

Nicotine pouches: a summary of regulatory approaches across 67 countries

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► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/tc-2022-057734>).

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Received 7 September 2022

Accepted 25 January 2023

Published Online First

7 February 2023

ABSTRACT

Introduction Nicotine pouches are small, permeable pouches containing nicotine. The nicotine may either be derived from tobacco plants or synthetically produced. Nicotine pouches are available worldwide, but little is known as to how various countries regulate these products. This study summarises nicotine pouch regulatory policies across 67 countries.

Methods This research summarises insights obtained through active policy surveillance work in which we requested information on the availability of nicotine pouches and applicable policies and analysed responses from representatives of 67 countries (representatives included subject matter experts in government or civil society organisations). These countries span all WHO regions.

Results We found significant variation in how countries classify nicotine pouches, with many countries' current regulatory approach failing to regulate nicotine pouches that used synthetic nicotine. We found 34 countries regulate nicotine pouches with 23 of these countries' policies encompassing synthetic nicotine. Countries regulating both synthetic and tobacco-derived nicotine pouches generally (1) rely on existing policies for tobacco products and/or medicines or (2) have developed new policies or regulatory classifications that specify nicotine as the substance at issue rather than linking policies solely to tobacco.

Conclusion Our work offers novel insight into nicotine pouch markets and national regulatory approaches. Policy approaches vary from not regulating nicotine pouches at all to banning both forms of nicotine pouches. Policies used by countries regulating both tobacco-derived and synthetic nicotine pouches offer a roadmap for how other jurisdictions can add effective guardrails to the use of these and other non-medicinal nicotine products.

INTRODUCTION

Nicotine pouches—such as Zyn and On!—are a type of oral nicotine product. A nicotine pouch is a small bag made of a permeable material, filled with a cellulose matrix of polymer fibres mixed with nicotine of varying concentrations, water, and other constituents that might include sweeteners or flavours.¹ Users typically place the pouch between the gum and lip,^{2,3} where it is kept for several minutes so that the nicotine can enter the bloodstream primarily via absorption through the mucous membrane of the mouth.^{4,5} Nicotine pouches contain nicotine either derived from tobacco or chemically produced. Tobacco-derived nicotine is extracted from the tobacco plant. Synthesised nicotine is created from petroleum-derived compounds

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Nicotine pouches are sold in countries worldwide.
- ⇒ Where nicotine pouches are sold, markets have products that use tobacco-derived nicotine and/or synthetic nicotine.

WHAT THIS STUDY ADDS

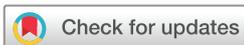
- ⇒ Nicotine pouches are sold in at least 33 countries, including 20 countries regulating nicotine pouches and 13 not regulating nicotine pouches.
- ⇒ We identified 34 countries regulating nicotine pouches; nicotine pouches were sold in 20 of these and were not sold in the remaining 14 countries.
- ⇒ Of the 14 countries we identified where nicotine pouches were not sold but were regulated, 6 countries ban nicotine pouches; 3 countries require a prescription; and 1 requires a premarket authorisation.
- ⇒ Of the 34 countries we identified as regulating nicotine pouches, 16 regulate pouches as a tobacco product; of these, 10 regulate only tobacco-derived nicotine pouches as a tobacco product.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Countries may be able to regulate nicotine pouches using existing drug/medicine approval pathways.
- ⇒ An effective long-term strategy to regulate synthetic nicotine pouches—as well as other nicotine products—could be to broaden existing definitions of tobacco products to include nicotine; alternatively, countries could develop a regulatory framework based on nicotine rather than tobacco.

that are enriched through chemical and enantiomeric purification processes to create nicotine.⁶ See [figure 1](#) for a nicotine pouch example.

Nicotine pouches represent a small yet growing global market. Euromonitor International—in its first year estimating global retail volume of nicotine pouches—estimated 292 million units were sold in 2018.⁷ In 2021, Euromonitor International estimated 6.8 billion units of nicotine pouches were sold, representing a more than 2000% increase in nicotine pouch sales since 2018.⁷ In recent years, global tobacco companies, such as British America Tobacco, Japan Tobacco International and Phillip Morris International, have expanded nicotine



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To cite: Duren M, Atella L, Welding K, et al. *Tob Control* 2024;**33**:e32–e40.



