Impact assessment

The purpose of the draft law is to protect public health interests, especially that of children and young persons establishing stricter regulation regarding tobacco and nicotine-containing products, reducing their availability and attractiveness among children and young consumers, with due regard to the harm caused by their consumption to health and the national economy of Latvia as a whole.

According to research data on smoking habits carried out by the Centre for Disease Prevention and Control (hereinafter — SPKC), traditional tobacco products smoking rates have been decreasing in Latvia in recent years among adults (at varying frequencies). At the same time the use of novel tobacco and nicotine products such as electronic cigarettes, heated tobacco, nicotine pouches etc. has increased (at varying frequencies). At the same time the smoking of tobacco products (including trying out) has been decreasing in recent years among schoolchildren, while the smoking of electronic cigarettes (both trying out and daily use) has increased. According to the data of the 2022 study on habits affecting the health of the population of Latvia,¹ 29 % of the population aged 15-74 years smoked tobacco products (excluding heated tobacco) on a daily basis in 2022. This indicator has increased compared to the data of the 2020 study,²which was 23 %. At the same time it should be stressed that since 2016 the proportion of daily smokers of tobacco products (excluding heated tobacco) in Latvia has decreased by 10 percentage points compared to 2020.³

At the same time it should be stressed that according to the 2022 study on habits affecting the health of the population of Latvia,⁴ the share of electronic cigarette smokers among men and women has increased significantly since 2020. The share of daily smokers of electronic cigarettes among men has more than doubled in 2022 compared to 2020 (from 2 % to 5 %) and among women there is a 13-fold increase — from 1 % to 13 %. The largest increase is among non-daily smokers of electronic cigarettes: In 2022 it increased from 8 % to 30 % for men compared to 2020, while for women the rate had gone up from 7 % to 23 %.

According to the study conducted by the SPKC in 2022, what concerns the use of tobacco substitute products - nicotine pouches,⁵ 3 % of the population

¹2022 study on habits affecting the health of the population of Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/18708/download?attachment

² 2020 study on habits affecting the health of the population of Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/16574/download

³ 2020 study on habits affecting the health of the population of Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/16574/download

⁴ 2022 study on habits affecting the health of the population of Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/18708/download?attachment

⁵ 2022 study on habits affecting the health of the population of Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/18708/download?attachment

have tried out nicotine pouches once. Compared to 2020 data, the proportion of persons that have tried out nicotine pouches has increased by one percentage point. According to the 2022 study conducted by the SPKC,⁶ the highest proportion of users of nicotine pouches is observed among younger age groups. The pouches are primarily tried out and consumed by young men aged 15–24. Nicotine pouches have been tried out by 11 % of young men aged 15–24, which is a two-fold increase compared to 2020.

What concerns the spread of the use of tobacco products, smoking of electronic cigarettes and tobacco substitute products among children and young people, currently there is access only to data from the SPKC study 2019. The data of the present study on children and young people will be available only in 2024. Notwithstanding the above, according to a report by the SPKC⁷ since 2011 the proportion of young people aged 13–15 who smoked traditional tobacco products has decreased by 18 percentage points compared to 2019 and has reached 23 %.⁸ Tobacco smoking has significantly decreased among both boys and girls in all age groups.⁹ However at the same time since 2011 the proportion of smokers of electronic cigarettes who have tried these products has doubled among 13–15 year-olds from 20 % in 2011 to 51 % in 2019.¹⁰ We hereby point out that in 2019, compared to studies carried out in previous years, the prevalence of electronic cigarettes use was higher than that of tobacco cigarettes among 13–15 year-olds in the given year.¹¹

Taking into account the results of studies indicating the increase in trying out and use of novel nicotine-containing products in Latvia's population, especially among young consumers, and considering the recommendations of the World Health Organisation (hereinafter — WHO) that it is essential to implement a comprehensive smoking control policy at a national level in order to reduce not only the prevalence of tobacco smoking, but also the formation of nicotine addiction in society, Latvia has developed a draft law. The abovementioned law was drafted in 2021 by the members of the 13th Saeima. The draft law was approved by the 13th Saeima in two readings, however taking into account the parliamentary elections of 2022 and the end of the term of office of the previous Saeima, the drafting of the law was taken over by 14th Saeima. The draft law has already been adopted by the 14th Saeima in two readings. The second reading of the draft law was completed on 23 March 2023. The revision of draft law proposals intended for the 3rd reading was closed on 13 June 2023.

