JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Institute for Global
Tobacco Control

CAMPAIGN for TOBACCO-FREE Kids®

GLOBAL REGULATORY SCENARIO OF NICOTINE POUCHES

Submitted to:
Agência Nacional de
Vigilância Sanitária (Anvisa)

Graziele Grilo
Deniece Carrington
Reiley Hartmuller
Beatriz Albuquerque
Monique Muggli
Kevin Welding

October 6, 2025

Tobacco Control Laws
Available at: tobaccocontrollaws.org

Inquiries
For inquiries, email Deniece Carrington (dcarrington@tobaccofreekids.org) or Kevin Welding (kwelding@jhu.edu).

Suggested Citation
Grilo, G., Carrington, D., Hartmuller, R., Albuquerque, B., Muggli, M., Welding, K. Global regulatory scenario for nicotine pouches. Institute for Global Tobacco Control, Johns Hopkins Bloomberg School of Public Health and International Legal Consortium, Campaign for Tobacco Free Kids. October 6, 2025.

Disclosure
This work was supported with funding from Bloomberg Philanthropies' Bloomberg Initiative to Reduce Tobacco Use (bloomberg.org).

Johns Hopkins Bloomberg School of Public Health
Institute for Global Tobacco Control

publichealth.jhu.edu/igtc

Campaign for Tobacco-Free Kids®

tobaccofreekids.org

Contents

Executive Summary

This report looks at the global landscape of regulatory scenarios for nicotine pouches.

The International Legal Consortium (ILC) at the Campaign for Tobacco-Free Kids (CTFK) has monitored nicotine pouch policies since 2021. The convenience sample is based on their internal tracking of government action taken to address nicotine pouches. Additional policy documents supporting the government's regulatory action were identified primarily through government websites. Regulations were grouped into one of seven categories: Sale Prohibited by Law; Sale Prohibited by Law (Pending Additional Action); Regulated as a Medicinal/Pharmaceutical Product (No Approved Products); Regulated using Other Measures; Regulated as a Tobacco or Related Product; Regulated as a Medicinal and Tobacco Product; and Regulated as a Natural Health Product (Approved Product). Regulations were analyzed for specific policy areas including health warning requirements, other packaging restrictions, minimum sales age, nicotine limits, restrictions on flavors, other contents restrictions, restrictions on where sales can be made, other sales restrictions, package size requirements, advertising, promotion and sponsorship and point of sale display measures, health claims prohibitions, notification and reporting requirements, and restrictions on use in public places. An in-depth analysis of a subset of countries highlights representative examples that illustrate more comprehensive regulation and approaches or regulatory proposals by governments in different regions.

The scan identified regulations in 45 countries as of August 15, 2025. It is noticeable that the highest prevalence of countries with policies are from the European region and from high-income countries. Amongst the countries regulating nicotine pouches, most regulate them as a tobacco or related product. Ten countries prohibit the sale by law, with one joining that group after the adoption of additional measures, which are currently pending. Other countries regulate nicotine pouches as medicinal/pharmaceutical products, medicinal and tobacco products, and natural health products. Three countries use other measures. In-depth analysis provides more details for countries using these different methods. Amongst the policy measures that are used, prohibiting misleading packaging, prohibiting attractive ingredients, and requiring health warning labels are the most prevalent.

There are limitations to this report. It does not include subnational regulations, reflect any current taxation policies, standards issued by national standards bodies, or general consumer safety measures. The policy landscape is changing quickly and since this data was analyzed after August 15, 2025, France has passed a policy banning the sale of nicotine pouches, which is not reflected here. The implementation of regulatory measures was not considered. Given that this is a convenience sampling, current policies that we are unaware of could be missing. In addition, legal provisions are often susceptible to more than one interpretation, giving rise to the possibility of interpretation error, especially where we do not have in-country lawyer assistance. Additionally, this legislative review is based strictly on the letter of the law and not based solely on information from government authorities regarding how the products are regulated.

We know that countries are starting to adopt policies to address nicotine pouches. These policies do cover a range of options, from banning the sale to regulations about packaging, labeling, ingredients, flavors, advertising, and public use. Having a clear picture of the options that other countries are using to address nicotine pouches can help other governments decide on their options and path forward. This should always include a country-specific assessment of current resources and regulatory capacity.

Introduction

Nicotine pouches are small disposable pre-portioned pouches made of microfiber that contain a white powder consisting of nicotine, flavorings, and other ingredients.[1] These products are similar to snus in style and nicotine content, yet do not contain tobacco leaf.[2,3] The pouches are used by placing them between the lip and gum and require no spitting or refrigeration. They are sold in a variety of fruit and other flavors (e.g., mint) and vary in nicotine content per pouch (examples include 2 mg, 4 mg, and 7 mg and ones with higher nicotine dosage of 20 mg and 30 mg).[2,4] There are two chemical forms of nicotine: S-nicotine and R-nicotine. Tobacco-derived nicotine mainly consists of S-nicotine with only minimal amounts of R-nicotine.[5] While some nicotine pouches contain tobacco-derived nicotine, others contain synthetic nicotine, which is a liquid created in a laboratory setting.[6] Synthetic nicotine added to products consists of one of these two forms, or as a mixture of both.[5] Pure synthetic S-nicotine is chemically indistinguishable from S-nicotine derived from tobacco. The pharmacological, metabolic and toxicological effects of R-nicotine are not yet well understood.[5] Products that use synthetic nicotine have similar nicotine content to those that use tobacco-derived nicotine.[7] There are also nicotine analogues, which are compounds structurally similar or related to nicotine.[8] The effects of nicotine analogues are not yet well understood. However, some research has suggested that the analogue 6-methyl nicotine could be more toxic and have higher abuse liability than nicotine. In addition, some nicotine pouch brands are describing their nicotine analogues as better than nicotine and potentially less addictive. However, it seems there is only industry evidence to back this claim.[9]

In 2022, 2.9% of U.S. adults reported ever using nicotine pouches, and 0.4% reported current use; there was a higher report of pouch use among younger age groups, men, and those who are non-Hispanic White.[10] In Great Britain, 5.4% of adults reported ever use of nicotine pouches and out of those, 1.0% were currently using them in 2024.[11] Common motivations for use include attempts to quit or reduce cigarette or e-cigarette use, interest in the available flavors and sensations from use, avoidance of odor, convenience of use, and ability to use the product discreetly, especially in places where smoking or vaping is prohibited.[12,13] Many also perceive nicotine pouches to be less harmful than cigarettes.[12,13]

The long-term health effects of nicotine pouches are still unknown.[1,6,14] However, side effects of use can include irritation of the gums and mouth, hiccups, nausea, and nicotine addiction.[14] Carcinogens found in tobacco products were also identified as being present in nicotine pouches; however, at lower levels than cigarettes or other oral smokeless tobacco products. In addition, there is some evidence that nicotine pouches have toxicity (e.g. increased cytotoxicity and inflammatory response).[12] Nicotine itself has been shown to harm health in several ways, such as posing risks for fetuses and pregnant women, harming brain development, and impacting attention and impulse control.[1] Adolescent use of nicotine may lead to increased risk of future substance abuse.[15]

Globally, the nicotine pouch market size was estimated at 5.39 billion (USD) in 2024 and is expected to reach 25.40 billion (USD) by 2030.[16] The United States was the largest nicotine pouch market in 2024 with a revenue share of 78.4%.[16] In the United States, overall sales of nicotine pouches increased from 126.06 million units from August-December 2019 to 808.14 million units from January-March 2022.[17] Nicotine pouch sales increased from 2022 to 2024 in the U.S. by 183.7% and by 207% between 2023 to 2025, demonstrating a continuation in growing sales over time.[18,19] Zyn (manufactured by Philip Moris International) led the overall unit share, followed by On!, Velo, and Rogue (manufactured by Altria Group, British American Tobacco, and Swisher International, respectively) during August 2019-March 2022.[17]

Nicotine pouches are advertised through various media channels, such as traditional outlets and online marketing. The leading nicotine pouch brands in the U.S. (Zyn, On!, and Velo) focused their marketing on radio advertisements, television, and online displays from 2019-2021.[12] The most common marketing

tactic used for these products is describing the pouch as "tobacco-free" or free of tobacco leaves.[2,12] Other common marketing tactics include the convenience of use (can be used anywhere, batteries and devices not needed), pureness or cleanliness, the variety of flavors available, "smoke-free," and as a potential alternative to other tobacco products.[2,6,12] "Tobacco-free" marketing has been found to be associated with reduced perceptions of harm and potential addictiveness compared to other marketing that does not contain this phrase.[12] In addition, adolescents who perceived nicotine products as having good-tasting flavors after viewing advertising were more likely to endorse future intention to use nicotine pouches.[12]

Nicotine pouches pose several regulatory challenges, especially due to synthetic nicotine or nicotine analogues. Synthetic nicotine can be used as a loophole to regulations that only cover tobacco-derived nicotine products. Furthermore, nicotine analogues also can potentially be used to loophole regulations that explicitly cover nicotine.[20] The World Health Organization (WHO) Study Group on Tobacco Product Regulation recommends that countries should amend their tobacco control laws to include synthetic nicotine and nicotine analogues, consider other products that may emerge, enforce purity standards and consider banning the mix of tobacco-derived and synthetic nicotine in products, enforce uniform labeling rules, consider banning synthetic nicotine products that contain R-nicotine, and restrict marketing that advertises these products as "tasteless and odorless", "purer" or "healthier" than tobacco-derived nicotine products.[5] Current policy approaches vary widely across countries, from no regulation covering nicotine pouches at all to banning both tobacco-derived and synthetic nicotine pouches. Countries that regulate both types generally either rely on pre-existing policies covering tobacco products or create new policies that specifically address nicotine-containing products.[21]

There is a general obligation under Article 5.2(b) of the WHO Framework Convention on Tobacco Control (WHO FCTC) to "adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing…nicotine addiction," in accordance with a Parties' national capabilities.[22] To date, the governing body of the WHO FCTC, the Conference of the Parties (COP), has not adopted specific regulatory guidance concerning nicotine pouches. However, regulating nicotine pouches is consistent with Parties' obligations under Article 5.2(b) of the treaty.

The main recommendations of the WHO Study Group on Tobacco Product Regulation report on regulating nicotine products include establishing or extending surveillance of these products and those that use them, including demographics, brand and flavor type used, and other tobacco product and substance co-use, taking any necessary action to limit youth access, appeal, and initiation of use, inform the public about the toxicity and addiction risks, and ensure that nicotine pouches are not classified as pharmaceutical products unless they are proven to be nicotine replacement therapies (NRTs), which would include obtaining authorization from the appropriate regulatory authority after undergoing strict pharmaceutical licensing registration.[5] Moreover, the report also recognizes that countries may regulate nicotine pouches by allowing or prohibiting their sale and recommends that countries consider whether domestic legislation can be applied to these products such as consumer, food and tobacco control laws.[5] In addition, the specific guidelines to address cross-border tobacco advertising, promotion and sponsorship and the depiction of tobacco in entertainment media for implementation of Article 13 adopted by COP10 urged Parties to "monitor advances and changes in communications technology, entertainment media consumption and marketing strategies relating to all tobacco products (including novel and emerging tobacco products), to ENDS/ENNDS and to nicotine products other than approved medicines," which encompasses nicotine pouches not regulated as medicinal products.[23] Other recommendations from the U.S. Centers for Disease Control and Prevention include licensing retailers who sell nicotine pouches, enforcing penalties for retailers who sell to underage persons, raising the

prices of nicotine pouches, reducing access to flavors, and developing educational initiatives that warn about the health risks.[24]

The third revision of the Tobacco Products Directive (TPD3), a tobacco and nicotine regulation governing the European Union, is still currently in development. However, TPD3 is likely to address nicotine pouches, which are largely unregulated currently under the Directive. Similarly, discussions among WHO FCTC Parties concerning nicotine pouches may possibly take place during COP11 (17-22 November, Geneva, Switzerland) in response to an agenda item included in the Provisional Agenda [Agenda Item 4.5 - Implementation of measures to prevent and reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke, and the protection of such measures from commercial and other vested interests of the tobacco industry in light of the tobacco industry's narrative on "harm reduction" (Articles 5.2(b) and 5.3 of the WHO FCTC)].[25]

As countries have started to regulate nicotine pouches, the goal of this report is to provide an overview of current global regulations of these products and to discuss different regulatory measures adopted by select countries where information is available and the purpose, rationale and/or evidence behind those choices.

Methods

A primary purpose of the policy scan from the International Legal Consortium (ILC) at the Campaign for Tobacco-Free Kids (CTFK) is to highlight representative examples that illustrate more comprehensive regulation and approaches or regulatory proposals by governments in different regions globally, rather than to provide an exhaustive inventory of all policies globally impacting nicotine pouches.

Legal measures (i.e., legislation, regulations, decrees, resolutions, or any other enactments that have legal force and effect) included in the policy scan were initially identified by lawyers (ILC at CTFK, based on their internal tracking of government action taken to address nicotine pouches. Forty-five countries were identified as regulating nicotine pouches primarily using the online resource TobaccoIntelligence.[26] Policy documents and legal instruments supporting the government's regulatory action were identified primarily through government websites, which are included in the country example summary.