Figure 1 Example nicotine pouch.

pouches' reach into new markets and devoted greater resources to promoting and expanding nicotine pouch production.⁸

There is a continuum of risk with tobacco and nicotine products.^{9–10} Like oral tobacco products, nicotine pouches present possible reduced harm compared with combustible products since users are not exposed to the harmful constituents generated through pyrolysis.¹¹ Oral tobacco use, such as dip or chew, is associated with numerous health problems including diseases of the mouth, increased risk of death from heart disease and stroke.^{12–14} Initial research suggests that nicotine pouches may represent a reduced harm compared with oral tobacco due to a lower toxicant profile, although this is a new area of research requiring confirmatory studies.¹⁵ One complicating factor in evaluating the health risks of nicotine pouch use is the variation in nicotine concentration; one study found the nicotine concentration ranged from 1.79 mg/pouch to 47.5 mg/pouch.¹⁶ Another study found pouch users are at risk of ingesting more nicotine than cigarette smokers and users of other tobacco products.¹⁷ Nicotine use has cognitive and cardiovascular effects and decreases immune response irrespective of administration mode, among other negative health effects.^{18–19} Little is known on the health impact of synthetic nicotine since it uses a form of nicotine that is different from the form found in tobacco leaves—a form that until recently has had limited human exposure.²⁰

At this time, we know nicotine pouches are regulated differently worldwide. Some countries ban retail sales, while other countries do not restrict the sale of nicotine pouches. As far as we are aware, no publications or reports have synthesised information on how various countries regulate nicotine pouches. Given the global consensus on the importance of tobacco control policies to end the tobacco epidemic,²¹ it is vital to understand if and how tobacco and nicotine products are being regulated, as these products pose a risk to public health. Since 2016, the Institute for Global Tobacco Control at Johns Hopkins Bloomberg School of Public Health has conducted semiannual policy surveillance work to understand how countries regulate e-cigarettes and heated tobacco products. The present study expanded this surveillance work to understand nicotine pouch markets and national regulatory approaches, specifically to identify which countries have nicotine pouches available in their markets, and which countries regulate nicotine pouches. This is critical work, given a recent finding that the tobacco industry is aggressively promoting products using synthetic nicotine throughout the world amid regulatory uncertainty.^{20–22} This is the first review to offer comparative information on country-level nicotine pouch policies.

METHODS

Sample

The Johns Hopkins Institute for Global Tobacco Control conducts biannual outreach to country representatives to obtain information on tobacco and nicotine product regulation as part of its policy scan. Beginning Summer 2021, questions on nicotine pouch policies were included in the outreach. Representatives from 97 countries were included in the outreach; these were contacts who work in countries among the 194 member states recognised by the WHO and who are active participants in policy surveillance work through the Johns Hopkins Institute for Global Tobacco Control related to e-cigarette and/or heated tobacco product regulation.²³ There are over 90 WHO member states for which we have no contact, although efforts are made during each iteration of the scan to increase the global reach. Our results are consequently derived from a convenience sample and are not generalisable. Respondents were typically bureaucrats working for a government ministry, such as the ministry of health, in tobacco control or were tobacco control experts working in civil society organisations. We received responses from contacts representing 67 countries. We received regulatory information for 61 countries; the remaining six confirmed nicotine pouches were not present in their markets but did not offer any regulatory information. The 67 countries included in our sample cover all WHO regions, including Africa (5), Americas (8), Eastern Mediterranean (5), Europe (27), South-East Asia (6) and Western Pacific (16). Our sample also covers various income categories, specifically, 3 low-income economies, 35 middle-income economies and 29 high-income economies.

Measures

The following three questions on nicotine pouches were included in the emails to country representatives: (1) were nicotine pouches sold in their jurisdiction? (2) how are or would nicotine pouches be classified? and (3) was the classification dependent on nicotine being derived from tobacco or synthetic? Survey questions were answered in narrative responses. Nicotine pouch markets were classified as 'yes' or 'no'. The appropriate legal classification for tobacco-derived and synthetic nicotine pouches was identified from the narrative response (eg, 'drug', 'tobacco product', etc).

After this initial inquiry, we followed up as needed. In some cases, we provided details to respondents on what nicotine pouches were if they were unfamiliar with this product type. In addition, we cross-validated information received from our contacts on market availability of nicotine pouches with information available through Euromonitor; no discrepancies were found.

The legal definition for nicotine pouches was identified through policy documents provided by the contact or in relevant laws we found through internet searches. The source documentation for each definition is cited where applicable; if citations are not provided, the contact provided definitions without any corresponding source documentation.

We analysed policies in nine domains: minimum age, sales, notification/reporting, health warning labelling, advertising/promotion/sponsorship, tax, packaging, ingredients and nicotine concentration. We coded each policy domain as yes or no based on the narrative received from the contact and our review of associated policy documents. For example, if a policy requires manufacturers or importers to notify a government authority prior to marketing nicotine pouches in a given country, the notification/reporting domain would be marked yes.