⁶ 2022 study on habits affecting the health of the population of Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/18708/download?attachment

⁷ https://www.spkc.gov.lv/lv/atkaribu-slimibas#smekesanas-izplatiba

⁸ Global Youth Tobacco Survey, 2018/2019 school year, Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/4339/download

⁹ Global Youth Tobacco Survey, 2018/2019 school year, Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/4339/download

¹⁰ Global Youth Tobacco Survey, 2018/2019 school year, Latvia. Centre for Disease Prevention and Control https://www.spkc.gov.lv/lv/media/4339/download

¹¹ https://www.spkc.gov.lv/lv/atkaribu-slimibas#smekesanas-izplatiba

Regulatory framework for tobacco substitute products

The draft law intends to define a legal framework (handling requirements and restrictions) for tobacco substitute products (e.g. tobacco-free nicotine pouches), given that tobacco-free nicotine pouches and other tobacco substitutes are neither regulated by the Tobacco Law nor the EU legislation – Tobacco Directive 2014/40/EU.¹² The draft law contains a definition of tobacco substitute products, covering tobacco-free nicotine pouches and other tobacco substitute products currently placed on the market and that could potentially enter the market. The draft law obliges manufacturers and importers to specify the composition of the tobacco substitute product, while sellers of tobacco substitute products are required to report their points of sale to the competent authority, the Health Inspectorate. The draft law also foresees specific composition requirements for tobacco substitute products to be placed on the Latvian market, including the maximum admissible nicotine concentration of 4 mg per g, restrictions on additives, including a restriction on the added flavourings, with the exception of flavours which produce the odour or taste of tobacco. The draft law also foresees a prohibition of sales to minors, including sales by means of distance communication, including distance contracts, restrictions on advertising and sponsorship, including restrictions on visible placement of tobacco products in retail stores. The draft law also requires placement of a mandatory health warnings on tobacco substitute products.

The necessity for such amendments to the draft law is based on the fact that tobacco-free nicotine pouches are a new product and thus, product-related information is limited, including independent clinical studies on the short and long-term health effects of such products. Tobacco-free nicotine pouches contain nicotine. Nicotine is a toxic substance that affects cardiovascular, reproductive, peripheral and central nervous systems. The use of products with high nicotine concentrations also significantly increase the risks of nicotine poisoning and overdose. The health effects of nicotine have been sufficiently studied and scientifically substantiated and the absorption, acute toxicity and long-term health effects of nicotine are well known.¹³ Moreover nicotine is also a psychoactive substance with high potential of addiction particularly among children and adolescents, as well as non-smokers. Nicotine addiction affects the mental health of children and adolescents. For adults it leads to a long-lasting addiction that is not easy to break. Nicotine pouches that are currently available on the Latvian market have attractive sales packaging, contain flavourings and are relatively easy to use, what encourages specifically non-smokers and youth to try and use them. These products therefore have a particularly high addiction

¹² https://health.ec.europa.eu/system/files/2016-11/dir_201440_en_0.pdf

¹³ https://www.spkc.gov.lv/lv/nikotins-un-nikotina-saindesanas-simptomi

potential, as non-smokers and vulnerable social groups (adolescents and young people) are tempted to try the product and start using it.

When drafting the law, the experience of other EU countries was taken into account to regulate tobacco substitute products at national level. Given the lack of sufficient scientific studies on the effects of such products, only few EU countries have introduced a regulation or restrictions on tobacco substitute products (including tobacco-free nicotine pouches). National regulation on tobacco substitute products is currently in place in Denmark, the Netherlands, Belgium, the Czech Republic and Germany. Only few EU countries have set limits on the nicotine concentration in pouches – the Netherlands¹⁴ and Germany¹⁵have imposed a ban for the placement on market of nicotine pouches containing more than 0.035 mg of nicotine. Moreover instead of introducing a regulation, Belgium intents to prohibit the placement of such products on the market¹⁶. Finland, which has an effective regulation of tobacco-free nicotine pouches, including nicotine concentration, intends to amend its Tobacco-free nicotine pouches in Finland.

