POSITION PAPER

The Global Case for Nicotine Pouches

—

Minimizing Risk, Honoring the Environment, and Liberating Women from Smoke

October 2025

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Executive Summary

As governments worldwide pursue smoke-free targets while grappling with stagnating smoking rates, a new consumer driven innovation of smoke-free and tobacco-free nicotine products presents a compelling opportunity to accelerate progress in reducing harmful smoking.

Oral nicotine pouches, in the form of small teabags, are socially non-intrusive products containing nicotine without tobacco leaf that sit between the lip and gum, facilitating absorption through the oral mucous membrane. When placed on a regulated market with product quality and safety standards, they are made from pharmaceutical-grade nicotine and food-grade ingredients – emerging as the lowest risk, the most considerate, the most environmentally-friendly alternative to smoking, and the most important to many women who smoked. In essence, nicotine pouches are available to policymakers seeking evidence-based solutions to reduce smoking-related harm.

The Case for Progressive Regulation

Scientific evidence demonstrates that nicotine pouches occupy a unique position in the risk spectrum of nicotine products. Unlike cigarettes, which contain thousands of harmful chemicals produced through combustion, nicotine pouches eliminate both tobacco and burning entirely. Leading European toxicology agencies, including Germany's Federal Risk Assessment Institute (BfR), the United States FDA, and the UK Committee on Toxicity, have concluded that switching from cigarettes to nicotine pouches could represent a significant reduction in health risk for individual smokers.

Studies reveal stark differences in harmful constituents: while cigarettes contain thousands of harmful chemicals, nicotine pouches have a chemical composition similar to nicotine replacement therapies (NRT). Several pouch products have been shown to contain no detectable tobacco-specific nitrosamines (TSNAs), illustrating that it is technologically feasible to eliminate these dangerous carcinogens entirely. Nicotine pouches pose substantially lower risks of cancer and cardiovascular disease compared to cigarettes.

The relative risk spectrum of 15 nicotine product categories
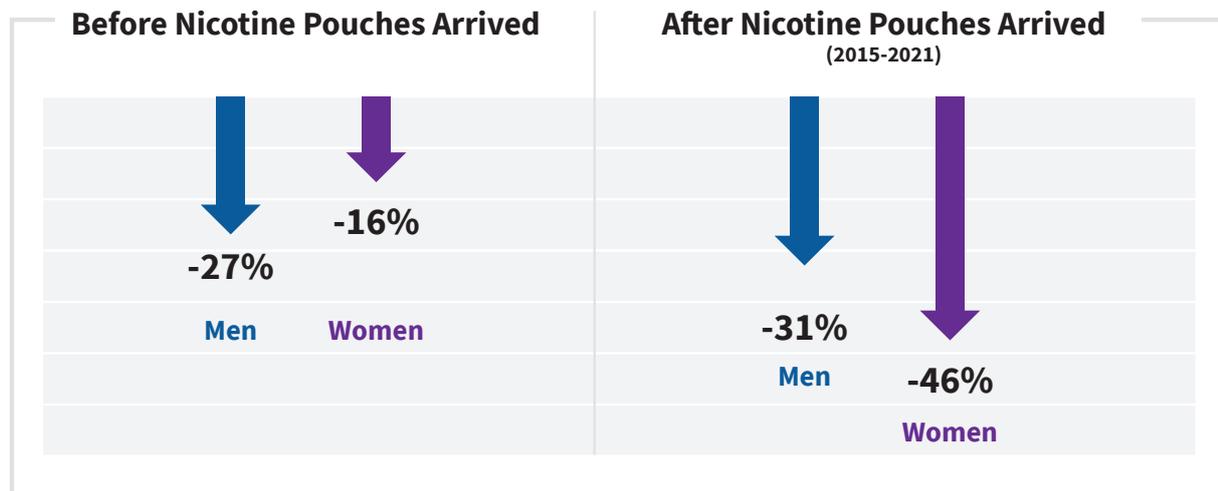

