Nicotine Pouches – A Legal Grey Area in India

Mains: *GS II – Governance*

Why in News?

A recent study has found that nicotine pouches are increasingly reaching Indian consumers through online platforms but the precise legal framework governing nicotine pouches in India remains unclear.

What are Nicotine Pouches?

- **Nicotine pouches** – These are small, tobacco-free oral pouches *containing nicotine, flavourings and plant-based fibres.*
- They are placed between the lip and gum, allowing nicotine to enter the bloodstream.
- They *do not involve smoke, combustion or vapour*.
- Nicotine may be extracted from tobacco plants or produced synthetically.
- Unlike conventional smokeless tobacco, they do not contain tobacco leaf, dust or stem.

Why are Nicotine Pouches Not Clearly Covered Under legal framework?

- **Cigarettes and Other Tobacco Products Act (COTPA), 2003** – It regulates the manufacture, advertising, sale and consumption of specified tobacco products.
- However, its definition of tobacco products is specific and does not automatically cover every product containing nicotine.
- Since nicotine pouches are tobacco-free, there is a legal argument that they fall outside the scope of COTPA.
- **Drugs and Cosmetics Act** – There are two competing interpretations.
    - **Argument for regulation as drugs** – Nicotine patches and gums have been approved for therapeutic use in treating nicotine addiction.
    - Schedule K of the Drugs and Cosmetics Rules provides exemptions for certain nicotine-containing gums and lozenges below specified nicotine levels.
    - This could indicate that other nicotine products may require regulatory approval and licensing.
    - **Argument against treating them as drugs –** Nicotine pouches generally do not claim to treat nicotine addiction.
    - They are marketed as alternatives to cigarettes or other tobacco products rather than therapeutic products.
    - Therefore, classifying recreational nicotine pouches as drugs remains legally debatable.
- **Not Covered by the Vape Ban** – The Prohibition of Electronic Cigarettes Act (PECA),

2019 specifically prohibits the production, manufacture, transport, sale, storage and advertising of **electronic cigarettes**.
    - Nicotine pouches, however, were not specifically included in PECA.
    - This creates an important regulatory gap: while e-cigarettes are expressly prohibited, there is no equivalent legislation specifically banning tobacco-free nicotine pouches.
- **Under food-safety laws** – Interpretation arises from the broad definition of "food" under Indian food-safety laws.
    - The **Supreme Court** has previously interpreted the concept of food broadly, including products that are chewed or consumed.
    - Since nicotine pouches are placed in the mouth and their contents are absorbed by the body, it could potentially be argued that they fall within the broad definition of food.
    - However, treating a nicotine-delivery product as food could create significant regulatory and public-health complications and requires clear statutory interpretation.
- **Under India imports** – India regulates imports primarily through the
    - Foreign Trade (Development and Regulation) Act, 1992
    - Customs Act, 1962
- The revised Harmonized System classification has created specific categories for oral nicotine products, including tobacco-free nicotine pouches.
- Under the DGFT classification cited in the article, tobacco-free oral nicotine pouches are categorised *as "restricted" rather than completely prohibited.*
    - Thus specific DGFT authorisation or permission may be required.
- Their importability would also depend upon how the relevant authorities classify them—for example, as drugs, food or another regulated product.
- **About Duty-Free Shops** – Duty-free shops operate under licences under the Customs Act and are subject to Indian legal requirements.
    - Their exemption primarily concerns applicable customs duties and taxes on permitted goods.

Nicotine Pouches

A new form of nicotine delivery raising regulatory questions in India

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What are Nicotine Pouches?

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- Placed between the lip and gum, allowing nicotine to enter the bloodstream.
- **Do not** involve smoke, combustion or **vapour**.
- Nicotine may be extracted from tobacco plants or produced synthetically.
- Unlike conventional smokeless tobacco, they do not contain tobacco leaf, dust or stem.

Tobacco-free
No smoke
No vapour

Why are Nicotine Pouches Not Clearly Covered Under the Legal Framework?