The convenience sampling used was further based on the accessibility and availability of legal and policy measures. Country examples were prioritized where their legal and policy measures were publicly available through government or legislation websites, or cited in academic or policy literature, or by intergovernmental organizations.

Legal measures that were not available in English were either (unofficially) translated by a translation service or machine-translated. Based on the analysis of the legal measures, nicotine pouch regulation was classified into one of seven categories: Sale Prohibited by Law; Sale Prohibited by Law (Pending Additional Action); Regulated as a Medicinal/Pharmaceutical Product (No Approved Products); Regulated using Other Measures; Regulated as a Tobacco or Related Product; Regulated as a Medicinal and Tobacco Product; and Regulated as a Natural Health Product (Approved Product). Where available, categorization of the regulatory status of nicotine pouches was confirmed with in-country partners.

In addition, where applicable, the legal measures were also analyzed for the regulation of specific policy areas including health warning requirements, other packaging restrictions, minimum sales age, nicotine limits, restrictions on flavors, other contents restrictions, restrictions on where sales can be made, other sales restrictions, package size requirements, advertising, promotion and sponsorship and point of sale display measures, health claims prohibitions, notification and reporting requirements, and restrictions on use in public places. Taxation of the products was not considered.

An in-depth analysis of a subset of countries consisted of establishing the current regulation of nicotine pouches and providing the purpose, rationale and/or evidence for the adoption of the regulatory measure. Parliamentary and explanatory memorandums, reports from governmental bodies (such as ministries of health or drug agencies), impact assessments, and notes from parliamentary hearings were examined to prepare this analysis.

Results

This global policy scan of nicotine pouches identified regulatory measures in 45 countries as of August 15, 2025 (Table 1, Figure 1). Categorization of the type of regulation of nicotine pouches in order of frequency were: 21 countries (47%) regulated as tobacco or related products; ten countries (22%) prohibited the sale by law; six countries (13%) regulated as medicinal/pharmaceutical products (no approved products); three countries (7%) regulated as medicinal and tobacco products; three countries (7%) regulated using other measures; one country (2%) regulated as natural health products (approved product); and one country (2%) prohibited the sale by law (pending additional action). See Table 1 and Figure 1 for specific country categorizations.

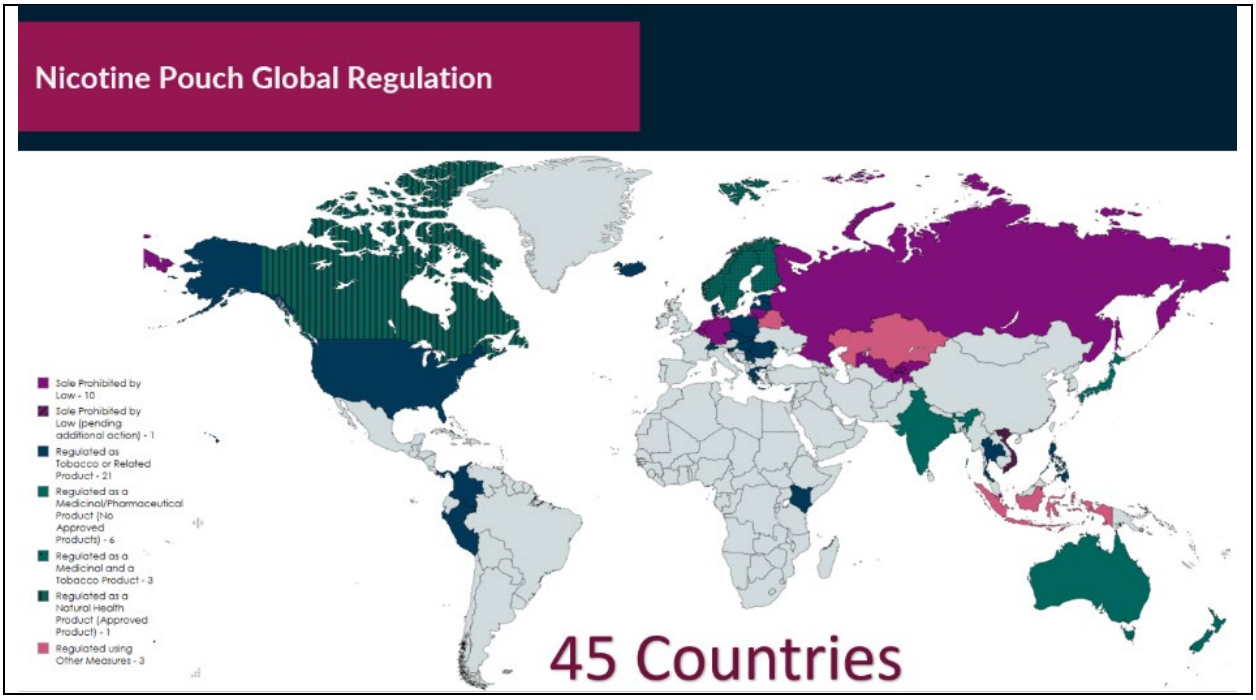
Table 1. List of countries adopting specific legal measures

Sale Prohibited by Law	**Regulated as Tobacco or Related Products**
1. Belgium 2. Germany 3. Kyrgyzstan 4. Lithuania 5. Mauritius 6. Netherlands 7. Russia 8. Singapore 9. Tajikistan 10. Uzbekistan	1. Colombia 2. Czech Republic 3. Denmark 4. Estonia 5. Greece 6. Hungary 7. Iceland 8. Kenya 9. Latvia 10. Moldova 11. Panama 12. Peru 13. Philippines 14. Poland 15. Romania 16. Serbia 17. Slovakia 18. Slovenia 19. Switzerland 20. Thailand 21. United States
Sale Prohibited by Law (Pending Additional Action) 1. Viet Nam	**Regulated as Medicinal and Tobacco Products** 1. Finland 2. Norway 3. Sweden

Regulated as Medicinal/Pharmaceutical Products (No Approved Products)	**Regulated as Natural Health Products (Approved Product)**
1. Australia 2. Cyprus 3. Hong Kong 4. India 5. Japan 6. New Zealand	1. Canada
Regulated using Other Measures 1. Belarus 2. Indonesia 3. Kazakhstan	

Notes: These exclude taxation, standards issued by standards bodies, and general consumer safety measures. They were identified by lawyers at the ILC at the CTFK based on their internal tracking of government action taken to address nicotine pouches as of August 15, 2025.

Figure 1. Map of countries adopting specific legal measures



Notes: These exclude taxation, standards issued by standards bodies, and general consumer safety measures. They were identified by lawyers at the ILC at the CTFK based on their internal tracking of government action taken to address nicotine pouches as of August 15, 2025.

Table 2 shows country examples of policy measures to reduce the supply and demand of nicotine pouches. Prohibiting misleading packaging (8 countries), prohibiting attractive ingredients (8 countries), and requiring health warning (7 countries) are some examples. Remote and location-based sales bans and indoor use restrictions are employed by multiple countries. There are also examples of countries requiring plain packaging (Denmark), prohibiting advertising (Slovenia), prohibiting health/cessation claims (Greece). Latvia also prohibits flavors other than tobacco, limits nicotine concentrations, and has a minimum sales age over 20.

Table 2. Country examples of nicotine pouch supply and demand reduction measures

Restrict indoor public use	Require health warnings	Require plain packaging	Prohibit misleading packaging	Prohibit advertising	Prohibit health/ cessation claims	Prohibit all flavors except tobacco	Nicotine content limit of 4 mg or less	Prohibit attractive ingredients	Disclosure to authorities	Minimum age sales of 20+	Ban vending/ remote sales	Ban sales near schools/ health facilities
Panama	Belarus	Denmark	Latvia	Slovenia	Greece	Latvia	Latvia	Poland	Sweden	Latvia	Serbia	Iceland
Slovenia	Kenya		Belarus					Czech Republic	Czech Republic		Latvia	Czech Republic
	Sweden		Czech Republic					Denmark	Iceland		Slovenia	Slovakia
	Hungary		Denmark					Hungary	Slovakia			
	Iceland		Hungary					Iceland				
	Latvia		Iceland					Latvia				
	Poland		Poland					Slovakia				
			Sweden					Sweden				

Note: This table excludes the regulation of products that are approved products for therapeutic use by the relevant medicines or drug authority.

Country-specific Examples

Of the 45 countries identified with policies in place, legal measures from eight countries (Australia, Canada, Colombia, Finland, Germany, Netherlands, Switzerland, and Norway) and regulatory proposals from two countries (United Kingdom and France) were further analyzed using a qualitative research design, drawing on a convenience sample of legislation, regulation or policy documents.

This group of countries with policies in place includes Canada, which regulates nicotine pouches as a natural health product and has approved products. Australia regulates as medicinal/pharmaceutical products, while Finland and Norway regulate as medicinal and tobacco products. Colombia and Switzerland regulate as tobacco or related products. Germany and the Netherlands prohibit the sale by law.

Regulated as a Natural Health Product (Approved Products) - Canada

Regulatory Status

At the federal level, nicotine pouches are not regulated under the Tobacco and Vaping Products Act (TVPA) because they do not contain tobacco and are not a vaping product.[27] Nicotine pouches are regulated as drugs under the Food and Drugs Act and are classified either as prescription drugs (containing or delivering more than 4 mg of nicotine per dose)[28] or natural health products (containing or delivering 4 mg or less of nicotine per dose) and subject to the Natural Health Products Regulations (Regulations), similar to 4 mg (or less) nicotine gum and lozenges.[29] In order for products to be legally sold in Canada, they must undergo a pre-market review evaluating their safety and efficacy and subsequently receive market authorization from Health Canada. To date, Health Canada has not authorized any nicotine pouch containing or delivering more than 4 mg of nicotine per dose.[30]

On July 19, 2023, Health Canada authorized the first nicotine pouches for use as a NRT.[31] Zonnic pouches, produced by Imperial Tobacco Canada, a subsidiary of British American Tobacco, and containing or delivering 4 mg or less of nicotine per dose, were authorized as natural health products and, therefore, are subject to the Regulations. Initially, pouches in five (5) flavors were authorized: Polar Mint, Berry Frost, Chill Mint, Cranberry Fizz and Tropic Breeze. Importantly, the authorized Zonnic pouches were not subject to the same sale and advertising restrictions as tobacco and vaping products under the TVPA, which establishes a minimum age of 18 to purchase products and prohibits most forms

of tobacco advertising, promotion and sponsorship, while restricting many forms for vaping products. Under federal law, there was no minimum age to purchase the approved nicotine pouches and advertisements for natural health products, including those with lifestyle imagery, were permitted in all forms of media.

Subsequently, in August 2024, Canada's Minister of Health, pursuant to an authority granted in section 30.01 of the Food and Drugs Act, adopted a Ministerial Order (also referred to as Supplementary Rules)[32] with new regulatory measures for NRTs administered through the oral cavity and subject to the Regulations. Further, certain measures would only apply to "new and emerging NRTs," which include nicotine pouches and nicotine pearls (small, round pellets with nicotine and other substances inside, such as flavorings, that dissolves when in contact with the saliva), given the lack of history of appropriate use as a cessation aid and the potential for widespread appeal to people who do not smoke and young people.

The Supplementary Rules enacted several measures to strengthen the regulation of authorized nicotine pouches, including:

- Prohibiting advertising and promotion that could appeal to young people;
- Prohibiting packaging and labeling that could appeal to young people;
- Prohibiting flavors other than menthol and mint;
- Restricting accessibility by requiring that sales be conducted only by a pharmacist or an individual working under the supervision of a pharmacist, and for the products to be kept behind the pharmacy counter; and
- Requiring a front-of-package nicotine addiction warning, as well as indicating that the product is a smoking cessation product for adults trying to quit smoking.

The Guide to the Supplementary Rules offers further guidance on regulating the products covered by the order.[33]

Purpose, Rationale and/or Evidence for Current Regulation

Health Canada has consistently taken the position that nicotine is highly toxic and addictive. In 2020, the department issued a recall and safety alert advising of such and informing the public that nicotine pouches were unauthorized in Canada.[30]

After Zonnic pouches received market authorization in 2023, Canada's Minister of Health publicly stated that Imperial Tobacco Canada's marketing of the flavored pouches was being carried out in a way that was geared toward youth was inconsistent with a cessation product.[34] At the same time, the Minister said that sales and age restrictions were up to the provinces to regulate, while public health advocates alleged that the provinces were not provided enough time to regulate the products. This prompted Health Canada to update its public advisory, emphasizing:[30]

- Nicotine pouches are authorized only as an NRT to help adults quit smoking;
- Only one type of nicotine pouch has been authorized;
- Nicotine pouches are not authorized for recreational use by people who do not smoke and people under 18 years old;
- Consumers should not to buy or use unauthorized products.

As a result of increasing popularity with youth, the Supplementary Rules were issued.[32] The Regulatory Impact Analysis Statement (Statement) for the Rules provides a detailed overview of the analysis that took place before the adoption of the rules, including the rationale and cost-benefit analysis.[32] Further, the Statement provides that the Objectives of the Supplementary Rules are to:

- "Mitigate the risk of harm to health associated with the unintended use of NRTs by young people and those who are not using such products for smoking cessation;
- Contribute to the prevention of nicotine exposure and dependence among young people through measures that reduce access and appeal of these products; and
- Avoid creating significant barriers for the access to safe and effective treatments by adults trying to quit smoking."