Source: GSTHR
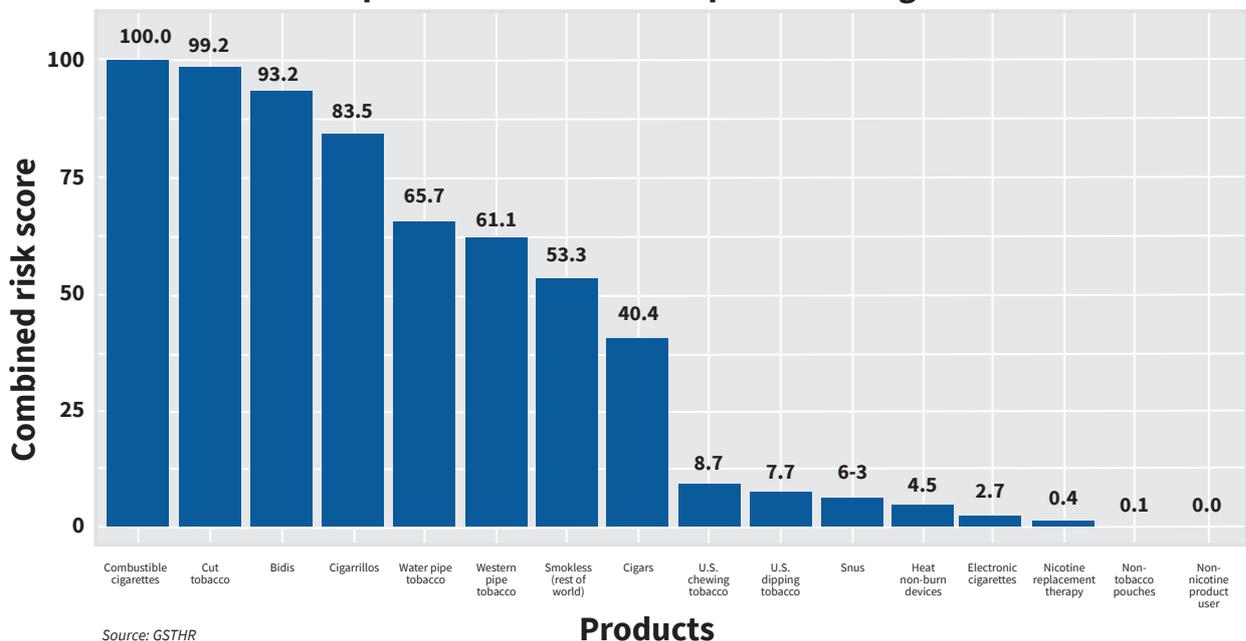
The Swedish Experience

Sweden's transformation from high smoking rates to near smoke-free status within European Union (EU) structures provides compelling real-world evidence of what is possible. With smoking prevalence falling below 5%, Sweden is poised to become the first smoke-free nation in the EU. Analysis of WHO mortality data suggests that if other EU countries adopted Sweden's nicotine use patterns, 355,000 lives could be saved annually.

Critically, Sweden's success occurred not through prohibition but through accessible alternatives. Since nicotine pouches' introduction in 2016, they have gained widespread acceptance, particularly among women and generations

who had not previously replaced cigarettes by snus, the product made from pasteurized tobacco leaves that has traditionally moved people who smoked in Sweden, mostly men, away from smoking. The comprehensive approach of Sweden has fostered a circumstance in which nicotine pouches became not only accepted but also preferred over cigarettes.

In fact, smoking among women in Sweden had declined by just 16% between 2009 and 2015, compared to 27% among men. After the arrival of nicotine pouches, however, the decline accelerated and outpaced that of men. The smoking rate among women declined from 11.2% in 2015 (just before the arrival of nicotine pouches in 2016) to 5.7% today.

Before Nicotine Pouches Arrived

-16%

-27%

Men   **Women**

After Nicotine Pouches Arrived
(2015-2021)

-31%

Men

-46%

Women

Triple Advantages: Health, Social, and Environmental

The One With the Lowest Risk: Nicotine pouches deliver nicotine without combustion, eliminating thousands of harmful chemicals while maintaining effectiveness for smokers. Their gradual nicotine delivery profile reduces both addiction potential and cardiovascular stress compared to cigarettes.

The Most Environmentally Friendly: Nicotine pouches address multiple environmental challenges simultaneously. They contribute to eliminating cigarette waste—including butts, smoke and residual pollutants—, require no electronic components or battery waste—representing a zero-e-waste nicotine delivery system—, and their recyclable tins contain a compartment to encourage a respectful disposal of used nicotine pouches.

The Most Considerate and Most Important to Many Women: Unlike cigarettes, vapes, or heated tobacco products, nicotine pouches produce no smoke, vapor, or odor. They expose no bystanders to second-hand effects, making them socially non-intrusive across workplaces, transport, and other public spaces. In addition, nicotine pouches emerged as a gender-neutral nicotine product, contributing to a 49% reduction in smoking among women in Sweden, which for decades had a significantly lower decline rate compared to that of smoking among men.

Transformative Potential for Low- and Middle-Income Countries

For LMICs facing a devastating convergence of rising smoking rates and overwhelmed healthcare systems, nicotine pouches offer a technological leapfrog solution. Their infrastructure-independent design requires no electricity, generates no electronic waste, and needs no specialized storage—making them as easily distributed by community health workers in any context, urban or rural.

This simplicity transforms harm reduction from a privilege of well-resourced health systems into a tool accessible to the world's most vulnerable populations. For countries where traditional smokeless tobacco products like gutkha and khaini pose significant health risks, nicotine pouches provide direct substitution opportunities that build on existing behavioral patterns while dramatically reducing health risks.

Going Forward

The scientific evidence, policy precedent, and real-world success stories converge on a clear conclusion: nicotine pouches represent a critical tool for achieving global smoke-free ambitions. For policymakers committed to eviden-

ce-based governance, the question is not whether to embrace this innovation, but how quickly they can implement frameworks that harness its potential while protecting public health.

As Sweden moves toward becoming smoke-free, the evidence and voices of consumers point the way forward. The opportunity exists for other nations to follow suit, accelerating their journey toward smoke-free status through progressive policies that distinguish between harm and harm reduction, which public health experts define as "helping people reduce their exposure to the most dangerous forms of nicotine use - namely, cigarettes - by offering them significantly safer alternatives."

Introduction

By Federico N. Fernández

Smoking remains one of the most pressing public health challenges of our time, claiming over 8 million lives annually worldwide while imposing enormous economic and social costs on nations across the development spectrum. Despite decades of traditional Tobacco control interventions—including taxation, advertising restrictions, public space restrictions, and cessation programs—progress toward smoke-free societies has stagnated in many regions. The European Union (EU), for instance, has seen smoking rates plateau at 24%, while many low- and middle-income countries (LMICs) face rising smoking rates among their populations.

This stagnation has prompted a fundamental reconsideration of anti-smoking strategies. Rather than relying solely on cessation-focused approaches that have yielded diminishing returns, policymakers worldwide are increasingly recognizing the potential of innovative nicotine products—providing smokers with significantly safer alternatives that can satisfy nicotine dependence without the catastrophic health consequences of cigarettes.

The landscape of nicotine products has evolved exponentially in recent years. Consumers now have access to an unprecedented array of alternatives: heated tobacco products, vapes, pharmaceutical nicotine replacement therapies (NRT), and most recently, nicotine pouches. These products exist along a continuum of risk, with substantial differences in their health, social, and environmental profiles.

