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Global landscape of nicotine and tobacco products additives policies

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ABSTRACT

Introduction Product design is a key tobacco industry strategy to recruit consumers and hinder cessation. An important technology in tobacco product design is the use of additives including those that create characterising flavours, that is, flavours that are perceived by taste and or smell by the user. To curb youth use, many countries are implementing policies to limit the use of flavours and other additives in tobacco products. This paper reviews the global landscape of tobacco additives policies including those focusing only on flavouring additives, updating a previous review.

Methods We gathered additives policy data from available online sources of tobacco control policies including parties' reports to the WHO Framework Convention on Tobacco Control (where WHO refers to World Health Organization), the website Tobacco Control Laws, government websites, searches with the Google search engine and consultations with the WHO to ensure comprehensiveness of the assessment. The policies were classified according to their objective and characteristics: Labelling regulations, sales bans and tobacco product design regulations. We classified and organised the regulations according to their stated intent.

Results We found that 62 countries had tobacco products' additives-related regulations at the regional, national or subnational levels. Most of these regulations focused on flavouring additives especially bans on the selling, importing and manufacturing tobacco products with characterising flavours.

Conclusions The data demonstrate various global policies addressing additives and/or flavours and a range of definitions of additives and flavours. Establishing common definitions and standards could facilitate cooperation between countries and regions.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Product design is a key tobacco industry strategy to recruit consumers and hinder cessation.
⇒ Flavoured tobacco products are particularly appealing to youth and lead to experimentation and initiation.
⇒ Emerging data demonstrate that bans or restrictions on flavoured tobacco products including menthol, decrease youth initiation and support cessation.

WHAT THIS STUDY ADDS

⇒ Updates the global mapping of regulatory policies of additives in nicotine/tobacco products.
⇒ Proposes a structure to classify and organise various policies addressing additives in tobacco products.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Provides a roadmap to countries interested in regulating additives in tobacco/nicotine products.
⇒ Discuss the challenges to implementing additive regulations in nicotine/tobacco products.

INTRODUCTION

Tobacco use is the leading cause of preventable death and disease in the world,[1] responsible for 8 million deaths every year.[2] Efforts to address this global epidemic must include strategies to prevent young people from starting to use tobacco and becoming addicted to nicotine. Estimates indicate that, globally, 82 000 to 99 000 children start smoking cigarettes every day.[3–7] The tobacco industry denies marketing its product to young people,[8] however, the importance of young people as a market for the tobacco industry is well known.[9 10]

Product design is a key tobacco industry strategy to recruit consumers and hinder cessation. Today's cigarettes are the result of innumerable technological developments where all aspects of their composition are engineered to optimise the delivery of nicotine to the user, to facilitate the initiation by new users, to mask secondhand tobacco smoke and to reduce production costs.[11–15] In tobacco product design, an important technology is the use of flavourings[15–18] including those that create characterising flavours, that is, flavours that are perceived by taste and or smell by the user (eg, menthol or fruit-flavoured cigarettes, candy flavoured vapes). Flavourings are defined by Codex Alimentarius as 'products that are added to food (or tobacco in this case) to impart, modify or enhance the flavour'[19] and characterising flavour is a 'clearly noticeable smell or taste other than one of tobacco' resulting from a flavouring additive or combination of them.[20]

Recognising that flavour is a barrier to tobacco control, the parties to the WHO Framework Convention on Tobacco Control (FCTC) recommended, in the partial guidelines for implementation of Articles 9 and 10,[21] the ban of ingredients used to increase palatability, that have colouring properties, ingredients used to create the impression that products have health benefits and ingredients associated with energy and vitality.

Data show that flavoured tobacco products are particularly appealing to youth and lead to experimentation and initiation.[1 10 22–24] To curb youth use,

countries are implementing policies to limit the use of flavours and other additives in tobacco products. Emerging data demonstrate that bans or restrictions on flavoured tobacco products including menthol, decrease youth initiation and support cessation.[25–31] These policies have maximum public health benefits when they are comprehensive, that is, include all tobacco products and all flavours.[25 28 29 32–38]

This paper reviews the landscape of nicotine and tobacco products' additives policies globally including those that focus only on flavouring additives, updating a previous review.[39] Identifying and classifying policies on additives in nicotine and tobacco products is important to provide legal and technical subsidies for countries that want to update or implement these policies. Additionally, knowledge of the global landscape could support the implementation of Articles 9 and 10 of the FCTC and seek standardisation of definitions.

METHODS

From August 2021 to July 2024, we gathered nicotine and tobacco products additives policy data (whether or not it had entered into force) from available online sources of tobacco control policies including parties' reports to the FCTC,[40] the database Tobacco Control Laws (https://www.tobaccocontrollaws.org/), government websites, searches with Google search engine and consultations with the WHO and its internal reports to ensure comprehensiveness of the assessment. The searches were carried out using the list of WHO member states (https://www.who.int/countries). Documents in languages different from English, Spanish and Portuguese were translated using Google translator. Countries with internet restrictions were accessed using a Virtual Private Network (VPN).