Furthermore, the Statement emphasized the benefit of preventing young people from becoming addicted to nicotine. The Statement noted in part:

- "A nicotine replacement therapy (NRT) is a treatment to help people stop smoking by delivering low doses of nicotine through means other than tobacco, such as through gums, patches, lozenges or sprays. NRTs deliver nicotine to the brain in a slower manner than through cigarettes, providing a means to reduce withdrawal symptoms and cravings for nicotine while quitting smoking. While Health Canada has only authorized NRTs for the specific use of smoking cessation by adults, there is concern that some of these products may be appealing to, and accessed by, people who do not smoke—and particularly by young people (under 18 years of age) in Canada. Nicotine is a toxic and addictive substance that can be harmful to health, particularly when consumed in excessive amounts; young people may be particularly susceptible to its harmful effects, including addiction."
- "Over the past decade, the ways in which NRTs are marketed and sold have become increasingly similar to tobacco and vaping products. Blurring the lines between tobacco products, vaping products, and NRTs may cause confusion and misuse by consumers, which may result in the initiation of nicotine use for unintended uses, or the concurrent recreational use of NRTs and tobacco or vaping products, including by young people."
- "Compared to other NRT dosage forms (such as transdermal patches), orally administered NRTs are more widely available, can be manufactured in a variety of flavours, are easy to use, and are advertised broadly. In addition, innovation in the NRT market is evolving both in Canada and internationally, with increasing interest in newer dosage forms of orally administered NRTs, such as nicotine pouches and pearls."
- "There are multiple factors that may contribute to the interest in and use of nicotine products by young people, including stress reduction, curiosity, and enjoyment. While most young people perceive that nicotine is harmful, one study in the U.S. found that almost three quarters of the young people surveyed perceived the nicotine in vaping products as less harmful than that in cigarettes and the nicotine in NRTs as less harmful than the nicotine in vaping products. Young people curious to try a nicotine product may first turn to a form they perceive as less risky, such as NRTs, although the nicotine in these products can still result in nicotine addiction if they are accessed and used inappropriately (i.e. recreationally)."
- "While NRTs are intended to support smoking cessation by lessening nicotine dependence in addition to replacing cigarettes with a safer nicotine alternative, inappropriate NRT access and use has the potential to create or potentiate nicotine dependence. Moreover, the potential for dependence on a specific NRT may be positively correlated to that NRT's rate of nicotine delivery. NRTs that are administered orally for buccal absorption, including pouches, lozenges, and gums, are usually faster acting than transdermal patches. Transdermal patches are designed to provide a slow, steady dose over 16 to 24 hours; in contrast, orally administered dosage forms are designed to elicit a more rapid response that permits greater user flexibility in self-regulating nicotine withdrawal symptoms. This more rapid absorption of nicotine may result in a head-rush or "buzz," particularly if multiple doses are taken at once. In the context of vaping, these sensations have been identified by some young people in Canada as a primary appeal of using the product. Similarly, young people seeking these short-term effects from inappropriate NRT use

may increase the dose quantity and/or frequency of such products over time, increasing their overall exposure to nicotine and its related harms (e.g. addictiveness, effects on the developing brain)."

- "Compared to other NRT dosage forms, orally administered NRTs are more widely available, can be manufactured in a variety of flavours, are easy to use, and are advertised broadly. These features may increase the likelihood that these products will appeal to, be accessed by, and be used by young people and people who do not already smoke or vape nicotine, especially in comparison to transdermal dosage forms (i.e. patches). Considering all of these risk factors together, a tailored regulatory approach focusing on orally administered NRTs is warranted to reduce the appeal of, access to, and use of these products by young people, which in turn may reduce the potential for nicotine exposure, dependence, and other health harms for this population."

Regulated as a Medicinal/Pharmaceutical Product (No Approved Products) - Australia

Regulatory Status

At the federal level in Australia, nicotine pouches are regulated under the Therapeutic Goods Act 1989[35] and are included within Schedule 4 of the Poisons Standard[36] as prescription-only products. The Therapeutic Goods Act 1989 provides a national system for regulating the import, export, manufacture and supply of therapeutic goods throughout Australia and includes requirements for including such products on the Australian Register of Therapeutic Goods (ARTG), among other requirements.

For nicotine pouches to be legally imported or sold (including in pharmacies), the approval of the Therapeutic Goods Administration (TGA) or a valid prescription from an Australian health provider is required. To date, the TGA has not approved any nicotine pouch, stating in August 2025 that, "There has been an increase in the illegal advertising and online sales of nicotine pouches, with many of these products being imported from overseas. It is important to note that nicotine pouches are considered therapeutic goods and there are no nicotine pouches approved in Australia by the TGA. This means that nicotine pouch products have not been tested for safety, quality, or effectiveness."[37]

However, there is an exemption available to import nicotine pouches via a Personal Importation Scheme,[38] in which several conditions must be met including that the product must be for personal use only (or use of an immediate family member only). Further, a valid Australian prescription or written authorization must be obtained at the time of importation, and the supply of personal importation is limited to certain quantities.

At the state and territory levels, nicotine pouches are also regulated as Schedule 4 prescription-only products under the Poisons Standard. Two states (Queensland[39,40] and South Australia[41,42]) have also adopted legislation prohibiting the supply of nicotine pouches under state-based tobacco legislation.

Purpose, Rationale and/or Evidence for Current Regulation

The TGA has made several statements related to its policy and regulatory rationale for making nicotine pouches illegal except by prescription or exemption. In June 2024, the TGA stated, "There is no strong evidence to support the use of nicotine pouches for smoking or vaping cessation. Evidence shows nicotine can be harmful and may have adverse impacts on adolescent brain development."[43]

In August 2025, the TGA stated that, "Nicotine pouches can be dangerous. Some contain high levels of nicotine, which can lead to side effects or overdose. They are not made to Australian standards and their safety hasn't been checked. They may contain unknown and dangerous ingredients. Nicotine is highly

addictive, especially for young people. It can interfere with brain development, affecting memory, learning, and attention.

Side effects linked to nicotine pouches include:

- fast heart rate and high blood pressure
- nausea, dizziness, and headaches
- dry mouth and strange jaw sensations
- mouth sores.

Some of these products may not list nicotine as an ingredient. The lack of clear ingredient information on the label can cause delays in treatment if the product is swallowed. This is particularly dangerous for children. Additionally, mis-declared or mislabelled products are considered counterfeit and cannot be imported or supplied under any circumstances."[37]

Further, the Delegate of the Secretary of the Department of Health and Aged Care's *Notice of decision to amend (or not amend) the current Poisons Standard in relation to nicotine* (May 2024) noted (in part) the following:[44]

- "Of particular concern is the promotion of nicotine pouches to young people as an aid to support smoking or nicotine vaping cessation. (…)[T]here is no evidence to support the use of these nicotine pouches or toothpicks for smoking or nicotine vaping cessation, nor the effects of long-term use of these products. Furthermore, exposure to nicotine may lead to increased heart rate, nausea, dizziness, and abdominal cramps, especially to those who do not usually smoke or vape. Evidence also shows nicotine may also have adverse impacts on adolescent brain development."
- "…[N]icotine pouches in particular are being marketed to the community through a range of channels and are easily accessible through the internet, convenience stores and tobacconists. Marketing strategies of these products include unproven health claims, brightly coloured packaging and flavours that appeal to young people. With regard to the matters in s 52E(1)(a) and (d) of the Act, I am also concerned in relation to the risks to the health of children from the packaging and presentation of nicotine pouches. The combination of diverse flavours and sale in small, easily openable plastic and metal containers, means the presentation resembles various confectionary products. This may lead to increased risks of accidental poisoning, especially in children."
- "There is an increasing trend in the importation, supply and advertisement of these products in Australia, particularly since 1 January 2024 when the prohibition on importation of disposable vapes commenced. I consider that the supply of these unlawful and unregistered nicotine products poses significant public health risks. I find urgent control under the current Poisons Standard is necessary to regulate the supply of such novel nicotine products and to protect public health. This scheduling change will not affect existing lawful nicotine products that are already included in the Register. It is my view that this additional restriction will support Commonwealth, state and territory authorities to identify unlawful nicotine products and carry out relevant law enforcement activities more effectively. It will also ensure consumers are accessing safe and efficacious nicotine cessation products that are supported by evidence."

Regulated as a Medicinal and Tobacco Product – Finland, Norway

Regulatory Status - Finland

Until April 2023, nicotine pouches were regulated as a medicinal product in Finland. However, this changed when the Finnish Medicines Agency (Fimea), the national competent authority for regulating pharmaceuticals, determined that nicotine pouches did not fall within the scope of the Medicines Act "unless they were specifically marketed for a medicinal purpose or it can be proven in some other way

that they are typically used like medicinal products."[45] Zonnic nicotine pouches, manufactured by Niconovum AB, an affiliate company of British American Tobacco, in mint flavor and strengths of 2 mg and 4 mg have received marketing authorizations from Fimea as medicinal products.[46]

Nicotine pouches that do not meet the requirements to be regulated under the Medicines Act are currently regulated as "smokeless nicotine products" under the Tobacco Act.[47,48] The Tobacco Act prohibits the sale of "smokeless nicotine products" that contain more than 16.6 mg of nicotine per gram and bans all flavors except menthol and mint. Furthermore, the law prohibits sales to those under 18 and bans use in certain places, including educational institutions.

Purpose, Rationale and/or Evidence for Current Regulation - Finland

Fimea previously classified nicotine pouches as medicinal products due to the pharmacological effects of nicotine. However, in a reassessment, Fimea ruled that they will no longer be routinely considered medicines unless marketed or used specifically for medicinal purposes. This policy change was due to the fact that Fimea found there was a large variety of nicotine products on the market and, therefore, concluded that nicotine pouch regulation should be included in tobacco legislation.

Additionally, Fimea's recommendations were supported by Valvira, the National Supervisory Authority for Welfare and Health. This agency found that nicotine pouches meet the definition of a tobacco substitute as defined in the Tobacco Act. Per Valvira, the term "tobacco substitute" means a product related to tobacco in its intended use but does not contain tobacco. The agency also stated that "the individual properties of each nicotine pouch determine whether the product is a tobacco substitute and what act applies to it."[49] Ultimately, under the amendments to the Tobacco Act, nicotine pouches are a type of "smokeless nicotine product," which is in turn a type of "tobacco substitute."

The Government Proposal to Parliament to amend the Tobacco Control Act provides a thorough analysis of the status of regulation of nicotine pouches before amendments were made to the Tobacco Act, the objectives of the proposed amendments and the impact of the proposals.[50] The primary reasons to enact measures to regulate nicotine pouches were to protect the youth and to combat an illegal snus market (a product which is banned in the EU, except for Sweden). In determining the nicotine limit, the government considered limits established in neighboring countries. The limit of 16.6 mg of nicotine per gram of product was selected to avoid acute toxicity when the product is ingested and to be lower than the 20 mg of nicotine per gram of product allowed in Iceland, which was the only neighboring country that regulated nicotine limits for nicotine pouches. Further, the proposal explains that prohibiting flavors such as sweet candy, fruit and berry flavors, will eliminate flavors that appeal to children. The government also considered Denmark's proposal to ban all flavors except menthol. Ultimately, the government proposal indicates that nicotine pouches in the flavors of menthol and mint were allowed to provide an attractive alternative to adult snus users. The proposal states:

- "Another alternative to the proposed regulation would have been to ban all characteristic smells and flavours from smokeless nicotine products in a similar way to the ban on cigarettes, roll-your-own tobacco and heated tobacco products, as well as nicotine liquids and nicotine-free liquids intended for vaporisation. The advantage of this alternative would have been that all flavours that appeal to children and young people would have been comprehensively banned. However, this alternative was not adopted because it was considered to restrict the flavours of nicotine pouches too much and to hinder the achievement of the goal of nicotine pouches being a sufficiently attractive alternative to snus."
- "During the preparation of the proposal, various nicotine limits were considered and their impact on, on the one hand, preventing the illegal import of snus and, on the other hand, protecting public health, especially the health of children and young people. Adjusting the nicotine limit to, for example, 4 milligrams per gram of product would have been quite effective in protecting

young children from nicotine poisoning and reducing other health problems caused by nicotine. On the other hand, snus users would not necessarily find such a product so attractive that they would want to switch to using it instead of snus. Based on the weighing of different options, the proposal has concluded that the proposed nicotine limit, i.e. 16.6 milligrams of nicotine per gram of product, is the best balance in terms of the objectives of the proposal. [unofficial translation or machine-translated]."

In the Impact Assessment submitted by Finland to the EU Technical Regulation Information System (TRIS),[51] the government highlighted the potential financial and health benefits of regulating nicotine pouches under the Tobacco Act as a "smokeless nicotine product' under the Tobacco Act. Some statements include:

- "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 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."
- "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. 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."
- "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."
- "It is possible that some of the current smokers will switch to nicotine pouches instead of smoking cigarettes…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. 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."
- "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."