The relative risk spectrum of 15 nicotine product categories

Source: GSTHR
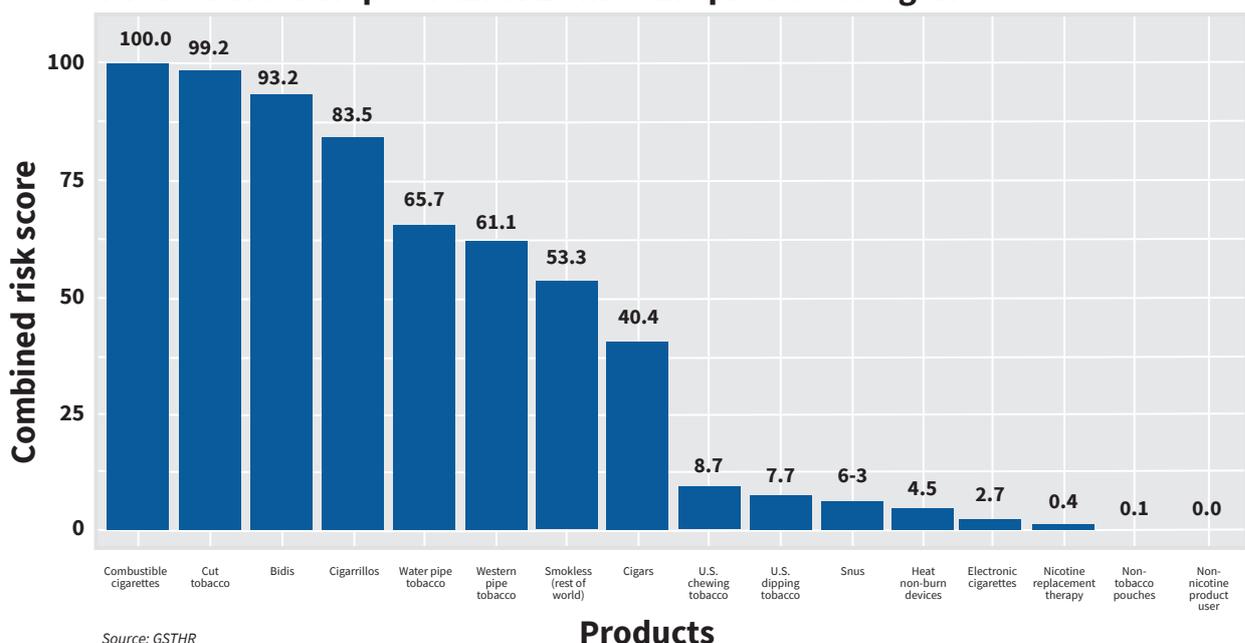
Among these alternatives, nicotine pouches represent a particularly compelling innovation. These socially non-intrusive products contain pharmaceutical-grade nicotine delivered through oral mucosa absorption, eliminating both tobacco and combustion entirely. Since their introduction, they have gained significant market acceptance, particularly in progressive regulatory environments that have embraced evidence-based approaches to tobacco control.

A Unique Convergence of Advantages

What distinguishes nicotine pouches from other alternatives is their unique ability to simultaneously address multiple policy objectives that have traditionally been viewed as separate challenges. While most policy discussions focus on single dimensions—public health, environmental, and social and gender-neutral suitability—nicotine pouches offer an integrated solution that advances all three simultaneously.

This convergence is not merely theoretical. Real-world evidence from Sweden, which has achieved the EU's lowest smoking rates while maintaining EU membership, demonstrates that accessible alternatives to smoking can drive population-level transformations. Sweden's success story—from high smoking rates to near smoke-free status—provides a roadmap that other nations can adapt to their own circumstances.

The Case for Evidence-Based Policy

The scientific foundation supporting nicotine pouches has reached critical mass. Leading European toxicology agencies have conducted comprehensive assessments demonstrating their substantially lower risk profile compared to cigarettes. Independent academic research has validated their potential for harm reduction, including by eliminating exposure to thousands of harmful chemicals—70 of which are known carcinogens—found in cigarette smoke, and by reducing the exposure to tar and other toxins known to contribute to periodontal disease and tooth decay. In addition, nicotine pouches have also been critical to reduce the gender gap in smoking prevalence, while remaining socially non-intrusive.

Finally, environmental lifecycle assessments have confirmed their improved ecological impact. As governments worldwide commit to climate targets and circular economy principles, the choice of alternative to smoking becomes increasingly relevant. Nicotine pouches, which contribute to eliminate cigarette waste and generate no electronic waste, offer an approach that aligns public health objectives with environmental sustainability.

Yet policy responses have been inconsistent. Some jurisdictions have embraced evidence-based approaches, creating regulatory frameworks that distinguish between high-risk and low-risk products. Others have implemented restrictions that paradoxically maintain cigarette availability while limiting access to demonstrably safer alternatives—a misalignment that undermines stated public health objectives.

A Global Opportunity

The implications extend far beyond individual consumer choice. For high-income countries struggling to achieve smoke-free targets, nicotine pouches offer a pathway to accelerate progress. For LMICs facing rising smoking rates with limited healthcare infrastructure, they provide a technological leapfrog solution that bypasses many implementation challenges associated with other harm reduction approaches.

The Central Thesis

Throughout this analysis, evidence consistently points to the same conclusion: among available alternatives to smoking, nicotine pouches uniquely combine the lowest risk profile, the most considerate social impact, and the most environmentally sustainable design. This convergence of advantages creates an unprecedented opportunity for policymakers to advance multiple objectives simultaneously through a single, evidence-based regulatory approach.

The future of the fight against smoking may well depend on our collective ability to embrace innovation as a powerful ally—and to craft policies that unleash its potential to accelerate progress toward smoke-free societies.

The One With the Lowest Risk

By Dr. Karl Fagerström, PhD

The idea behind these new products is to offer nicotine in a purer and less contaminated administration form. Today, we have more nicotine products available than ever before. The consumer has a choice between traditional tobacco products, heated tobacco products, vapes, nicotine replacement (NR) medications, and nicotine pouches. These pro-

ducts are not equally harmful, and therefore, there exists today a continuum of harm, e.g., recognized by the commissioners of the FDA when they state:

"For these currently nicotine-addicted adult smokers, the opportunity to convert to noncombustible products offering nicotine delivery without the combustion-related health risks should be a renewed part of the public health agenda."

For its part, Mallock-Ohnesorg et al. claim:

"The combustion of tobacco and the inhalation of smoke is the primary cause of smoking-related diseases."

