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1 ARTICLE 2

1.1 Text of Article 2

**Article 2**

*Preparation, Adoption and Application of Technical Regulations by Central Government Bodies*

With respect to their central government bodies:

2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products.

2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical
regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.

2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

2.7 Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

2.8 Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

2.9 Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;

2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;

2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;

2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

2.10 Subject to the provisions in the lead-in to paragraph 9, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 9 as it finds necessary, provided that the Member, upon adoption of a technical regulation, shall:

2.10.1 notify immediately other Members through the Secretariat of the particular technical regulation and the products covered, with a brief indication of the objective and the rationale of the technical regulation, including the nature of the urgent problems;

2.10.2 upon request, provide other Members with copies of the technical regulation;

2.10.3 without discrimination, allow other Members to present their comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

2.11 Members shall ensure that all technical regulations which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them.

2.12 Except in those urgent circumstances referred to in paragraph 10, Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.
1.2 Article 2.1

1.2.1 General

1. The Appellate Body observed that Article 2.1 of the TBT Agreement contains a national treatment and a most-favoured nation treatment (MFN) obligation. The MFN treatment obligation prohibits discrimination among like products imported from different countries, while the national treatment obligation prohibits discrimination between domestic and imported like products.

2. The Panel in Russia – Railway Equipment examined whether the application of a conformity assessment procedure could be inconsistent with Article 2.1 of the TBT Agreement. After considering the differences between the substantive contents of Articles 2-4 and Articles 5-9 of the TBT Agreement, as well as the definition of a technical regulation in its Annex 1.1, the Panel concluded that:

"[T]he explicit distinction in the TBT Agreement between, on the one hand, disciplines applicable to substantive technical requirements and, on the other hand, disciplines applicable to procedures for assessment of conformity with substantive technical requirements indicates that issues relating to conformity with substantive technical requirements do not fall within the scope of application of Article 2.1."  

1.2.2 Legal test

3. The Appellate Body in US – Clove Cigarettes and US – Tuna II (Mexico) set out a three-pronged legal test for this provision:

"Article 2.1 of the TBT Agreement consists of three elements that must be demonstrated in order to establish an inconsistency with this provision, namely: (i) that the measure at issue constitutes a 'technical regulation' within the meaning of Annex 1.1; (ii) that the imported products must be like the domestic product and the products of other origins; and (iii) that the treatment accorded to imported products must be less favourable than that accorded to like domestic products and like products from other countries."

4. For the definition of a technical regulation, see the Section on Annex 1.1 of the TBT Agreement.

1.2.3 "Like products"

5. In US – Clove Cigarettes, the Appellate Body endorsed a competition-oriented approach to the "like products" analysis under Article 2.1 of the TBT Agreement and rejected the approach based on the regulatory objectives of a technical regulation. While the Appellate Body did not object to the Panel’s reliance on the likeness criteria developed in the jurisprudence under Article III of the GATT 1994, it disagreed with the particular weight the Panel attached to the health objective of the technical regulation at issue in its assessment of the products' physical characteristics and consumers' tastes and habits. According to the Appellate Body:

"[T]he very concept of 'treatment no less favourable', which is expressed in the same words in Article III:4 of the GATT 1994 and in Article 2.1 of the TBT Agreement, informs the determination of likeness, suggesting that likeness is about the 'nature and extent of a competitive relationship between and among products'. Indeed, the concept of 'treatment no less favourable' links the products to the marketplace, because it is only

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1 Appellate Body Report, US – Clove Cigarettes, para. 87.
3 Panel Report, Russia – Railway Equipment, para. 7.878.
5 Appellate Body Report, US – Clove Cigarettes, paras. 107-120.
in the marketplace that it can be determined how the measure treats like imported and domestic products."?

6. The Appellate Body further elaborated on why likeness is a determination about a competitive relationship between and among the products rather than a determination based on the regulatory objectives of the measure:

"More importantly, however, we do not consider that the concept of 'like products' in Article 2.1 of the TBT Agreement lends itself to distinctions between products that are based on the regulatory objectives of a measure. As we see it, the concept of 'like products' serves to define the scope of products that should be compared to establish whether less favourable treatment is being accorded to imported products. If products that are in a sufficiently strong competitive relationship to be considered like are excluded from the group of like products on the basis of a measure's regulatory purposes, such products would not be compared in order to ascertain whether less favourable treatment has been accorded to imported products. This would inevitably distort the less favourable treatment comparison, as it would refer to a 'marketplace' that would include some like products, but not others. As we consider further below in respect of the United States' appeal of the Panel's less favourable treatment finding, distinctions among products that have been found to be like are better drawn when considering, subsequently, whether less favourable treatment has been accorded, rather than in determining likeness, because the latter approach would alter the scope and result of the less favourable treatment comparison."8

7. Notwithstanding its conclusion that that the determination of likeness should not be based on the regulatory objectives of technical regulations, the Appellate Body also acknowledged the relevance of regulatory concerns:

"[T]he regulatory concerns underlying a measure, such as the health risks associated with a given product, may be relevant to an analysis of the 'likeness' criteria under Article III:4 of the GATT 1994, as well as under Article 2.1 of the TBT Agreement, to the extent they have an impact on the competitive relationship between and among the products concerned".9

1.2.4 "Treatment no less favourable"

1.2.4.1 Two-step analysis

8. In US – Clove Cigarettes, the Appellate Body set out the current understanding of the "treatment no less favourable" requirement in Article 2.1 of the TBT Agreement on the basis of the interpretation of that provision in light of its context, as well as the object and purpose of the TBT Agreement.10 The Appellate Body began its analysis by noting the definition of a technical regulation in Annex 1.1 of the TBT Agreement and considered that:

"As such, technical regulations are measures that, by their very nature, establish distinctions between products according to their characteristics or their related processes and production methods. This suggests, in our view, that Article 2.1 should not be read to mean that any distinction, in particular those that are based exclusively on particular product characteristics or their related processes and production methods, would per se accord less favourable treatment within the meaning of Article 2.1."11

9. The Appellate Body further observed that:

"The context provided by Article 2.2 suggests that 'obstacles to international trade' may be permitted insofar as they are not found to be 'unnecessary', that is, 'more

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trade-restrictive than necessary to fulfil a legitimate objective'. To us, this supports a reading that Article 2.1 does not operate to prohibit a priori any obstacle to international trade. Indeed, if any obstacle to international trade would be sufficient to establish a violation of Article 2.1, Article 2.2 would be deprived of its effet utile."\textsuperscript{12}

10. Continuing its analysis, the Appellate Body noted that the sixth recital of the preamble to the TBT Agreement made clear that "technical regulations may pursue the objectives listed therein, provided that they are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, and are otherwise in accordance with the provisions of the TBT Agreement".\textsuperscript{13}

11. Finally, the Appellate Body recalled its earlier observation that the object and purpose of the TBT Agreement is to strike a balance between the objective of trade liberalization and Members' right to regulate.\textsuperscript{14} In view of this, the Appellate body considered that Article 2.1 should not be interpreted as prohibiting any detrimental impact on competitive opportunities for imports in cases where such detrimental impact on imports stems exclusively from legitimate regulatory distinctions.\textsuperscript{15}

12. The Appellate Body thus found that the context and object and purpose of the TBT Agreement weigh in favour of reading the "treatment no less favourable" requirement of Article 2.1 as prohibiting both \textit{de jure} and \textit{de facto} discrimination against imported products, while at the same time permitting detrimental impact on competitive opportunities for imports that stems exclusively from legitimate regulatory distinctions.\textsuperscript{16}