In view of the above, and in order to prevent significant health risks, the draft law contains a regulation for this product group, setting the maximum nicotine concentration as low as possible (not exceeding 4 mg per g), which is in line with similar nicotine-containing medicinal products (nicotine chewing gums) used for long-term smoker addiction treatment. Meanwhile there is lack of studies and evidence to prove that nicotine pouches with higher nicotine concentrations pose no significant health risks, by introducing the regulation Latvia intends to apply the public health protection principle and to set such nicotine concentration levels that are studied on equivalent products and pose lowest possible health risks. There is extensive research and evidence based data on nicotine-containing medicinal products and smokeless tobacco products (tobacco for oral use) that are used the same way as tobacco-free nicotine pouches (orally). Comparative studies on the health effects of these products that are available in research databases show high absorption of nicotine through oral mucosa during the use of these products. The formation of addiction is related to the concentration of nicotine in the blood, which depends on the dose of nicotine in the consumed product. Clinical studies on nicotine addiction conducted by medical companies have concluded that products with nicotine concentrations below 4 mg have a low risk of forming a nicotine addiction.

The draft law also provides for a transition period for the introduction of the new requirements for tobacco substitute products, with the new handling requirements coming into force on 1 January 2025.

¹⁷ https://api.hankeikkuna.fi/asiakirjat/7321ad5b-cb05-42a5-9657-30262961158d/265cea7e-3bfe-4e7c-afa5-d45fca46d01a/ LAUSUNTOPYYNTO_20230419135642.PDF

¹⁴ <u>https://bnn.network/breaking-news/dutch-government-bans-sale-of-nicotine-pouches-and-tightens-tobacco-rules/</u>

¹⁵ https://tobaccointelligence.com/banned-as-a-novel-food-one-day-tobacco-might-be-accepted-as-a-super-food/

¹⁶ http://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel

Establishing a regulatory framework for electronic heating devices and heated herbal products for smoking

Currently the Tobacco Law and the EU Tobacco Directive 2014/40/EU do not regulate tobacco heating devices (e.g. IQOS). Tobacco Directive 2014/40/EU and the Tobacco Law only regulate heated tobacco products which are used in tobacco heating devices. Given that tobacco heating devices (such as IQOS) in Latvia are not defined and regulated they are not subject to any restrictions on handling, sale, advertising and sponsorship laid down in the Tobacco Law, i.e. there is no ban on the sale of these products by distance contract, no ban on selling to minors, the sellers may offer free trials and promote the products and there is no prohibition on visible demonstration of such devices in retail stores etc. In view of the above, the draft law aims to impose on tobacco heating devices the same regulation that is applied to other electronic smoking devices regulated under the Tobacco Law by incorporating a definition of electronic heating devices. The WHO report on novel and emerging tobacco products (heated tobacco products)¹⁸ published in 2021 at the 9th Session of the Conference of the Parties (COP9) to the WHO Framework Convention on Tobacco Control also stressed that the regulations and restrictions, including bans, on heated tobacco products should also apply to the heated tobacco device itself, given that the device is used as an indirect means to promote heated tobacco products.

Moreover new herbal products for smoking that can be used in tobacco heating devices have been commercialised in the European Union.¹⁹ The current definition contained in the Tobacco Law and Tobacco Directive 2014/40/EU states that herbal products for smoking can only be used via a combustion process and thus herbal products for smoking that are used in electronic heating devices and heated do not fall under this definition. In consideration of the previously stated and along with new trends in product development, the draft law aims to amend the current definition of herbal products for smoking contained in the Tobacco Law and extend the regulation and restrictions to herbal products for smoking that can be heated. The draft law also provides for a transition period for the introduction of the new requirements, stipulating that

