



Experiences to protect the population's health by regulating novel and emerging tobacco products

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Outline

- **Novel and Emerging Tobacco and Nicotine Products**

 - **Definitions**

 - **WHO FCTC Articles**

 - **Conference of the Parties' decisions**

 - **Novel and Emerging Tobacco Products**
 - Heated Tobacco Products (HTPs)
 - **Novel and Emerging Nicotine Products**
 - Electronic Nicotine Delivery Systems (ENDS)
 - Electronic Non-Nicotine Delivery Systems (ENNDS)
 - Nicotine pouches

- **Regulatory developments on ENDS/ENNDS/HTPs globally**

- **WHO call to action**

NOVEL AND EMERGING TOBACCO AND NICOTINE PRODUCTS

- **Novel and emerging**
- **Novel and emerging tobacco products (as per WHO FCTC [Article 1](#) definition)**
 - **Heated Tobacco Products (HTPs)**
- **Novel and emerging nicotine [and non nicotine] products**
 - **Electronic Nicotine Delivery Systems (ENDS)**
 - **Electronic Non Nicotine Delivery Systems (ENNDS)**
 - **Nicotine pouches**

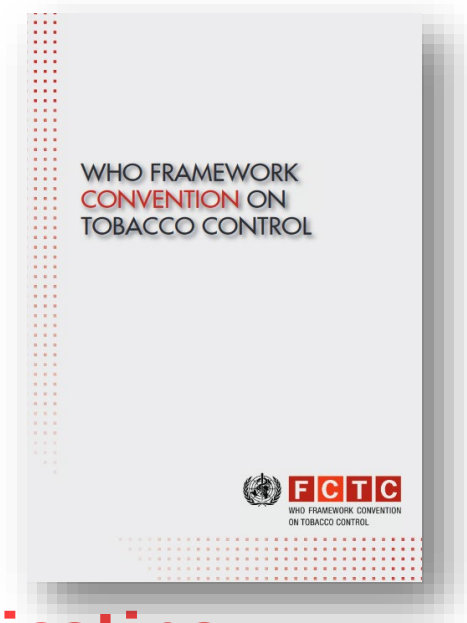
Does WHO FCTC apply to these products?

Article 5 General Obligations

2. "...each Party shall, in accordance with its capabilities...
(b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for **preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.**"

WHO FCTC Article 2.1

"In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law."





New and emerging tobacco products

Heated Tobacco Products(HTPs)



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NOVEL AND EMERGING TOBACCO PRODUCTS: HTPs

Insert: tobacco stick



Device: heats tobacco

FCTC/COP8(22)

...Recognizing heated tobacco products are **tobacco products** and are therefore **subject to the provisions of the WHO FCTC**;

TWO KEY QUESTIONS:

ARE THEY SAFE? **NO** (compared to not smoking at all)

ARE THEY SAFER? **WE DON'T KNOW YET** (e.g. FDA was very explicit in its market authorization, that they cannot be presented as lower risk, only lower exposure to certain toxicants)



NEW AND EMERGING NICOTINE PRODUCTS: ENDS/ENNDS



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ENDS & ENNDS:

Electronic device that heats a liquid with or without nicotine



Cig-a-likes

These are disposables that have the look and feel of conventional cigarettes. This may renormalize smoking.



Vape-pens

These enable users to vary e-liquid formulations according to their preferences. Some use pre-filled cartridges while others allow users to refill them.



Disposables

These are the latest version of ENDS, often shaped like pods, but are meant to be discarded after the e-liquid has been used. They are available in a wide variety of flavours and are also easily concealable.



Tank systems

These enable users to vary almost every element of the user experience, including e-liquid formulations and battery power.



Pods

These are a newer generation of ENDS. Because this generation often uses nicotine salts, they provide higher doses of nicotine without a harsh sensation. The devices often look like USB sticks allowing users (e.g. young people or students) to conceal them.