Table 1 Reported market presence of nicotine pouches and reported policies regulating nicotine pouches

Description	Countries (n)	Countries
Nicotine pouches present in market and policies regulating these products	20	Argentina, Bangladesh, Belgium, Brazil, Czechia, Denmark, Finland, France, Iceland, Indonesia, Israel, Italy, Japan, Lithuania, Norway, Poland; Seychelles, Portugal, Thailand, USA
Nicotine pouches present but no policies regulating these products	13	Fiji; Germany; Mexico; Montenegro; Netherlands; Pakistan; Philippines; Sweden; Uganda; UK (England, Northern Ireland, Scotland, Wales); Ukraine; Uzbekistan; Yemen
No nicotine pouches in the market; currently, there are policies that would regulate nicotine pouches	14	Australia, Brunei Darussalam, Canada, Costa Rica, Georgia, India, Iran, Malaysia, Mauritius, New Zealand, Nigeria, Palau, Singapore, Spain
No nicotine pouches present in the market, no current policies that would regulate nicotine pouches	12	Albania, Azerbaijan, Egypt, Jordan, Niue, Papua New Guinea, Paraguay, Romania, Turkey, Tuvalu, Uruguay, Vanuatu

In addition to the countries noted previously, our contacts confirm that nicotine pouches are not present in the following countries but did not confirm whether any policies exist for these products: China, Luxembourg, Nepal, Republic of Korea, Sudan and Vietnam. In Mongolia and the Cook Islands, we received confirmation that no policies currently cover nicotine pouches, but we were unable to confirm whether these products are currently being sold. For Canada, nicotine pouch products have been observed on the Canadian market, but they have not had the necessary premarket authorisation from Health Canada and are therefore illegal. Sale at some tobacco shops has been reported to Health Canada, and compliance and enforcement action has been taken, including seizures and recalls.

Analysis

Responses to the emailed questions were reviewed and classified as described previously. We organised nicotine pouch regulatory information based on legal classifications, market presence and applicable policy domains. The information was directly taken either from the email responses or from a review of the policy identified by respondents. We presented results based on frequencies. We further synthesised the available information to develop regulatory archetypes of county-level approaches to regulating nicotine pouches.

RESULTS

Nicotine pouch availability

Representatives from 67 countries responded to the survey. Among the sample, respondents reported that nicotine pouches were being sold in 33 countries, including 20 countries regulating these products and 13 countries indicating that nicotine pouches are unregulated. Respondents reported that nicotine pouches were not being sold in 32 countries at our time of inquiry; this includes 14 countries with policies, 12 countries without policies and an additional 6 countries where the contact did not provide regulatory information. In the remaining two jurisdictions—Mongolia and the Cook Islands—we were not able to confirm whether nicotine pouches were sold. [Table 1](#) presents country information in terms of nicotine pouch market presence and whether policies applicable to nicotine pouches exist.

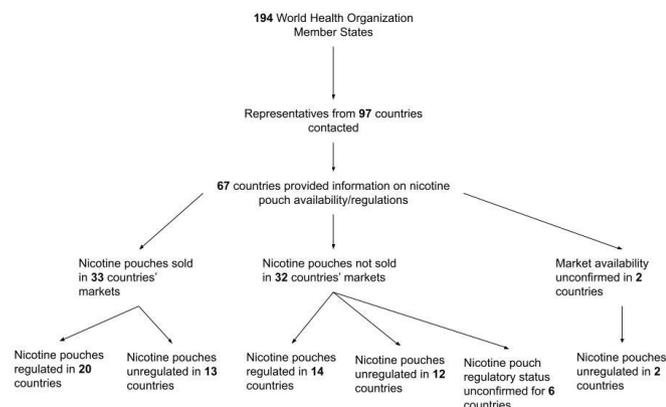


Figure 2 Characterization of country-level responses on nicotine pouch availability and regulations.

Nicotine pouch policies

We identified 34 countries regulating nicotine pouches among the countries included in our policy scan. See [figure 2](#) for an illustration of the number of countries by nicotine pouch market availability and regulatory status from our sample of 67 countries. A majority of countries where nicotine pouches are being sold have policies in place (20 of 33 countries). The survey identified 14 countries where nicotine pouches were not sold, but policies were in place. The majority of these countries ban or severely limit the ability to sell these products, while a few have limited policies, such as minimum purchase age requirements or advertising restrictions. Specifically, six countries—Australia (for tobacco-derived nicotine pouches), Brunei Darussalam, Iran, Mauritius, New Zealand (unless approved as medicines) and Singapore—ban nicotine pouches. Spain requires premarket authorisation from the Spanish Agency for Medicines and Health Products; no nicotine pouches have been approved as of June 2022. Additionally, three countries require prescriptions for nicotine pouches; these include Australia (synthetic nicotine pouches), Canada (for pouches delivering more than 4 mg of nicotine per dose) and Malaysia. Our analysis found that eight countries implemented new or amended laws that specifically address synthetic nicotine products, such as Iceland's 2022 policy defining a nicotine product as one containing nicotine, whether or not it is derived from tobacco.²⁴