¹⁸ <u>https://untobaccocontrol.org/downloads/cop9/main-documents/FCTC_COP9_9_EN.pdf</u>

¹⁹ Advertisement of herb-based product heating devices <u>https://www.lazada.com.ph/products/menthol-healcier-botanical-heated-healthier-</u> <u>stick-i303638658-s554470391.html?</u>

spm=a2o4l.pdp.recommendation 1.2.2ed178885sw3et&mp=1&scm=1007.16389.126158.0&clickTrackInfo=92854998-f82b-42ef-9020d16591c81dd8 303638658 11310 trigger2i 124572 0.443 0.4469329 0.0 0.5216588 0.0 0.4469329 1 null null _null_null_null_

the requirements for heated herbal smoking products and electronic heating devices will enter into force on 1 June 2024.

Restrictions on placing on the market of liquids of electronic smoking devices and tobacco substitute products containing flavourings, except for flavourings which produce the odour or taste of tobacco

At EU level the Tobacco Directive 2014/40/EU does not prohibit the addition of flavourings (flavours) to liquids of electronic smoking devices. Equally there is also no restriction on adding flavourings to tobacco substitute products (e.g. tobacco-free nicotine pouches). The Tobacco Directive 2014/40/EU however, gives Member States the right to introduce a regulation for allowing or restricting flavours in electronic cigarettes (Tobacco Directive 2014/40/EU Preamble, Paragraph 47).

Several WHO reports also contain recommendations to restrict flavoured electronic cigarettes and cut the quantity of flavourings available to reduce the attractiveness of such products among children and young people²⁰. More than 16 thousand different electronic cigarette flavourings are available on the world market. Most flavourings have a sweet and pleasant taste – flavours of fruits, berries, menthol, mint, sweets or sweetened drinks. The available studies^{21;22}on the association among electronic cigarette, its flavour and consumers' preferences or dislike of a given product found that of all the flavours available for electronic cigarettes, sweet flavours or flavours that give a cooling sensation in the mouth were preferred by consumers over\ for example bitter or intense flavours.

Most of the flavourings added to e-cigarette liquids are widely used in food production and are considered to be safe food additives, but their inhalation cannot be considered to be safe and harmless to human health²³. The WHO continues to conduct long-term studies on the health effects of electronic smoking devices, including the risks of addiction, taking into account the nicotine content of these products,²⁴as well as focusing on the effects of various flavourings that are included in the liquids used in these devices²⁵.

Given the above, a ban on flavourings in e-cigarette liquids has already been introduced in several EU countries. In most cases they do not impose a total ban on flavourings but issue a permission for the use of one or two flavourings. For example in Estonia (all flavourings are banned except for tobacco and menthol flavour), Lithuania (all flavourings are banned except for tobacco flavour), Denmark(all flavourings are banned except for tobacco and menthol flavour), Hungary (all flavourings are banned except for tobacco

²⁰ https://www.euro.who.int/__data/assets/pdf_file/0009/443673/Electronic-nicotine-and-non-nicotine-delivery-systems-brief-eng.pdf

²¹ https://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl_2/ii55.full.pdf

²² https://pubmed.ncbi.nlm.nih.gov/29543907/

²³ <u>https://pubmed.ncbi.nlm.nih.gov/27633767/</u>

²⁴ <u>https://www.euro.who.int/__data/assets/pdf_file/0009/443673/Electronic-nicotine-and-non-nicotine-delivery-systems-brief-eng.pdf</u>

²⁵ <u>https://pubmed.ncbi.nlm.nih.gov/27633767/</u>

flavour), the Netherlands (all flavourings are banned except for tobacco flavour). The Dutch National Institute of Health²⁶has published on its website a list of permitted flavourings (substances) that produce the taste or odour of tobacco and this list must be complied with when marketing electronic smoking devices.