ENDS/ENNDS – e-Liquids

ENDS

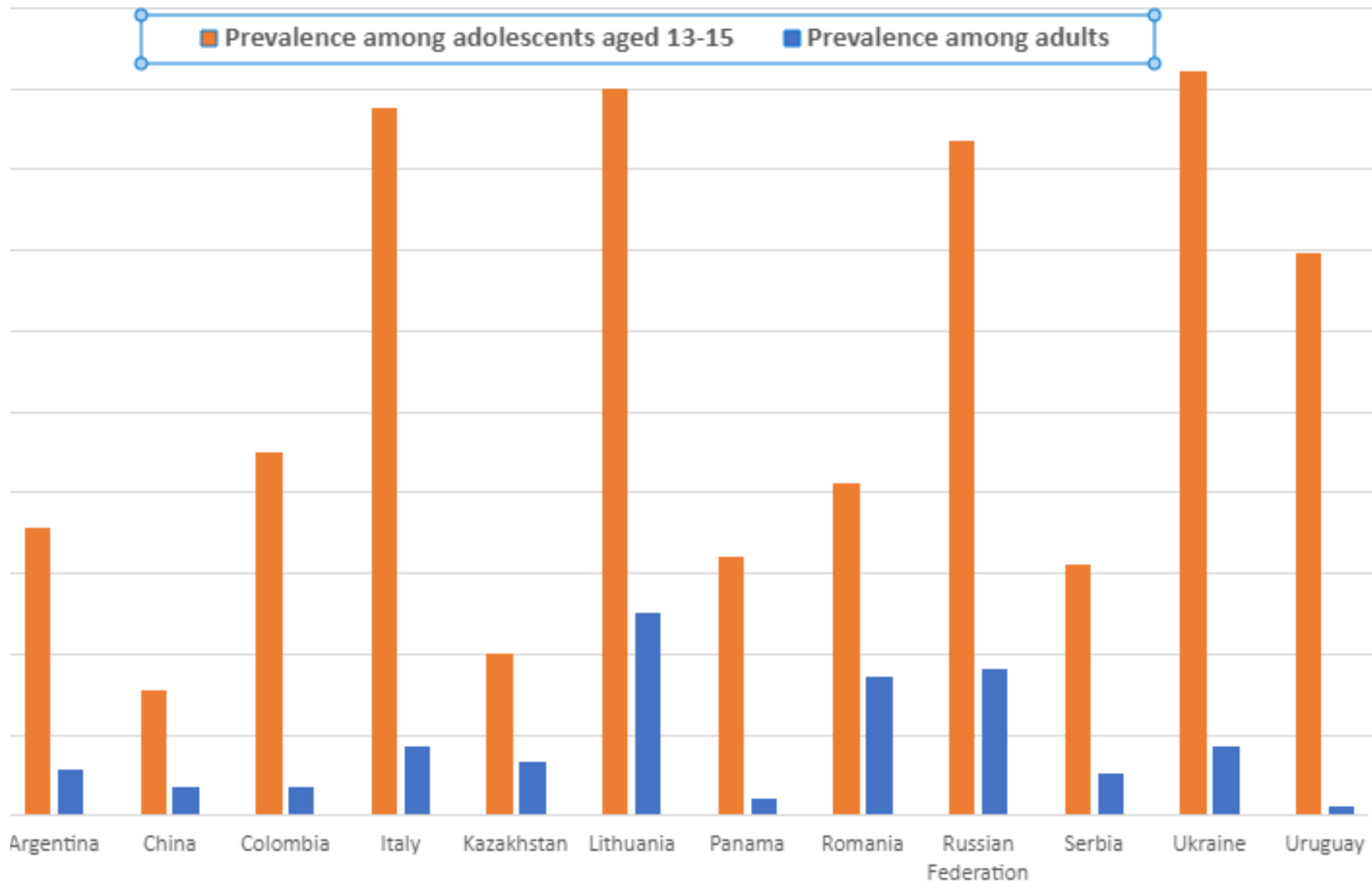
1. Contains nicotine
2. Thousands of flavours
3. Diverse volumes
4. Range of colours
5. Can be manipulated
6. Disposable/refills for devices
7. Pods or cartridges
8. Contain other chemicals
9. Varying nicotine concentration



ENNDS

1. Not supposed to contain nicotine
2. Thousands of flavours
3. Comes in diverse volumes
4. Range of colours
5. Can be manipulated
6. Disposable/refills for devices
7. Pods or cartridges
8. Contain other chemicals

Countries reporting e-cigarette use among adolescents aged 13-15 and adults in the period 2017-2022



Retailers Warned to Stop Selling Illegal E-Cigarettes Resembling Youth-Appealing Characters, School Supplies, Toys, and Drinks

**US FDA
(23 August 2023)**

Retailers Given 15 Working Days to Respond with Corrective Action or Risk Enforcement

The unauthorized products described in the warning letters include e-cigarettes that:

- Feature youth-appealing characters from TV shows, movies, and video games, including “SpongeBob,” “Lots-o’-Huggin’ Bear,” and “Mario;”



- Are designed to look like youth-appealing school supplies, such as highlighters, and toys like Nintendo Game Boy and digital cameras;

<https://www.fda.gov/tobacco-products/ctp-newsroom/retailers-warned-st-selling-illegal-e-cigarettes-resembling-youth-appealing-characters-school>