Countries regulating tobacco-derived and synthetic nicotine pouches

Within the subset of countries regulating nicotine pouches, the majority (23 of 34 countries) regulate both tobacco-derived and synthetic nicotine pouches. [Table 2](#) presents details on how countries classify nicotine pouches, among countries regulating both tobacco-derived and synthetic nicotine pouches. Countries employ a variety of approaches for regulating nicotine pouches—some relying on existing legal definitions, others broadening existing definitions to encompass nicotine products and others creating new categories specific to nicotine products. The respondent from Czechia established new policies specific to these recent synthetic nicotine products. When synthetic nicotine pouches were first introduced to Czechia, they were not covered by any existing policy because they did not contain tobacco. They amended existing policies to expressly cover synthetic nicotine products. Spain noted that existing policies on tobacco products did not cover nicotine pouches, and instead, the country regulated them as a medicine. Many respondents from Europe noted

Table 2 Product classification of nicotine pouches for countries regulating all nicotine pouches

Country	Classification	Definition
Australia	Smokeless tobacco (tobacco-derived nicotine pouches)	Chewing tobacco and snuffs intended for oral use ³⁰
	Medicine (synthetic nicotine pouches)	Nicotine in preparations for human use except <ul style="list-style-type: none"> ▶ In preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking. ▶ In tobacco prepared and packed for smoking.³¹
Belgium	Tobacco products	Tobacco, tobacco-based products and similar products ³²
Brazil	Tobacco products	Products derived or not from tobacco, designed to be smoked or used like a tobacco product
Brunei Darussalam	Imitation tobacco products	Any confectionery or other food product or any toy or other article that is designed to resemble a tobacco product or which is sold in a package designed to resemble the packaging commonly associated with tobacco products ³³
Canada	Drug	Nicotine or its salts for human use, except <ul style="list-style-type: none"> ▶ In natural substances. ▶ In the form of a chewing gum containing 4 mg or less of nicotine per dosage unit. ▶ In the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day. ▶ 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 mg or less of nicotine per dose for buccal absorption. ▶ In the form of a lozenge containing 4 mg or less of nicotine per dosage unit.³⁴
Czechia	Tobacco products (tobacco-derived nicotine pouches)	A product which can be used and contains unprocessed or wholly or uncoated tobacco parts of genetically modified tobacco ³⁵
	Tobacco-free nicotine pouches (synthetic nicotine pouches)	Definition not known; defined in Act No. 174/2021 Coll. on food and tobacco products.
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 authorisation 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. ³⁶
Finland	Medicine	Nicotine products are classified either as over-the-counter medicines (nicotine up to 4 mg of nicotine) or as prescription medicines (more than 4 mg of nicotine). ³⁷
France	Poisonous substance	Substances or preparations and medicinal products for human use and products presenting the highest health risks ³⁸
Iceland	Nicotine products	A product that contains nicotine, whether or not it is derived from tobacco and does not otherwise contain substances derived from tobacco, for example, a nicotine patch, but is not intended for inhalation. ²⁴
India	Drug	<ul style="list-style-type: none"> ▶ All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on the human body for the purpose of repelling insects like mosquitoes. ▶ Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the central government by notification in the official gazette. ▶ All substances intended for use as components of a drug, including empty gelatin capsules. ▶ Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the central government by notification in the official gazette, after consultation with the board.³⁹
Italy	Tobacco products (tobacco-derived nicotine pouches)	Products that can be consumed and including, even partially, tobacco, genetically modified or otherwise ⁴⁰
	Nicotine-containing products (synthetic nicotine pouches)	Products, other than manufactured tobacco subject to excise duty, containing nicotine and prepared for the purpose of enabling, without combustion and without inhalation, the absorption of this substance by the organism, including through casings functional to their consumption ⁴¹
Iran	Tobacco products	Any material or product entirely or partly made of tobacco plant or its derivatives (except authorised pharmaceutical compounds used for cessation of tobacco consumption to the discretion of the ministry of health and medical education). ⁴²
Japan	Tobacco products (tobacco-derived nicotine pouches)	Cigarettes, cigars, pipe tobacco, shredded tobacco, chewing tobacco and snuffs ⁴³
	Medicine (synthetic nicotine pouches)	<ul style="list-style-type: none"> ▶ Items listed in the Japanese Pharmacopoeia. ▶ Items which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, and which are not medical appliances or instruments, etc (referring to medical appliances or instruments, dental materials, medical supplies, sanitary goods and programmes (referring to instructions given to a computer and built so as to obtain a certain result; hereinafter the same applies), and recording media on which programmes are recorded, hereinafter the same applies) (excluding quasi-pharmaceutical products and regenerative medicine products). ▶ Items which are intended to affect the structure and functioning of a human or animal's body, and which are not medical appliances or instruments, etc (excluding quasi-pharmaceutical products, cosmetics and regenerative medicine products).⁴⁴