The application of the same restrictions on flavourings to tobacco substitute products e.g., liquids used in electronic devices is also necessary to reduce the attractiveness of tobacco substitute products among non-smokers, adolescents and young people. Although no EU country currently restricts the addition of flavourings to tobacco substitute products, given the conclusion of the German Federal Institute for Risk Assessment⁹ that the use of any flavouring in tobacco-free nicotine pouches makes them more attractive to consumers, a regulation is needed to make this product less appealing to consumers. Wellknown additives used in food production (humectants, acidity regulators, sweeteners, stabilisers, food fillers, binding agents) are added to tobacco substitute products, giving consumers the impression that the product is safe for oral consumption. These factors combined give a misleading impression of substitute products as an alternative to smoking.

Taking this into account, the draft law provides for a ban on the placing on the market of electronic smoking device liquids and tobacco substitute products containing flavourings, with the exception of flavourings that produce the taste or odour of tobacco. In addition the draft law stipulates that the list of permitted flavourings that produce the odour or taste of tobacco shall be included in the Annex to the Tobacco Law. The list includes flavourings that have been studied by the Dutch National Institute of Health and used by the Netherlands and other countries for monitoring and control of the set restrictions. Restricting the addition of flavourings will reduce the attractiveness of products among younger consumers, non-smokers and will facilitate protection of vulnerable groups such as adolescents and young people from commencing use of these products, as well as help reduce addiction risks. At the same time, allowing only flavourings that produce the taste or odour of tobacco will ensure that long-term smokers who are unwilling or unable to quit, as well as those currently smoking electronic cigarettes or using tobacco substitute products will be able to switch to or continue using the product. The draft law also provides for a transition period for the introduction of this restriction, stipulating that the ban on placing on the market of electronic smoking device liquids and tobacco substitute products containing flavourings other than flavourings that produce the taste or odour of tobacco, as well as the Annex containing the list of permitted flavourings, will enter into force on 1 January 2025.

²⁶ https://www.rivm.nl/en/documenten/reducing-attractiveness-of-e-liquids-to-youth-proposal-for-restrictive-list-of-tobacco

Increasing the age for the purchase and sale of tobacco products, tobacco substitute products, herbal smoking products, electronic smoking devices and refill containers from 18 to 20 years

The current wording of the Tobacco Law prohibits the sale of tobacco products, herbal smoking products, electronic smoking devices and refill containers to persons under the age of 18. However secondary school students reach the age of majority, i.e. 18 years of age, before they graduate the secondary school, so there is a risk that adult students who are eligible to purchase tobacco and nicotine-containing products may pass them on to schoolmates who are minors, i.e. under 18 years of age. In order to restrict access and transfer of tobacco and nicotine-containing products to minors, the draft law increases the age limit for the purchase and sale of tobacco products, tobacco substitute products, herbal products for smoking, electronic smoking devices and refill containers from the current 18 years to 20 years of age. The draft law also provides for a transition period for the implementation of the provision, with the restriction coming into force on 1 January 2025.

Prohibition of the addition of menthol, its equivalents and geraniol additives to tobacco products for smoking (including novel tobacco products)

Since20 May 2020 Latvia has banned the placing on the market of cigarettes and loose tobacco that have a characteristic aroma, including a characteristic menthol aroma. At the same time Article 3(2)(4) of the Tobacco Law prohibits the placing on the market of tobacco products used for smoking if they contain additives that facilitate inhalation or nicotine intake. These requirements derive from the Tobacco Directive 2014/40/EU. Currently neither the Tobacco Directive 2014/40/EU nor the Tobacco Law specifies which additives cannot be added to tobacco products making it difficult for the regulatory authority to monitor compliance with these requirements and for manufacturers to comply with them. It has been found that adding menthol to cigarettes eases inhalation of cigarette smoke, soothes throat and respiratory irritation, and suppresses coughing. It has been proven that menthol cigarettes attract non-smokers, especially young people, to try or start smoking, thus increasing the risk of nicotine attraction.^{27,28,29} Similarly as menthol, menthol equivalents (substances similar in molecular and spatial structure) can have the same effect as adding menthol to cigarettes.