In a paper where a risk score was calculated for different nicotine products, cigarettes were set to 100, and no nicotine use was set to 0. The risk for cigars was set to 30, snus to 6, and nicotine pouches to 0,1. In a Swedish study, the number of harmful and potentially harmful constituents was measured in cigarettes, snus, NRT (gum and lozenge), and nicotine pouches. In cigarettes, 84 potentially toxic substances were found, 19 in snus, 9 in NRT gum, 5 in nicotine pouch, and 2 in NR lozenge. In another study from the UK, harmful and potentially harmful constituents were measured, and no difference was found between NR lozenges and gums and four different nicotine pouches.

Absorption Patterns and Safety Implications of Nicotine Pouches

The nicotine content in the pouches varies significantly, ranging from some brands with no nicotine to specific products, often from Eastern Europe, with up to 50 mg of nicotine. Such products are potentially harmful, and it therefore seems sensible to regulate the nicotine content in the pouches. The leading brands typically contain less than 20 mg of nicotine per pouch. When a single pouch is used for approximately 30 minutes, about half of the nicotine is usually extracted, and about half of the extracted amount is absorbed into the bloodstream. Thus, a pouch with 10 mg gives a bioavailable dose of 2,5 mg.

The nicotine from pouches is absorbed across the oral mucosa, which is less sensitive than lung tissue, with safety implications. It takes significantly longer to reach the brain than nicotine from lung inhalation, which has implications for abuse potential. Strengths with approximately 6 to 8 mg achieve a maximum increase in blood concentration of 10-15 ng/mL. This is equivalent to cigarettes, but for a pouch, it takes approximately 60 minutes to reach the maximum concentration, compared to 5 minutes with a cigarette or the time it takes to smoke one. Part of the popularity of nicotine pouches is likely the higher nicotine absorption than what is seen with NR products.

Dependence Mechanisms and Cessation Difficulty by Product Type

The dependence on nicotine products comes from two factors: behavior and drug. The strongest dependence is seen with products where much behavior is needed and the dose of the drug is high, and with a fast uptake. Some 50 years ago, the difficulties of stopping smoking were wholly explained by a powerful and ingrained habit. Today, the pharmacological dependence on nicotine is dominating. Cigarette smoking is the most dependent producing nicotine product due to the fastest uptake of nicotine, rich sensory stimulation, and more behavior required than with any of the other nicotine products. For example, a nicotine patch that requires very little behavior and with slow delivery of nicotine does not seem to have any abuse potential at all. The nicotine pouches have an abuse potential, but less than with cigarettes and inhaled products. Studies have shown that it is easier to stop using smokeless tobacco than cigarettes. In all likelihood, it will also be easier to stop with nicotine pouches than with cigarettes.

Social Considerations in Modern Nicotine Product Design

Burning tobacco products like cigarettes has a significant impact on the people nearby. The smoke cannot only irritate the nose and eyes but also increase the risk of severe disease if exposure is long-term. That has been one of the significant reasons for banning smoking in public places to protect others from environmental smoke. Apart from its health effects, the smoke also has a distinct smell. It sticks to the clothes of the smoker and bystanders, and can cause the smoker to have bad breath and stained teeth. Traditional smokeless products, such as snus, can also have flavors and smells that are aversive to non-users. The nicotine pouches create no smoke but may have a flavor and smell that are hardly noticeable to anyone except the user.

Pouches thus involve no combustion or vaporization, meaning they do not expose non-users to nicotine or com-

bustion-related toxins, and they do not produce vapor, smell, or require spitting, which makes them more socially acceptable in shared environments such as workplaces, transport, and public areas. Because pouches are odorless and leave no residue, they are socially non-intrusive and do not raise hygiene concerns.

Smoking cigarettes is a very visible behavior and might influence others to smoke. Because nicotine pouches do not involve a continuous behavior (other than placing the pouch under the lip and removing it later), they are less likely to serve as behavioral cues or role models for nicotine uptake among non-users and adolescents. The nicotine pouches are very similar in composition to NR products, and the exposure to possible toxins is similar. The difference from NRT is the availability of more flavors and higher strengths of nicotine. In comparison to heated tobacco products and vapes, nicotine pouches are likely the safest of these harm reduction products.

The Most Environmentally-Friendly

By José Alberto León

As governments worldwide pursue smoke-free targets and addressing climate change commitments, policymakers must consider both public health implications and environmental impact of different nicotine products. While much attention focuses on public health benefits of transitioning from cigarettes to less harmful alternatives, the environmental dimension deserves equal scrutiny. Emerging evidence suggests that nicotine pouches represent the most environmentally sustainable option within the spectrum of nicotine products, offering a pathway toward both public health improvement and environmental protection that extends far beyond any single region.

The environmental costs of smoking extend far beyond the act of smoking itself. With the persistent pollution caused by cigarette waste—including butts, smoke and residual pollutants—, these products impose substantial environmental burdens. In contrast, nicotine pouches present a fundamentally different environmental profile that addresses the most pressing ecological concerns associated with nicotine consumption.

Solving the Cigarette Butt Crisis

Perhaps no aspect of smoking's environmental impact is more visible than cigarette butt pollution. Cigarette filters, composed primarily of cellulose acetate (a form of plastic), represent the most common form of litter worldwide, with an estimated 5.6 trillion cigarettes smoked annually producing a corresponding volume of filter waste.

Cigarette butts represent a global environmental crisis extending far beyond aesthetic concerns. Research indicates that cigarette filters can take between 2 and 3 years to decompose, during which time they leach toxic chemicals into soil and waterways. The cellulose acetate in cigarette filters breaks down into microplastics that persist in environmental systems, contaminating food chains and accumulating in marine ecosystems.

The European Environment Agency has identified cigarette butts as among the most problematic forms of single-use plastic pollution, with billions of filters entering European waterways annually. These filters contain concentrated toxicants from tobacco smoke, including heavy metals, pesticide residues, and carcinogenic compounds that leach into environmental systems over time.

