
# Nicotine pouches: characteristics, use, harms, regulatory considerations

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Co-funded by the European Union

# TobReg background paper on nicotine pouches

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## WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: ninth report of a WHO study group

23 August 2023 | Report


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### Overview

This report of the WHO Study Group on Tobacco Product Regulation provides the Director-General with scientifically sound, evidence-based recommendations for Member States about tobacco product regulation. The outcomes and recommendations address emerging issues in tobacco product regulation, such as newer ways in which non-therapeutic nicotine, particularly in nicotine products, is promoted and delivered to people in different age groups. The five topics addressed in the report, based on the commissioned background papers for the eleventh meeting of the study group, are enumerated below:

1. Additives that facilitate inhalation, including cooling agents, nicotine salts and flavourings (Section 2);
2. Synthetic nicotine: science, global legal landscape and regulatory considerations (Section 3);
3. Nicotine pouches: characteristics, use, harmfulness and regulation (Section 4);
4. Biomarkers of exposure, effect and susceptibility for assessing electronic nicotine delivery devices and heated tobacco products, and their possible prioritization (Section 5) and
5. Internet, influencer and social media marketing of tobacco and non-therapeutic nicotine products and associated regulatory considerations (Section 6).

**WHO TEAM**
No Tobacco (TFI), Study Group on Tobacco Regulation

**EDITORS**
World Health Organization

**NUMBER OF PAGES**
165

**REFERENCE NUMBERS**
**ISBN:** 978-92-4-007941-0

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# Nicotine pouches: characteristics, use, harmfulness and regulation


Photo credit: WHO

## 4. Nicotine pouches: characteristics, use, harmfulness and regulation

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# Characteristics nicotine pouch

- ‘White snus’: powder containing nicotine
- Claimed not to contain tobacco
- Placed under the (upper) lip. Ingestion via the mucous membrane and saliva in the mouth
- Ingredients: nicotine, fillers and other additives, stabilisers, sweeteners, and flavourings
- 20-25 pouches per can
- Nicotine dose 3-50 mg/g (2-33 mg per pouch); snus 7–21 mg/g.
- Variety of flavours

Photo credit: WHO

150mg/gm

# Risks of nicotine pouches

- Attractive features
- Flavours and sweeteners
- Easy and discrete in use
- Perceived as less harmful than other tobacco products
- Perceived as effective to quit smoking
- High nicotine levels
- Harmful to health (nervous system, cardiac arrhythmias)
- Sustain addiction, but not 'fast kick' like inhaled products
- Maybe gateway product to other nicotine and tobacco products
- Undermine tobacco control policies
- Use at places with a smoke-free policy

# Marketing

“Advantages”

- less harmful, no smoke, tobacco-free
- no smell
- mild, slim, flavoured
- discrete and can be used anywhere

Packaging

- Colourful and appealing to youth

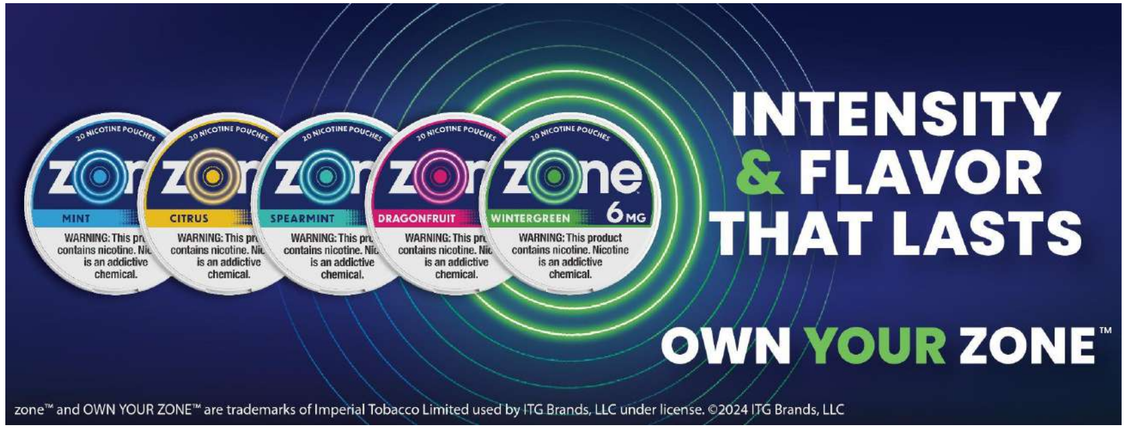
Social media

- Music artists, football players, influencers




# Flavours

- variety of flavours
- popular: menthol/mint, cooling (ice, frozen) and fruity and sweet categories
- flavours can be combined and described for example as “a balanced combination of sweet and tart pineapple with creamy coconut and a nutty undertone” (Lyft) and given “concept” names, such as “tropic breeze” (Velo)