Based on studies on how adding of menthol and other equivalents to tobacco products facilitates nicotine intake, the legislation of several EU

https://jaotc.eu/wp-content/uploads/2021/04/D9.3-Report-on-the-peer-review-of-the-enhanced-reporting-information-on-priority-additives.pdf

²⁷ https://www.cdc.gov/tobacco/basic_information/tobacco_industry/menthol-cigarettes/index.html

²⁸ https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations

²⁹ WP9: D9.3 Report on the peer review of the enhanced reporting information on priority additives

countries – Germany³⁰, Austria³¹, Finland³², Belgium and Hungary³³ prohibits the placing on the market of tobacco products containing additives that facilitate inhalation and nicotine intake, with a specific list of additives including menthol, its equivalents and geraniol. In addition what concerns heated tobacco products on 29 June 2022 the European Commission adopted a Commission Delegated Directive.³⁴ Starting from 23 October 2023 the delegated directive will extend the EU-wide ban on characteristic flavour to heated tobacco products, thus extending the ban on flavourings to a broader group of tobacco products, including cigarettes and loose tobacco as well as heated tobacco.

To limit the accessibility of tobacco products containing menthol and its analogues, as well as to facilitate compliance by manufacturers and importers with the requirements of the Tobacco Law, and to facilitate the monitoring and control of restrictions, the draft law only clarifies the existing prohibition on placing on the market of tobacco products intended for smoking if they contain additives to facilitate inhalation or nicotine intake. The clarification is made by adding to the law specific additives namely menthol, its equivalents and geraniol, which should be prohibited from being added to products intended for smoking. The draft law also provides for a transition period until 1 June 2024.

Provision for cigarette manufacturers and importers to ensure compliance of cigarettes with combustion and fire safety requirements

As of 2011 the testing of cigarette samples and assessment of their compliance with reduced combustibility and fire safety requirements in accordance with the international ISO standards is conducted by the national regulatory authority of Latvia - the State Revenue Service. An assessment of the experience of other EU Member States in meeting the reduced combustibility and fire safety requirements for cigarettes has shown that the responsible authorities of other EU countries do not carry out regular sample testing but rather have included in the legislation the obligation for cigarette manufacturers and importers to ensure that the cigarettes they place on the market meet the reduced combustibility requirements. Moreover since the testing of cigarette samples in Latvia was started in 2011, no non-compliance with the reduced combustibility requirements for cigarettes has been detected among the samples tested. In view of the above, the draft law foresees the obligation for cigarette manufacturers and importers in Latvia to ensure that the cigarettes they place on the market meet the manufacturers and importers in Latvia to ensure that the cigarettes they place on the market meet step place on the market comply with the reduced combustibility requirements for cigarettes has been detected among the samples tested. In view of the above, the draft law foresees the obligation for cigarette manufacturers and importers in Latvia to ensure that the cigarettes they place on the market comply with the reduced combustibility requirements and that

³⁰German legislation on the prohibition of menthol, its equivalents and geraniol— <u>http://www.gesetze-im-internet.de/tabakerzv/BJNR098010016.html/</u>

³¹Austrian legislation on the prohibition of menthol, its equivalents and geraniols – https://www.ris.bka.gv.at/Dokumente/Erv/ERV_1995_431/ERV_1995_431.pdf

³²Information for industry published on the website of the Finnish market surveillance authority VALVIRA: https://www.valvira.fi/web/en/-/menthol-tobacco-products-and-menthol-e-cigarette-liquids-may-not-be-sold-in-finland/

³³ https://jaotc.eu/wp-content/uploads/2021/04/D9.4-Additional-additives-for-independent-assessment.pdf

³⁴Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 is available here: <u>https://eur-lex.europa.eu/legal content/EN/TXT/?</u> uri=uriserv%3AOJ.L__2022.283.01.0004.01.ENG &toc=OJ%3AL%3A2022 %3A283 %3ATOC

cigarette manufacturers and importers henceforth test cigarettes in accordance with all international ISO standards and, before placing cigarettes on the market, submit to the Health Inspectorate test reports issued by accredited laboratories along with an assessment report proving compliance of cigarettes with the reduced combustibility requirements. This requirement will not apply to cigarette brands that are already being marketed and regarding which manufacturers and importers have already submitted information to the Health Inspectorate.