"Nicotine pouches leave no combustible waste and no plastic-filter litter — a key difference from cigarettes, which are a major source of persistent environmental pollution," as documented in the ONDS Report (2020).

This distinction reflects fundamental design differences between nicotine pouches and cigarettes. Nicotine pouches produce no ash, tar, or other combustion byproducts, and used pouches can be stored in the recyclable product's container (tins) until proper disposal, preventing litter.

Zero Electronic Waste

As the nicotine product landscape evolves, different technologies present varying environmental profiles. While heated tobacco products and vapes represent innovation in safer alternatives, they do require electronic components as

part of their design. This creates opportunities for nicotine pouches to offer complementary environmental advantages through their fundamentally different approach.

Nicotine pouches distinguish themselves through their remarkably simple design that requires no electronic infrastructure whatsoever:

"Unlike electronic nicotine delivery systems, nicotine pouches generate no battery waste or heavy-metal disposal concerns," noted Travis et al.

This technological simplicity creates unique environmental benefits. Nicotine pouches operate without batteries, eliminating any concerns about lithium-ion disposal or heavy metal waste.

They require no electronic circuits, heating elements, or charging infrastructure, making them entirely independent of electronic waste streams. Their construction relies on simple materials consisting primarily of plant-based fibers and pharmaceutical-grade nicotine.

For policymakers worldwide developing comprehensive environmental strategies, this zero-electronics approach offers particular advantages. It aligns with circular economy principles by eliminating complex waste streams and avoiding the growing challenge of electronic waste management. The pouches' mechanical rather than electronic operation means they place no demands on rare earth minerals, precious metals, or electronic recycling infrastructure.

This design philosophy represents a different path toward sustainable nicotine delivery—one that achieves its environmental benefits through elegant simplicity rather than technological complexity.

Environmental Assessment and Policy Implications

Recent academic research has applied rigorous environmental assessment models to evaluate the ecological impact of nicotine pouches across their entire lifecycle. These studies, which utilize methodologies developed initially by regulatory agencies such as the FDA, provide policymakers with evidence-based assessments of environmental risk.

The most comprehensive environmental assessment found that nicotine pouches, under all modeled disposal scenarios, do not exceed de minimis ecological impact thresholds. This finding encompasses municipal waste systems, wastewater treatment, septic systems, and even litter scenarios.

In particular, for EU policymakers developing frameworks for sustainable consumption, nicotine pouches offer unique advantages in addressing multiple environmental policy objectives simultaneously. The EU's Circular Economy Action Plan emphasizes designing products for minimal waste generation and maximum resource efficiency. Nicotine pouches align with these principles by contributing to eliminate cigarette pollution and avoiding electronic waste through purely mechanical, chemical delivery systems.

The Most Considerate and Most Important to Many Women Who Smoked

By Carissa Düring

As someone deeply involved in consumer advocacy and tobacco harm reduction in Sweden, I have had the privilege of witnessing firsthand how nicotine pouches have transformed lives, not only through public health outcomes but through individual stories.

Through my work with Considerate Pouchers Sweden, I have spoken to countless individuals who describe nicotine pouches as the first solution that truly worked for them - products that fit seamlessly into their everyday lives, allowing them to leave smoking behind for good.

These stories, shared by men and women of all ages and backgrounds, affirm what the data already shows: that nicotine pouches are one of the most promising tools we have in the fight against smoking-related disease.

In Sweden, snus has been around for over 200 years. It is not some fringe habit - it is completely mainstream. You will find it in every corner shop, every supermarket, and almost every workplace. Even when nicotine pouches emer-

ged, they caught on quickly, especially among women, who did not always like the traditional snus. The pouches are white, do not stain your teeth, and are socially non-intrusive. They fit our culture: subtle, efficient, and respectful of others. So in Sweden, most of us do not smoke - and that is not by chance.

Why Sweden Succeded

That is precisely how Sweden has become a global leader in tobacco harm reduction. While most EU countries still battle double-digit smoking rates, Sweden is on the verge of becoming the first smoke-free nation in the EU, defined as a smoking prevalence falling below 5%. This milestone was not reached through bans or punitive policies - it was made possible through a consistent, evidence-based approach that gave consumers access to safer alternatives, such as snus and, more recently, nicotine pouches.

Since their introduction in 2016, nicotine pouches have become a more preferred alternative to smoking across Sweden. Due to their similarity to snus, they gained widespread acceptance among consumers, and policymakers refrained from regulating them within a non-progressive framework. This pragmatic approach has fostered a circumstance in which low-risk products are available, accepted, and even preferred over cigarettes.

In fact, smoking among women in Sweden had declined by just 16% between 2009 and 2015, compared to 27% among men. After the arrival of nicotine pouches, however, the decline accelerated and outpaced that of men. The smoking rate among women declined from 11.2% in 2015 (just before the arrival of nicotine pouches in 2016) to 5.7% today.

Sweden offers an important lesson: when governments let people make better choices and provide them with practical tools, those choices follow.

In Sweden, being considerate in public and private spaces is a core cultural value. Smoking does not just harm one's own health - it also disrupts the health of others through the smell of smoke, litter, and other unpleasant effects. That is why nicotine pouches are so well-suited to modern lifestyles here. They are clean and unobtrusive. No second-hand effects. No need to step outside. No judgment from colleagues, friends, or fellow commuters.

Empowering Women's Choices

One of the most potent things I hear from pouchers - especially women - is that they finally feel in control. Nicotine pouches offer precise dosing, no social stigma, and no mess. They fit into professional settings, family life, and public transit - all without friction.

The EU and LMICs alike have a remarkable opportunity to learn from Sweden's success. Restrictive or prohibitionist policies on nicotine pouches may feel like a protective measure. Still, in reality, they risk cutting off access to the very tools that could dramatically reduce smoking rates.

What is needed is a regulatory environment that distinguishes between high-risk and low-risk products, supporting innovation rather than stifling it. A progressive framework should include product standards, underage use prevention, and transparent labeling - it must preserve access for adult consumers who need alternatives now.