Continued

Table 2 Continued

Country	Classification	Definition
Malaysia	Poison	Nicotine: all preparations unless exempted ⁴⁵
Mauritius	Smokeless tobacco	A tobacco product used without combustion, heating or pyrolysis, at the time of use, such as chewing tobacco, snus and snuff and dissolvable products ⁴⁶
New Zealand	Oral nicotine products	Oral nicotine products ⁴⁷
Norway	New tobacco or nicotine products	Products that can be smoked, sniffed, sucked or chewed if they are completely or partially made of tobacco (tobacco products); nicotine products are understood to mean any product which contains nicotine and which is intended for consumption by inhalation, chewing, absorption, in solutions or otherwise ingested, with the exception of tobacco products ⁴⁸
Portugal	Medicine	Means any substance or combination of substances presented as having curative or disease-preventing properties in human beings or its symptoms or that it can be used or administered in the human being with a view to establishing a medical diagnosis or, exercising a pharmacological, immunological or metabolic action, to restore, correct or modify physiological functions ⁴⁹
Singapore	Tobacco products	<ul style="list-style-type: none"> ▶ A cigarette or cigar, or any other form of tobacco. ▶ A tobacco derivative. ▶ A tobacco substitute. ▶ A mixture containing any form of tobacco or a tobacco derivative or tobacco substitute, but does not include a therapeutic product registered under the Health Products Act (Cap. 122D).⁵⁰
Spain	Medicine	Any substance or combination of substances that is presented as having properties for the treatment or prevention of diseases in human beings, or that can be used, or administered to human beings in order to restore, correct or modify physiological functions, exerting a pharmacological, immunological or metabolic action, or establishing a medical diagnosis ⁵¹
Thailand	Tobacco products	Products derived from the tobacco leaf or from (other parts of) the plant <i>Nicotiana tabacum</i> , 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 ⁵²
USA	Tobacco products	Any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption ⁵³

that they are waiting for the European Commission to clarify how nicotine pouches should be regulated.

Countries regulating tobacco-derived nicotine pouches only

A smaller number of countries with nicotine pouch policies (11 of 34 countries) regulate only tobacco-derived nicotine pouches. Table 3 presents detail on how countries classify nicotine pouches, among countries regulating only tobacco-derived nicotine pouches. Countries falling into this category regulate nicotine pouches under existing tobacco control policies, with most relying on existing definitions of tobacco products to regulate these new products. Nine of these countries have policies that specifically reference tobacco in their classification comprising nicotine pouches. Respondents of the two countries whose definitions of tobacco products do not specifically reference tobacco—Indonesia and Palau—reported that it is currently unclear how the definitions employed preclude regulating synthetic nicotine pouches.

Within the sample of countries not regulating synthetic nicotine pouches—including both countries regulating only tobacco-derived nicotine pouches (11 countries) and countries not regulating nicotine pouches at all (27 countries)—representatives mentioned not being able to regulate synthetic nicotine due to the wording of existing legislation. Seven of these representatives noted their countries were considering new policies to address these emerging products, such as preparing to ban nicotine pouches or to regulate all products containing nicotine as tobacco products.

Characterising nicotine pouch policies

When considering policies regulating nicotine pouches, the most common regulatory domains are marketing restrictions, health warning label requirements, minimum age purchase requirements

and sales bans. Most notably, no country has a policy covering a policy domain for synthetic nicotine pouches where that domain is not regulated for tobacco-derived nicotine pouches. Tobacco-derived nicotine pouches have a greater extent of regulated policy domains, namely, restrictions on nicotine concentrations and additives used in nicotine pouches. Of the policy domains covering synthetic pouches, the most common relate to sales restrictions, including requiring a prescription, premarket authorisation or banning the product entirely. In contrast, for tobacco-derived pouches, the most common policy is to restrict or ban advertising, promotion and sponsorship of those products. Specifically, 15 countries have such marketing restrictions for tobacco-derived nicotine pouches, but only 6 of those countries' marketing restrictions apply to synthetic nicotine pouches.

The policy domains covered by nicotine pouch policies are detailed in table 4. Table 4 denotes the number of countries with policies corresponding to 10 policy domains—minimum age requirements (eg, limiting sale of pouches to those of a certain age), sale restrictions (ie, banning sale or requiring a prescription), premarket authorisation, health warning label, advertising/promotion/sponsorship requirements (eg, prohibiting nicotine pouch advertisements), tax, packaging requirements, ingredient restrictions or a nicotine concentration threshold. Country frequencies are further delineated in terms of whether the restrictions apply to only tobacco-derived nicotine pouches, only synthetic nicotine pouches or both forms of nicotine pouches.

