This page looks at common arguments in challenges to tobacco product ingredients regulation in domestic courts. Regulation of tobacco product ingredients has also been the subject of a WTO dispute and WTO committee discussions, generally concerning discrimination and trade-
Introduction
Under Article 9 of the WHO FCTC, parties commit to adopting and implementing effective legislative, executive and administrative or other measures for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions.

These include measures to regulate tobacco product ingredients in order to reduce their attractiveness, addictiveness, and toxicity. The Articles 9 and 10 Partial Guidelines provide that in regulating tobacco product ingredients, parties ‘should aim to implement the most effective measures that they can achieve’, in light of their national circumstances and priorities, scientific and other evidence, and the experiences of other countries (3.1.2). Such measures may include:

- Prohibiting or restricting ingredients which may be used to increase palatability in tobacco products, including added sugars and sweeteners, flavourings, herbs and spices.
- Prohibiting or restricting ingredients in tobacco products that have colouring properties
- Prohibiting or restricting ingredients used to create the impression that products have health benefits (such as vitamins, essential oils, and amino acids)
- Prohibiting or restricting ingredients associated with energy and vitality (such as stimulants)

Common grounds of challenge and responses
Measures regulating ingredients have been challenged in domestic and regional courts both on the basis of the relevant regulatory agency’s power to adopt the measure and on the grounds of proportionality to their public health objectives.

Parties have successfully argued that the measure is proportionate to its objectives in light of recommendations under articles 9 and 10 of the WHO FCTC and its guidelines. The WHO FCTC and its guidelines, as well as public health imperatives more generally, have also helped strengthen the legal basis for the regulator’s power to regulate tobacco product ingredients.

Illustrative case examples
The cases below provide examples of how tobacco product ingredients regulation has been challenged since the WHO FCTC came into force; how parties have framed their defences to such challenges; and how courts have considered the issues at stake. The list is not exhaustive but rather shows examples of how issues have been framed in different legal challenges.

*Ação Direta de Inconstitucionalidade 4.874 / DF, Supreme Federal Court of Brazil*
February 2018 (Brazil, 2018)

The National Confederation of Industry challenged Brazil's ban on tobacco product additives, arguing that ANVISA, the health regulatory agency, did not have the authority to regulate tobacco products and that the ban constrained freedom of enterprise. The Supreme Federal Court of Brazil found that ANVISA did have authority to regulate tobacco products, and it also found that freedom of enterprise did not prevent conditions and limitations on private activities, in light of the public interest in protecting and promoting health, and the right of consumers to information.


The Court of Justice of the European Union upheld the validity of the prohibition on all characterising flavours including menthol in the Tobacco Products Directive (Directive 2014/40).

The Court found that the Directive was validly adopted. It had a valid legal basis because it aimed to improve the functioning of the internal market by partially harmonising product requirements so as to ensure consistent rules across the internal market and remove an obstacle to trade, while still ensuring a high level of health protection. (The relevant EU bodies have the power to adopt rules to ensure the functioning of the internal market, but not for health protection as an independent basis).

The flavouring ban was proportionate to this aim of ensuring a functioning internal market while ensuring a high level of health protection. The Court noted that the characterizing flavour ban took into account recommendations in the Guidelines to Articles 9 and 10 of the WHO FCTC, which are intended to assist the parties in the implementation of binding obligations under the Convention and are based on the best available scientific evidence and should therefore be considered ‘of particularly high evidential value’. The Partial Guidelines recommended the prohibition of characterising flavours without drawing distinctions between them, and specifically mentioned menthol as a flavour which contributes to increased palatability and attractiveness of tobacco products. It was therefore within the broad discretion conferred on the relevant EU bodies to prohibit all characterising flavours including menthol. Less restrictive measures suggested by Poland, such as age limits or health warnings specific to flavoured tobacco products, were not equally suitable for achieving the aim of ensuring a high level of health protection for all consumers by reducing the attractiveness of tobacco products, because restricting access or providing further information did not function in the same way as making the products themselves less attractive.

The characterising flavour ban was also consistent with the principle of subsidiarity (which requires the EU to act only when the objective of an action cannot be achieved by national legislatures alone). The risk of divergent regulations on characterising flavours and the need to ensure consistent regulation of tobacco products within the internal market meant that the aims were better achieved at the EU than the member state level.

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Partial guidelines for implementation of articles 9 and 10 (tobacco product contents and disclosures) http://www.who.int/fctc/guidelines/adopted/article_9and10/en/

https://untobaccocontrol.org/kh/legal-challenges/domestic-courts