for snus, in which case the Proposal would not have a positive impact on crime prevention.

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

Impact on fundamental and human rights

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

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