Countries not regulating nicotine pouches

The remaining 33 countries either confirmed that no existing tobacco control policies cover nicotine pouches or did not provide any applicable policies in their responses to our inquiry. Specifically, 27 countries confirmed no national policies addressing nicotine pouches; we did not consider general

Table 3 Product classification of nicotine pouches for countries regulating tobacco-derived nicotine pouches

Country	Classification	Definition
Argentina	Tobacco products	Preparations that use totally or partially tobacco as raw material and are intended to be smoked, sucked, chewed, snorted, inhaled or used as snuff ⁵⁴
Bangladesh	Tobacco products	Any product made from tobacco that through smoking is inhaled, and bidi, cigarette, cheroot, cigar and pipe mixture ⁵⁵
Costa Rica	Tobacco products	Tobacco products encompass products prepared totally or in part using tobacco leaf as raw material, and intended to be smoked, sucked, chewed or used as snuff ²⁸
Georgia	Tobacco products	Any product containing tobacco or its components, except for nicotine-containing medications, which are intended for smoking, chewing or sniffing, including <ul style="list-style-type: none"> ▶ Filtered and unfiltered cigarettes. ▶ Papirosas, cigars and cigarillos. ▶ Tobacco for pipes. ▶ Rolling tobacco. ▶ Chewing tobacco and snuff.⁵⁶
Indonesia	Other tobacco products	Tobacco products which contain <i>Nicotiana tabacum</i> , <i>Nicotiana rustica</i> , and other species and/or their processed products, including manufactured synthetics of the same or similar type and nature as those produced by <i>Nicotiana</i> species and their use by burning and sucking and/or inhaling the smoke ⁵⁷
Israel	Smoking products	Any product that contains tobacco ⁵⁸
Lithuania	Tobacco for oral use	A tobacco product intended for oral use, other than for inhalation or chewing, which is made exclusively of or containing tobacco and which is supplied in portions, usually in plain or porous sachets, as a powder or as fine particles or as any mixture thereof ⁵⁹
Nigeria	Tobacco products	Products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing ⁶⁰
Palau	Tobacco products	Tobacco product includes, but is not limited to, each of the following: <ul style="list-style-type: none"> ▶ Tobacco in any form, including cigarettes, cigars, pipe tobacco, chewing tobacco and leaf tobacco. ▶ Pipes, filters, rods, rolling papers, hookahs and other tobacco paraphernalia used for smoking. ▶ Any product bearing the name and/or insignia of a brand of cigarette, cigar or other tobacco product. ▶ Any other product other than tobacco that contains nicotine in an amount more than incidental and is intended for human consumption, but not limited to nicotine water, nicotine candy, e-cigarettes and dissolvable tobacco.⁶¹
Poland	Smokeless tobacco product	A tobacco product that does not involve the combustion process, including chewing tobacco, nasal and oral tobacco ⁶²
Seychelles	Tobacco product	Tobacco product means a product containing tobacco in any form ⁶³

product policies or food product policies as they do not restrict the sale or consumption of nicotine pouches, with the exception of Germany. Germany currently regulates nicotine pouches as a food product; under this authority, some products have been withdrawn from Germany by classifying pouches as a health hazard due to their high nicotine content. In general, countries regulating nicotine pouches as a food product have placed no restrictions on this manufacture, sale or use, but Germany presents a unique counterpoint. Six additional countries noted that nicotine pouches are not sold within their markets but did not offer any information on possible policies for nicotine pouches if they were sold.

Table 4 Number of countries regulating nicotine pouches by policy domain and by product type

Policy domain	Covers all nicotine pouches	Covers tobacco-derived pouches only	Covers synthetic nicotine pouches only
Minimum age	4	7	0
Sale banned/require prescription	8	2	0
Premarket authorisation	6	1	0
Health warning label	3	9	0
Advertising/promotion/sponsorship	6	9	0
Tax	1	1	0
Packaging	3	1	0
Ingredients	1	2	0
Nicotine concentration	0	1	0

Note: Brazil is not included in the table due to insufficient information available to characterise policies.

Online supplemental appendix I provides definitions for tobacco products in existing tobacco control policies for the countries that confirmed these policies do not apply to nicotine pouches; in cases where several definitions in tobacco control policies could relate to nicotine pouches, multiple definitions are provided. Although several countries have additional policies pertaining to smokeless tobacco, tobacco for oral use, 'novel tobacco products' and tobacco substitutes, most policies relate to tobacco products. One country contact noted that while Uruguay does not regulate nicotine pouches, it defines these products as a nicotine replacement therapy. Thus, the country has made the decision to allow the sale and use of these products to transition people from more harmful tobacco products; yet, there is no supplier of nicotine pouches in Uruguay at present.