# Addictiveness of nicotine pouches


- Nicotine blood plasma concentrations same order as smoking
  - Cigarette smoking: 10-30 ng/mL
  - Nicotine pouch (3-30 mg) use: 8–29 ng/mL
- Concentrations peak much faster after smoking
  - Cigarette: ~5 minutes
  - Nicotine pouch: ~20-60 minutes
- Fast peak (‘rush’, ‘buzz’) after smoking vital to addiction, as it causes strong conditioning between behavior and rewarding effects
- Rate at which nicotine is absorbed from nicotine pouches appears to be closer to that of nicotine gum than that of inhalable nicotine-containing products
- However, high concentration pouches may be different

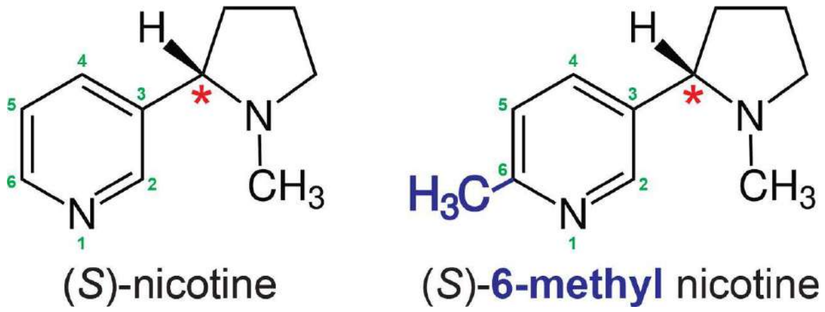

150mg/gm

# Risk assessment of nicotine in pouches

- EFSA Acute Reference Dose (ARfD) = 0,0008 mg/kg body weight
- Highest single dose that can be taken without health risk
- Based on Lindgren et al. 1999: 3,5 µg/kg nicotine caused 10% increased heart rate
- Exposure scenario: one pouch absorption via oral mucosa
- For adults (60 kg): ARfD not exceeded by consumption of pouch < 0,035 mg nicotine
- Nicotine dose typically 2-33 mg per pouch
- Pouches with nicotine levels above 35 µg prohibited in NL under the Commodities Act Decree on the Preparation and Treatment of Foodstuffs (Article 2, fifth paragraph) and Regulation (EC) No. 178/2002 (Article 14, first and second paragraph).

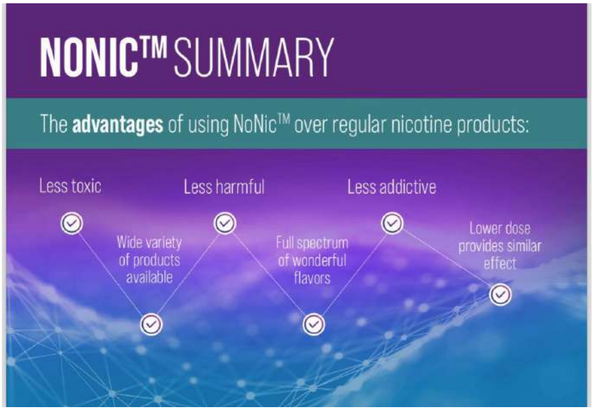
# Nicotine analogues such as 6-methylnicotine

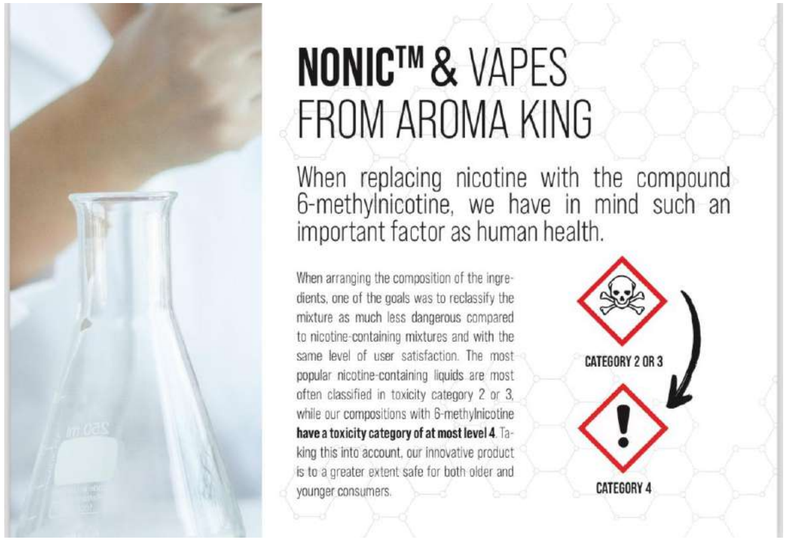

- NA: compounds that resemble nicotine with respect to chemical structure and/or physiological action
- sometimes not covered by tobacco laws
  - US FDA not authorized to regulate products containing NA instead of nicotine
  - In the EU TPD, nicotine is defined as nicotine alkaloid
  - But many nicotine products such as pouches not covered by TPD
- No sufficient data are available about their toxicity and addictive potential
- To prevent law evasion, close this regulatory loophole