13. Based on its interpretation of Article 2.1, the Appellate Body in \textit{US – Clove Cigarettes} explained that:

\"[W]here the technical regulation at issue does not \textit{de jure} discriminate against imports, the existence of a detrimental impact on competitive opportunities for the group of imported \textit{vis-à-vis} the group of domestic like products is not dispositive of less favourable treatment under Article 2.1. Instead, a panel must further analyze whether the detrimental impact on imports stems exclusively from a legitimate regulatory distinction rather than reflecting discrimination against the group of imported products. In making this determination, a panel must carefully scrutinize the particular circumstances of the case, that is, the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed, in order to determine whether it discriminates against the group of imported products.\"\textsuperscript{17}

14. In subsequent cases, this analytical approach crystallised into the following two-step assessment of whether the technical regulation at issue accords \textit{de facto} less favourable treatment under Article 2.1: (i) whether the technical regulation modifies the conditions of competition to the detriment of imported products \textit{vis-à-vis} like products of domestic origin and/or like products originating in any other country; and (ii) whether such detrimental impact "stems exclusively from a legitimate regulatory distinction".\textsuperscript{18}

\textbf{1.2.4.2 Burden of proof}

15. In \textit{US – Tuna II (Mexico)}, the Appellate Body explained that the complainant must prove its claim by showing less favourable treatment, which the respondent may rebut:

\begin{itemize}
  \item \textsuperscript{12} Appellate Body Report, \textit{US – Clove Cigarettes}, para. 171.
  \item \textsuperscript{13} Appellate Body Report, \textit{US – Clove Cigarettes}, para. 173.
  \item \textsuperscript{14} Appellate Body Report, \textit{US – Clove Cigarettes}, paras. 174 and 94-95.
  \item \textsuperscript{15} Appellate Body Report, \textit{US – Clove Cigarettes}, para. 174.
  \item \textsuperscript{16} Appellate Body Report, \textit{US – Clove Cigarettes}, para. 175.
  \item \textsuperscript{17} Appellate Body Report, \textit{US – Clove Cigarettes}, para. 182.
  \item \textsuperscript{18} Appellate Body Reports, \textit{US – Tuna II (Mexico)}, para. 215; \textit{US – COOL}, para. 271; and \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)}, para. 7.26. See also Panel Reports, \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)}, para. 7.73; and \textit{US – COOL (Article 21.5 – Canada and Mexico)}, paras. 7.60-7.62.
\end{itemize}
"In the context of Article 2.1 of the TBT Agreement, the complainant must prove its claim by showing that the treatment accorded to imported products is 'less favourable' than that accorded to like domestic products or like products originating in any other country. If it has succeeded in doing so, for example, by adducing evidence and arguments sufficient to show that the measure is not even-handed, this would suggest that the measure is inconsistent with Article 2.1.\(^{19}\) If, however, the respondent shows that the detrimental impact on imported products stems exclusively from a legitimate regulatory distinction, it follows that the challenged measure is not inconsistent with Article 2.1."\(^{20}\)

16. In US – Tuna II (Mexico) (Article 21.5 – Mexico), the Appellate Body, however, reproached the Panel for not recognizing the responsibilities of both parties in its discussion of the burden of proof.\(^{21}\) While the Appellate Body affirmed its earlier jurisprudence that places the burden of showing less favourable treatment on the complainant\(^{22}\), it opined that the respondent will be best situated to adduce arguments and evidence with respect to the second element of the assessment under Article 2.1 – whether the detrimental impact on imports stems exclusively from a legitimate regulatory distinction:

"[H]aving promulgated the technical regulation containing the regulatory distinctions that result in the detrimental impact, the responding Member will be best situated to adduce the arguments and evidence needed to explain why, contrary to the complainant's assertions, the technical regulation is even-handed and thus why the detrimental impact on imports stems exclusively from a legitimate regulatory distinction."\(^{23}\)

1.2.4.3 Temporal scope of a panel's analysis

17. The Appellate Body in US – COOL agreed with the participants that Article 2.1 does not establish a rigid temporal limitation on the evidence a panel could review when assessing the consistency of the measure with this provision:

"We agree with the participants that Article 2.1 does not establish a rigid temporal limitation on the evidence that the Panel could review in assessing Indonesia's claim under Article 2.1. Nothing in Article 2.1 enjoins panels from taking into account evidence pre-dating the establishment of a panel to the extent that such evidence informs the panel's assessment of the consistency of the measure at that point in time. This is particularly so in the case of a de facto discrimination claim, where a panel must base its determination on the totality of facts and circumstances before it, including the design, architecture, revealing structure, operation, and application of the technical regulation at issue. Therefore, evidence that Section 907(a)(1)(A) had "chilling" regulatory effects on domestic producers of flavoured cigarettes prior to the entry into force of the ban on those cigarettes could be relevant in the Panel's assessment of Indonesia's claim under Article 2.1."\(^{24}\)

1.2.4.4 Detrimental impact on the conditions of competition

1.2.4.4.1 General

18. In US – COOL, the Appellate Body provided the following guidance to panels regarding their analysis of whether a measure has a de facto detrimental impact on the conditions of competition of the relevant group of products:

"We first recall that, as explained above, Article 2.1 of the TBT Agreement prohibits both de jure and de facto discrimination between domestic and like imported products. Therefore, where a technical regulation does not discriminate de jure, a panel must

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19 (footnote original) Appellate Body Report, US – Clove Cigarettes, para. 182. See also para. 215.
21 Appellate Body Report, US – Tuna II (Mexico) (Article 21.5 – Mexico), para. 7.34.
determine whether the evidence and arguments adduced by the complainant in a specific case nevertheless demonstrate that the operation of that measure, in the relevant market, has a de facto detrimental impact on the group of like imported products. A panel’s analysis must take into consideration the totality of the facts and circumstances before it, including any implications for competitive conditions discernible from the design and structure of the measure itself, as well as all features of the particular market at issue that are relevant to the measure’s operation within that market. In this regard, ‘any adverse impact on competitive opportunities for imported products vis-à-vis like domestic products that is caused by a particular measure may potentially be relevant’ to a panel’s assessment of less favourable treatment under Article 2.1.25

19. In US – Tuna II (Mexico), the Appellate Body agreed with the Panel that the lack of access to the “dolphin-safe” label of tuna products containing tuna caught by setting on dolphins had a detrimental impact on the competitive opportunities of Mexican tuna products in the US market.27 With respect to the question of whether the detrimental impact on Mexican tuna products resulted from the measure itself rather than from the actions of private parties, the Appellate Body recalled the Panel’s findings that while US consumers’ decisions to purchase dolphin-safe tuna products were the result of their own choices rather than of the measure, it was the measure itself that controlled access to the label and allowed consumers to express their preferences for dolphin-safe tuna.28 Thus, in the Appellate Body’s view:

“These findings by the Panel suggest that it is the governmental action in the form of adoption and application of the US ‘dolphin-safe’ labelling provisions that has modified the conditions of competition in the market to the detriment of Mexican tuna products, and that the detrimental impact in this case hence flows from the measure at issue. Moreover, it is well established that WTO rules protect competitive opportunities, not trade flows.29 It follows that, even if Mexican tuna products might not achieve a wide penetration of the US market in the absence of the measure at issue due to consumer objections to the method of setting on dolphins, this does not change the fact that it is the measure at issue, rather than private actors, that denies most Mexican tuna products access to a ‘dolphin-safe’ label in the US market. The fact that the detrimental impact on Mexican tuna products may involve some element of private choice does not, in our view, relieve the United States of responsibility under the WTO Agreement, where the measure it adopts modifies the conditions of competition to the detriment of Mexican tuna products.30