Regulatory Status – Norway

Norway's tobacco control measures require that new tobacco and nicotine products (defined as products placed on the market after May 19, 2014 that are not cigarettes, roll-your-own tobacco, pipe tobacco, water pipe tobacco, cigars, cigarillos, chewing tobacco, snuff, or snus) be approved by the Directorate of Health, before such products can be placed on the market.[52] New tobacco and nicotine products include nicotine pouches. To date, no nicotine pouches have been approved to be marketed or sold in Norway under its tobacco control measures. Further, according to the Directorate of Health, the import of nicotine pouches is also prohibited:

> "Importation of nicotine pouches from abroad: The regulations prohibit the import of products that have not been approved for sale in Norway. The import of nicotine pouches from abroad will therefore also be prohibited for private individuals who wish to bring this to Norway or order it from foreign online shops."[53]

Norway has also approved two Zonnic mint flavored nicotine pouches in strengths of 2 mg and 4 mg as medicinal products, which are available for sale as non-prescription NRT products.[54]

Purpose, Rationale and/or Evidence for Current Regulation – Norway

Through the current regulations, all new tobacco and nicotine products must be approved by the Norwegian Directorate of Health in order to be introduced and sold on the Norwegian market. On its "Tobacco Control in Norway" website,[55] the Directorate of Health states:

> "The main purpose of the approval scheme is to protect children and young people from new products and nicotine addiction. In the assessment, considerable emphasis must therefore be placed on whether the product will be able to appeal to children and young people."

The website also indicates that several manufacturers submitted applications to sell their nicotine pouch products. However, the Directorate of Health has denied the applications on the basis of protecting children and young people from new products and nicotine addiction. An appeal was made in two cases to the Ministry of Health and Care Services. In its decisions issued in July 2023, the Ministry upheld the Directorate's decision and emphasized that new research demonstrated that nicotine pouches appeal to young people and can be a product which initiates nicotine addiction.

Regulated as a Tobacco or Related Product – Colombia, Switzerland

Regulatory Status – Colombia

In Colombia, nicotine pouches are subject to the same restrictions as tobacco products under Law N. 2354 of 2024.[56] These include prohibiting use of the product in indoor public places, workplaces and

public transport; restrictions on advertising, promotion and sponsorship; mandatory combined picture/text warning label on packaging; ingredient and emission disclosure requirements; and the prohibition on the sales to persons under the age of 18.

Purpose, Rationale and/or Evidence for Current Regulation – Colombia

Colombia adopted a comprehensive tobacco control law in 2009 (Law 1335 of 2009)[57] and updated its legislation in 2024 to regulate electronic nicotine delivery systems (ENDS), electronic non-nicotine delivery systems (ENNDS), HTPs, and oral nicotine products through Law N. 2354 of 2024.[58]

Between 2017 and 2022, at least eight bills were introduced in Congress aiming to regulate tobacco and nicotine products, primarily HTPs and e-cigarettes.[59] Three of these were introduced in 2022, including the bill that was eventually debated and passed as Law 2354 of 2024. Throughout this period, tobacco industry policy interference was documented.[60]

The process began with the bill being introduced in the Senate on July 20, 2022. It passed its first Senate committee debate in November 2022, followed by unanimous approval in the Senate plenary in December 2022. The measure then progressed to the House of Representatives, where it gained further approval in its third and fourth debate on March 6, 2024. By April 2, 2024, the Senate plenary endorsed the final conciliatory version.

During the House debate, the Superintendency of Industry and Commerce (SIC) criticized the draft bill for allegedly overstepping constitutional principles by extending Law 1335 of 2009 to non-tobacco products such as e-cigarettes, oral nicotine, and HTPs, calling instead for differentiated regulation and warning that packaging and labeling requirements should comply with WTO technical barriers to trade procedures. The Ministry of Commerce, Industry and Tourism stated that the bill did not include discriminatory or restrictive measures and did not conflict with Colombia's international trade commitments.[61]

Like the SIC, the National Trade Federation (FENALCO) opposed equating these products with tobacco products like cigarettes, promoted a so-called harm reduction approach citing foreign examples, and argued for the inclusion of commercial stakeholders and adult consumers in the process.[62] FENALCO emphasized differentiated regulation, harm reduction framing, and procedural objections.[62]

Finally, as stated in Article 1 of Law No. 2354, the object of the law is to "contribute to guarantee the rights of health of the inhabitants of the national territory, especially that of minors under 18 years of age and the non-smoking population." Lawmakers referenced Colombia's commitments under the WHO FCTC, highlighting global recommendations to regulate these products comprehensively. The broad definition of the products included in the new law is seen as a strategic tool to maintain regulatory flexibility in response to future industry innovation. The law was broadly supported by the Ministry of Health, civil society, and academia.

Regulatory Status – Switzerland

In Switzerland, nicotine pouches are regulated under the Federal Tobacco Products and Electronic Cigarettes Act (TabPG).[63] TabPG was adopted on October 1, 2021, and entered into force on October 1, 2024. However, some provisions do not take effect until October 1, 2025. Further, an amendment to include additional advertising restrictions was adopted on June 20, 2025 (but is subject to a referendum set to take place in October 2025).[64]

The following definitions are included in Art. 1 of TabPG (unofficial translation or machine-translated):

> a. Tobacco product: any product consisting of or containing parts of leaves of plants of the genus *Nicotiana* (tobacco) and intended to be smoked, inhaled after heating or sniffed, as well as any **nicotine product for oral use within the meaning of letter d**, and any herbal smoking product within the meaning of letter e [emphasis added];
>
> d. Nicotine product for oral use: nicotine-containing product with or without tobacco that comes into contact with the oral mucosa during consumption and is not intended for smoking or heating.

Because the law incorporates the definition of "nicotine product for oral use" into the meaning of "tobacco product," provisions applying to tobacco products (such as restrictions on sales, marketing and certain flavors) also apply to nicotine pouches, unless otherwise stated. TabPG also requires text-only health warnings for nicotine pouches.

Purpose, Rationale and/or Evidence for Current Regulation – Switzerland

Before October 1st, 2024, tobacco products were subject to the Foodstuffs Act.[65] As part of the harmonization of Swiss foodstuffs law with European Union (EU) law, in 2014, Parliament decided to create a specific law for tobacco products,[64] which was adopted in 2021. TabPG is primarily aimed at protecting public health, with a specific focus on preventing initiation and exposure among the youth.[63]

In February 2022, the popular initiative "Yes to protecting of children and young people from tobacco advertising" was approved and the TabPG was revised to ban all advertising and sponsorship of tobacco, e-cigarettes, and nicotine pouches that can potentially reach minors. The partial revision was approved on June 20th, 2025, but it must still pass a referendum scheduled before October 9th, 2025.[66]

Before the adoption of the TabPG, the government held a consultation period for the draft law, which was followed by the publication of a Regulatory Impact Assessment in November 2015.[67] A revised Regulatory Impact Assessment was published in November 2018.[68] Both regulatory impact assessments focused heavily on the regulation of smoked tobacco products, snus, and e-cigarettes (with and without nicotine). The assessments do not specifically address tobacco-free nicotine products other than e-cigarettes.

In addition to TabPG, a Tobacco Products Ordinance (TabPV) was adopted as additional regulations for tobacco products (which by definition in the TabPG includes nicotine pouches), electronic cigarettes and similar products (herbal heated products, nicotine products consumed nasally and tobacco-free waterpipe products).[69] In the Explanatory Memo for the TabPV, the government considered regulation of nicotine pouches in other European countries, including Austria, Italy, France, Germany and the Netherlands.[70] The Memo also acknowledged that the regulation of these products changes rapidly.

Further, in justifying the need to regulate new products (non-tobacco products or e-cigarettes), the Memo provides:

> "Due to their content or method of consumption, these products pose a risk to consumer health, even if this risk is generally lower than that associated with tobacco products for smoking. Nicotine is highly addictive, which is why nicotine-containing products must be regulated. Some products are not without health risks due to the way they are consumed, which produces toxic substances. In addition, they represent a potential gateway to tobacco consumption, especially for young people." [unofficial translation or machine-translated].

While neither the TabPG or TabPV established a nicotine content limit for nicotine pouches, the consultation for the TabPV shows that this measure was of interest to the public.[71] Proposals included

16.6 mg per pouch, 20 mg per pouch, or setting the limit not to exceed the nicotine dose in one cigarette.

Sale Prohibited by Law– Germany, Netherlands

Regulatory Status – Germany

In Germany, nicotine pouches are not subject to tobacco control laws because the products do not contain tobacco. Instead, because of the way nicotine pouches are ingested and consumed, the products are classified as an unsafe food within the meaning of the EU law.[72,73] On October 7, 2022, the German Federal Institute for Risk Assessment (BfR) issued a "Health risk assessment of nicotine pouches."[74] The Risk Assessment indicates that:

> "Currently, nicotine in pouches is classified as a novel food by the German surveillance authorities. If the ARfD [Acute Reference Dose] value of 0.0008 mg/kg bodyweight is used, nicotine pouches containing all nicotine quantities presented in this report will be withdrawn from the market."

In essence, nicotine pouches are banned as an unauthorized food product because they exceed the amount of nicotine recommended by the European Food Safety Authority and nicotine is an unauthorized novel food product within the meaning of EU law.

Purpose, Rationale and/or Evidence for Current Regulation – Germany

The BfR tested a sample of 44 nicotine pouches, which were purchased online, and found the median weight per pouch was 0.6 g and the nicotine content per pouch was 9.48 mg. However, the range of nicotine content was 1.79 mg per pouch to 47.5 mg per pouch. The BfR found that these strengths were not accurately represented on the packaging of the products.

The BfR also reported on dangers posed by nicotine pouches, including:

- "At the December 2020 session of the BfR Committee for the Assessment of Poisonings, representatives from the poison information centres in Germany reported on some cases of poisoning from nicotine pouches. In one case, a pouch with 20 mg nicotine had been swallowed. The affected person was given activated charcoal by the emergency service team but did not develop any symptoms other than stomach pain. In April 2022, several new cases of poisonings involving nicotine pouches were reported. Most of the symptoms reported involved nausea/vomiting and cold sweats."

Several judicial decisions have upheld the ban on the sale of nicotine pouches as a harmful food product.[75]

Regulatory Status – Netherlands

In the Netherlands, the sale of "tobacco-free nicotine pouches for oral use" ("NZT for oral use") is prohibited under the Tobacco and Smoking Products Act.[76] In addition, the advertising and promotion of the product and use in public places are also banned.

Purpose, Rationale and/or Evidence for Current Regulation – Netherlands

Before the Tobacco and Smoking Products Act was amended to prohibit the sale of NZT for oral use, nicotine pouches in the Netherlands were regulated as "foodstuffs" (similar to the regulation that Germany has in place). In the Netherlands, pouches containing more than 0.035 mg of nicotine were deemed unsafe for consumption and therefore prohibited.[76-78] However, in an Explanatory Memo for the

amendments to the Tobacco and Smoking Products Act (Explanatory Memo),[79] the Dutch Government subsequently determined that even allowing the placement of nicotine pouches with less than 0.0035 mg of nicotine was undesirable, as they could be used as an alternative to oral tobacco products such as snus, which is prohibited in all EU Member States except Sweden. The resemblances between snus and nicotine pouches were highlighted in the Explanatory Memo, which stated:

> "Snus and nicotine pouches also have striking similarities in terms of product appearance, method of use, effect, and invisibility when used. Furthermore, the presence of flavors and attractive packaging contribute to the appeal of both products to young people. Both products also contain harmful and addictive nicotine, with snus also containing tobacco, which exposes the user to a range of carcinogenic substances. The government assesses nicotine pouches in line with the Court's assessment of the risks of snus and believes that nicotine pouches should be prevented from becoming more popular, particularly among young people." [unofficial translation or machine-translated]

The Explanatory Memo also relied on a 2021 report from the Dutch National Institute for Public Health and Environment (RIVM) on tobacco-free nicotine products ("NZT") (Report),[80] which was presented to the cabinet. The Report concluded that nicotine pouches contain enough nicotine to cause and maintain addiction. In addition, the data showed that 31% of people who used nicotine pouches had never smoked before, which raised concerns that the products could quickly gain popularity among young people.

Furthermore, in its notification to the European Commission, the Dutch government stated that enacting partial measures for NZTs for oral use - such as imposing a minimum age to purchase, requiring health warnings, or banning flavors - was insufficient to protect public health.[81] Its decision to ban the products aligned with its goal of achieving a smoke-free generation by 2040 and protecting children from the harms of nicotine addiction. In addition, as outlined in the Explanatory Memo, the government concluded that such actions were consistent with its obligations under the WHO FCTC, including reducing tobacco consumption and nicotine addiction.