# 6-methylnicotine risk assessment

- Early 2024, pouches with 6-MN appeared on the market, with the explicit claim that they do not contain nicotine
- Various 6-MN levels, in carefully designed cans and with several flavors including sweet, fruit, menthol and ice
- According to the manufacturer, 6-MN is synthetic and unlike tobacco-extracted nicotine, cannot be considered an alkaloid, since not being of natural origin
- Very limited toxicity and addictiveness data are available for 6-MN
- Assuming 6-MN is as potent as nicotine, no acute harmful effects are expected at a dose of 38 µg 6-MN per pouch (vs 35 µg for nicotine due to correction for molecular weight)
- If 6-MN more potent than nicotine, this dose will be smaller
- 6-MN levels declared for pouches exceed the dose considered to be not harmful by more than two orders of magnitude



# Ban on nicotine pouches in the Netherlands as of 2025

- Now: ban on the marketing of nicotine pouches that contain 0.0350 milligrams or more of nicotine or 0.0382 milligrams or more of 6-methylnicotine per pouch
- As of 1 January 2025, sale of nicotine pouches no longer allowed at all. Not even if they contain less nicotine or 6-methylnicotine. As of that date, nicotine pouches fall under the Tobacco and Smoking Products Act and a total sales ban applies to these products
- They belong to the group of nicotine products without tobacco for oral use. A total sales ban will apply to these products from then on. In addition, the smoking ban and advertising ban also apply to these products

# Other regulatory approaches

- Consumer product
- Food
- Poison
- Medicine or pharmaceutical product
- Nicotine pouch/Nicotine-containing product/Tobacco-free products/Tobacco alternatives/Imitation tobacco
- Tobacco product

# Key findings, challenges and regulatory implications

- Nicotine pouches have recently become available in many markets worldwide, and their sales are growing rapidly.
- Nicotine pouches deliver sufficient nicotine to induce and sustain nicotine addiction.
- Nicotine pouches have attractive properties, such as appealing flavours, and can be used discretely without the stigma of smoking.
- Nicotine is harmful to health, including to the nervous and cardiac systems.
- There are few data on nicotine pouches because they have been on the market for only a short time. A cautionary approach is warranted, given their similarities to conventional oral tobacco products, in particular snus.
- Nicotine pouches are not regulated or not specifically regulated in several jurisdictions. Some countries had already made their regulations and laws “future-proof ” and resilient, so that nicotine pouches are regulated under existing laws. Others have recently updated their laws, while some retain definitions that refer only to conventional tobacco products.

# Document FCTC COP 10/7 (2024)

Progress report on technical matters related to Articles 9 and 10 of the WHO FCTC. Parties should consider the recommendations of TobReg in its Ninth report, as follows:

a. establish or extend surveillance of products and their users, including demographics, use of other tobacco and related products, brand, type and flavour used in nicotine pouches to acquire knowledge and assess the prevalence of use and user profiles
b. regulate nicotine pouches to prevent all forms of marketing and take all other action necessary to minimize: young people's access to them, their appeal to young people and initiation of use by young people
c. regulate non-therapeutic nicotine products in the same manner as products of similar appearance, content and use
d. ensure that nicotine pouches are not classified as pharmaceutical products unless they are proven to be nicotine replacement therapies by following stringent pharmaceutical pathways for licensing as nicotine replacement therapies, as prescribed by the appropriate national regulatory authority

7th ICO-WHO

# SYMPOSIUM

ON TOBACCO CONTROL

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# Prevalence of use and user profile

| Group | Ever use (%) | Current use (%) | Countries (year) |
|---|---|---|---|
| smokers, vapers, dual users, recent ex-users | 4.4 | | UK (2019) |
| current established smokers (adults ≥18 y.) | 5.6 | | US (2021) |
| current cigarette smokers, recent ex-smokers | | 0.8 (0.1-1.1) | AU, CA, GB, US (2020) |
| males | | 1.1 | |
| females | | 0.5 | |
| age 18-24 | | 2.3 | |
| age 25-39, 40-54, 55+ | | 1.4, 0.4, 0.1 | |
| total population | 0.6 | 0.06 | NL (2020) |
| current smokers | 1.9 | | |
| menthol cigarettes smokers | 6.3 | | |
| adolescents (13-17) | 0.3 | 0.0 | |
| young people (age 16-19) | | 1-1.5 | CA, GB, US (2019) |
| youth (middle and high school students) | 1.9 | 0.8 | US (2021) |