Some tobacco control measures may constitute technical regulations, in which case obligations under the TBT Agreement will also be relevant.

Under the TBT, members commit that technical regulations be ‘no more trade restrictive than necessary to fulfil a legitimate objective’.

Health is explicitly recognised as a legitimate objective in the TBT agreement.

A measure must contribute to health and restrict trade no more than necessary to achieve the
States have significant space under this provision to implement WHO FCTC obligations.

40 default wide line Introduction

WTO members commit to ensure that technical regulations are ‘no more trade-restrictive than necessary to achieve a legitimate objective [such as] the protection of human health or safety ... taking account of the risks non-fulfilment would create’ under Article 2.2 of the Agreement on Technical Barriers to Trade (TBT).

The requirement that a technical regulation be no more trade-restrictive than necessary for the fulfilment of a legitimate objective has three components:

- whether a measure is a technical regulation, and therefore subject to obligations under the TBT
- whether the measure pursues a legitimate objective
- whether the measure is more trade-restrictive than necessary to achieve that objective, taking into account the importance of the objective and the level of protection sought by the member

The concept of trade-restrictiveness in a tobacco control context was extensively discussed in the Australia – Plain Packaging and US – Clove Cigarettes disputes. The WTO panels’ and Appellate Body findings in those cases suggest that WTO members have significant space under TBT article 2.2 to implement bona-fide tobacco control measures implementing the WHO FCTC. See our page on examples of WTO disputes relating to tobacco control for a summary of these cases.

Note that technical regulations are also subject to other obligations under the TBT, including non-discrimination, discussed on our discrimination page, and notification requirements to the TBT Committee, discussed on our dispute settlement and committees page.

20 default 2. What is a technical regulation? line Item 1

Obligations under the TBT apply to ‘technical regulations’ (as well as standards and conformity assessment procedures). A technical regulation, as defined in Annex 1 of the TBT Agreement and interpreted by the Appellate Body,[tooltip hint= "Appellate Body Report, EC – Asbestos, paras. 59-77; Appellate Body Report, EC – Sardines, paras. 171-195. See also US — Clove Cigarettes, para 7.24."][*][/tooltip] is a document that:

- although the product does not need to be explicitly identified in the document
- Lays down one or more characteristics of the product, including ‘terminology, symbols, packaging, marking or labelling requirements’. This can be expressed in either a positive form (e.g. a product must...) or a negative form (e.g. a product must not...).
- Requires mandatory compliance with the product characteristics i.e. must regulate the
product characteristics in a binding or compulsory fashion.

The Panel and Appellate Body in US – Clove Cigarettes examined whether a US law (section 907(a)(1)(A) of the Family Smoking Prevention and Tobacco Control Act) was a technical regulation. The law prohibited the production or sale of cigarettes containing characterising flavours, including cigarettes containing clove (which were largely produced in Indonesia), but continued to permit production and sale of cigarettes containing menthol (which were largely produced in the US).

The Panel and Appellate Body both found that section 907(a)(1)(A) was a technical regulation, because:

- It explicitly identified the products it applied to: cigarettes and their component parts
- It laid down characteristics relating to a product's composition: it stated that no cigarette could contain an artificial or natural “characterizing flavour” (other than tobacco or menthol). The fact that it laid down product characteristics in a negative form (“a cigarette ... shall not contain”) did not alter the conclusion that it laid down product characteristics.
- the mandatory nature of Section 907(a)(1)(A) was apparent from the language of that provision, which provided that a cigarette “shall not” contain any artificial or natural characterizing flavour (other than tobacco or menthol). In addition, the effect of the law was “to prohibit the manufacture and sale” of cigarettes with certain characterizing flavours.

It is likely that many measures implementing articles 9 (tobacco product contents), article 10 (tobacco product disclosures) and article 11 (packaging and labelling) of the WHO FCTC will constitute technical regulations, as well as measures implementing article 13 (tobacco advertising, promotion and sponsorship) to the extent that they regulate advertising, promotion and sponsorship on packaging or on products.