Closing Thoughts

Every time I speak to a poucher who says they feel healthier, more confident, or simply freer, I am reminded why this work matters. Nicotine pouches may be small, but their impact is anything but.

As Sweden moves toward becoming smoke-free, I hope more countries will look at what is working—and dare to follow suit. Let's not waste time reinventing the wheel when the evidence and the voices of consumers are already pointing the way.

An Opportunity for the EU

By Beatriz Santos

With smoking rates stagnating at 24% within the EU and traditional interventions yielding diminishing returns, the evidence increasingly points toward a comprehensive approach that includes innovative alternatives to smoking. The scientific foundation for this shift has never been stronger, while Sweden's pioneering success demonstrates that

smoke-free status is not merely aspirational but achievable within the EU framework.

The Scientific Imperative for Innovation

The evidence base supporting nicotine pouches as a harm reduction tool has reached critical mass. Germany's Federal Risk Assessment Institute (BfR), one of Europe's most respected toxicology agencies, has provided perhaps the most precise articulation of the potential:

"Switching from cigarettes to nicotine pouches could represent a reduction of a smoking individual's health risk," the BfR concluded *in its comprehensive 2022 assessment.*

The BfR's analysis reveals the stark differences between cigarettes and nicotine pouches. While cigarettes contain thousands of harmful chemicals produced through combustion, nicotine pouches contain pharmaceutical-grade nicotine with dramatically lower levels of toxic compounds. Several pouches were shown to contain no tobacco-specific nitrosamines (TSNAs)—illustrating that it is technologically feasible to avoid these substances entirely.

The pharmacokinetic evidence further supports their potential for harm reduction. Studies show that nicotine pouches can deliver nicotine at levels comparable to cigarettes and smokeless tobacco, but with significantly faster nicotine extraction rates—up to 59% compared to 32% for traditional snus. This efficiency means that smokers can satisfy their nicotine dependence without the combustion-related toxins that cause the vast majority of smoking-related disease.

Policy Alignment with EU Health Objectives

The integration of nicotine pouches into the EU's anti-smoking strategy aligns seamlessly with existing policy frameworks. Article 1(d) of the WHO Framework Convention on Tobacco Control explicitly endorses harm reduction strategies as part of tobacco control, defining tobacco control as "a range of supply, demand and harm reduction strategies that aim to improve the health of a population." The European Parliament's report on the EU's Beating Cancer Plan similarly recognizes harm reduction as a legitimate strategy for reducing tobacco-related mortality.

This policy coherence extends beyond abstract principles to practical implementation. The BfR recommends treating nicotine pouches through quality control via standardization and regulation measures to achieve harm reduction, rather than prohibition. This approach mirrors successful pharmaceutical regulation, where products are evaluated based on their risk-benefit profile rather than being subjected to blanket restrictions.

The regulatory pathway becomes even clearer when considering the WHO's inclusion of nicotine replacement therapy (NRT) on its Model List of Essential Medicines. Nicotine pouches contain the same pharmaceutical-grade nicotine as approved medical products, suggesting that the active ingredient itself poses manageable risks when properly regulated.

The Swedish Experience

Sweden's transformation from a high-smoking to virtually smoke-free society within EU structures proves that such change is possible without abandoning European values or regulatory standards.

If other EU countries practiced the same nicotine use patterns as Sweden, encouraging smokers to switch from cigarettes to safer alternatives, no less than 355,000 lives per year could have been saved,", according to analysis of WHO mortality data.

Sweden's approach demonstrates that pro-innovation policies and traditional tobacco control measures work synergistically rather than in opposition. The country maintains robust restrictions on cigarette marketing, comprehensive smoke-free policies, and strong health education programs while simultaneously providing accessible, acceptable, and affordable alternatives for smokers who cannot or will not quit entirely.

The Swedish experience's applicability across the EU is evidenced by migration data showing that EU citizens from high-smoking countries who relocate to Sweden see their smoking rates plummet to approach Swedish norms. This suggests that policy environment, rather than immutable cultural factors, drives smoking behavior—offering hope for similar transformations elsewhere in the Union.

Addressing Regulatory Inconsistencies

The current European regulatory landscape creates perverse incentives that undermine public health objectives. Rather than maintaining restrictions that keep cigarettes legal while limiting access to significantly safer alternatives, regulators should prioritize safer, innovative alternatives.

This regulatory misalignment forces European smokers into a false choice between complete cessation and continued cigarette use. Evidence suggests that many smokers would readily adopt lower-risk products if they were accessible and affordable. Countries like Estonia, which have implemented restrictive approaches including flavor bans for vapes, have seen smoking rates increase by 40% since 2020. This serves as a sobering reminder of the unintended consequences of prohibition.

The solution requires risk-proportionate regulation that treats products according to their relative risk profiles. Nicotine pouches, with their absence of combustion, tobacco leaf, and most toxic compounds, warrant regulatory treatment that reflects their substantially lower risk compared to cigarettes, while maintaining appropriate safeguards to prevent underage use and enhance product quality.

The Innovation Advantage

By establishing clear regulatory pathways for reduced-risk products, the EU can foster improved safety and efficacy rather than maintaining the status quo. The result could be a virtuous cycle where innovation drives down both risk and cost, making alternatives to smoking increasingly attractive to European smokers.

The economic implications extend beyond direct industry benefits. Healthcare systems across the EU spend billions annually treating smoking-related diseases. Sweden's spectacular reduction in smoking-related mortality—31.3% fewer total cancer deaths related to smoking than the EU average, 36% fewer lung cancer deaths in particular—demonstrates the potential for substantial healthcare cost savings when populations successfully transition away from cigarettes.

To achieve its 2040 smoke-free target, the EU must apply risk-proportionate regulation that recognizes the fundamental differences between combustible and non-combustible nicotine products. Member States banning nicotine pouches, even de facto, while allowing cigarettes undermine the EU's smoke-free goal by eliminating safer alternatives that could accelerate the transition away from smoking.