20. In US – COOL, the Panel concluded that, given the particular circumstances of the US livestock market, the least costly way of complying with the COOL measure was for producers to rely exclusively on domestic livestock.32 Relying on that conclusion, the Panel found that the COOL measure created an incentive for US market participants to process exclusively domestic livestock and reduced the competitive opportunities of imported livestock as compared to domestic livestock.33 On appeal, the Appellate Body rejected the United States’ contention that the Panel had wrongly attributed to the COOL measure a detrimental impact on imports caused exclusively by factors "external" to that measure, noting that the COOL measure itself, as applied in the US livestock and meat market, created an incentive for US producers to segregate livestock according to origin, in particular by processing exclusively US-origin livestock.34 The Appellate Body explained as follows:

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25 (footnote original) Appellate Body Report, US – Tuna II (Mexico), para. 225. (original emphasis)
30 (footnote original) See Appellate Body Report, Korea – Various Measures on Beef, para. 146.
31 Appellate Body Report, US – Tuna II (Mexico), para. 239.
“We further emphasize that, while detrimental effects caused solely by the decisions of private actors cannot support a finding of inconsistency with Article 2.1, the fact that private actors are free to make various decisions in order to comply with a measure does not preclude a finding of inconsistency. Rather, where private actors are induced or encouraged to take certain decisions because of the incentives created by a measure, those decisions are not ‘independent’ of that measure. As the Appellate Body noted, the ‘intervention of some element of private choice does not relieve [a Member] of responsibility … for the resulting establishment of competitive conditions less favourable for the imported product than for the domestic product’, and thus does not preclude a finding that the measure provides less favourable treatment.35\textsuperscript{36}

1.2.4.4.2 Relevant groups of like products

21. The Appellate Body in US – Clove Cigarettes disagreed with the Panel's finding that its terms of reference limited the scope of its analysis to the comparison of treatment accorded to the groups of products identified by the complainant.37 The Appellate Body explained that Article 2.1 rather "requires the panel to identify the domestic products that stand in a sufficiently close competitive relationship with the products imported from the complaining Member to be considered like products within the meaning of that provision".38 In the Appellate Body's view, once the imported and domestic like products have been properly identified, a panel dealing with a national treatment claim is required to compare the treatment accorded to all like products imported from the complaining Member with that accorded to all like domestic products.39 The Appellate Body noted, however, that this does not preclude any regulatory distinctions between like products:

"However, the national treatment obligation of Article 2.1 does not require Members to accord no less favourable treatment to each and every imported product as compared to each and every domestic like product. Article 2.1 does not preclude any regulatory distinctions between products that are found to be like, as long as treatment accorded to the group of imported products is no less favourable than that accorded to the group of like domestic products."40

22. In its assessment of the impact of the measures on the conditions of competition of Mexican tuna products, the Panel in US – Tuna II (Mexico) (Article 21.5 – Mexico) compared the costs and burdens that the different certification and tracking and verification requirements entail for, on the one hand, Mexican tuna products derived from tuna caught other than by setting on dolphins, and, on the other hand, tuna products of US or other origin derived from tuna caught other than by setting on dolphins. The Appellate Body disagreed and held that the Panel had employed an incorrect analytical approach by engaging in a "comparison of the treatment accorded to subsets of the relevant groups of like products".41 The Appellate Body considered that, in order to reach its conclusions on detrimental impact, the Panel was called upon to compare the treatment that the labelling conditions under the amended tuna measure accorded to "the group of Mexican tuna products, on the one hand, with the treatment accorded to the groups of like tuna products from the United States and other countries, on the other hand".42

1.2.4.5 Legitimate regulatory distinctions

23. In US – Clove Cigarettes, the measure at issue prohibited primarily clove cigarettes imported from Indonesia, while permitting primarily domestically-produced menthol cigarettes. Upholding the Panel's finding that the measure accorded to clove cigarettes imported from Indonesia less favourable treatment than that accorded to domestic like products, the Appellate Body elaborated on why it was not persuaded that the detrimental impact of the measure on competitive opportunities for imported clove cigarettes stemmed from a legitimate regulatory distinction. First,

\textsuperscript{35} (footnote original) Appellate Body Report, Korea – Various Measures on Beef, para. 146.
\textsuperscript{36} Appellate Body Reports, US – COOL, para. 291.
\textsuperscript{37} Appellate Body Report, US – Clove Cigarettes, paras. 185 and 191.
\textsuperscript{38} Appellate Body Report, US – Clove Cigarettes, para. 185.
\textsuperscript{39} Appellate Body Report, US – Clove Cigarettes, para. 193.
\textsuperscript{40} Appellate Body Report, US – Clove Cigarettes, para. 193.
\textsuperscript{41} Appellate Body Report, US – Tuna II (Mexico) (Article 21.5 – Mexico), para. 7.75.
\textsuperscript{42} Appellate Body Report, US – Tuna II (Mexico) (Article 21.5 – Mexico), para. 7.72.
the Appellate Body noted that, from the perspective of the objective of the measure, menthol cigarettes had the same product characteristic that justified the prohibition of clove cigarettes:

“We recall that the stated objective of Section 907(a)(1)(A) is to reduce youth smoking. One of the particular characteristics of flavoured cigarettes that makes them appealing to young people is the flavouring that masks the harshness of the tobacco, thus making them more pleasant to start smoking than regular cigarettes. To the extent that this particular characteristic is present in both clove and menthol cigarettes, menthol cigarettes have the same product characteristic that, from the perspective of the stated objective of Section 907(a)(1)(A), justified the prohibition of clove cigarettes.”

24. The Appellate Body then considered that the reasons presented by the United States for the exemption of menthol cigarettes from the ban on flavoured cigarettes did not demonstrate that the detrimental impact on competitive opportunities for imported clove cigarettes stemmed from a legitimate regulatory distinction:

“The United States argues that the exemption of menthol cigarettes from the ban on flavoured cigarettes aims at minimizing: (i) the impact on the US health care system associated with treating 'millions' of menthol cigarette smokers affected by withdrawal symptoms; and (ii) the risk of development of a black market and smuggling of menthol cigarettes to supply the needs of menthol cigarette smokers. Thus, according to the United States, the exemption of menthol cigarettes from the ban on flavoured cigarettes is justified in order to avoid risks arising from withdrawal symptoms that would afflict menthol cigarette smokers in case those cigarettes were banned. We note, however, that the addictive ingredient in menthol cigarettes is nicotine, not peppermint or any other ingredient that is exclusively present in menthol cigarettes, and that this ingredient is also present in a group of products that is likewise permitted under Section 907(a)(1)(A), namely, regular cigarettes. Therefore, it is not clear that the risks that the United States claims to minimize by allowing menthol cigarettes to remain in the market would materialize if menthol cigarettes were to be banned, insofar as regular cigarettes would remain in the market.”

1.2.4.5.1 Interpretative concepts utilized by the Appellate Body and panels: “even-handedness”, “calibration”

25. In conducting its own analysis of whether the US "dolphin-safe" labelling provisions stemmed exclusively from a legitimate regulatory distinction, the Appellate Body in US – Tuna II (Mexico) stated that it "will scrutinize, in particular, whether ... the US measure is even-handed in the manner in which it addresses the risks to dolphins arising from different fishing methods in different areas of the ocean". In assessing whether the measure at issue was even-handed, the Appellate Body examined whether the differences in access to the dolphin-safe label prescribed by the measure were "calibrated" to the risk that dolphins may be killed or seriously injured when tuna is caught. Based on its analysis, the Appellate Body rejected the United States' arguments that the US "dolphin-safe" labelling provisions were "calibrated" to the risks to dolphins arising from different fishing methods in different areas of the ocean and reasoned as follows:

"In the light of the above, we conclude that the United States has not demonstrated that the difference in labelling conditions for tuna products containing tuna caught by setting on dolphins in the ETP, on the one hand, and for tuna products containing tuna caught by other fishing methods outside the ETP, on the other hand, is 'calibrated' to the risks to dolphins arising from different fishing methods in different areas of the ocean. It follows from this that the United States has not demonstrated that the detrimental impact of the US measure on Mexican tuna products stems exclusively from a legitimate regulatory distinction. We note, in particular, that the US measure fully addresses the adverse effects on dolphins resulting from setting on dolphins in the ETP, whereas it does 'not address mortality (observed or unobserved) arising from fishing methods other than setting on dolphins outside the ETP'. In these circumstances, we

are not persuaded that the United States has demonstrated that the measure is even-handed in the relevant respects, even accepting that the fishing technique of setting on dolphins is particularly harmful to dolphins. 46

26. In US – COOL, the Appellate Body considered that the Panel’s findings provided a sufficient basis for it to determine whether the detrimental impact on Canadian and Mexican livestock stemmed exclusively from a legitimate regulatory distinction. The Appellate Body indicated that its assessment would include an inquiry into whether the COOL measure lacked even-handedness because it was designed or applied in a manner that constituted a means of arbitrary or unjustifiable discrimination:

“In our view, these findings provide a sufficient basis for us to determine whether the detrimental impact on Canadian and Mexican livestock stems exclusively from a legitimate regulatory distinction. That is, these findings allow us to pronounce on whether the COOL measure is designed and applied in an even-handed manner, or whether it lacks even-handedness, for example, because it is designed or applied in a manner that constitutes a means of arbitrary or unjustifiable discrimination, and thus reflects discrimination in violation of Article 2.1 of the TBT Agreement. If we determine that the regulatory distinctions drawn by the COOL measure are designed or applied in a manner that constitutes arbitrary or unjustifiable discrimination, those distinctions cannot be considered ‘legitimate’, and the COOL measure will be inconsistent with Article 2.1. In order to make this determination, we proceed to scrutinize ‘the particular circumstances’ of this case, including ‘the design, architecture, revealing structure, operation, and application’ of the COOL measure.” 47

27. The Appellate Body found that the detrimental impact of the COOL measure on Canadian and Mexican livestock did not stem exclusively from a legitimate regulatory distinction because the manner in which the COOL measure sought to provide information to consumers on origin was arbitrary, and the disproportionate burden imposed on upstream producers and processors was unjustifiable:

“For all of these reasons, the informational requirements imposed on upstream producers under the COOL measure are disproportionate as compared to the level of information communicated to consumers through the mandatory retail labels. That is, a large amount of information is tracked and transmitted by upstream producers for purposes of providing consumers with information on origin, but only a small amount of this information is actually communicated to consumers in an understandable manner, if it is communicated at all. Yet, nothing in the Panel’s findings or on the Panel record explains or supplies a rational basis for this disconnect. Therefore, we consider the manner in which the COOL measure seeks to provide information to consumers on origin, through the regulatory distinctions described above, to be arbitrary, and the disproportionate burden imposed on upstream producers and processors to be unjustifiable.” 48

28. Similarly, in US – COOL (Article 21.5 – Canada and Mexico), the Appellate Body agreed with the Panel that the detrimental impact on imported livestock arising from the amended COOL measure did not stem exclusively from legitimate regulatory distinctions:

“As we see it, the discrete findings made by the Panel outlined above support the conclusion that the recordkeeping and verification requirements of the amended COOL measure impose a disproportionate burden on producers and processors of livestock that cannot be explained by the need to provide consumers with information regarding where livestock were born, raised, and slaughtered. Accordingly, the detrimental impact on imported livestock arising from these same recordkeeping and verification requirements does not stem exclusively from legitimate regulatory distinctions.” 49

49 Appellate Body Reports, US – COOL (Article 21.5 – Canada and Mexico), para. 5.47.
29. The Panel in *US – Tuna II (Mexico) (Article 21.5 – US)* understood the Appellate Body’s position in the previous compliance proceedings to mean “that (a) the form and content of the calibration test must be appropriately informed by the objectives pursued by the measure, and (b) the calibration test should itself be applied taking account of the measure’s objectives”.\(^{50}\)

30. In *US – Tuna II (Mexico) (Article 21.5 – US)*, the Appellate Body underlined that the calibration test is a means to assess whether the detrimental impact stems exclusively from a legitimate regulatory distinction:

"Thus, rather than being a separate legal test, calibration is the means to assess whether the detrimental impact of the measure at issue in this dispute stems exclusively from a legitimate regulatory distinction, in the context of the second step of the 'treatment no less favourable' analysis under Article 2.1. As we explain in greater detail in section 6.1.3 below, if done properly, the calibration analysis should encompass consideration of the rational relationship between the regulatory distinctions and the objectives of the 2016 Tuna Measure. Thus, if calibrated properly, these regulatory distinctions will not amount to arbitrary or unjustifiable discrimination and will thus comply with the requirements of Article 2.1 of the TBT Agreement."\(^{51}\)

31. In *US – Tuna II (Mexico) (Article 21.5 – US)*, the Appellate Body pointed out that “the nature of the calibration analysis is defined by the nature of the regulatory distinctions under the measure itself.”\(^{52}\) The Appellate Body also made the following observation as to whether a calibration analysis should involve a separate assessment of the nexus between the relevant regulatory distinctions and the objectives of the challenged measure:

"As discussed above, the Appellate Body’s findings in the first compliance proceedings indicate that considerations regarding label accuracy are encompassed in a proper calibration analysis. Accordingly, we disagree that a calibration analysis, on the basis of the risks to dolphins, would fail to ascertain whether the labels granted under the relevant labelling conditions are accurate and, as a consequence, whether the regulatory distinctions in such conditions are rationally related to the measure’s objectives.

Instead, we consider that, where the calibration analysis is conducted properly, taking account of the objectives pursued by the 2016 Tuna Measure, this exercise should also ascertain whether the label granted under the measure at issue conveys the information regarding the dolphin-safe nature of the tuna products to consumers. This is because, if the calibration analysis shows that the strictness of the different labelling conditions is indeed commensurate with the risks to dolphins, it indicates that the labels granted under these conditions would allow consumers to obtain information regarding whether the tuna in the tuna products is harvested in a manner that harms dolphins. Therefore, we agree with the Panels that a proper calibration to the risks to dolphins arising from the use of different fishing methods in different areas of the ocean would take into account the objectives of the 2016 Tuna Measure, and would help to ascertain the nexus between such objectives and the different labelling conditions under the measure. In the same vein, we also agree with the Panels that the existence of a rational relationship between the regulatory distinctions and the objectives of the 2016 Tuna Measure need not be assessed as a separate or distinct step in their analysis."\(^{53}\)

32. In *US – Tuna II (Mexico) (Article 21.5 – US)*, the Appellate Body clarified that the calibration analysis does not test for uniformity in assessing the relevant regulatory distinctions:

"[T]he calibration analysis is not intended to test for uniformity in the requirements applicable to the different fisheries. Rather, the sensitivity of the labelling conditions under the 2016 Tuna Measure should be calibrated to the risks to dolphins arising from the use of different fishing methods in different areas of the ocean. Thus, requiring the 2016 Tuna Measure to be calibrated to the risks to dolphins does not mean that the differences between the AIDCP regime and the NOAA regime must be eliminated under

\(^{50}\) Panel Reports, *US – Tuna II (Mexico) (Article 21.5 – US)*, para. 7.116.


the 2016 Tuna Measure, given that the ETP large purse seine fishery has a special risk profile that distinguishes it from other fisheries.\textsuperscript{54}

1.2.4.5.2 Relevance of the jurisprudence under the chapeau of Article XX of the GATT 1994

33. Reviewing the Panel’s articulation of the legal standard for determining whether the detrimental impact on imported products stems exclusively from a legitimate regulatory distinction, the Appellate Body in \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)} observed as follows:

"[G]iven that the sixth recital of the preamble of the TBT Agreement serves as relevant context for understanding Article 2.1, and the language of that recital has important commonalities with the chapeau of Article XX of the GATT 1994, the jurisprudence under the chapeau of Article XX is not irrelevant to understanding the content of the second step of the 'treatment no less favourable' requirement under Article 2.1 of the TBT Agreement. Indeed, previous Appellate Body decisions concerning one provision of a covered agreement may shed light on a proper understanding of the scope and meaning of a different provision in another agreement where the same or similar language is used in both provisions\textsuperscript{55}, provided always that due account is taken of more immediate context, and of the function of each provision.\textsuperscript{56}

34. In considering whether the detrimental impact caused by a technical regulation can be reconciled with, or is rationally related to, the policy objective pursued by the technical regulation, the Appellate Body in \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)} opined as follows:

"As regards the specific insight that the Panel drew from the jurisprudence under the chapeau of Article XX, we recall that, in the context of its analysis of Article XX, in \textit{EC – Seal Products}, the Appellate Body stated that '[o]ne of the most important factors in the assessment of arbitrary or unjustifiable discrimination is the question of whether the discrimination can be reconciled with, or is rationally related to, the policy objective with respect to which the measure has been provisionally justified under one of the subparagraphs of Article XX.'\textsuperscript{57} This was the test adopted by the Panel for purposes of the second step of its 'treatment no less favourable' analysis under Article 2.1 of the TBT Agreement, to which the United States now objects. In the context of the chapeau of Article XX, the Appellate Body has explained that the reason why the assessment of whether discrimination is arbitrary or unjustifiable should be made in the light of the objective of the measure is that it is difficult to understand 'how discrimination might be viewed as complying with the chapeau of Article XX when the alleged rationale for discriminating does not relate to the pursuit of or would go against the objective that was provisionally found to justify a measure under a paragraph of Article XX.'\textsuperscript{58} The same considerations, in our view, are valid in the context of the second step of the analysis of "treatment no less favourable" under Article 2.1 of the TBT Agreement.\textsuperscript{59}

35. The Appellate Body cautioned, however, that, as recognized by the Panel, "merely inquiring into whether the detrimental impact of the amended tuna measure can be reconciled with the objectives of that measure might not, alone, be sufficient to ascertain whether the amended tuna measure discriminates against Mexican tuna products in an arbitrary or unjustifiable manner".\textsuperscript{60} The Appellate Body also noted that, as acknowledged by the Panel, an examination of whether a measure is designed or applied in a manner that constitutes a means of arbitrary or unjustifiable


\textsuperscript{55} \textit{(footnote original)} For instance, the Appellate Body has highlighted that, in view of the similarities between the language of Article XIV of the GATS and Article XX of the GATT 1994, previous decisions under each provision may be relevant in understanding the scope and meaning of the other. (Appellate Body Reports, \textit{US – Gambling}, para. 291; \textit{China – Publications and Audiovisual Products}, fn 452 to para. 239)

\textsuperscript{56} Appellate Body Report, \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)}, para. 7.88.

\textsuperscript{57} \textit{(footnote original)} Appellate Body Reports, \textit{EC – Seal Products}, para. 5.306 (referring to Appellate Body Reports, \textit{US – Shrimp}, para. 165; and \textit{Brazil – Retreaded Tyres}, paras. 227-228 and 232).

\textsuperscript{58} \textit{(footnote original)} Appellate Body Report, \textit{Brazil – Retreaded Tyres}, para. 227. See also Appellate Body Reports, \textit{EC – Seal Products}, para. 5.306.

\textsuperscript{59} Appellate Body Report, \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)}, para. 7.92.

\textsuperscript{60} Appellate Body Report, \textit{US – Tuna II (Mexico) (Article 21.5 – Mexico)}, para. 7.93.
discrimination is "one" but not the "only" way to assess whether a measure lacks even-handedness.61

1.2.4.5.3 Elements of a technical regulation relevant for a panel's analysis

36. In US – COOL (Article 21.5 – Canada and Mexico), the Panel considered that the exemptions under the COOL measure were relevant for its analysis of whether the detrimental impact of the amended COOL measure stemmed exclusively from legitimate regulatory distinctions.62 On appeal, the United States argued that the Panel had erred in finding that the exemptions were relevant for its analysis, submitting that only regulatory distinctions that account for the detrimental impact on like imported products can answer the question of whether such detrimental impact reflects discrimination. Upholding the Panel's finding, the Appellate Body explained that while a panel's analysis must focus on those regulatory distinctions that account for the detrimental impact of a technical regulation on like products, other elements of the technical regulation may also be relevant:

"We consider, therefore, that the inquiry into whether the detrimental impact of a technical regulation on like imported products stems exclusively from legitimate regulatory distinctions must focus on those regulatory distinctions that account for such detrimental impact. Further, the legitimacy of such regulatory distinctions, for the purposes of Article 2.1, is a function of whether they are designed and applied in an even-handed manner. While the assessment of even-handedness focusses on the regulatory distinction(s) causing the detrimental impact on imported products, other elements of the technical regulation are relevant for that assessment to the extent that they are probative of whether such detrimental impact stems exclusively from legitimate regulatory distinctions. Indeed, as the Appellate Body explained in the original disputes, a panel, in assessing even-handedness for the purposes of Article 2.1, must 'carefully scrutinize the particular circumstances of the case, that is, the design, architecture, revealing structure, operation, and application of the technical regulation at issue'.63

Thus, the inquiry under Article 2.1 must situate the regulatory distinctions that account for the detrimental impact on imported products within the overall design and application of the technical regulation at issue. In this way, a determination can be made as to whether these distinctions are designed and applied in an even-handed manner such that they may be considered 'legitimate' for the purposes of Article 2.1, or whether, instead, they lack even-handedness because, for example, they are designed and applied in a manner that constitutes arbitrary or unjustifiable discrimination in violation of Article 2.1."64

1.3 Article 2.2

1.3.1 Relationship between the first and the second sentences

37. The Appellate Body in US – COOL observed as follows:

"The first two sentences of Article 2.2 establish certain obligations with which WTO Members must comply when preparing, adopting, and applying technical regulations. In accordance with the first sentence, they must ensure that such preparation, adoption, and application is not done 'with a view to or with the effect of creating unnecessary obstacles to international trade'; and, in accordance with the second sentence, they must ensure that their technical regulations are 'not ... more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create'. The words 'for this purpose' linking the first and second sentences suggest

64 Appellate Body Reports, US – COOL (Article 21.5 – Canada and Mexico), paras. 5.93-5.94.
that the second sentence informs the scope and meaning of the obligation contained in the first sentence.6566

1.3.2 Second sentence

1.3.2.1 "Legitimate objective"

1.3.2.1.1 The identification of the objective(s) of the measure

38. The Appellate Body in US – Tuna II (Mexico) provided the following guidance to panels adjudicating claims under Article 2.2 of the TBT Agreement:

"Accordingly, in adjudicating a claim under Article 2.2 of the TBT Agreement, a panel must assess what a Member seeks to achieve by means of a technical regulation. In doing so, it may take into account the texts of statutes, legislative history, and other evidence regarding the structure and operation of the measure. A panel is not bound by a Member's characterization of the objectives it pursues through the measure, but must independently and objectively assess them. Subsequently, the analysis must turn to the question of whether a particular objective is legitimate, pursuant to the parameters set out above."67

39. In US – COOL, the Appellate Body found that the Panel had correctly identified the provision of consumer information on origin as the objective pursued through the COOL measure:

"Because, however, the Panel ultimately evaluated all relevant features relating to the COOL measure's objective, including evidence and arguments presented by the parties relating to the measure's text, design, architecture, structure, and legislative history, as well as its operation, we do not agree with Canada and Mexico that the Panel erred in its application of Article 2.2 of the TBT Agreement by determining the objective of the COOL measure in the 'abstract', and solely on the basis of the United States' declared objective."68

40. The Panel in US – Clove Cigarettes considered that "It would be entirely possible, both as a factual and a legal matter, for a single technical regulation to pursue more than one objective"69, while the Panel in US – Tuna II (Mexico) concluded that the measures at issue in that dispute had two different objectives, namely consumer information and dolphin protection.70

41. According to the Panel in Australia – Tobacco Plain Packaging (Cuba), the identification of the objective of a challenged measure is designed to clarify its "underlying purpose.71 In that case, the Panel was careful to distinguish between the identification of the objective that is pursued by or through a measure, on the one hand, and the level at which a Member aims to achieve that objective, which is a separate question, on the other hand.72 Additionally, the Panel explained that the identification of the objective of a measure is distinct from the question of how or through what means that objective is to be pursued.73

1.3.2.1.2 The legitimacy of the objective

42. Appellate Body in US – Tuna II (Mexico) noted:

"[T]he word 'objective' describes a 'thing aimed at or sought; a target, a goal, an aim'. The word 'legitimate', in turn, is defined as 'lawful; justifiable; proper'. Taken together,

68 Appellate Body Reports, US – COOL, para. 396. See also paras. 391 and 424.
71 Panel Report, Australia – Tobacco Plain Packaging (Cuba), paras. 7.198 and 7.229.
72 Panel Report, Australia – Tobacco Plain Packaging (Cuba), paras. 7.196 and 7.231.
73 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.197.
this suggests that a ‘legitimate objective’ is an aim or target that is lawful, justifiable, or proper. Furthermore, the use of the words ‘inter alia’ in Article 2.2 suggests that the provision does not set out a closed list of legitimate objectives, but rather lists several examples of legitimate objectives. We consider that those objectives expressly listed provide a reference point for which other objectives may be considered to be legitimate in the sense of Article 2.2. In addition, we note that the sixth and seventh recitals of the preamble of the TBT Agreement specifically recognize several objectives, which to a large extent overlap with the objectives listed in Article 2.2. Furthermore, we consider that objectives recognized in the provisions of other covered agreements may provide guidance for, or may inform, the analysis of what might be considered to be a legitimate objective under Article 2.2 of the TBT Agreement."74

43. The Panel in US – Clove Cigarettes considered it to be self-evident that the objective of reducing youth smoking is a "legitimate" one:

"We have already concluded that the objective of the ban on clove cigarettes is to reduce youth smoking. It is self-evident that measures to reduce youth smoking are aimed the protection of human health, and Article 2.2 of the TBT Agreement explicitly mentions the 'protection of human health' as one of the 'legitimate objectives' covered by that provision. In EC – Asbestos, the Appellate Body stated that 'the objective pursued by the measure is the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks posed by asbestos fibres. The value pursued is both vital and important in the highest degree.' In addition, we recall that in Brazil – Retreaded Tyres, the Appellate Body agreed with the panel that 'few interests are more 'vital' and 'important' than protecting human beings from health risks'.7577

44. Similarly, the Panel in US – Tuna II (Mexico) found that the objectives of the measure at issue in that dispute (consumer information and dolphin protection) were "legitimate":

"Article 2.2 of the TBT Agreement provides a non-exhaustive list of legitimate objectives under this provision. This list includes, as the United States has pointed out, the 'prevention of deceptive practices' and the 'protection of ... animal or plant life or health, or the environment'. We are satisfied that the objectives of the US dolphin-safe provisions, as described in the previous section, fall within the scope of these two categories of legitimate objectives. The objective of preventing consumers of tuna products from being deceived by false dolphin-safe allegations falls within the broader goal of preventing deceptive practices. Similarly, the protection of dolphins may be understood as intended to protect animal life or health or the environment. In this respect, a measure that aims at the protection of animal life or health need not, in our view, be directed exclusively to endangered or depleted species or populations, to be legitimate. Article 2.2 refers to 'animal life or health' in general terms, and does not require that such protection be tied to a broader conservation objective. We therefore read these terms as allowing Members to pursue policies that aim at also protecting individual animals or species whose sustainability as a group is not threatened."79

45. The Panel in US – COOL considered that providing consumer information on origin is a legitimate objective within the meaning of Article 2.2:

"We are persuaded, based on the evidence before us regarding US consumer preferences as well as the practice in a considerable proportion of WTO Members, that consumers generally are interested in having information on the origin of the products they purchase. We also observe that many WTO Members have responded to that interest by putting measures in place to require the provision of such information, albeit

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76 (footnote original) Appellate Body Report, Brazil – Retreaded Tyres, para. 144 (footnotes omitted).
77 Panel Report, US – Clove Cigarettes, para. 7.347.
with different definitions of 'origin'. In this regard, we once again recall the words of the panel in EC – Sardines referring to the conclusion of the panel in Canada – Pharmaceutical Patents that a legitimate objective refers to 'protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms.\(^81\) In our view, whether an objective is legitimate cannot be determined in a vacuum, but must be assessed in the context of the world in which we live.\(^82\) Social norms must be accorded due weight in considering whether a particular objective pursued by a government can be considered legitimate. It seems to us, based on the evidence before us, that providing consumers with information on the origin of the products they purchase is in keeping with the requirements of current social norms in a considerable part of the WTO Membership.\(^83\)

1.3.2.2 "More trade-restrictive than necessary to fulfil a legitimate objective"

46. In US – Tuna II (Mexico), the Appellate Body explained that, in the context of Article 2.2, "the assessment of 'necessity' involves a relational analysis of the trade-restrictiveness of the technical regulation, the degree of contribution that it makes to the achievement of a legitimate objective, and the risks non-fulfilment would create".\(^84\) The Appellate Body also observed that this assessment also involves "a comparison of the trade-restrictiveness and the degree of achievement of the objective by the measure at issue with that of possible alternative measures that may be reasonably available and less trade restrictive than the challenged measure, taking account of the risks non-fulfilment would create".\(^85\) The Appellate Body further found that the obligation to consider "the risks non-fulfilment would create" suggests another element of this analysis – the determination of whether a reasonably available and less trade restrictive alternative measure would make an equivalent contribution to the relevant legitimate objective, taking account of the risks non-fulfilment would create.\(^86\)

47. Regarding the meaning of trade-restrictiveness, the Appellate Body stated as follows:

"We recall that the Appellate Body has understood the word 'restriction' as something that restricts someone or something, a limitation on action, a limiting condition or regulation. Accordingly, it found, in the context of Article XI:2(a) of the GATT 1994, that the word 'restriction' refers generally to something that has a limiting effect.\(^87\) As used in Article 2.2 in conjunction with the word 'trade', the term means something having a limiting effect on trade."\(^88\)

48. The Appellate Body in US – Tuna II (Mexico) summarized the steps involved in an assessment of whether a technical regulation is "more trade-restrictive than necessary" within the meaning of Article 2.2:

"In sum, we consider that an assessment of whether a technical regulation is 'more trade-restrictive than necessary' within the meaning of Article 2.2 of the TBT Agreement involves an evaluation of a number of factors. A panel should begin by considering factors that include: (i) the degree of contribution made by the measure to the legitimate objective at issue; (ii) the trade-restrictiveness of the measure; and (iii) the

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\(^81\) (footnote original) Panel Report on EC – Sardines, para. 7.121, referring to Panel Report on Canada – Pharmaceutical Patents, para. 7.69. The Panel also refers to the Panel in US – Section 110(5) Copyright Act, which stated that the term has "the connotation of legitimacy from a more normative perspective, in the context of calling for the protection of interests that are justifiable in the light of the objectives that underlie the protection of exclusive rights" (para. 6.224).