In countries with nicotine pouches present, some respondents indicated that these products were recently introduced to their market. For example, one respondent stated that nicotine pouches entered the Danish market in 2019, at which time they were not covered by existing tobacco legislation and were being advertised on social media platforms like Instagram. Since this time, Denmark has passed new legislation to regulate nicotine pouches, including banning advertisement. Nicotine pouches were introduced to the Uzbekistan market in 2019, and in 2021, the parliament in Uzbekistan introduced legislation covering nicotine pouches. In a response from Fiji, officials noted that the tobacco industry was planning to import nicotine pouches, which would not fit under any existing policies. In Mauritius, an official noted there had been attempts by the tobacco industry to import nicotine pouches, but so far, the ministry of health has successfully opposed these attempts using their authority.

DISCUSSION

This study identified variation in how countries regulate nicotine pouches. Some countries used existing policies to block attempts to sell nicotine pouches in their jurisdictions or to regulate the advertising and sale of these products. Other countries decided their existing policies do not cover nicotine pouches, with some of these countries implementing new policies to address a perceived gap in their regulatory authority. The results of this policy surveillance indicate most countries that report nicotine pouches being sold also have policies applying to nicotine pouches. Specifically, of the 33 countries with a nicotine pouch market presence, 20 have regulations in place to some extent. Regulations most frequently restrict advertising (15 countries), require a health warning label (12 countries) or institute a minimum purchase age (11 countries). There is less clarity on how nicotine pouches made with synthetic nicotine will be regulated with many countries' nicotine pouch policies only applying to pouches using tobacco-derived nicotine. Of the 33 countries reporting a presence of nicotine pouches, around one-third (n=13) regulate synthetic nicotine pouches.

Countries that have opted to regulate both tobacco-derived and synthetic nicotine pouches fall under two approaches. Countries relying on existing tobacco control policies to regulate synthetic nicotine generally classify synthetic nicotine pouches under tobacco product or medicine/drug definitions. Alternatively, countries adopting new legislation or amending existing legislation have added new classifications. These new classifications, such as those adopted by Norway and New Zealand, have focused on the chemical compound (nicotine) rather than the plant this chemical was historically derived from (tobacco). Both approaches can present a path forward for other countries still determining if and how to regulate nicotine pouches and synthetic nicotine in general, including synthetic nicotine used in other products like e-cigarettes, vape pens and snuff.

Countries regulating only tobacco-derived nicotine pouches exclusively rely on their existing tobacco control framework. These countries generally have very limited definitions of tobacco products that specify these as products composed wholly or partially of tobacco. Given the limited scope allowed by existing tobacco product definitions, countries could turn to adjacent policies to regulate synthetic nicotine products. For instance, countries could use policies regulating medical products or could consider amending existing tobacco control legislation to include nicotine in addition—or in place of—references to tobacco.

The USA offers a unique case study on this topic. Prior to March 2022, the US regulatory authority for nicotine pouches defined 'tobacco products' as 'any product *made or derived from tobacco* 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)'.²⁵ This definition was largely perceived as precluding US regulators from regulating synthetic nicotine in the same manner as tobacco. A congressional omnibus spending bill passed in March 2022 promulgated a new tobacco product definition that clearly encompassed synthetic nicotine products.^{26 27} In section 201(rr) of the Federal Food, Drug, and Cosmetic Act, a tobacco product is now defined as 'any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption' 21 U.S.C. 321(rr).

Amending tobacco product policies to include synthetic nicotine offers one approach to close regulatory gaps for synthetic

nicotine. Alternative approaches include regulating synthetic nicotine pouches as a drug, as done by Australia and Japan, which both regulate synthetic nicotine differently from tobacco-derived nicotine pouches. In contrast, Canada, Finland, Portugal and Spain all regulate both types of nicotine pouches as a medicine or drug. The USA took the path of expanding the definition of tobacco products, but in the absence of new legislation, relying on drug/medicine policies is one approach some countries have employed to regulate synthetic nicotine. See [table 2](#) for more detail on which countries regulate synthetic nicotine using drug/medicine classifications.

Approximately two out of every five countries responding to our inquiry (n=27) stated they do not have any policies applying to nicotine pouches (neither tobacco-derived nor synthetic). On further review, these countries had similar definitions to countries regulating tobacco-derived nicotine pouches. For example, the first definition that follows is perceived by government authorities as granting regulatory authority over tobacco-derived nicotine pouches, while the second is perceived as not permitting nicotine pouch policies by government authorities.