India's existing laws regulate tobacco products, drugs, e-cigarettes, food and imports, but nicotine pouches fall in a grey area. This has created a **regulatory gap.**

1. Cigarettes and Other Tobacco Products Act (COTPA), 2003

- Regulates manufacture, advertising, sale and consumption of specified tobacco products.
- Definition of tobacco products is specific and does not automatically cover every product containing nicotine.
- Since nicotine pouches are tobacco-free, there is a legal argument that they **fall outside the scope of COTPA.**

2. Drugs and Cosmetics Act

- Two competing interpretations:
  - **Argument for regulation as drugs**
    - Nicotine patches and gums approved for therapeutic use to treat nicotine addiction.
    - Schedule K provides exemptions for certain nicotine-containing gums gums and lozenges below specified levels.
    - This may indicate that other nicotine products require regulatory approval.

3. Not Covered by the Vape Ban (PECA), 2019

- The Prohibition of Electronic Cigarettes Act, 2019 prohibits production, manufacture, transport, sale, storage and advertising of electronic cigarettes.
- **Nicotine pouches are not specifically included in PECA.**
- This creates a regulatory gap — while e-cigarettes are prohibited, there is no equivalent legislation specifically banning tobacco-free nicotine pouches.

4. Under Food-Safety Laws

- Broad definition of "food" under Indian food-safety laws.
- Supreme Court has interpreted food broadly, including products that are chewed or consumed.
- Since nicotine pouches are placed in the mouth and **absorbed by the body, they could potentially fall within this definition.**
- However, treating a nicotine-delivery product as food could create significant regulatory and public-health complications and requires clear statutory interpretation.

5. Under India Imports

- Imports regulated through:
  - Foreign Trade (Development and Regulation) Act, 1992
  - Customs Act, 1962
- Revised Harmonized System classification has created specific categories for oral nicotine products, including tobacco-free nicotine pouclcts.
- Under the DGFT classification, these pouches are categorised as **"restricted" rather than completely prohibited.**
- Specific DGFT authorisation or permission may be required.
- Importability also depends on how authorities classify them (e.g., as drugs, food or another regulated product).

6. About Duty-Free Shops

- Duty-free shops operate under licences under the Customs Act and are subject to Indian legal requirements.
- Their exemption primarily concerns applicable customs duties and taxes on permitted goods.

What are the key challenges associated with the regulation?

- **Regulatory ambiguity** – The absence of a specific legal category for recreational nicotine pouches creates uncertainty regarding applicable legislation.
- **Public-health concerns** – Easy availability could encourage nicotine dependence, particularly among young people.
- **Online and informal distribution** – Online platforms, delivery services and hookah shops can make regulatory enforcement difficult.
- **Risk of regulatory arbitrage** – Products could exploit gaps between tobacco, drug, food and customs regulations.
- **Smuggling concerns** – A delayed regulatory response could result in the growth of an illicit market, as witnessed with prohibited vaping products.

What could be done?

- **Provide clear definition** – Explicitly define nicotine pouches under an appropriate tobacco-control or public-health legislation.
- **Product distinction** – Establish a clear distinction between therapeutic nicotine-replacement products and recreational nicotine products.
- **Strengthen import norms** – Strengthen DGFT, Customs, CDSCO and FSSAI coordination to remove classification ambiguity.
- **Regulate e-commerce** – Regulate online sales, advertising and influencer marketing of nicotine products.
- **Ensure market restrictions** – Introduce age restrictions, health warnings and restrictions on flavours and youth-oriented marketing where legally appropriate.
- **Surveillance strengthening** – Strengthen surveillance at airports and e-commerce platforms.
- **Research developments** – Undertake independent research on the health impacts and prevalence of nicotine-pouch use in India.

What lies ahead?

- Nicotine pouches occupy a legal grey zone in India because existing laws were primarily designed around tobacco products and electronic cigarettes.
- India needs a precautionary, evidence-based and technology-neutral framework that prevents companies from exploiting legislative gaps.
- It is also important to ensure that legitimate nicotine-replacement therapies remain accessible.

Reference

[The Hindu| Nicotine Pouches – A Legal Grey Area in India]

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