Discrete 'Vape' – younger generation appeal





Conference of the Parties to the WHO FCTC - Decisions



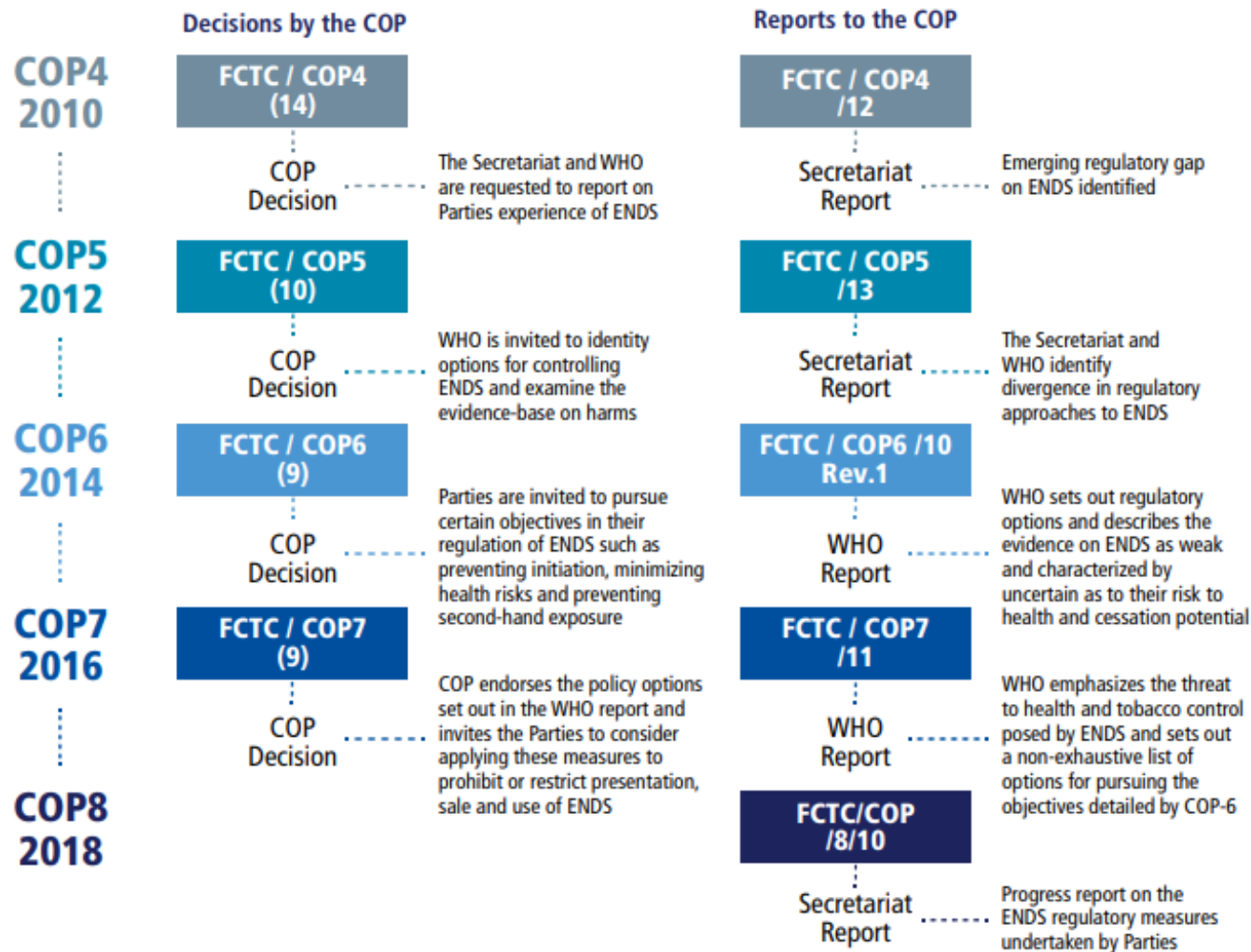
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COP DECISIONS AND THE SCIENCE BEHIND

TIMELINE OF ENDS-RELATED DECISIONS AT, AND REPORT TO, THE COP



Source: WHO Report on the global tobacco epidemic, 2021

WHO FCTC COP DECISIONS ON ENDS/ENNDS

Decision FCTC/COP6(9)

INVITES Parties, when addressing the challenge posed by ENDS/ENNDS, **to consider taking measures such as those referred to in document FCTC/COP/6/10 Rev.1** in order to achieve at least the following objectives, in accordance with national law:

- (a) prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;
- (b) minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;
- (c) prevent unproven health claims from being made about ENDS/ENNDS; and
- (d) protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry;