The scientific evidence, policy precedent, and real-world stories all point toward the same conclusion: nicotine pouches represent a critical tool for achieving Europe's smoke-free ambitions.

An Opportunity for Low- and Middle-Income Countries

By Tetiana Rak

LMICs face some of the highest smoking rates globally. Thus, smoking-related diseases are becoming the leading cause of non-communicable deaths worldwide, disproportionately affecting LMICs where public health systems are already overstretched. Yet within this crisis lies an unprecedented opportunity: nicotine pouches could provide LMICs with a technological leapfrog solution that bypasses the infrastructure limitations plaguing other harm reduction approaches.

Infrastructure-Independent Safer Alternative

The most compelling advantage of nicotine pouches for LMICs lies in their fundamental simplicity:

"Unlike e-cigarettes, [nicotine] pouches do not involve combustion or electronics and can be distributed without the logistical or environmental challenges of [Electronic Nicotine Delivery Systems] ENDS," notes research by Travis et al.

This observation carries profound implications for resource-constrained settings where electricity access remains

inconsistent, waste disposal systems are inadequate, and supply chains for complex technologies prove unreliable.

Consider the infrastructure requirements that limit safer alternatives to smoking in LMIC contexts. Vapes require reliable electricity for charging, replacement parts for maintenance, and sophisticated waste management for batteries and cartridges. NRTs often demand cold storage chains, pharmacy networks, and medical supervision. Heated tobacco products require both electricity and proprietary tobacco inserts, necessitating complex manufacturing and distribution networks.

Nicotine pouches sidestep these constraints entirely. They are shelf-stable products that require no electricity, generate no electronic waste, and need no specialized storage or handling. A community health worker in a rural environment can distribute them as easily as a shop owner in an urban one. This simplicity transforms harm reduction from a privilege of well-resourced health systems into a tool accessible to the world's most vulnerable populations.

Economic Prevention vs. Crisis Treatment

The economic argument for nicotine pouches in LMICs extends beyond simple cost calculations to encompass the prevention of future healthcare catastrophes. By offering a safer alternative early, LMICs can reduce future healthcare costs and disease burdens, which is critical where access to cancer screening or treatment is limited. This preventive approach represents a fundamental shift from reactive to proactive public health strategy.

This is a critical counterpoint for many LMICs considering the pros and cons of regulating safer alternatives – as many LMIC countries also heavily rely on cigarette taxes for a large chunk of annual state revenues. Often hostility towards innovations such as vapes or nicotine pouches is not for health reasons but for fiscal reasons due to fear of lost tax revenues.

Current smoking trajectories in many LMICs mirror those seen in high-income countries decades ago. However, with a crucial difference: these countries lack the healthcare infrastructure to manage the coming epidemic of smoking-related disease. A middle-aged smoker in an LMIC who develops lung cancer faces dramatically different treatment prospects than their counterpart in Europe. Prevention through safer alternatives becomes not just economically sensible but ethically imperative.

The cost-effectiveness calculations become even more compelling when considering the broader economic impacts of smoking-related illness. In countries where individual productivity directly affects family survival, the premature disability and death associated with smoking create cascading effects through entire communities. Nicotine pouches, typically costing a fraction of cigarette prices in most markets, could prevent these economic disruptions while providing a safer alternative to smoking.

Addressing Existing Smokeless Tobacco Hazards

Many LMICs, particularly in South Asia, Central Asia, and parts of Africa, already have established markets for oral tobacco products that pose significant health risks. Traditional smokeless tobacco products used in LMICs, such as nasvay (naswar), gutkha and khaini, are highly carcinogenic and unregulated, containing dangerous levels of tobacco-specific nitrosamines and other carcinogens. Nicotine pouches offer a direct substitution opportunity that builds on existing behavioral patterns while dramatically reducing health risks.

The substitution potential is particularly relevant because it leverages familiar consumption methods rather than requiring the adoption of entirely new behaviors. Users of traditional oral tobacco products have already adopted the mechanics.

In contrast to traditional smokeless products, newer alternatives show significant potential for harm reduction. As Germany's Federal Risk Assessment Institute (BfR) observed in 2022:

"The fact that no [tobacco-specific nitrosamines] TSNAs were detected in many products demonstrates that excluding these substances is indeed technically possible."

This finding represents a harm reduction opportunity of enormous magnitude. It suggests the possibility of transforming products that carry substantial cancer risks into alternatives with risk profiles that could approach those of pharmaceutical NRTs.

Leapfrogging Regulatory Development

LMICs have a unique opportunity to implement [progressive regulatory frameworks](#) from the outset, avoiding the policy missteps that have characterized tobacco control in many high-income countries. Rather than spending decades locked in prohibitionist approaches that fail to eradicate smoking, LMICs can build comprehensive systems that acknowledge the reality of nicotine dependence while minimizing harm.

This regulatory advantage extends beyond simple policy choices to encompass broader strategic positioning:

"Tobacco-free oral nicotine delivery systems may be the breakthrough public health has been waiting for," [according](#) to analysis in the ONDS Commission Report.

LMICs that position themselves as early adopters of evidence-based harm reduction could find themselves ahead of international policy curves rather than constantly playing catch-up to approaches developed in high-income settings.

The regulatory framework needed for nicotine pouches is also substantially simpler than that required for other tobacco products or NRTs. Quality standards, age restrictions, and risk-based taxation structures provide sufficient oversight for most contexts, avoiding the elaborate licensing and monitoring systems that overwhelm regulatory capacity in resource-constrained environments.

Afterword – Addressing Societal Concerns and Misinformation

By Federico N. Fernández

The advancement toward smoke-free societies confronts a complex dual challenge: legitimate policy considerations regarding youth protection alongside persistent misconceptions fueled by misinformation. Sorting this issue requires careful distinctions between evidence-based concerns and ideological resistance to innovation.