20 default 3. What is a legitimate objective? line Item 2
If a measure implementing the WHO FCTC is a technical regulation, under TBT article 2.2, it must be no more trade-restrictive than necessary for the fulfilment of a legitimate objective. A WTO panel will determine what the objective of a measure is by independently and objectively assessing the measure. It is not bound by a Member’s characterization of the objective it pursues through the measure. Previous panels have determined the objective by examining the text of the legislation or regulations and associated preparatory materials or guidance documents for bodies applying the legislation.[tooltip hint="For example, in the Clove Cigarettes case, the panel considered a report of the House of Representatives and guidance to the Food and Drug administration - see panel decision at 7.336-7.338"][^][/tooltip]

WHO FCTC parties can be fairly confident that bona fide measures implementing the WHO FCTC will
be considered to be for a legitimate objective. Article 2.2 of the TBT explicitly lists the protection of human health as a legitimate objective, and WTO panels have recognised that tobacco control measures protect health. The preamble to the TBT recognises that ‘no country should be prevented from taking measures necessary ...for the protection of human, animal or plant life or health ... at the levels it considers appropriate’, subject to the requirement they are not applied in a manner that is arbitrarily or unjustifiably discriminatory or constitutes a disguised restriction on international trade.

The panel in Australia – Plain Packaging considered that the objective of plain packaging was to reduce ‘the use of, and exposure to, tobacco’, based on the objectives outlined in the legislation itself (para 7.226-7.232). It was not disputed in the case that this was a public health objective.

The Panel in the US – Clove Cigarettes case identified the objective of a ban on flavoured cigarettes as preventing youth smoking, based on a report presented to the legislature in relation to the passing of the legislation. The panel stated it was “self-evident” that measures to reduce youth smoking were aimed at the protection of human health.[*]

20 default 4. Is the measure more trade-restrictive than necessary? A measure must not be more trade-restrictive than necessary to fulfil the legitimate objective in question. A panel will decide this through a weighing and balancing process. This test is similar to that under the health exception in the GATT,[*] and takes into account:

- the importance of the objective pursued by a government
- the level of protection sought by a government
- the degree of contribution a measure makes to its objective
- the degree of trade-restrictiveness of a measure
- the risks non-fulfilment of the objective would create
- whether there are reasonably available alternative measures that provide an equal contribution to the objective at the member’s desired level of protection

**The importance of the objective and the level of protection sought by the member**

The weighing and balancing test takes into account the importance of the objective and the level of
protection sought by the member. The WTO Appellate Body has recognised the importance of public health on multiple occasions, and has affirmed that each member has the right to set its desired level of protection against health risks.[19x773][tooltip hint="See, e.g., TBT preamble, EC Asbestos, Appellate Body, para 172; Brazil Tyres, Appellate Body, para 144, 156, 179"]*[19x757][/tooltip]. The assessment of whether a measure is more trade-restrictive than necessary is done in light of the member's chosen level of protection.[19x709][tooltip hint="See Brazil Tyres, Appellate Body, para 156"]*[19x693][/tooltip]

**Degree of contribution to the objective**

A measure must make a material contribution to fulfilling its objective. The Panel will discern to what extent a measure is necessary and capable of achieving its objective by looking at its design, structure, and operation, as well as evidence relating to its application.[19x633][tooltip hint="US – Tuna II, Appellate Body Report, paragraphs 315-317"]*[19x617][/tooltip] The Appellate Body has confirmed a measure can meet this requirement where it ‘partially achieves’ its objective: a measure need not completely attain its objective in order to be considered necessary to achieve it.[19x585][tooltip hint="US – COOL, Appellate Body Report, n 647"]*[19x569][/tooltip] The assessment of a measure’s contribution is similar to that under the GATT – it can be assessed in qualitative terms, and panels will recognise that effects of measures may only be evident in the future, or may not be able to be disentangled from the effects of other measures.[19x537][tooltip hint="US – COOL, Appellate Body Report, n 647"]*[19x521][/tooltip]

In *Australia – Plain Packaging*, the panel, after extensively reviewing the evidence relating to plain packaging, considered that plain packaging was ‘apt to, and does, contribute’ to the achievement of its public health objectives, because it would reduce the appeal of tobacco packs, increase the effectiveness of graphic health warnings, and reduce the ability of the pack to mislead, and thus contribute to reduced tobacco use and exposure. The panel considered both pre- and post-implementation evidence on plain packaging’s impact, and took into account the fact that plain packaging was implemented in a comprehensive suite of measures intended to act over the long-term. It also used the WHO FCTC article 11 and 13 guidelines to confirm some of its factual findings, such as the use of branding on tobacco packs as a form of tobacco product promotion. These findings were extensively challenged on appeal, and the Appellate Body upheld the panel’s conclusions.