Each policy related to additives was downloaded and information was extracted into a spreadsheet. The policies were classified into three categories based on the nature and scope of each policy as well as their stated intent and characteristics: Packaging and labelling regulations, sales bans, tobacco product design regulations.

RESULTS

We found that 62 countries had nicotine and tobacco product additives-related regulations at the regional, national or subnational levels (online supplemental file 1). The majority of these regulations focused on flavouring additives, especially bans on sales, import and manufacture of tobacco products with characterising flavours (table 1).

Europe was the WHO region with the most countries (n=37/44) regulating additives and/or flavours. This is, at least partly, influenced by the European Union Tobacco Products Directive (2014/40/EU)[41] applicable to its 27 member states which prohibits flavoured cigarettes and other flavoured tobacco products including heated tobacco products (table 2).

While some policies describe additives that are banned by name as in the case of the Gulf Cooperation Council (GCC) countries, others address these additives broadly, for example, Mauritania and Cape Verde focus on banning additives that improve palatability or taste and additives that change tobacco products' aroma. Sugar, as an additive, is explicitly banned in four countries (although some allow for replacing sugar lost during the curing process only) and ammonia, as an additive, is banned in five countries.

Types of policies

We divided the existing regulation into three categories:

1. Packaging and labelling regulations: Prohibit the mention or reference, through text or images, of flavours or foods on packaging without necessarily prohibiting the use of the additive in the nicotine and tobacco product. These policies regulate manufacturers (which need to change packaging) and importers (where there is no manufacturing, to ensure that only compliant products are imported). Kiribati is an example of a country that adopted this type of policy.
2. Sales bans: Prohibit retail outlets from selling products that use additives mostly focused on characterising flavours. This regulation is directed at distributors and points of sale and not manufacturers as it does not ban these additives from being added to nicotine and tobacco products. This type of regulation can be observed, for example, in several cities and two states (Massachusetts and California) in the USA and in the Canadian provinces of Alberta and Nova Scotia.
3. Nicotine and tobacco product design regulations: Restrict or prohibit the addition of certain additives during nicotine or tobacco products' manufacturing process. These policies are directed at manufacturers to change manufacturing practices and importers (to ensure that only compliant products are imported). Brazil, Canada, the USA and the European Union (EU) are examples of countries/regions using this type of policy.

We further organised policies focusing on product design by the key areas of focus or rationale for the policy as stated in its text: Functional, sensorial and health concerns. This division was created to facilitate analysis but in some cases a country's policy fits more than one category (tables 1 and 2).

1. Function-focused policies address the use of additives based on their function regardless of the quantities used. Examples include Canada and Brazil which prohibit additives classified in the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives and the Flavour and Extract Manufacturers Association[42 43] as flavouring regardless of amount levels used, that is, it bans additives in concentration levels that might be below consumers' perception.
2. Sensory-focused policies address additives used to produce clearly noticeable (before or during consumption) smell or taste different from tobacco, for example, fruit, menthol or vanilla flavour. For example, the European Union Tobacco Products Directive[41] prohibits the use of menthol in amounts that make the product menthol-flavoured. However, use of menthol in concentrations below perceptible levels (ie, not sold as a 'menthol product') is authorised.
3. Health concerns-focused policies include restrictions on the use of additives that are known to be harmful to health without combustion especially those with carcinogenic, mutagenic and reprotoxic properties. Policies concerning additives that increase nicotine uptake are included in this group. For example, EU member states, member states of the GCC and Uruguay adopted this type of regulation.

Types of product included in the policy

There was variation in the types of nicotine and tobacco products included in the additive-related policies depending on each country's definition of tobacco product. Electronic nicotine and non-nicotine delivery devices are included in some but not all policies and sometimes they are explicitly exempted. Similarly, exclusions or explicit inclusions are seen for cigars, cigarillos, loose tobacco for roll-your-own cigarettes and smokeless

Table 1 Summary of additive regulation by type of policy and country and inclusion of exclusion of menthol, 1 July 2024