- ▶ Costa Rica: Tobacco products encompass products prepared totally or in part using tobacco leaf as raw material, and intended to be smoked, sucked, chewed or used as snuff²⁸ (*regulates only tobacco-derived nicotine pouches*).
- ▶ Germany: Tobacco products are products made of raw tobacco or products manufactured using raw tobacco, which are intended for smoking, chewing or other oral consumption or snuffing²⁹ (*does not regulate nicotine pouches*).

Despite the similarity in wording of the tobacco product definitions, the different interpretations have significant ramifications for tobacco and nicotine use. Both of these definitions are rooted in tobacco, which is typical of countries only regulating tobacco-derived nicotine pouches. In contrast, countries regulating synthetic nicotine pouches have their regulatory authority rooted in nicotine—either regulating it similar to tobacco or regulating this as a drug/medicine.

Our response rate on nicotine pouch policies (67 out of 97 inquires) may indicate lower awareness of these products among health officials. Eight respondents who did not immediately respond to our questions on nicotine pouches indicated unfamiliarity with these products and were able to better direct our inquiry after receiving more detail on these products. An additional two (not included in our response rate) were unable to provide any information on nicotine pouches due to unfamiliarity with any applicable policies.

This work sheds new light on the regulatory frameworks for nicotine pouches used by countries throughout the world. We focused our review on national policies; subnational policies could be relevant in many countries but were not assessed as part of our review. We asked officials to indicate how (and whether) nicotine pouches would be regulated. Regulatory approaches could be emergent in countries where this product is not yet marketed or newly marketed. It could also be the case that different departments or different officials may have differing perspectives on how existing laws should be applied in cases where regulatory approaches are not settled matters. Moreover, this work captures a point in time; every year is an opportunity for new legislation to pass or for a court opinion to change how policies are applied. Lastly, this work is not comprehensive and cannot be established as a generalisable subset of regulatory approaches. To develop a more comprehensive scan, continued outreach is needed to jurisdictions currently not participating in our policy surveillance. Nevertheless, this information offers

unique insight into regulatory approaches for a sizeable and diverse set of countries.

CONCLUSION

The emergence of nicotine pouches throughout the world has heightened concern about nicotine addiction increasing, particularly for naïve nicotine users such as youth. Nicotine pouches—and especially synthetic nicotine pouches—often do not clearly fit within existing definitions of regulated tobacco products. Our work has offered insight into how countries have begun regulating tobacco-derived and synthetic nicotine pouches. By highlighting approaches taken by countries regulating both types of nicotine pouches, our work has also suggested that countries not currently regulating one or both of these products may have more authority than initially realised. For example, countries not regulating nicotine pouches have policies in place that are similar to countries regulating tobacco-derived nicotine pouches. Future work is needed to (1) expand the number of countries reporting their regulatory approaches, (2) track how policies influence use of nicotine pouches and related products, (3) update this continually evolving tobacco and nicotine product regulatory landscape and (4) assess the effect of different regulatory approaches. While our focus was on nicotine pouches, there are other nicotine products where a similar approach would be beneficial. For example, e-cigarettes using synthetic nicotine may be regulated differently from e-cigarettes using tobacco; further research is needed to understand these potential distinctions. Moving forward, policymakers must consider if their tobacco regulatory regimes need to adjust to changing market forces and shift from a tobacco-centric regulatory approach to one focused on nicotine. At the same time, policymakers need to weigh to what extent regulatory approaches for nicotine pouches should mirror those used for other tobacco products. As the tobacco industry adjusts its product constituents—and product mix—policy priorities and policy approaches need to be re-examined.

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Acknowledgements We extend our deepest gratitude to all our in-country contacts whose regulatory knowledge and insight serve as the backbone of this analysis. We recognise the early contributions of Michael Iacobelli and Ayodeji Awopegba to the repository of policies, policy domains and knowledgeable contacts of Dhruva Patel to the expansion of the contacts base and of Darlene Huang to the summaries of policies. We also recognise the early funding of tobacco policy surveillance work by the Robert Wood Johnson Foundation.

Contributors The paper was conceptualised by RDK and LA. Policy collection and review were conducted by MD and LA. MD authored the first draft. All authors reviewed and made contributions to the final version. MD is the guarantor.

Funding Funding was provided by Bloomberg Philanthropies' Bloomberg Initiative to Reduce Tobacco Use. MD was supported by a grant from the US Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health to the Johns Hopkins Education and Research Center for Occupational Safety and Health (award number T42 OH0008428).

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or are publicly available. The data for this paper were primarily from country laws, which we cite in the paper. We provide citations for, and links to, the relevant laws. Additional data obtained directly from in-country contacts are included in the article.

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