In *US – Clove Cigarettes*, the Panel found the measure made a material contribution because it reflected a widely held view among states and the scientific community that regulation of flavoured cigarettes would help reduce youth smoking. The Panel noted the WHO FCTC Partial Guidelines on Articles 9 and 10, stating that they demonstrated “a growing consensus within the international community to strengthen tobacco control policies through regulation of the content of tobacco products, including additives that increase the attractiveness and palatability of cigarettes”.[19x282][tooltip hint="Clove Cigarettes, panel, para 7.230"]*[19x266][/tooltip]
How much does the measure restrict trade?

The degree of contribution that a measure makes will be compared to the extent to which it restricts trade. If a measure restricts trade and provides little contribution to the achievement of its objective, a member may not be able to demonstrate that it is ‘necessary' to fulfil the objective.[

Are there reasonably available alternatives that would provide an equal contribution to the objective at the member’s desired level of protection, taking into account the risk non-fulfilment would create?

A panel will compare the challenged measure with any possible alternative measures identified by the complaining member. A panel will consider whether an alternative measure would be less trade restrictive, would make an equivalent contribution to the objective (taking account of the risks non-fulfilment would create), and whether it is reasonably available.[

In Australia – Plain Packaging, the complainants argued that Australia could have implemented one or all of four alternative measures, instead of plain packaging – raising the minimum legal purchasing age, raising excise tax, improving social marketing, and pre-vetting all tobacco packs to check for misleading branding. The panel considered that the first three of these measures were complements rather than alternatives to plain packaging, as they acted through different mechanisms as part of a comprehensive overall package of tobacco control measures. Substituting any of these alternatives would leave the impact of branding unaddressed, and therefore not provide the same level of protection. The pre-vetting mechanism alternative, on the other hand, was more trade-restrictive than plain packaging, and did not provide the same level of protection compared to standardizing the packs to remove branding altogether. The panel also found that none of the alternatives could be clearly demonstrated to be less trade-restrictive than plain packaging. On appeal, the complainants argued that two of these measures (tax and raising the minimum legal purchase age) were not less trade-restrictive than plain packaging and made an equivalent contribution. The Appellate Body upheld the panel’s finding that the two measures would have been equally trade restrictive and
therefore not a less trade-restrictive alternative to plain packaging, although the Appellate Body considered that the two measures could make an equivalent contribution to reducing tobacco use and exposure to tobacco smoke.

In *US — Clove Cigarettes*, Indonesia argued there were less trade-restrictive alternatives to the ban on flavoured cigarettes, such as restrictions on advertising and sponsorship and placing greater controls on the sale of products. However, the panel found that the ‘alternatives’ identified by Indonesia involved a greater risk of non-fulfilment of the objective of reducing youth smoking compared with the ban, and that Indonesia therefore could not show that they would make an equivalent contribution to the objective at the US’ desired level of protection. The panel noted that ‘where an alternative measure would entail a greater risk of non-fulfilment of the objective, it would be difficult to find that it would make an ‘equivalent’ contribution to the achievement of the objective, at the level of protection sought’. The panel also took into account that a ban on flavoured cigarettes was recommended in the WHO FCTC Partial Guidelines on Articles 9 and 10. Additionally, the panel held that many of the alternative measures proposed by Indonesia were either already in place or in the process of being implemented.

These decisions highlight that in a number of regulatory areas (including tobacco control), WTO members will take into account, as part of the regulatory context, that measures operate as part of a suite of complementary measures designed to achieve a particular objective. This is similar to acknowledgements of the complementary nature of Members’ measures under the GATT health exception.

**Nature and gravity of risk of non-fulfilment of the objective**

The panel will make its assessment of the alternatives in light of the nature of the risk toward which the measure is directed and the consequences that would arise should the objective of the measure not be achieved. The Appellate Body has indicated that the higher the risk of not fulfilling the objective, the more restrained a tribunal should be in determining whether alternative measures proposed by the complaining government are ‘reasonably available’ or ‘make an equivalent contribution’.

In the context of WHO FCTC measures, this would involve consideration of the devastating health, economic, social and environmental consequences of tobacco use, and the potential risks of not addressing them. In *Australia – Plain Packaging*, the panel considered that failing to address tobacco use and exposure to tobacco smoke was a risk that was ‘exceptionally grave’, and that it was ‘especially grave for youth’.
5. Relevant case law line References