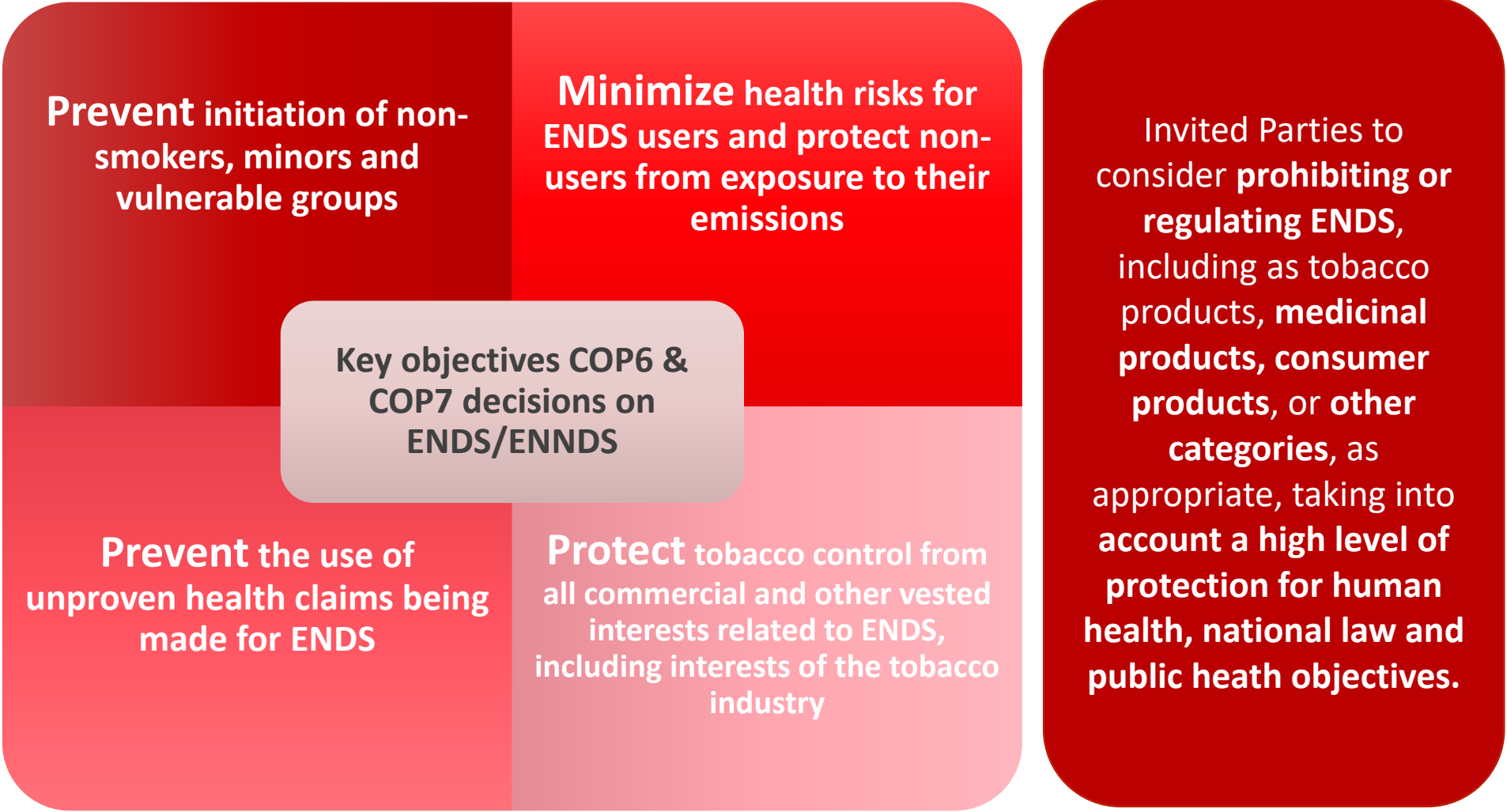
3. INVITES Parties **to consider prohibiting or regulating ENDS/ENNDS**, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health;

4. URGES Parties to consider banning or restricting advertising, promotion and sponsorship of ENDS;

Decision FCTC/COP7(9)

INVITES Parties **to consider applying regulatory measures such as those referred to in document FCTC/COP/7/11 to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives**

ENDS and ENNDS: WHO Policy Options



Sources:
https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf
https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf



New and emerging nicotine products: Nicotine Pouches



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Nicotine Pouches

- Recently become available, sales growing rapidly
- Few data available, similar to other oral tobacco products, in particular snus.
- Deliver enough nicotine to **induce** and **sustain addiction**,
- **Attractive properties:** can be used discreetly; avoiding the stigma of smoking.
- Diversity of products, varying nicotine content and bioavailability.