	Type of regulation					
Country	**Packaging and labelling**	**Sales ban**	**Product design**		**Health concerns**	**Exempt menthol**
			Sensorial	Functional		
Albania	–	–	X		–	–
Antigua and Barbuda	–	–	–	X	–	–
Australia	–	X	X	–	–	–
Bermuda	–	–	X	–	–	X
Brazil	–	–	–	X	–	–
Cape Verde	–	–	–	X	–	–
Canada	–	X	–	X	–	–
China	–	–	X	–	–	X
Congo	–	–	X	–	–	–
Cooperation Council for the Arab States of the Gulf (GCC)—six countries	–	–	X (Saudi Arabia)	–	X (CMR)	X
Ethiopia	–	–	X	–	–	–
European Union (EU)—27 countries	–	–	X	X (Netherlands and Belgium)	X (CMR/nicotine uptake)	–
Iran	–	–	X (no longer in force)	–	–	X
Kiribati	X	–	–	–	–	X
Mauritania	–	–	–	X	–	
Mauritius	–	–	X	–	–	–
Moldova	–	–	X	–	X (CMR/nicotine uptake)	–
Montenegro	–	–	X	–	X (CMR/nicotine uptake)	–
Niger	–	–	X	–	–	X
Nigeria	–	–	X	–	–	–
Norway	–	–	X (not in force)	–	–	X
Philippines	X	–	X	–	–	X
Senegal	–	–	X	–	–	–
Sierra Leone	–	–	X	–	X (nicotine uptake)	–
Sri Lanka	–	–	X	–	–	–
Turkey	–	–	X	–	X (CMR/nicotine uptake)	–
Ukraine	–	–	X	–	X (CMR/nicotine uptake)	–
Uganda	–	–	X	–	–	–
UK	–	–	X	–	X (CMR/nicotine uptake)	–
USA	–	X	X	–	–	X (only in certain jurisdictions)
Uruguay	–	–	–	X (only ammonia is banned)	X (nicotine uptake)	–

CMR—carcinogenic, mutagenic and reprotoxic properties.

tobacco products. Some policies include waterpipe tobacco, others exclude these products (online supplemental file 1).

Menthol, one of the most commonly used tobacco product additive,[44] was not always included in policies and in some cases is explicitly excluded (table 1). More than one country that initially exempted menthol later passed a policy to ban its use, often recognising that a menthol exemption limited the public health benefits of the policy.[32 45] Flavouring capsules that are inserted in the cigarette filters are sometimes, but not always, included in these policies as are the other flavour-related accessories.

DISCUSSION

There is limited but growing evidence that additives-related policies, mostly focused on characterising flavour bans, are effective in preventing youth uptake and supporting cessation,[28 29 38 46–50] although there is a paucity of research evaluating the impact of these policies in low-income and middle-income countries. Analysis of these policies and the potential challenges with enforcement they pose indicate that a comprehensive ban of all flavouring and other additives in any concentration covering all nicotine and tobacco products would produce better public health outcomes as the use of these additives even in non-perceptible concentrations

Table 2 Number of countries with policies regulating additives and/or flavours by WHO region as of 1 July 2024

WHO region	Number of countries with regulations	Total countries in region (% with policy)
African region (AFR)	10	47 (21.3)
Eastern Mediterranean region (EMR)	6	21 (28.6)
European region (EUR)	34	53 (64.6)
Region of the Americas (AMR)	6	35 (17.1)
South-East Asia region (SEAR)	1	11 (9.1)
Western Pacific region (WPR)	4	27 (14.8)

Countries with regulation at any level (national, subnational or local) are included.
AFR—Cape Verde, Congo, Ethiopia, Mauritania, Mauritius, Niger, Nigeria, Senegal, Sierra Leone, Uganda.
EMR—members of the GCC.
EUR—members of the EU (27), plus Albania, Moldova, Montenegro, Norway, Turkey, Ukraine, UK.
AMR—Antigua and Barbuda, Bermuda, Brazil, Canada, USA, Uruguay.
SEAR—Sri Lanka.
WPR—Australia, China, Philippines, Kiribati.

can increase product's attractiveness.[51] Considering the different political realities, the tobacco industry's opposition to these policies, countries' technical-scientific capacity and legal frameworks, a comprehensive ban focusing on product design might facilitate reducing the attractiveness of these products thus reducing initiation and nicotine dependence. We propose that each policy approach has advantages and disadvantages (table 3). For example, while a ban on characterising flavours appears to be a predominant choice, its disadvantage is the difficulty in defining characterising flavours such as what concentration of menthol is necessary to consider a cigarette a menthol cigarette? The perception of flavours varies between individuals and populations thus a tobacco product with a characterising flavour in one region could be considered non-flavoured in another. Further, this approach often excludes the use of additives at levels below consumers' perception. For example, low levels of menthol reduce irritation and alter the taste of tobacco[51] but may not be described as a characterising flavour. Therefore, policies that focus on characterising flavours should be carefully monitored as manufacturers use a range of additives which can change products' palatability and acceptability, impacting the public health results from these policies.