\(^82\) (footnote original) The Appellate Body in EC – Hormones states: "It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die" (Appellate Body Report, EC – Hormones, para. 187).


\(^84\) Appellate Body Report, US – Tuna II (Mexico), para. 318.

\(^85\) Appellate Body Report, US – Tuna II (Mexico), para. 320.


\(^87\) (footnote original) The Appellate Body addressed this question in the context of Article XI:2(a) of the GATT 1994 in Appellate Body Reports, China – Raw Materials, para. 319.

nature of the risks at issue and the gravity of consequences that would arise from non-fulfilment of the objective(s) pursued by the Member through the measure. In most cases, a comparison of the challenged measure and possible alternative measures should be undertaken. In particular, it may be relevant for the purpose of this comparison to consider whether the proposed alternative is less trade restrictive, whether it would make an equivalent contribution to the relevant legitimate objective, taking account of the risks non-fulfilment would create, and whether it is reasonably available.\footnote{Appellate Body Reports, US – COOL, para. 373. See also Appellate Body Reports, US – COOL (Article 21.5 – Canada and Mexico), para. 5.197.}

49. Elaborating on its prior jurisprudence, the Appellate Body in US – COOL set out the following considerations on the meaning of the word "fulfil" in Article 2.2:

"The Appellate Body in US – Tuna II (Mexico) found that, while, read in isolation, the word 'fulfil' could be understood to signify the complete achievement of something, as used in Article 2.2 this term is concerned with the degree of contribution that the technical regulation makes towards the achievement of the legitimate objective.\footnote{Appellate Body Report, US – Tuna II (Mexico), para. 315.} The Appellate Body found relevant contextual support for this reading in the sixth recital of the preamble of the TBT Agreement, which provides that, subject to certain qualifications, a Member shall not be prevented from taking measures necessary to achieve its legitimate objectives 'at the levels it considers appropriate'.\footnote{Appellate Body Report, US – Tuna II (Mexico), para. 316.} The degree or level of contribution of a technical regulation to its objective is not an abstract concept, but rather something that is revealed through the measure itself. In preparing, adopting, and applying a measure in order to pursue a legitimate objective, a WTO Member articulates, either implicitly or explicitly, the level at which it pursues that objective.\footnote{Appellate Body Report, US – Tuna II (Mexico), para. 316.} Thus, a panel adjudicating a claim under Article 2.2 must seek to ascertain—from the design, structure, and operation of the technical regulation, as well as from evidence relating to its application—to what degree, if at all, the challenged technical regulation, as written and applied, actually contributes to the achievement of the legitimate objective pursued by the Member.\footnote{We can identify at least two instances where a comparison of the challenged measure and possible alternative measures may not be required. For example, it would seem to us that if a measure is not trade restrictive, then it may not be inconsistent with Article 2.2. Conversely, if a measure is trade restrictive and makes no contribution to the achievement of the legitimate objective, then it may be inconsistent with Article 2.2.}

50. In US – COOL, the Appellate Body found that the Panel had erred in its interpretation of Article 2.2 because it had "considered it necessary for the COOL measure to have fulfilled the objective completely, or satisfied some minimum level of fulfilment to be consistent with Article 2.2, it erred in its interpretation of Article 2.2".\footnote{Appellate Body Report, US – COOL, para. 5.197.} The Appellate Body observed that, in US – Tuna II (Mexico), it "did not find or imply that, in order for a measure to comply with Article 2.2, it must meet some minimum threshold of fulfilment".\footnote{Appellate Body Report, US – Tuna II (Mexico), footnote 640 to para. 317}

51. The Panel in US – Clove Cigarettes agreed with the parties that the concept of the "level of protection" is related to the question of whether a measure is "more trade-restrictive than necessary" within the meaning of Article 2.2:

"In this case, both parties agree that the 'level of protection' sought is directly connected to the question of whether a measure is 'more trade-restrictive than necessary' within
the meaning of Article 2.2 of the TBT Agreement. We see no reason to disagree. Although the concept is not explicitly referred to in the text of Article 2.2 of the TBT Agreement, the sixth recital to the preamble of the TBT Agreement states no country should be prevented from taking measures 'necessary ... for the protection of human ... life or health ... at the levels it considers appropriate'. In addition, panels and the Appellate Body have considered the "level of protection" in the context of analysing measures under Article XX(b) of the GATT 1994, notwithstanding that these words are not found in that provision either. Among other things, the Appellate Body has explained that 'in order to qualify as an alternative, a measure proposed by the complaining Member must be not only less trade restrictive than the measure at issue, but should also 'preserve for the responding Member its right to achieve its desired level of protection with respect to the objective pursued'.

52. Recalling the sixth recital of the preamble to the TBT Agreement, the Appellate Body in US – Tuna II (Mexico) considered that "a WTO Member, by preparing, adopting, and applying a measure in order to pursue a legitimate objective, articulates either implicitly or explicitly the level at which it seeks to pursue that particular legitimate objective".

53. In US – COOL (Article 21.5 – Canada and Mexico), the Appellate Body observed that, while "Article 2.2 does not explicitly prescribe, in rigid terms, the sequence and order of analysis in assessing whether the technical regulation at issue is more trade restrictive than necessary", "a certain sequence and order of analysis may, nonetheless, flow logically from the nature of the examination under Article 2.2". The Appellate Body further explained that "panels are afforded a certain degree of latitude to tailor the sequence and order of analysis", which is "informed by the specific claims, measures, facts, and arguments at issue".

54. The absence of any required order of analysis was noted by the Panel in Australia – Tobacco Plain Packaging (Cuba), which stated that there is no a priori order of analysis that must be followed. Rather, the appropriate order of analysis will depend on the circumstances of the case at hand.

55. The Appellate Body in US – COOL (Article 21.5 – Canada and Mexico) also made several observations regarding a panel's assessment of the various factors involved in the determination of whether the measure is more trade-restrictive than necessary. Concerning the relevant factors in respect of the technical regulation itself, the Appellate Body opined that it will not always be possible to quantify a particular factor, or to do so with precision. The Appellate Body recalled that it had previously "considered that the demonstration of a limiting effect on competitive opportunities in qualitative terms might suffice in the particular circumstances of a given case". Regarding the factors pertaining to the comparison with alternative measures, the Appellate Body did not consider that a complainant must demonstrate that its proposed alternative measure achieves a degree of contribution "identical to that achieved by the challenged technical regulation in order for it to be found to achieve an equivalent degree". The Appellate Body further explained that:

"[F]or the purpose of assessing the equivalence between the respective degrees of contribution of the challenged technical regulation and the proposed alternative measures, it is the overall degree of contribution that the technical regulation makes to
the objective pursued that is relevant, rather than any individual isolated aspect or component of contribution.109\textsuperscript{110}

56. With respect to the obligation to "take account of the risks non-fulfilment would create", the Appellate Body opined that "the nature of the risks and the gravity of the consequences that would arise from non-fulfilment would themselves, in the first place, need to be identified".\textsuperscript{111} In this regard, the Appellate Body noted that:

"Article 2.2 does not prescribe further a particular methodology for assessing 'the risks non-fulfilment would create' or define how they should be 'taken account of'. However, in the context of Article XX of the GATT 1994, the Appellate Body has recognized that risks may be assessed in either qualitative or quantitative terms.\textsuperscript{112} Some kinds of risks might not be susceptible to quantification\textsuperscript{113}, and some types of risk assessment methods might not be of assistance in respect of particular kinds of objectives listed in Article XX of the GATT 1994.\textsuperscript{114}\textsuperscript{115}