Source: WHO



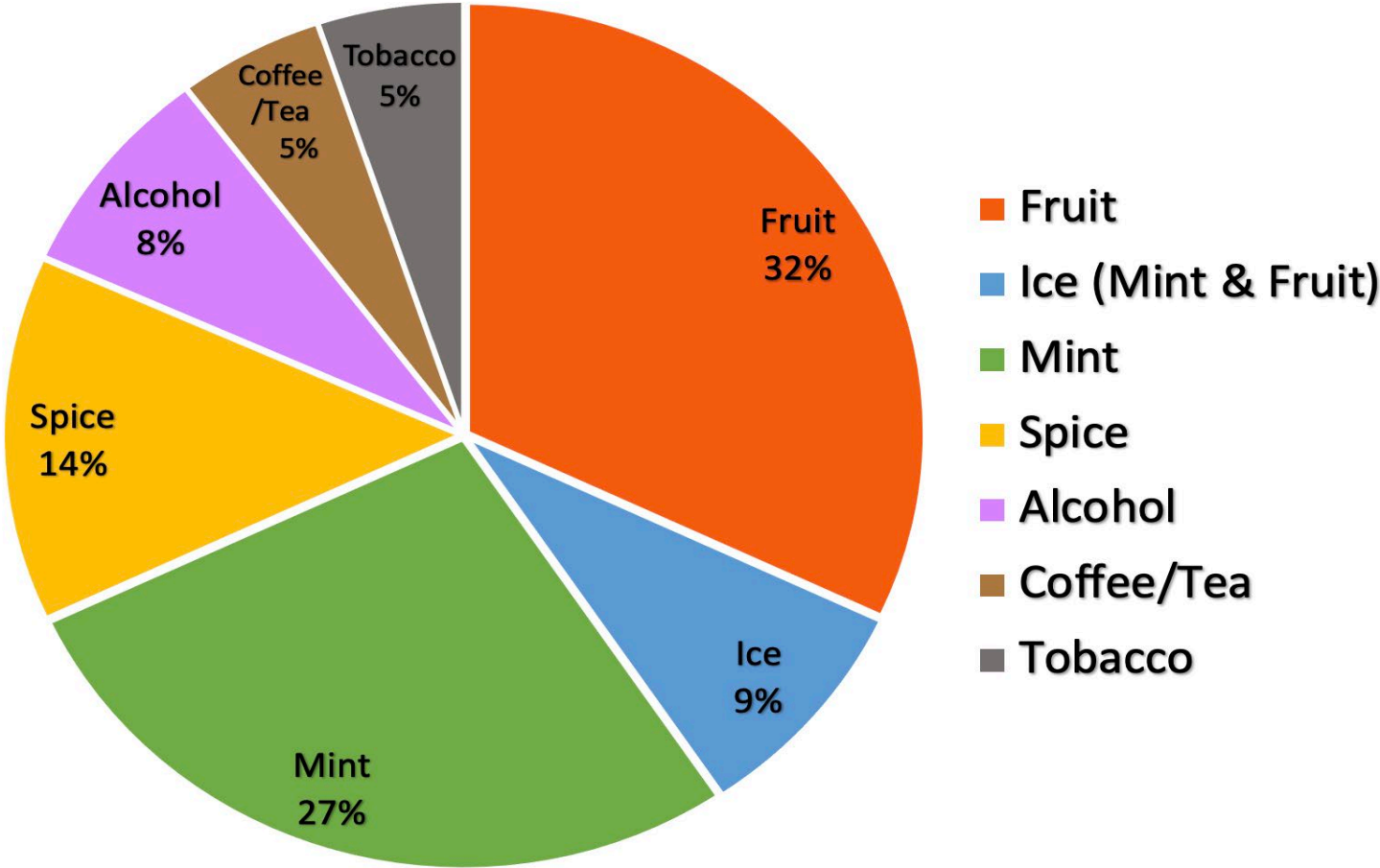
Nicotine Pouches – Nicotine Content



Source WHO

Nicotine Pouches - Flavours

Pouch Flavors by Category



Source: WHO

Candy – Children and Adolescents



Source: WHO



COP 10 decisions and reports



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COP10 decisions

1- No explicit decisions on new and emerging tobacco and nicotine products

2- Some documents and/or decisions refer or include them

FCTC/COP10(12) – **Forward-looking tobacco control measures:**

“RECALLING that Article 5 of the Convention calls on Parties to adopt and implement measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, **nicotine addiction** and exposure to tobacco smoke”

FCTC/COP10(14) – **Implementation of Article 18 of WHO FCTC**

“CONSIDERING the pollution of soil and water resources by waste from tobacco products and related electronic devices, including filters of cigarettes as well as **batteries, plastic cartridges and metals**”

“NOTING that that WHO has recommended an immediate ban on cigarette filters and **vaporizers** in its submission to the Intergovernmental Negotiating Committee on Plastic Pollution”

“URGE Parties to take into account the environmental impacts from cultivation, manufacture, consumption and waste disposal of tobacco products **and related electronic devices**, and to strengthen the implementation of Article 18 of the WHO FCTC, including through national policies related to tobacco and/or protection of the environment”

“URGE Parties to coordinate their efforts to address plastic waste of tobacco products **and related electronic devices** with the objectives of the WHO FCTC in relation to national policies and international treaties and fora dealing with plastics and hazardous waste, as appropriate”

“ENCOURAGE Parties to consider comprehensive regulatory options regarding filters in cigarettes and in other tobacco and related products, **and their related electronic devices**, taking into consideration their public health impacts and in accordance with national law”

COP10 decisions that refer to all new and emerging tobacco products

[FCTC/COP10\(23\)](#) – **Article 13 Specific guidelines**

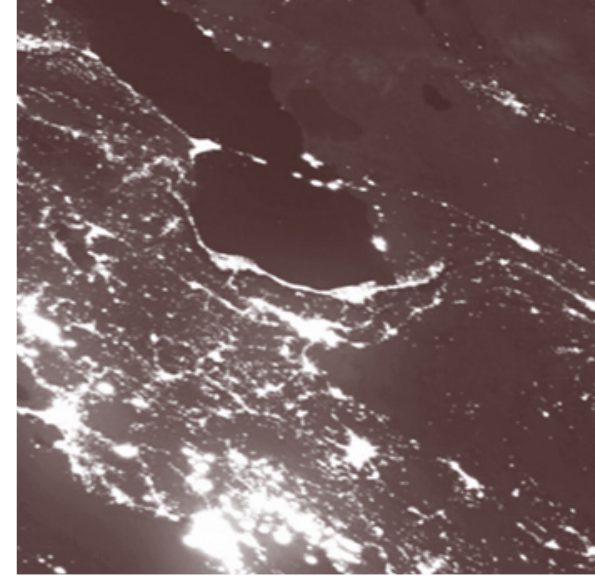
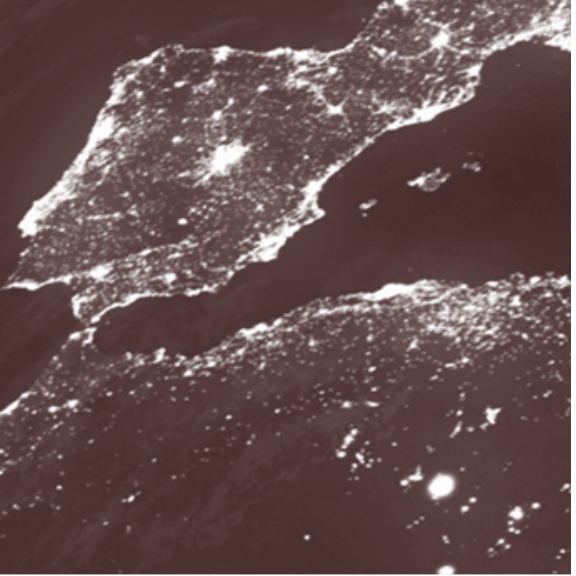
“REAFFIRMING ALSO decision FCTC/COP8(18) on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry in line with Article 5.3 of the WHO FCTC”