The government found that the ban on NZTs for oral use was reasonable, given the existing ban on snus, and prohibiting its use in public places facilitated compliance and enforcement (the use of snus is also banned in public places).[82] Furthermore, given the lifestyle promotion of nicotine pouches and their attractive and youth-appealing design, the advertising and promotion of nicotine pouches was also prohibited under the law.[82] The Dutch government also attempted to future-proof the law by including the following definitions of NZTs and NZTs for oral use:[83]

- "nicotine product without tobacco: a product that contains nicotine and does not contain tobacco, that is intended for the consumption of nicotine and that is not an electronic vapor product or an herbal product for smoking;"
- "tobacco-free nicotine product for oral use: a tobacco-free nicotine product intended for oral use, whether in the form of powder, fine particles, a combination thereof or any other form, in particular those presented in portion sachets or porous bags, with exception of products intended to be inhaled;"[unofficial translation or machine-translated]

According to the Explanatory Memo, the definitions were drafted broadly to capture other potential products to which nicotine could be added, such as sweets, drinks, and food supplements. The Explanatory Memo also highlights why only NZT for oral use are banned:

> "For NZTs that are not used orally, such as nicotine spray, no ban will be imposed for the time being. Instead, these products will be regulated in more or less the same way as related products. The reason for this is that there is currently limited research available on the risks of

these products. These products also appear to be relatively unpopular at present. However, because these products also contain nicotine and their use is therefore not without risk, regulation is necessary."[unofficial translation or machine-translated]

Regulatory Proposals Involving Nicotine Pouches

United Kingdom

Currently, nicotine pouches are regulated under general consumer product safety regulations in the United Kingdom.[84] However, the UK Parliament is considering The Tobacco and Vapes Bill, which includes proposed provisions related to nicotine pouches, among other tobacco control measures.[85,86] The Tobacco and Vapes Bill would allow UK governments to regulate all aspects of nicotine pouches, including sales, marketing, packaging and product regulation. As of August 2025, the Bill completed its 3rd reading in the House of Commons, 1st and 2nd reading in the House of Lords and is currently in the Committee stage. To become law, the Bill needs to move through a Committee stage to a 3rd reading prior to the final stages of the consideration of amendments and Royal Assent.[87]

France [a]

In February 2025, France notified the European Commission that it intended to "prohibit the production, manufacture, transport, import, export, possession, offering, transfer, purchase, distribution, and use of products for oral use containing nicotine, except for medicinal products and medical devices.[89] This draft decree covers nicotine pouches. After its notification, six EU Member States objected to France's intention citing conflicts with the free movement of goods within the internal EU market, among other concerns.[89] France's regulatory action has been postponed from May 26, 2025 until August 25, 2025.[90]

European Commission

On June 6, 2025, a question was presented from a Member of the European Parliament to the European Commission concerning the regulation of nicotine pouches.[91] The question raised concerns over the non-harmonized regulation of nicotine pouches within the European Union, and specifically asked whether the Commission intends to propose regulation for nicotine pouches and for plans to address the rising popularity among young people.

The European Commission responded on August 20, 2025, and acknowledged that the rise in popularity of the products causes public health concerns.[90] The response reiterated that there is no safe level of nicotine and acknowledged that while the products are currently outside of the scope of the EU Tobacco Products Directive, an assessment was being conducted of the tobacco control legislative framework to determine next steps. The answer also stated that:

> "Nicotine pouches may be subject to national measures, provided that those measures comply with EU law, including the provisions on the free movement of goods of the Treaty on the Functioning of the European Union (TFEU). The TFEU, does not preclude restrictions justified on one of the grounds of public interest laid down in Article 36 TFEU, including the protection of public health."

According to the European Commission's website, revisions to the EU TPD are anticipated to be adopted in Q1 2026.[92]

[a] The adoption of this Decree[88] occurred after legal analysis for this paper was completed.

Discussion

This global policy scan identified 45 countries that have regulated nicotine pouches as of August 15, 2025. It is noticeable that the highest prevalence of countries with policies are from the European region and from high-income countries. Amongst the countries regulating nicotine pouches, 21 countries (47%) regulated them as a Tobacco or Related Product; ten countries (22%) Prohibited the Sale by Law; six countries (13%) regulated them as Medicinal/Pharmaceutical Products (No Approved Products); three countries (7%) regulated them as Medicinal and Tobacco Products (3, 7%); three countries (7%) regulated nicotine pouches using Other Measures; one country (2%) regulated them as Natural Health Products (Approved Product); and one country (2%) Prohibited the Sale by Law (Pending Additional Action).

Amongst the policy measures that are used, prohibiting misleading packaging, prohibiting attractive ingredients, such as vitamins, caffeine, etc., and requiring health warning labels are the most prevalent. In-depth analysis provides more details for countries using these different methods. The toxicity and addictiveness of nicotine and its health hazards were recurrent themes in many countries that guided regulation. Concerns regarding youth uptake were included in multiple country reviews. In addition, being in accordance with existing legal commitments (e.g., WHO FCTC and EU law) was also a recurrent topic. For example, the Netherlands' regulation considered nicotine pouches as a similar product to snus, which is banned under the EU TPD, justifying also banning pouches. Some countries positioned nicotine pouches against current NRTs.

There are limitations to this report. It does not include subnational regulations, reflect any current taxation policies, standards issued by national standards bodies, or general consumer safety measures. Given that this is a convenience sampling, some policies in place that we are unaware of would be missing. The implementation of regulatory measures was not considered. The policy landscape is changing quickly and since this data was analyzed after August 15, 2025, France has since passed a policy which is not fully described here. In addition, legal provisions are often susceptible to more than one interpretation, giving rise to the possibility of interpretation error, especially where we do not have in-country lawyer assistance. Additionally, this legislative review is based strictly on the letter of the law and not based solely on information from government authorities regarding how the products are regulated.

There are several inherent challenges to consider when seeking to regulate nicotine pouches. First, evidence on the health, social and environmental risks and harms of these products is evolving given they are a relatively new product category. Nevertheless, ensuring that regulations include strong measures to address flavors and limit nicotine levels can potentially help prevent the widespread use of nicotine pouches, which are not a "safe" product. Second, the tobacco industry's appropriation of 'harm reduction' and its related lobbying efforts have put pressure on governments to place weaker regulation on these products even though the companies target adolescents and young people and market them to people who currently smoke as a way of continuing to use nicotine when they cannot smoke – therefore both initiating and sustaining nicotine addiction. The *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health on harm reduction for sustainable peace and development* recognizes that harm reduction involving tobacco requires "adequately and effectively regulating corporate actors;" and highlights that the "[t]he scepticism towards the tobacco industry's harm reduction initiatives stems from their long and well-documented history of duplicitous behaviour, concealing and downplaying the health risks of their products, while deceptively marketing alternatives as harm reduction or quitting alternatives as ascertained in judicial proceedings." Third, the absence of clear product classification results in regulatory gaps; thus, it is essential that legal measures clearly define and regulate nicotine pouches and not rely on existing legislation that may not

clearly cover these products. Further, existing legislation may not also cover pouches manufactured with synthetic nicotine or nicotine analogs.

Conclusions

We know that countries are beginning to adopt policies to address nicotine pouches. These policies do cover a range of options, from regulating packaging, labeling, ingredients, flavors, advertising and public use of the products to prohibiting their sale altogether.

Parties to the WHO FCTC can fulfill their obligations to adopt and implement effective measures for preventing and reducing tobacco and nicotine addiction through their efforts to regulate what COP documents refer to as novel and emerging nicotine products, such as nicotine pouches. In developing comprehensive tobacco control strategies, it is also important to support adult tobacco users who can benefit from evidence-based cessation tools, which include nicotine such as gum, lozenge, transdermal patch, nasal spray, and oral inhaler, and medications such as bupropion and varenicline.

The consideration of differing regulatory pathways taken by countries to address nicotine pouches can help other governments decide on their options and path forward, recognizing differing public health objectives and national circumstances, including the countries' tobacco burden, health disparities, government capacity and resources.

References

1. U.S. Centers for Disease Control and Prevention. Nicotine pouches. CDC.gov. 2025 Jan 31. https://www.cdc.gov/tobacco/nicotine-pouches/index.html
2. Robichaud MO, Seidenberg AB, Byron MJ. Tobacco companies introduce 'tobacco-free' nicotine pouches. *Tob Control.* 2020;29:e145–6. doi:10.1136/tobaccocontrol-2019-055321. https://tobaccocontrol.bmj.com/content/29/e1/e145
3. Stanfill S, Tran H, Tyx R, et al. Characterization of total and unprotonated (free) nicotine content of nicotine pouch products. *Nicotine Tob Res.* 2021;23(9):1590–6. doi:10.1093/ntr/ntab030. https://doi.org/10.1093/ntr/ntab030
4. Mallock-Ohnesorg N, Rabenstein A, Stoll Y, et al. Small pouches, but high nicotine doses: nicotine delivery and acute effects after use of tobacco-free nicotine pouches. *Front Pharmacol.* 2024 May 22;15:1392027. doi:10.3389/fphar.2024.1392027. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11150668/
5. World Health Organization. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: ninth report of a WHO study group. WHO. 2023 Aug 23. https://www.who.int/publications/i/item/9789240079410
6. Connecticut Department of Public Health. Synthetic nicotine. Ct.gov. 2023 Sep. https://portal.ct.gov/-/media/departments-and-agencies/dph/dph/hems/tobacco/pdf/fact-sheets-and-resources-2023/fact-sheet_synthetic-nicotine.pdf?rev=2aa0ecb14a08442da7844cefefe04224&hash=E8886B787896E057B193AC0B6C8CFE7D
7. Editorial Staff of American Lung Association. What is synthetic nicotine?. Lung.org. 2022 Aug 18 https://www.lung.org/blog/synthetic-nicotine
8. Vagg R, Chapman S. Nicotine analogues: a review of tobacco industry research interests. *Addiction.* 2005;100:701–12. doi:10.1111/j.1360-0443.2005.01014.x. https://doi.org/10.1111/j.1360-0443.2005.01014.x
9. Czaplicki L, Moran MB, Kennedy RD, et al. Nicotine analogue pouches: a growing regulatory challenge. *Tob Control.* 2025 Aug 11 [Epub ahead of print]. doi:10.1136/tc-2025-059581. https://doi.org/10.1136/tc-2025-059581
10. Dai HD, Leventhal AM. Prevalence of nicotine pouch use among US adults. *JAMA.* 2024;332(9):755–7. doi:10.1001/jama.2024.10686. https://doi.org/10.1001/jama.2024.10686
11. Brose LS, Bunce L, Cheeseman H. Prevalence of nicotine pouch use among youth and adults in Great Britain: analysis of cross-sectional, nationally representative surveys. *Nicotine Tob Res.* 2025;ntae295. doi:10.1093/ntr/ntae295. https://doi.org/10.1093/ntr/ntae295
12. Zamarripa CA, Dowd AN, Elder HJ, et al. A comprehensive review on oral nicotine pouches: available scientific evidence and future research needs. *Exp Clin Psychopharmacol.* 2025;33(2):123–32. doi:10.1037/pha0000755. https://doi.org/10.1037/pha0000755
13. Al-Otaibi HM, Althobiani MA. Nicotine pouches: a narrative review of the existing literature. *Front Public Health.* 2025;13:1641308. doi:10.3389/fpubh.2025.1641308. https://doi.org/10.3389/fpubh.2025.1641308
14. University of Nebraska Medicine. Are nicotine pouches safer than chewing, smoking or vaping?. 2021 Jun 1. https://www.nebraskamed.com/cancer/lung/quit-smoking/are-nicotine-pouches-safer
15. Yuan M, Cross SJ, Loughlin SE, et al. Nicotine and the adolescent brain. *J Physiol.* 2015;593(16):3397–412. doi:10.1113/JP270492. https://doi.org/10.1113/JP270492
16. Grand View Research, Inc. Nicotine pouches market size, share & trends analysis report by product type (tobacco-derived nicotine, synthetic nicotine), by distribution channel (offline, online), by flavor, by strength, by region, and segment forecasts, 2025–2030. Grand View Research; 2025. https://www.grandviewresearch.com/industry-analysis/nicotine-pouches-market-report