Exemptions on the types of products covered under these policies pose another challenge particularly for young people attracted to flavoured tobacco products who might initiate consumption through one of the flavoured products exempted from the policy. Countries' experiences show menthol exemptions or the exclusion of non-cigarette products, for example, may limit the full public health potential in terms of initiation and cessation with some flavoured tobacco users migrating to menthol and some youth migrating to non-cigarette flavoured products.[10 44 48 50 52 53]

There is a growing and largely unregulated market that provides alternative means of delivering flavours to the tobacco product for use by consumers. These include flavour capsules, beads, flavoured tips, flavoured sprays, flavoured paper and other products, collectively known as additives or flavour accessories. Accessories, often not included in flavour-related policies, could create additional challenges and potential loopholes in implementation and enforcement and negatively impact public health outcomes.[54 55]

Nicotine and tobacco products' additive policies can be challenging to implement. These difficulties are exacerbated in

Table 3 Advantages and disadvantages of different tobacco products additive policies regarding the attractiveness

Policy type*		Pros	Cons	Comments
Sales ban		► Adaptable for local circumstances. ► Easily understood by the public. ► Easy to implement. ► Low implementation cost.	► Limited scope because usually applied to products with characterising flavours and explicit flavour mention in the product.	► Exceptions (products and additives) create loopholes where flavoured products remain available. ► Evidence of effectiveness at local level.[29]
Labelling		► Easy to implement. ► Low implementation cost.	► Does not interfere with product flavour. ► Allows additive/flavour use.	► Can strengthen other regulatory additive/flavour policies (if combined). ► No evidence of effectiveness available.
Tobacco product design	Functional	► Comprehensive scope if all products are included. ► Prevents use of additives that make tobacco products more palatable or acceptable regardless of the perception by user.	► Demands highly qualified human resources for enforcement. ► Time before implementation might be longer. ► Additives that change flavour can be described as having a different function to avoid compliance.	► Can be applied to prevent use of additives that make tobacco products more palatable and flavoured products. ► Enforcement might be facilitated if policy is inclusive of all additives and all products. ► Evidence of effectiveness (Canada).[28 38 48]
	Sensorial	► Easy to implement if evidence of characterising flavour is readily available. ► Low implementation cost. ► Easily understandable to the population.	► Allows the use of additives at levels that are not perceived by the consumer or branding. ► Enforcement requires highly qualified workforce and laboratory facilities.	► The most common regulatory approach. ► Enforcement needs might be facilitated by the establishment of an independent advisory panel to inform on the presence of characterising flavours. ► Evidence of effectiveness (EU and USA).[36 48–50]

* Health concerns focused regulations are not included in this table.
EU, European Union.

low-income and middle-income countries. The tobacco industry is known to oppose these additive policies[35 56–62] including the threat of litigation.[56] In some cases, these policies may be reversed by government decision. For example, the Islamic Republic of Iran reversed a policy pertaining to additives in nicotine and tobacco products.[63] Therefore, countries considering these policies should be informed by experience from countries that have adopted such restrictions. Partnerships with civil society[56 64] could support countries' in defending their additives-related policies. Countries have a range of resources to support the formulation, implementation, enforcement and defence of additives-related policies including those provided by the WHO and the Conference of the Parties to the FCTC especially the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC: Regulation of the contents of tobacco products and regulation of tobacco product disclosures.[21]

Limitations

Despite best efforts, it is possible that some countries' policies were missed or misinterpreted due to our inability to conduct searches in several languages. Additionally, this is a rapidly changing policy environment and policies that have been approved after July 2024 are not included.

There is a range of definitions of additives and flavours within and between regions creating difficulties for cross-country and cross-regional evaluation and comparisons especially when evaluating the impact of these policies. In addition, policies may differ by policy type (ie, sales restrictions vs bans); product categories (ie, cigarettes only vs all tobacco products), flavours (ie, menthol only vs flavours excluding menthol vs flavours including menthol) and point of purchase (eg, sales to minors only vs all age groups, online vs in person) as well as by level of compliance and enforcement adding challenges for comparing policies. We did not assess implementation, enforcement and compliance with existing policies and lack or weak enforcement could undermine the expected positive public health impact of these policies.

CONCLUSIONS

The data demonstrate that there is a wide range of nicotine and tobacco policies addressing additives and/or flavours globally. There are discrepancies in the rate at which these policies are being evaluated with low-income and middle-income countries in need of additional support to assess policy impact post-adoption. As countries consider these policies, they may also need legal support to defend against tobacco and related industry-initiated litigation.

Emerging research mostly from the EU and high-income countries, however, demonstrates that comprehensive bans which include all types of nicotine and tobacco products and a wider range of additives, specifically flavours, lead to a decrease in consumption through lower youth initiation and quitting among existing tobacco users. Thus, efforts should be made to close regulatory gaps and support a full ban on flavours and/or additives in nicotine and tobacco products. The establishment of common definitions and standards could facilitate cooperation between countries and regions.

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