“REAFFIRMING ALSO decision FCTC/COP7(9) inviting Parties to consider applying regulatory measures such as those referred to in document FCTC/COP/7/11 to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS), as appropriate to their national laws and public health objectives”

“CALLS on Parties to monitor advances and changes in communications technology, entertainment media consumption and marketing strategies relating to all tobacco products (including novel and emerging tobacco products), to **ENDS/ENNDS and to nicotine products other than approved medicines**”

[FCTC/COP/10/7](#) Progress report on technical matters related to Articles 9 and 10 of the WHO FCTC Report by WHO

“74. Nicotine pouches: Based on the evidence described in the Ninth TobReg report (see item 9, Annex 2) and the background paper on nicotine pouches (paragraphs 53 – 59), as well the growing market of these products, Parties should consider the recommendations of TobReg in its Ninth report, as follows:



Regulatory developments on new and emerging tobacco and nicotine products globally



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Measures to regulate HTPs

- Under which category are HTPs regulated
- If the sale is allowed or banned
- Regulation on:
 - Advertising/Marketing
 - Packaging/Health warnings
 - Excise tax
 - Use in public places

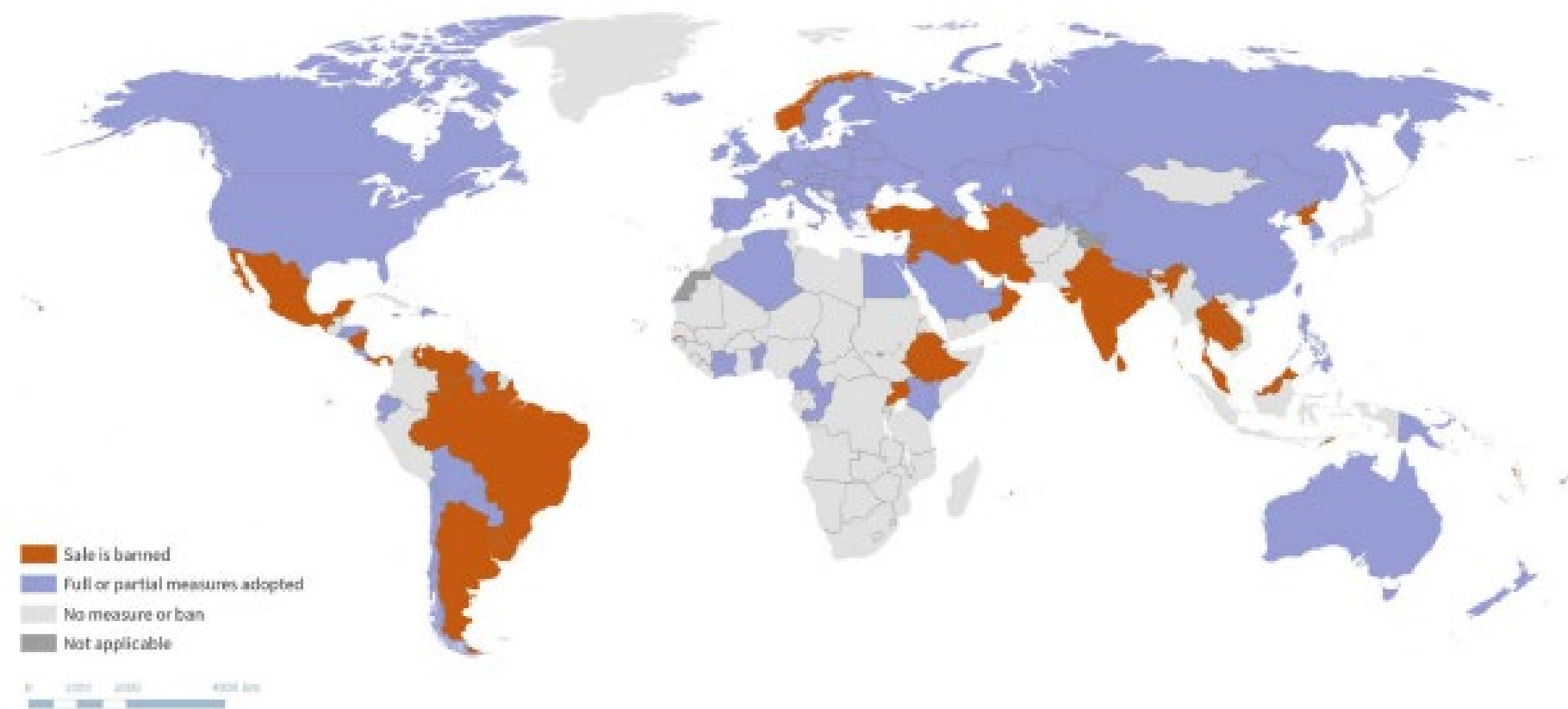
ANNEX 1

**EXAMPLES OF MEASURES RELATED TO HEATED TOBACCO PRODUCTS (HTPs) IN SELECTED PARTIES
(AS OF 31 DECEMBER 2022, TAX DATA AS OF 31 JULY 2022)¹**

Party/Classification of HTPs	WHO region	Advertisement/marketing	Packaging/health warning	Excise tax	Use in public places