17. Majmundar A, Okitondo C, Xue A, et al. Nicotine pouch sales trends in the US by volume and nicotine concentration levels from 2019 to 2022. *JAMA Netw Open.* 2022;5(11):e2242235. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794417
18. CDC Foundation. Monitoring Sales: Nicotine Pouch Trends. Tobacco Monitoring. 2025 Jan 10. https://tobaccomonitoring.org/wp-content/uploads/2025/01/Nicotine-Pouch-Brief_1.10.2025.pdf
19. CDC Foundation. Monitoring Sales: Nicotine Pouch Trends. Tobacco Monitoring. 2025 Apr 20. https://tobaccomonitoring.org/wp-content/uploads/2025/07/Nicotine-Pouch-Brief-4.20.2025.pdf
20. Jordt SE, Jabba SV, Zettler PJ, et al. Spree Bar, a vaping system delivering a synthetic nicotine analogue, marketed in the USA as 'PMTA exempt.' *Tob Control.* 2025;34:414–18. https://tobaccocontrol.bmj.com/content/34/5/414
21. Duren M, Atella L, Welding K, et al**.** Nicotine pouches: a summary of regulatory approaches across 67 countries. *Tob Control.* 2024;33:e32–40. https://tobaccocontrol.bmj.com/content/33/e1/e32
22. World Health Organization**.** WHO Framework Convention on Tobacco Control, Article 5.2(b). https://fctc.who.int
23. World Health Organization**.** WHO Framework Convention on Tobacco Control. FCTC/COP10(23) Specific guidelines to address cross-border tobacco advertising, promotion and sponsorship and the depiction of tobacco in entertainment media for implementation of Article 13 (Tobacco advertising, promotion and sponsorship). 2023 May 19. https://iris.who.int/bitstream/handle/10665/377357/fctc-cop-10-23-en.pdf?sequence=1
24. U.S. Centers for Disease Control and Prevention**.** Addressing use of nicotine pouches. 2024 Sep 17. https://www.cdc.gov/tobacco/nicotine-pouches/addressing-use-of-nicotine-pouches.html
25. World Health Organization**.** WHO Framework Convention on Tobacco Control. FCTC/COP/11/10 Provisional agenda. 2025 Jun 17. https://storage.googleapis.com/who-fctc-cop11-source/Main%20documents/fctc-cop11-1-en.pdf
26. TobaccoIntelligence. Market and legal tracking of the tobacco alternative sector. 2025. https://tobaccointelligence.com/
27. Tobacco and Vaping Products Act, S.C. 1997, c. 13. Current through July 24, 2025. Available from: https://laws-lois.justice.gc.ca/eng/acts/t-11.5/
28. Canada. *Food and Drugs Act*, R.S.C., 1985, c. F-27. Ottawa: Department of Justice; 2025 Jul 24. https://laws-lois.justice.gc.ca/eng/acts/f-27/
29. Canada. Natural Health Products Regulations, SOR/2003-196. Current through 24 Jul 2025. Ottawa: Department of Justice. https://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/
30. Health Canada. Public advisory: Only use authorized nicotine pouches as directed, and do not use unauthorized nicotine pouches. Ottawa: Health Canada; 2025 Aug 21.https://recalls-rappels.canada.ca/en/alert-recall/only-use-authorized-nicotine-pouches-directed-and-do-not-use-unauthorized-nicotine
31. Health Canada. Health Canada License: Zonnic. Ottawa: Health Canada. https://web.archive.org/w.eb/20230925194149/https:/health-products.canada.ca/lnhpd-bdpsnh/info?licence=80125630
32. Health Canada. Supplementary Rules Respecting Nicotine Replacement Therapies Order: SOR/2024-169. Ottawa: Canada Gazette; 2024 Aug 28. https://gazette.gc.ca/rp-pr/p2/2024/2024-08-28/html/sor-dors169-eng.html
33. Health Canada. Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order. Ottawa: Health Canada; 2025 Feb 12. https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/supplementary-rules-respecting-nicotine-replacement-therapies-order.html
34. CBC News. 'We were duped': Health minister vows to close 'loophole' on flavoured nicotine pouches. Ottawa: CBC News; 2023 Nov 30. https://www.cbc.ca/news/politics/we-were-duped-health-minister-regulations-zonnic-nicotine-pouches-1.7044806
35. Therapeutic Goods Administration. Therapeutic Goods (Determined Goods) Determination 2024 (Cth). Canberra: Department of Health and Aged Care; 2024. https://www.legislation.gov.au/Details/F2024L00789

36. Therapeutic Goods Administration. Therapeutic Goods (Poisons Standard—June 2025) Instrument 2025. Canberra: Department of Health and Aged Care; 2025 May 28. https://www.legislation.gov.au/F2025L00599
37. Therapeutic Goods Administration. Nicotine pouches are illegal in Australia unless prescribed. Canberra: Department of Health and Aged Care; 2025 Aug 7. https://www.tga.gov.au/news/news/nicotine-pouches-are-illegal-australia-unless-prescribed
38. Therapeutic Goods Administration. Personal Importation Scheme. Canberra: Department of Health and Aged Care; 2025 Jul 7. https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme
39. Queensland Government. Tobacco and Other Smoking Products Regulation 2021. Brisbane: Queensland Government; 2021. https://www.legislation.qld.gov.au/view/pdf/inforce/current/sl-2021-0111
40. Nicholls T. Human rights certificate: Health and Other Legislation Amendment Regulation 2025 [Internet]. Brisbane: Queensland Parliament; 2025 May 24. https://www.parliament.qld.gov.au/docs/find.aspx?id=5825T0374
41. Government of South Australia. Declaration of prohibited product under section 39C(1) of the Tobacco and E-Cigarette Products Act 1997 (SA). Adelaide: Preventative Health SA; 2025 Jan 30. https://www.preventivehealth.sa.gov.au/about/news-announcements/new-laws-to-restrict-sale-and-use-of-nicotine-pouches
42. Government of South Australia. New laws to restrict sale and use of nicotine pouches [Internet]. Adelaide: Preventative Health SA; 2025 Jan 30. Available from: https://www.preventivehealth.sa.gov.au/about/news-announcements/new-laws-to-restrict-sale-and-use-of-nicotine-pouches
43. Therapeutic Goods Administration. Nicotine pouches [Internet]. Canberra: Department of Health and Aged Care; 2024 Jul 24. Available from: https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/nicotine-pouches
44. Therapeutic Goods Administration. Notice of decision to amend (or not amend) the current Poisons Standard in relation to nicotine. Canberra: Department of Health and Aged Care; 2024 May 24. https://www.tga.gov.au/sites/default/files/2024-05/notice-decision-amend-or-not-amend-poisons-standard-nicotine.pdf
45. Fimea. Fimea supports legislative reform concerning nicotine pouches [Internet]. Helsinki: Finnish Medicines Agency; 2023 Apr 4. Available from: https://fimea.fi/en/-/fimea-supports-legislative-reform-concerning-nicotine-pouches
46. Fimea. Zonnic marketing authorization. Helsinki: Finnish Medicines Agency; . https://fimea.fi/en/databases_and_registers/fimeaweb?query=Zonnic&humanmed=true&selfcare=true&receptmed=true&marketedmed=true&prefillonly=false
47. Finland. Act Amending the Tobacco Act (251/2025) [Internet]. Helsinki: Ministry of Social Affairs and Health; 2025 May 23. Available from: https://www.finlex.fi/fi/lainsaadanto/saadoskokoelma/2025/251
48. Finland. Tobacco Act (549/2016) [Internet]. Helsinki: Ministry of Social Affairs and Health; 2016 Jun 29 . https://www.finlex.fi/fi/lainsaadanto/saadoskaannokset/2016/eng/549
49. Valvira. The Tobacco Act applies to nicotine pouches. Helsinki: National Supervisory Authority for Welfare and Health; 2023 Apr 14. https://valvira.fi/en/-/the-tobacco-act-applies-to-nicotine-pouches
50. Finland. Government proposal to Parliament for an Act amending the Tobacco Act. Helsinki: Ministry of Economic Affairs and Employment; 2024 Jul 3. Available from: https://www.finlex.fi/fi/hallituksen-esitykset/2024/221
51. Finland. Government proposal to Parliament for an Act amending the Tobacco Act. Helsinki: Ministry of Economic Affairs and Employment; 2023 Oct 16. https://technical-regulation-information-system.ec.europa.eu/en/notification/24952
52. Norway. Regulations No. 2131 of 17 June 2021: Regulations on approval schemes for new tobacco and nicotine products (as amended). Oslo: Ministry of Health and Care Services. https://lovdata.no/dokument/SF/forskrift/2021-06-17-2131

53. Norway Directorate of Health. Tobacco control in Norway. Oslo: Norwegian Directorate of Health. https://www.helsedirektoratet.no/english/tobacco-control-in-norway
54. Norway Directorate for Medical Products. Zonnic Niconovum [Internet]. Oslo: Norwegian Directorate for Medical Products. Available from: https://www.felleskatalogen.no/medisin/zonnic-niconovum-590881?markering=0.
55. Norway Directorate of Health. Tobacco control in Norway [Internet]. Oslo: Norwegian Directorate of Health. Available from: https://www.helsedirektoratet.no/english/tobacco-control-in-norway
56. Colombia. Ley 2354 de 2024: Por medio de la cual se modifica el artículo 1° de la Ley 1335 de 2009 y se dictan otras disposiciones. Bogotá: Congreso de la República; 2024 May 9. Disponible en: https://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=154660.
57. Colombia. Ley 1335 de 2009: Por medio de la cual se previenen daños a la salud de los menores de edad, la población no fumadora y se estipulan políticas públicas para la prevención del consumo del tabaco y el abandono de la dependencia del tabaco del fumador y sus derivados en la población colombiana. Bogotá: Congreso de Colombia; 2009 Jul 21. Disponible en: https://www.secretariasenado.gov.co/senado/basedoc/ley_1335_2009.html
58. Colombia. Law No. 2354 of 2024: By means of which Article 1 of Law 1335 of 2009 is amended and other provisions are enacted. Bogotá: National Government; 2024 May 9. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Colombia/Colombia-Law-No.-23542024-native.pdf
59. Severini L, de Figueiredo BA, Severini G, et al. Shaping the future: proposed bills to regulate new and emerging tobacco and nicotine products in Latin America and the Caribbean amidst public health concerns and industry interests. *Nicotine Tob Res.* 2024 Dec 23;27(1):148-151. doi: 10.1093/ntr/ntae161. PMID: 38970330. Available from: https://pubmed.ncbi.nlm.nih.gov/38970330/
60. Guarnizo PD, Angarita TP, Torres BA. *Diferentes industrias, un mismo manual. Interferencia de las industrias de tabaco, alcohol y ultraprocesados en las políticas para la prevención de enfermedades no transmisibles en Colombia*. Bogotá: Dejusticia; 2025. p. 38–39. Available from: https://www.dejusticia.org/wp-content/uploads/2025/02/9786287764170.pdf
61. Ministry of Commerce, Industry and Tourism. Response to request made by the Secretary General of the Seventh Committee of the House of Representatives – Opinion on Bill 001 of 2022 Senate – 325 of 2022 House. 2023 Mar 3 [Internet]. Available from: https://www.camara.gov.co/camara/visor?doc=/sites/default/files/2023-03/P.L.No_.325.pdf
62. National Trade Federation (FENALCO). Comments on Subcommittee Report PL 01/22S – 325/22C "By which Article 1 of Law 1335 of 2009 is amended and other provisions are issued". 2023 Aug 4 https://www.camara.gov.co/camara/visor?doc=/sites/default/files/2023-09/Comentarios%20fenalco%20info.%20subcom.%20pl.%20325C-23%20%28agosto%204-23%2C%2017-00%20H.%29.pdf
63. Switzerland. Federal Act 818.32 of 1 October 2021 on Tobacco Products and Electronic Cigarettes (Tobacco Products Act, TabPG) [Internet]. Available from: https://www.fedlex.admin.ch/eli/cc/2024/457/de
64. Switzerland. Federal Act on Tobacco Products and Electronic Cigarettes (Tobacco Products Act, TabPG) Amendment of 20 June 2025 [Internet]. Available from: https://www.fedlex.admin.ch/eli/fga/2025/2038/fr
65. Switzerland. Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FSA) of 20 June 2014 (status as of 1 Oct 2024). https://www.fedlex.admin.ch/eli/cc/2017/62/en
66. Switzerland. Loi fédérale sur les produits du tabac et les cigarettes électroniques (Loi sur les produits du tabac, LPTab) — modification du 20 juin 2025. Parlement no 23.049 [Internet]. Available from: https://www.fedlex.admin.ch/eli/fga/2025/2038/fr.
67. Switzerland. Regulatory impact assessment of the first version of the Tobacco Products Act. https://www.bag.admin.ch/dam/de/sd-web/syT150fbm03l/2015_RFA_TabPG_Schlussbericht.pdf
68. Switzerland. Regulatory impact assessment on the revised Tobacco Products Act [Internet]. Available from: https://www.bag.admin.ch/dam/de/sd-web/sE5VlLnVDr8T/rfa_tabpg.pdf

69. Switzerland. 2024 Federal Act cc/2024/491 [Internet]. Available from: https://www.fedlex.admin.ch/eli/cc/2024/491/de
70. Switzerland. Explanatory report on the Tobacco Products Ordinance. https://www.bag.admin.ch/dam/de/sd-web/PrwaOILxst3e/erlaeuternder-bericht-tabpv.pdf
71. Switzerland. Tobacco Products Ordinance. Report on the results of consultation procedure. https://backend.bag.admin.ch/fileservice/sdweb-docs-prod-bagadminch-files/files/2025/03/18/82fa6110-c6b2-4ce8-9ad5-bb94e32e5a26.pdf
72. European Union. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [Internet]. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178
73. European Union. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. (https://eur-lex.europa.eu/eli/reg/2015/2283/oj/eng).
74. German Federal Institute for Risk Assessment (BfR). Health risk assessment of nicotine pouches. https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf
75. Tobacco Wholesaler v. Respondent, M 26b S 20.6309 (Admin. Ct Munich 2021) [Internet]. https://www.tobaccocontrollaws.org/litigation/decisions/tobacco-wholesaler-v-respondent
76. Netherlands. Tobacco and Smoking Products Act (current through 2025 Jul 12) [Internet]. Available from: https://wetten.overheid.nl/BWBR0004302/2025-07-12
77. Netherlands. Commodities Act (current through 2025 Jul 12) [Internet]. Available from: https://wetten.overheid.nl/BWBR0001969/2025-07-12.
78. Netherlands. Commodities Act Decree on the Preparation and Treatment of Foodstuffs (current through 1 Jan 2025) [Internet]. https://wetten.overheid.nl/BWBR0005758/2025-01-01
79. Netherlands. Decision note on the amendment of the Tobacco and Smoking Products Act, regulating nicotine products without tobacco and nicotine devices. 2023 Aug 31. https://www.eerstekamer.nl/overig/20230831/beslisnota_bij_wijziging_van_de/meta
80. RIVM. Tobacco-free nicotine products for oral use. 2020. https://www.rivm.nl/bibliotheek/rapporten/2020-0152.pdf
81. Netherlands. Notification detail: amendment to the Tobacco and Smoking Products Act regulating non-tobacco nicotine products and nicotine devices. 2023 May 23 [Internet]. Available from: https://technical-regulation-information-system.ec.europa.eu/en/notification/23743
82. Netherlands. Explanatory memorandum (Memorie van Toelichting) [Internet]. Available from: https://www.eerstekamer.nl/behandeling/20230831/memorie_van_toelichting/info
83. Netherlands. Act of 2 October 2024 amending the Tobacco and Smoking Products Act, regulating tobacco-free nicotine products and nicotine devices, Article 1. https://zoek.officielebekendmakingen.nl/stb-2024-292.html
84. Great Britain. General Product Safety Regulations 2005. Available from: https://www.gov.uk/government/publications/general-product-safety-regulations-2005
85. UK Government, Department of Health & Social Care. Consultation outcome: creating a smokefree generation and tackling youth vaping consultation: government response. Updated 2024 Feb 12. https://www.gov.uk/government/consultations/creating-a-smokefree-generation-and-tackling-youth-vaping/outcome/creating-a-smokefree-generation-and-tackling-youth-vaping-consultation-government-response
86. UK Parliament. Publications: Bill documents. https://bills.parliament.uk/publications/60034/documents/6282
87. UK Parliament. Parliamentary Bills: Tobacco and Vapes Bill. https://bills.parliament.uk/bills/3879
88. France. Decree No. 2025-898 of September 5, 2025 relating to the prohibition of products for oral use containing nicotine. Enters into force on March 6, 2026 [Internet]. Available from: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000052197959