The most substantive policy challenge centers on regulatory calibration—establishing frameworks that rigorously protect minors while ensuring adult smokers and users of harmful oral tobacco products retain access to regulated, affordable, and demonstrably safer alternatives. Decades of empirical evidence have demonstrated what remains inadequately acknowledged in policy discourse: prohibitionist approaches systematically fail to achieve stated public health objectives. When governments ban these products, they inadvertently cede markets to illicit operators who neither verify consumer age nor maintain product quality standards. The cascading consequences of prohibition are well-documented and severe, condemning both adults and minors to demonstrably worse outcomes. Fortunately, successful models exist—Sweden's evidence-based approach provides a proven framework that other nations can adapt to their specific contexts.

A secondary concern emerged from the unregulated markets that developed in certain jurisdictions, where reports surfaced of illicit nicotine pouches containing dangerous nicotine concentrations far exceeding safe levels. These cases highlight the importance of smart regulation and market compliance enforcement. Paradoxically, categorical product bans exacerbate precisely this problem—transferring entire markets to criminal enterprises and amplifying the very risks that motivated the prohibition.

The question of oral health implications represents another recurring consideration in policy discussions. Although nicotine pouches eliminate both combustion and tobacco, they maintain oral nicotine delivery. Understanding this issue requires applying the fundamental principle of relative risk assessment. Without regulated access to acceptable alternatives like compliant nicotine pouches, populations continue smoking, consuming far more harmful tobacco products, or sourcing unregulated products from illicit markets. The causal relationship between smoking, tobacco use, and oral health complications—including periodontal disease and tooth decay—is firmly established in scientific literature. Conversely, no evidence indicates that tobacco-free nicotine pouches carry comparable risks. Most critically, these products present substantially reduced risk profiles for adults who would otherwise persist in consuming demonstrably harmful alternatives.

About the Authors:

Carissa Düring

is the Director of Considerate Pouchers in Sweden, a consumer advocacy group dedicated to promoting a smoke-free world and consumers' rights to alternative products. She also studies clinical psychology at Uppsala University in Sweden. As an advocate, she brings attention to how successful nicotine pouches have been in helping Sweden achieve the lowest smoking rates in the European Union, and how the rest of the world can follow in its footsteps.

Dr. Karl Fagerström

earned his PhD in nicotine dependence and smoking cessation in 1981. He is best known as the inventor of the Fagerström Test for Cigarette Dependence, a widely used diagnostic tool. As a founding member of the Society for Research on Nicotine and Tobacco (SRNT), he has made significant contributions to tobacco research and currently serves as a deputy editor of Nicotine & Tobacco Research. His outstanding work in tobacco control earned him the World Health Organization medal in 1999, and in 2013, he received the Award on Clinical Science from SRNT.

Federico N. Fernández

is a visionary leader dedicated to driving innovation and change. As the CEO of We Are Innovation, a global network of 50+ think tanks and NGOs, Federico champions innovative solutions worldwide. His expertise and passion for innovation have earned him recognition from prestigious publications such as The Economist, El País, Folha de São Paulo, and Newsweek. Federico has also delivered inspiring speeches and lectures across three continents, authored numerous scholarly articles, and co-edited several books on economics.

José Alberto León

is the Project Director at We Are Innovation. He is also Project Director at Fundación Internacional Bases, as well as Senior Fellow at the think tanks CEDICE Libertad and Fundación Ciudadano Austral. Previously, research and content assistant at Fundación Para el Progreso. Co-author of the book "Después del Socialismo, Libertad" (After Socialism, Freedom). He studied Law at Universidad Central de Venezuela.

Tetiana Rak

is the Chief Operations Officer (COO) at We Are Innovation. A journalist and freedom activist with 8 years of experience, Tania has worked with renowned media outlets including CNN, TechCrunch, Fox News, HackerNoon, the BBC, and Radio Free Europe, among others. Her unwavering dedication to championing the ideas of technological advancements and global digital transformations has earned her a distinguished reputation in the field. Through her work, Tania promotes the ideas of liberty, and individual rights as a cornerstone of any rights-respecting society. Strengthened by the experience of war in Ukraine, Tania's beliefs also stand for promoting technological advancements as the transformative tool to advance liberty, giving people the opportunity to speak, act, and pursue happiness without unnecessary external restrictions.
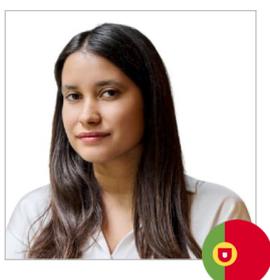
Beatriz Santos

is the Chief Communications Officer (CCO) at We Are Innovation. She is based in Lisbon, Portugal. Beatriz started publishing articles through her University newspaper and eventually moved to national and international reach outlets, including the well known Portuguese outlets NOVO and Observador. Her professional career includes international communications experience with the ATREVIA agency and the European Parliament. She also has two published books and is an essential part of the Students For Liberty organization in Portugal. With a focus on positive change and global cooperation, Beatriz actively seeks partnerships across the globe to promote innovative initiatives.

PATH TO SMOKE-FREE

Path to Smoke-Free is a comprehensive analytical platform developed by We Are Innovation that reveals how countries can harness innovation to defeat smoking and accelerate their journey toward smoke-free status. Drawing from Sweden's remarkable success in dramatically reducing smoking rates far below global averages—we identified three key elements: Accessibility, Acceptability, and Affordability of innovative nicotine products. Our platform combines comprehensive policy data with real insights from Swedish ex-smokers, offering interactive tools to compare how countries are harnessing innovation to defeat smoking. The platform features powerful forecasting charts that project smoking prevalence and when countries will reach smoke-free status under three scenarios: current policy trajectories, outcomes if countries matched Sweden's success rate, or results following the combined pace of leading nations. Policymakers, researchers, and health professionals can explore evidence-based strategies that could help their countries reach smoke-free targets faster, guided by proven success stories. Discover how your country could accelerate its journey to smoke-free status at https://pathtosmokefree.global/.

WE ARE INNOVATION

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