Brazil HTPs are classified as ENDS.	AMR	Ban on sale, importation and advertising of any electronic smoking devices and any accessories or refills intended for use in any electronic smoking devices. HTPs are subject to same advertising restrictions as other tobacco products.	NA/sale is banned	NA/sale is banned	Existing smoke-free legislation applies to HTPs.
Cabo Verde HTPs are classified as novel tobacco products.	AFR	HTPs are legally sold. HTPs are subject to same advertising restrictions as other tobacco products.	HTPs (tobacco inserts) are subject to same warning requirement as smokeless tobacco products.	*	Existing smoke-free legislation applies to HTPs.
Cambodia HTPs are classified as ENDS.	WPR	Ban on sale, use and import of HTPs. HTPs (tobacco inserts) are subject to same advertising restrictions as other tobacco products.	NA/sale is banned	NA/sale is banned	Existing smoke-free legislation applies to HTPs.

1 The data presented in this Annex are based on a legal desk review and have not been reviewed and validated by Parties.

Measures to regulate ENDS



121 countries have some measures regarding ENDS:

- 34 ban the sale of ENDS
- 87 allow the sale, but have taken one or more measures, either fully or partially to regulate them:
 - bans on the use of ENDS in public indoor areas
 - bans on advertising, promotion and sponsorship
 - graphic health warnings required on packaging
 - age restrictions on the sale of ENDS
 - flavoring bans or restrictions.

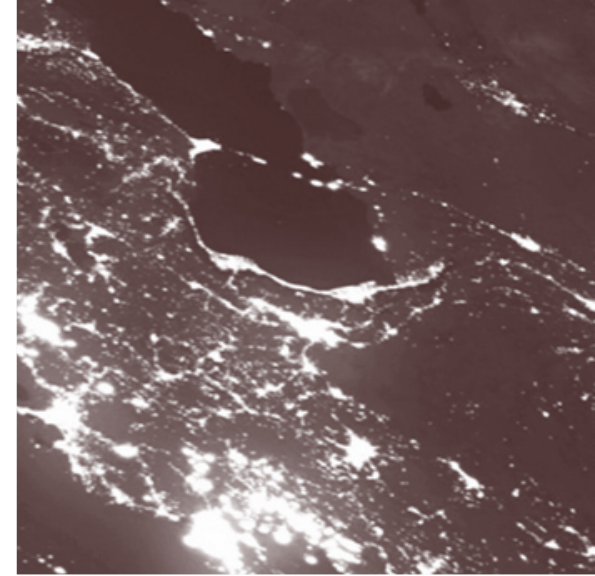
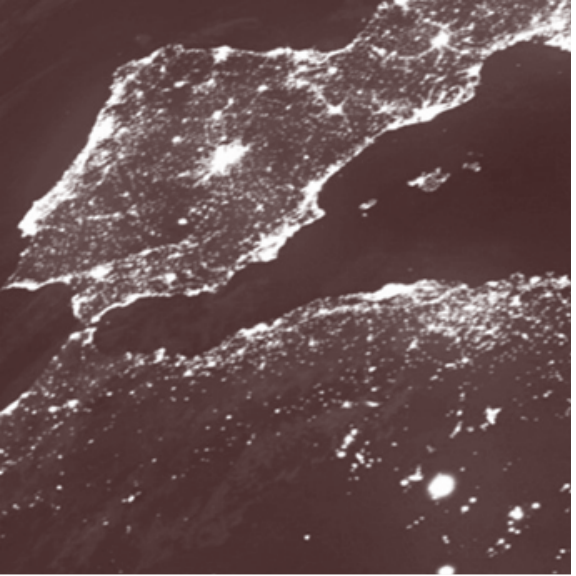
74 countries have no regulations in place addressing ENDS.