89. TRIS-European Commission. Prevention of technical barriers to trade. Notification detail: Proposal for a decree on the prohibition of products for oral use containing nicotine. Other messages [Internet]. https://technical-regulation-information-system.ec.europa.eu/en/notification/26692
90. Mr Várhelyi on behalf of the European Commission, E-002286/2025. (https://www.europarl.europa.eu/doceo/document/E-10-2025-002286-ASW_EN.pdf).
91. Kulmuni K. Question for written answer E-002286/2025 [Internet]. 2025. Available from: https://www.europarl.europa.eu/doceo/document/E-10-2025-002286_EN.pdf
92. European Commission. Evaluation of the legislative framework for tobacco control https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en
93. Belgium**.** Royal Order of March 14, 2023 prohibiting the marketing of certain similar products, Article 1(1) [Internet]. 2023 Mar 14 [cited 2025 Oct 5]. https://www.ejustice.just.fgov.be/eli/arrete/2023/03/14/2023041247/justel
94. Kyrgyz Republic. Law No. 21 on the Protection of Health of the Citizens of the Kyrgyz Republic from the Effects of Tobacco and Nicotine Consumption and from Exposure to Ambient Tobacco Smoke and Aerosol, Article 2(16). 2021. https://assets.tobaccocontrollaws.org/uploads/legislation/Kyrgyzstan/Kyrgyzstan-Law-No.-1212021.pdf
95. Imperial Lithuania v. Department of Drugs, Tobacco and Alcohol Control. Ruling of April 7, 2021, Supreme Administrative Court of Lithuania. 2021 Apr 7. https://www.tobaccocontrollaws.org/litigation/decisions/imperial-lithuania-v-department-of-drugs-tobacco-and-alcohol-control
96. Mauritius**.** Public Health (Restrictions on Tobacco Products) Regulations 2022 (as amended), Section 4(4)(e) [Internet]. 2022. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Mauritius/Mauritius-PH-Regs-2022-native.pdf
97. Netherlands**.** Act of 2 October 2024 amending the Tobacco and Smoking Products Act, regulating tobacco-free nicotine products and nicotine devices, Article 1 [Internet]. 2024 Oct 2. Available from: https://zoek.officielebekendmakingen.nl/stb-2024-292.html
98. Russian Federation. Federal Law No. 303-FZ of July 31, 2020 "On Amendments to Certain Legislative Acts of the Russian Federation on the Protection of Citizens' Health from the Consequences of Consuming Nicotine-Containing Products," Article 19, Part 8. 2020 Jul 31. https://assets.tobaccocontrollaws.org/uploads/legislation/Russia/Russia-No.-303-FZ-on-Nicotine-Products.pdf
99. Singapore. Tobacco (Control of Advertisements and Sale) Act (as amended), Sections 2, 16 [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Singapore/Singapore-Control-of-Ads-Sale-native.pdf
100. Tajikistan. Law No. 649 on Restrictions of the Use of Tobacco Products (as amended), Article 1 [Internet]. . Available from: https://mmk.tj/content/қонуни-ҷумҳурии-тоҷикистон-дар-бораи-маҳдуд-намудани-истифодаи-маҳсулоти-тамоку-0
101. Uzbekistan**.** Law No. ZRU-844 on Restricting the Distribution and Consumption of Alcohol and Tobacco Products, Article 3 [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Uzbekistan/Uzbekistan-Law-No.-ZRU-844.pdf
102. Viet Nam. National Assembly Resolution No. 173/2024/QH15, Section 2.2. 2024 . https://assets.tobaccocontrollaws.org/uploads/legislation/Viet%20Nam/Viet-Nam-Resolution-No.-173-2024-QH15.pdf
103. Australia. Therapeutic Goods (Poisons Standard – June 2025) Instrument 2025. 2025. https://www.legislation.gov.au/F2025L00599/asmade/text
104. Cyprus. Ministry of Health. Decision regarding nicotine pouches [Internet]. https://www.moh.gov.cy/Moh/phs/phs.nsf/All/6419238898ACC32CC2258BCB0024671C/$file/Ανακοίνωση%20για%20Nicotine%20Pouches.pdf

105. Hong Kong. Pharmacy and Poisons Ordinance (Cap 138). https://www.elegislation.gov.hk/hk/cap138
106. India. Drugs and Cosmetics Rules, 1945, Schedule K, Entry No. 33 [Internet]. 1945. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf
107. India. Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011, Section 2.3.4 [Internet]. 2011 . Available from: https://www.fssai.gov.in/upload/uploadfiles/files/Compendium_Prohibition_Regulations_04_03_2021.pdf
108. Japan. Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. [Internet]. Available from: https://laws.e-gov.go.jp/law/335AC0000000145
109. New Zealand. Smokefree Environments and Regulated Products Act 1990 (Public Act 1990 No. 108) (as amended), Section 54(3) [Internet]. . Available from: https://www.legislation.govt.nz/act/public/1990/0108/latest/whole.html#LMS428638
110. Colombia**.** Law No. 2354 amending Law No. 1335, Article 1 [Internet]. . Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Colombia/Colombia-Law-No.-23542024.pdf
111. Czech Republic. Act No. 65/2017 (as amended), Section 2 [Internet]. Available from: https://www.zakonyprolidi.cz/cs/2017-65
112. Denmark**.** Act No. 2071 of 2020 amending the Tobacco Products Act, etc., Section 2(25) [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Denmark/Denmark-Act-No.-2071-of-2020.pdf
113. Estonia. Tobacco Act, Section 31(1)(1) [Internet]. Available from: https://www.riigiteataja.ee/akt/104012021017
114. Greece. Law 3730/2008 on the Protection of Minors from Tobacco and Alcoholic Beverages, Article 2(2) [Internet]. Available from: https://www.kodiko.gr/nomothesia/document/141125/nomos-3730-2008
115. Hungary. Government Decree 120/2024 amending Government Decree 39/2013, Section 19F [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Hungary/Hungary-Regulation-1202024.pdf
116. Iceland. Act on Electronic Cigarettes and Refill Containers for Electronic Cigarettes (No. 87/2018) (as amended), Article 3(3) [Internet]. Available from: https://www.althingi.is/lagas/nuna/2018087.html
117. Kenya. *Kenya Gazette* Vol. CXXVII-No. 31 [Internet]. 2025 Feb 14. Available from: https://new.kenyalaw.org/akn/ke/officialGazette/2025-02-14/31/eng@2025-02-14
118. Latvia. *Act on the Circulation of Tobacco Products, Tobacco Substitute Products, Herbal Smoking Products, Electronic Smoking Devices and their Liquids*, Section 1(301) [Internet]. Available from: https://likumi.lv/ta/id/282077-tabakas-izstradajumu-augu-smekesanas-produktu-elektronisko-smekesanas-iericu-un-to-skidrumu-aprites-likums
119. Moldova. *Law No. 278-XVI on Tobacco Control* (as amended), Article 2 [Internet]. Available from: https://www.legis.md/cautare/getResults?doc_id=128322&lang=ro
120. Panama. *Ministry of Health Resolution No. 146 of January 31, 2025*, Article 3(7) [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Panama/Panama-Res.-No.-146-2025.pdf
121. Peru. *Law No. 32159, Law on the Consumption Control of Tobacco and Nicotine Products, or their Substitutes, for the Protection of Life and Health*, Article 5(o) [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Peru/Peru-Law-No.-32159.pdf
122. Philippines. *Republic Act No. 11900*, Section 3(n) [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Philippines/Philippines-Rep.-Act-No.-11900-native.pdf

123. Poland. *Act of May 21, 2025 amending the Act on Protection of Health Against the Consequences of Using Tobacco and Tobacco Products*, Articles 2(21) and 2(44a) [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Poland/Poland-2025-TC-Amendment-Related-Products.pdf
124. Romania. Law No. 201 of 2016 (as amended), Article 2(p4) [Internet]. Available from: https://legislatie.just.ro/Public/DetaliiDocument/280269
125. Serbia. Law on Tobacco (as amended), Article 2(16) [Internet]. Available from: https://www.paragraf.rs/propisi/zakon_o_duvanu.html.
126. Slovakia. *Act on Production, Labelling and Sale of Tobacco and Other Related Products* (as amended), Section 2(3)(r) [Internet]. Available from: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2016/89/20250101.html
127. Slovenia**.** Law on Restriction of the Use of Tobacco Products, Articles 3(19a), 3(25) [Internet]. Available from: https://pisrs.si/pregledPredpisa?id=ZAKO6717
128. Switzerland. *Tobacco Act*, Article 3 [Internet]. Available from: https://www.fedlex.admin.ch/eli/cc/2024/457/de
129. Thailand. *Tobacco Products Control Act, 2017*, Article 4 [Internet]. https://assets.tobaccocontrollaws.org/uploads/legislation/Thailand/Thailand-TC-Act-2017.pdf
130. United States Code. 21 U.S.C. § 321(rr)(1). https://www.law.cornell.edu/uscode/text/21/321
131. Finland. *Tobacco Act* 549/2016 (as amended through 2016), Section 2(14) [Internet]. https://www.finlex.fi/api/media/statute-foreign-language-translation/687849/mainPdf/main.pdf?timestamp=2016-06-28T21%3A00%3A00.000Z
132. Finland. *Act 251/2025 amending Tobacco Act*, Section 2(14a) [Internet]. Available from: https://www.finlex.fi/en/legislation/collection/2025/251
133. Norway. Regulations no. 2131 of 17 June 2021 on approval schemes for new tobacco and nicotine products (as amended), Section 2 [Internet]. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Norway/Norway-Regs.-No.-2131-of-2021-native.pdf.
134. Sweden. *Act (2022:1257) on Tobacco-Free Nicotine Products*, Section 3(1) [Internet]. https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-20221257-om-tobaksfria-nikotinprodukter_sfs-2022-1257/
135. Prescription Drug List . Drug and Health Product Register. https://hpr-rps.hres.ca/pdl-phu.php.
136. Canada. Supplementary Rules Respecting Nicotine Replacement Therapies Order, SOR/2024-169. Canada Gazette [Internet]. 2024 Aug 28 ;158(17):HTML. Available from: https://gazette.gc.ca/rp-pr/p2/2024/2024-08-28/html/sor-dors169-eng.html
137. Belarus. Resolution of the Council of Ministers No. 703, July 22, 2014, on the approval of the rules for the sale of certain types of goods (as amended). Official Internet Portal of Legal Information of the Republic of Belarus [Internet]. 2014 Jul 22. Available from: https://etalonline.by/document/?regnum=c21400703
138. Indonesia. Government Regulation No. 28 of 2024 concerning Implementing Regulation of Law No. 17 of 2023 concerning Health. Jakarta: Government of Indonesia; 2024 Jul 26. Available from: https://assets.tobaccocontrollaws.org/uploads/legislation/Indonesia/Indonesia-MoH-Reg.-No.-28-of-2024.pdf
139. Kazakhstan. Law of the Republic of Kazakhstan on Public Health and the Healthcare System. Almaty: Ministry of Justice of the Republic of Kazakhstan; 2000 Dec 10. Available from: https://adilet.zan.kz/rus/docs/K2000000360#z3492

Appendix

Table A1: Definitions

Sale Prohibited by Law	
Country	Definition
Belgium	*Nicotine pouch*: all tobacco-free oral products consisting entirely or partly of synthetic or natural nicotine, including those presented in portions of pouches or porous pouches, and which are in the form of powder, particles or paste or any combination of these forms.[93] [unofficial translation or machine-translated].
Germany	No defined term.
Kyrgyzstan	*Nicotine-containing non-smoking products* - products containing nicotine or nicotine salts, vegetable raw materials and (or) food additives that are not tobacco products and are intended for sucking, chewing, sniffing, with the exception of medicines, as well as food products of natural origin containing nicotine in its natural form.[94] [unofficial translation or machine-translated].
Lithuania	No term defined. The Supreme Administrative Court of Lithuania ruled that the sale of nicotine pouches is prohibited because the law prohibits the manufacture and sale of food products and other goods that imitate tobacco products.[95]
Mauritius	No defined term. The law prohibits the manufacture, import, distribution, or sale of any other product containing nicotine, excluding those products a medical practitioner may prescribe as nicotine replacement therapy.[96]
Netherlands	*Nicotine product without tobacco:* a product that contains nicotine and does not contain tobacco, that is intended for the consumption of nicotine and that is not an electronic vapor product or a herbal product for smoking; *tobacco-free nicotine product for oral use:* tobacco-free nicotine product intended for oral use, whether in the form of powder, fine particles, a combination thereof or any other form, in particular those presented in portion sachets or porous bags, with the exception of products intended to be inhaled.[97] [unofficial translation or machine-translated].
Russia	No defined term.