Measures to regulate Nicotine Pouches

- **22** countries regulate nicotine pouches
- **161** countries don't regulate them

Regulatory approach	Countries	Law or regulation	Description
Consumer product	Austria, Bulgaria, Croatia, Cyprus, Dominican Republic, Greece, Iceland, Luxembourg, Malta, Poland, Portugal	Consumer laws apply	In Austria, nicotine pouches are classified as both "consumer products" and "medicines". As long as no claims are made about smoking cessation aids, they are classified as "consumer products". In other situations, nicotine pouches are classified as "medicines".
Food	Germany, Netherlands (Kingdom of the)	Commodity law and Article 14 Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 (Netherlands, Kingdom of the)	In Germany, nicotine pouches are banned because they contain nicotine, an unauthorized novel food ingredient. In Netherlands (Kingdom of the), nicotine pouches containing ≥ 0.035 mg of nicotine per pouch may no longer be sold or traded, as they are classified as harmful foods.
Poison	Brunei Darussalam, Ireland	Poisons Act	In Brunei Darussalam, nicotine pouches are classified as both a "poison" and an "imitation tobacco product". They are listed as a "poison" under the Poisons Act; importation and sale of poisons require a license. (See note on "imitation tobacco product" below).
Medicine or pharmaceutical product	Austria, Canada, Chile, Finland, Hungary, Japan, Malaysia, South Africa	Canadian Food and Drugs Act and Finnish Medicinal Products Act (section 3)	In Austria, nicotine pouches are classified as "medicines" if smoking cessation claims are made. Otherwise, they are classified as a "consumer product". Pouches that deliver < 4 mg of nicotine per dose are exempt from prescription, are regulated as "natural health products" and are subject to the Natural Health Products Regulations in Canada and as a licensed self-medication product in Finland. Pouches that deliver > 4 mg per dose are considered a prescription drug and subject to the requirements of the Food and Drug Regulations (Canada) and the Medicinal Products Act (Finland). The pouch that delivers the drug is considered a Class I medical device. No nicotine pouch has yet been granted authorization for sale as a drug in Canada.
Nicotine pouch pouch Nicotine-containing product Tobacco-free products Tobacco alternatives Imitation tobacco	Belgium, Brunei Darussalam, Estonia, New Zealand, Republic of Moldova	Tobacco Order 2005 (Brunei Darussalam) Smoke free Environments and Regulated Products Amendment Act 2020 (New Zealand) Law No. 278-XVI on Tobacco and Tobacco Products, as amended in 2015 (Republic of Moldova)	In Belgium, nicotine pouches are classified as "similar to tobacco products". In Brunei Darussalam, nicotine pouches are classified as both a "poison" and as an "imitation tobacco product". Nicotine pouches may be considered an "imitation tobacco product" and are therefore prohibited. Nicotine pouches are not currently sold in the country. See note on "poisons". In Estonia, nicotine pouches are considered "snus imitation products" and taxed as "alternative tobacco products". See Table 2. In New Zealand, the Government prohibits the import for sale, packaging and distribution of oral nicotine products (unless approved as medicines). A significant change to the legislation by amending the definition of "tobacco product" was avoided; instead, oral nicotine pouches are directly prohibited, consistent with regulation of snus and chewing tobacco under New Zealand law. See Table 2 for more details on regulation in the Republic of Moldova.
Tobacco product	USA	Code of Federal Regulations – Title 21, Volume 8	See Table 2.

Source: WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: ninth report of a WHO study group (WHO Technical Report Series, No. 1047)
<https://iris.who.int/bitstream/handle/10665/372463/9789240079410-eng.pdf?sequence=1>



WHO: call to action



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Call to action : WHO

Where countries permit commercialization of e-cigarettes as consumer products, strong regulation is necessary.

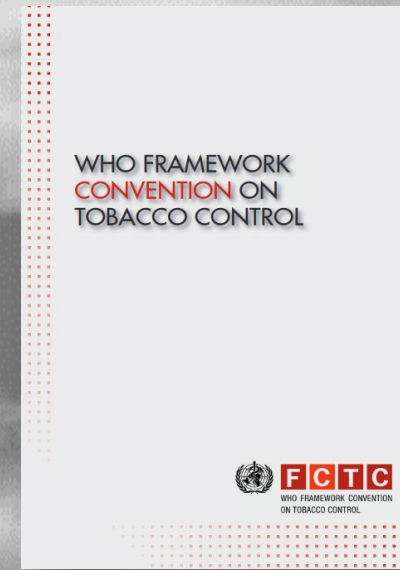
Protecting the public from misleading or deceptive claims, such as false claims on safety or efficacy for quitting cigarette smoking.

Prohibiting sale of e-cigarettes to children, controlling the supply chain to reduce the risk of children gaining access and enforcing these restrictions against responsible entities.

Applying tobacco control measures to e-cigarettes, including the supply and demand reduction measures of the WHO FCTC.

Countries should implement a comprehensive approach to tobacco control / WHO FCTC, which includes;

- raising tobacco excise taxes- Art 6
- bans on tobacco advertising, promotion and sponsorship- Art 13
- health warnings- Art 11
- smoke-free areas- Art 8
- mass-media campaigns- Art 12 & Art 13



WHO DG WHO 154: Statement



“History [is] repeating itself, but with a different form. The **same nicotine**, but with a **different packaging**. And the sad part is the industry is saying it's harm reduction. And what has got **harm reduction to do with children?**”

To call it harm reduction and, **deliberately, recruit children and use schools as battleground, is dishonest”**.

WHO Director-General Dr Tedros Adhanom Ghebreyesus

WHO Executive Board 154, January 2024



**Thank
you!**



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