	The law prohibits the wholesale and retail sale of nicotine-containing products for eating, chewing, sucking and snorting.[98]
Singapore	No defined term. The law prohibits the sale of imitation products.[99]
Tajikistan	*Non-smoking products containing nicotine* - products containing nicotine or nicotine salts, solutions, nicotine liquids or gels containing nicotine, plant raw materials and (or) nutritional supplements (except medicines), which are not tobacco products and are intended for sucking, chewing, sniffing including snus and knick-knacks, as well as natural food products containing original nicotine.[100] [unofficial translation or machine-translated].
Uzbekistan	*Nicotine snus* – a type of nonsmoking nicotine-containing product intended for sucking (suction), prepared from vegetable raw materials and nicotine or its derivatives, including nicotine salts (with the exception of the tobacco leaf and (or) another part of the tobacco plant, including purified tobacco dust and (or) the fine fraction of cut tobacco), with or without the addition of other ingredients.[101] [unofficial translation or machine-translated].
Sale Prohibited by Law (Pending Additional Action)	
Country	Definition
Viet Nam	No defined term. The production, trading and import of addictive substances are banned but the term is not defined.[102]
Regulated as Medicinal/Pharmaceutical Products (No Approved Products)	
Country	Definition
Australia	Schedule 4 (prescription only medicines) of the Poisons Standards includes:[103] *NICOTINE in preparations for human use* ***except****:* (a) when included in Schedule 3; or (b) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or (c) in tobacco prepared and packed for smoking.
Cyprus	No defined term. In an announcement, the Cyprus Ministry of Health informed that nicotine pouches are classified as pharmaceuticals under the Medicines

	for Human Use (Quality, Supply and Price Control) Law and require authorization to be sold.[104]
Hong Kong	Nicotine is a Poison under the Pharmacy and Poisons Ordinance (Cap 138) and the Pharmacy and Poisons Regulations (Cap 138) [105] The Regulations exempt from the requirements for registration and authorization (license for sale is still required, however): *Nicotine* when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy. The list also exempts nicotine alkaloids and nicotine pharmaceutical products with these same requirements.
India	No defined term. Schedule K to the Drugs and Cosmetics Rules, 1945 exempts nicotine gums and lozenges containing up to 2 mg of nicotine from requiring a prescription or a specific sale license for retail sale.[106] Further, tobacco and nicotine are prohibited ingredients in food products.[107]
Japan	No defined term. Nicotine is regulated as a pharmaceutical under the law. [108]
New Zealand	No term defined. The law prohibits the import for sale, sale, packing, or distribution of any oral nicotine product unless the Minister of Health has given consent or provisional consent to the distribution of the product under the Medicines Act 1981.[109]
Regulated as Tobacco or Related Products	
Country	Definition
Colombia	*Substitute*: any product marketed or otherwise presented as a partial or total substitute for tobacco products, whether or not such product is suitable for that purpose. *Imitator*: any product intended to replace or substitute another product by exploiting its physical properties or consumption characteristics. For this law, when the expressions "tobacco," "tobacco and its derivatives," "tobacco products,"

	"tobacco products and its derivatives," "cigarettes, tobacco or its derivatives," or "cigarette products, tobacco and its derivatives" are used, it shall be understood as "cigarettes, tobacco products, its derivatives, substitutes or imitators and the devices necessary for their operation; among which are...Oral Nicotine Products (ONP), among others.[110] [unofficial translation or machine-translated].
Czech Republic	*Tobacco-free nicotine pouch* means a tobacco-free product containing nicotine for oral use that is not regulated by directly applicable European Union legislation.[111] [unofficial translation or machine-translated].
Denmark	*Tobacco substitute*: Product containing nicotine that is not a tobacco product, cf. no. 2, or an electronic cigarette, cf. § 2, no. 1, of the Electronic Cigarettes Act, etc. and that is not approved through a marketing authorization in accordance with the Danish Medicines Act or rules of EU law on the establishment of community procedures for the approval of human medical products, and equipment intended to be used together with the product.[112] [unofficial translation or machine-translated].
Estonia	*Products related to tobacco products are*: 1) products used similarly to tobacco products which imitate consumption of tobacco products and products used to replace tobacco products, including electronic cigarette, herbal products for smoking, different materials to replace waterpipe tobacco and tobacco-free snus, regardless of the nicotine yield of such products.[113] [unofficial translation or machine-translated].
Greece	*Other nicotine-containing products* for the purposes of this Regulation are products that contain nicotine and do not fall within the definitions of novel tobacco product and electronic cigarette.[114] [Unofficial machine translation].
Hungary	The law regulates "nicotine-containing smoking substitutes" (unofficial translation or machine-translated) but does not define the term.[115] These products are different than electronic cigarettes, which are regulated separately under the law.
Iceland	*Nicotine product*: A product containing nicotine, whether or not the nicotine is derived from tobacco, and the product does not otherwise contain substances derived from tobacco, e.g. a nicotine patch, but is not intended for inhalation. [116] [unofficial translation or machine-translated].
Kenya	No defined term.

	Pictorial health warnings were published for novel nicotine products.[117]
Latvia	*Tobacco substitute product* - a product that contains or does not contain nicotine (except medicinal products, tobacco products, herbal smoking products, electronic smoking devices and their filling containers) and which is intended to be used for the same or similar purposes as tobacco products, herbal smoking products, smokeless tobacco products, electronic smoking devices and their filling containers, regardless of the nicotine content of these products and their use.[118] [unofficial translation or machine-translated].
Moldova	*Nicotine-containing products* – any products that can be consumed by inhalation, ingestion or otherwise, in which nicotine is added during manufacture or self-administered by the user before or during consumption.[119] [unofficial translation or machine-translated].
Panama	The law does not define "oral nicotine products," but these products are considered "regulated products."[120]
Peru	*Nicotine Product*: A product containing nicotine intended for human use. This includes electronic nicotine delivery systems (ENDS) and any other form of nicotine delivery, current or future, that is non-therapeutic. It includes refills and cartridges. [121] [unofficial translation or machine-translated].
Philippines	*Novel Tobacco Products* shall refer to all non-combusted substances in solid or liquid form, and innovations, either made partly of tobacco leaf as raw material or containing nicotine from tobacco, intended to be used as a substitute for cigarettes or other combusted tobacco products.[122]
Poland	*Related product* - an electronic cigarette, a refill container, an herbal product for smoking, and a nicotine pouch; *Nicotine pouch* - all products for oral use, except those intended for inhalation, not containing tobacco but containing nicotine, mixed or unmixed with other ingredients, which are portioned in pouches or available in pouches.[123] [unofficial translation or machine-translated].
Romania	*Nicotine Pouch for Oral Use* - a non-tobacco product containing nicotine and which is used for the oral consumption of nicotine, in the form of powder or particles or in any combination of those forms.[124] [unofficial translation or machine-translated].
Serbia	16) *Related products*, in the sense of this law, are products with or without nicotine, which do not

	consist of tobacco, but which in terms of other criteria correspond to tobacco products, namely: liquid for filling electronic cigarettes, herbal products for smoking or heating, nicotine pouches and water pipe products; … ...16(3) *nicotine pouches* are disposable products containing nicotine or nicotine compounds and other ingredients, packed in pouches or porous pouches and intended exclusively for oral use. Nicotine bags are covered by tariff code 2404 91 90 00 of the Customs Tariff nomenclature. Regulations on harmonizing the nomenclature of the Customs Tariff are applied to the specified tariff label. [125] [unofficial translation or machine-translated]
Slovakia	*Tobacco-free nicotine pouch* means a product that contains nicotine and does not contain tobacco or genetically modified tobacco, is not consumed during the combustion process or by inhalation, and is intended for oral use by sucking, chewing or otherwise.[126] [unofficial translation or machine-translated].
Slovenia	A *new nicotine product* is a product that does not fall into any of the following categories of products that contain nicotine but do not contain tobacco: electronic cigarettes, refill containers and registered nicotine replacement therapy products. *Related products* according to Directive 2014/40/EU are electronic cigarettes and refillable containers, and herbal smoking products. According to this law, related products also include nicotine-free electronic cigarettes and nicotine-free refillable containers, herbal heating products, new tobacco products, *new nicotine products*. In accordance with this law, connected products are also accessories or devices for using connected products from the first sentence and the previous sentence of this point, without which the connected products cannot be used.[127] [unofficial translation or machine-translated].
Switzerland	a. *Tobacco product*: any product consisting of or containing parts of leaves of plants of the genus Nicotiana (tobacco) and intended to be smoked, inhaled after heating or sniffed, *as well as any nicotine product for oral use within the meaning of letter d*, and any herbal smoking product within the meaning of letter e. … d. *Nicotine product for oral use*: nicotine-containing product with or without tobacco that comes into contact with the oral mucosa during

	consumption and is not intended for smoking or heating.[128] [unofficial translation or machine-translated].
Thailand	*Tobacco Products* shall mean products derived from the tobacco leaf, or from [other parts of] the plant nicotiana tabacum, and shall further include any product containing nicotine as an ingredient for consumption by smoking, sucking, sniffing, chewing, eating, burning, or snuffing into the mouth or nose, or by any other means to achieve the same purpose, but excluding items regulated by the drug laws.[129]
United States	(1) The term "*tobacco product*" means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). (2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title. [130]
Regulated as Medicinal and Tobacco Products	
Country	Definition
Finland	*Tobacco substitute* means a product which corresponds to tobacco in its intended use but does not contain tobacco. [131] [Official Government translation]. *Smokeless nicotine product*: smokeless nicotine product means a tobacco substitute that corresponds in its intended use to a tobacco product referred to in paragraphs 10–12 and that contains nicotine.[132] [unofficial translation or machine-translated].
Norway	In these regulations, *nicotine products* are understood to mean any product that contains nicotine and is intended for consumption by inhalation, chewing, absorption, in solutions or ingested in any other way, with the exception of tobacco products, cf. the first paragraph. In these regulations, *new tobacco and nicotine products* are understood to mean products that are placed on the market after 19 May 2014 and that do not fall under the following categories: cigarettes, rolling tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing

	tobacco, nasal tobacco or snus, cf. the Tobacco Harmful Effects Act § 34 d.[133] Nicotine products for therapeutic use (NRTs) are regulated under the Medicinal Products Regulations.[133]
Sweden	*Tobacco-free nicotine product*: a product without tobacco that contains nicotine for consumption.[134] [unofficial translation or machine-translated].
Regulated as Natural Health Products (Approved Product)	
Country	Definition
Canada	Nicotine pouches delivering 4 mg or less of nicotine per dose are subject to the Natural Health Products Regulations (Regulations) and are excepted from the Prescription Drug List.[135] The Prescription Drug List provides: *Nicotine or its salts for human use except*: … d. in a form to be administered into the oral cavity by means of a non-active device (one that operates on energy generated by the human body or by gravity) that delivers 4 milligrams or less of nicotine per dose for buccal absorption… The Supplementary Rules, for products that fall under the Regulations, define Nicotine Replacement Therapy as: [136] nicotine replacement therapy means a natural health product, other than a homeopathic medicine, that (a) contains nicotine or its salts; and (b) is for administration in the oral cavity.
Regulated using Other Measures	
Country	Definition
Belarus	*Non-tobacco nicotine-containing product* - a product containing raw materials of plant and (or) synthetic origin (except for tobacco raw materials) and nicotine, intended for sucking, chewing, sniffing, other way of use (consumption), when nicotine penetrates into human body, with exception of medicinal and veterinary preparations, liquids for electronic smoking systems with nicotine content, food products of plant origin.[137] [unofficial translation or machine-translated].
Indonesia	An elucidation in the law provides: "*Addictive substances*" refer to products that contain tobacco or do not contain tobacco, whether in the form of cigarettes or other

	addictive forms, the use of which can cause harm to oneself and/or the surrounding community. These substances can be in solid, liquid, or gas form. Other addictive forms include electronic products and candies that, among others, contain nicotine like cigarettes.[138] [unofficial translation or machine-translated]. An elucidation in the implementing regulations provides: What is meant by "other formats that are addictive" includes electronic cigarettes and/or nicotine in various forms and packaging, including nicotine candies and nicotine pouches.[138] [unofficial translation or machine-translated].
Kazakhstan	*Smokeless tobacco (nicotine-containing) products* - products containing nicotine, fully or partially made from tobacco leaves and (or) other parts of the tobacco plant as raw materials and their synthetic analogues, prepared in such a way as to be used for sucking, chewing, sniffing.[139][unofficial translation or machine-translated].