57. In the context of assessing whether the technical regulation at issue was more trade-restrictive than necessary, the Panel in \textit{US – Clove Cigarettes} \textsuperscript{116} rejected the alternative measures proposed by the complainant because all of them involved a greater risk of non-fulfilment of the objective pursued by the technical regulation (reducing youth smoking):

"In addition, each of the alternative measures suggested by Indonesia appears to involve a greater risk of non-fulfilment of the objective of reducing youth smoking, as compared with the outright ban currently in place. In analysing the existence of alternative measures, we are required by the terms of Article 2.2 to take into account 'the risks that non-fulfilment would create'. Thus, Article 2.2 suggests that if an alternative means of achieving the objective of reducing youth smoking would involve greater 'risks of non-fulfilment', this may not be a legitimate alternative. This is consistent with the jurisprudence developed under Article XX(b) of the GATT 1994, pursuant to which the relevant question is, as explained above, whether there is one or more alternative measures that would make an 'equivalent' contribution to the achievement of the objective at the level sought. In our view, 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."\textsuperscript{116}

58. In \textit{Australia – Tobacco Plain Packaging (Cuba)}, the Panel examined Article 2.2 of the TBT Agreement in extensive detail.\textsuperscript{117} The Panel first focused on identifying the degree to which a measure contributes to its objective. The Panel explained that it needed to determine, based on the arguments and evidence before it, to what degree, if at all, the tobacco plain packaging measures contributed to Australia's objective of improving public health by reducing the use of, and exposure to, tobacco products. It noted that it needed to focus on ascertaining the actual contribution of the measures, as written and applied, to the objective.\textsuperscript{118}

59. The Panel considered it appropriate to begin its examination by analysing the "design, structure, and operation of the measures".\textsuperscript{119} In this connection, it noted the importance of examining the actual "impact" of the measure on smokers' behaviour, because modification of such
behaviour was the measure’s objective.120 With respect to the relative value of evidence concerning the measure as written, on the one hand, and the actual impact of the measure, on the other hand, the Panel explained that:

"[T]he relative weight to be attributed to specific evidence, including evidence relating to the design, structure and intended operation of the measures, on the one hand, and evidence relating to their application, on the other hand, will depend on the nature and quality of such evidence and its probative value for the question before us."121

60. The Panel also emphasized the importance of examining the contribution of the challenged measures within their broader regulatory context. However, the Panel noted that examining the challenged measures in their context does not reduce the need for a panel to identify as precisely as possible the contribution made by the challenged measures themselves.122

61. Additionally, the Panel noted that the contribution to an objective made by a measure will sometimes only be measurable over the medium- or long-term.123 The Panel explained that the available evidence, as well as possible limitations in, or unavailability of, certain evidence, may need to be understood in the light of that possibility.124 The Panel noted that, in such circumstances, not only data relating to the past and the present, but also "quantitative projections" and "qualitative reasoning based on a set of hypotheses that are tested and supported by sufficient evidence" may be relevant to a panel’s assessment.125

62. Moving on to assess the meaning of the term "trade-restrictiveness", the Panel noted that the way in which trade-restrictiveness is demonstrated to exist will depend on the circumstances of a given case. The Panel noted that such demonstration "could be based on qualitative or quantitative arguments and evidence, or both, including evidence relating to the characteristics of the challenged measure as revealed by its design and operation".126

63. The Panel also explained that there is no need for a complaining party to demonstrate the existence of a trade-restrictive effect on the trade of all WTO Members in all products that are subject to the technical regulation. Thus, according to the Panel, a Member could demonstrate the existence of a trade restriction on a particular product in which it trades, even if the trade(s) of other Member(s) has increased.127

64. The Panel next observed that "demonstration that the challenged measures may result in some alteration of the overall competitive environment for suppliers on the market would not, in itself, demonstrate their trade-restrictiveness within the meaning of Article 2.2".128 According to the Panel, the existence of some modification "of the conditions under which all manufacturers will compete against each other on the market, would [not], in itself, be sufficient to demonstrate the[] trade-restrictiveness" of the measures at issue. Rather, what must be established is that the challenged measures have a "limiting effect on international trade".129 Thus, according to the Panel, a complainant needs to show how any modification of the conditions of competition give rise to a limiting effect on international trade.130

65. In this connection, the Panel further explained that:

"[A]ppropriate evidence of such limiting effect will in particular be required in the case of a non-discriminatory internal measure. We do not consider, however, that this demonstration must be based on actual trade effects. Rather, it could in principle be based on a qualitative assessment, taking into account in particular the design and

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120 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.495.
121 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.499.
122 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.506.
123 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.938.
124 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.940.
125 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.982.
126 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1076.
127 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1078.
128 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1166.
129 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1166.
130 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1167.
operation of the measures, or on a quantitative assessment of its actual trade effects, or both".131

66. The Panel observed that, in assessing whether a restriction exists, the standard applied in determining the existence of a restriction under Article XI of the GATT 1994 may be relevant.132 In this connection, the Panel observed that under certain circumstances, the adoption of a technical regulation may impose costs that are not, or not exclusively, ongoing in nature. In the Panel's view, such "initial compliance costs"133 could be of such a magnitude or nature as to limit the competitive opportunities available to imported products and thereby have a limiting effect on trade.134 However, the Panel was not persuaded that the existence of any level of costs associated with initial compliance with a technical regulation will be sufficient, in and of itself, to demonstrate that a technical regulation is trade-restrictive.135 The Panel explained:

"[A] technical regulation may create costs of such a magnitude or nature as to have a limiting effect on trade. However, it may also create a regulatory environment in which operating costs are reduced, thereby enhancing competitive opportunities and facilitating trade. For these reasons, we are not satisfied that the existence of some initial adaptation costs would in all cases be sufficient, in and of itself, to indicate that a technical regulation has a limiting effect on trade. The extent to which such costs may be trade-restrictive must, in our view, be assessed on a case-by-case basis".136

67. Additionally, the Panel stated that a technical regulation imposing costly penalties on importation may, in the circumstances of a given case, have a limiting effect on trade and, as a result, be trade-restrictive.137 However, the Panel did not consider that:

"[T]he imposition of penalties to ensure compliance with the requirements of the TPP measures results, in itself, in an "additional" limiting effect on imports beyond what would be induced by full compliance with the TPP requirements themselves, which is what the penalties seek to ensure. We are not persuaded, therefore, that the existence of these penalties, or their level, lead to a greater degree of trade-restrictiveness than that arising from compliance with the relevant requirements of the TPP measures (which we have concluded, above, have not been demonstrated to be trade-restrictive)".138

68. The Panel next turned to examine "the gravity of the consequences of non-fulfilment". It observed that:

"[A] Panel's assessment of 'the risks non-fulfilment would create' entails, in the first place, identifying the nature and gravity of the 'risks non-fulfilment would create', and that this does not entail a comparison of the challenged measures and possible alternative measures, or a consideration of their respective degrees of contribution to the objective. Rather, such identification involves assessing the following two key aspects: the nature of the risks and the gravity of the consequences of non-fulfilment of the objective of the challenged measures".139

69. Finally, the Panel turned to examine the importance of comparing the challenged measures with possible alternative measures. The Panel observed that:

"[F]or a proposed alternative measure to form the basis of a determination that the challenged measure is more trade-restrictive than necessary, it would need to cumulatively satisfy all of the elements of the comparative analysis. It would thus need to be demonstrated that a proposed alternative measure would not only be less trade-restrictive than the challenged measures, but also that it would make at least an

131 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1168.
132 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1230.
133 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1242.
134 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1234.
135 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1235.
136 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1235.
137 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1248.
138 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1254.
139 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1321.
equivalent contribution to the objective being pursued through the challenged measure, and be 'reasonably available' to the Member as an alternative to the challenged measures".\textsuperscript{140}

70. With respect to identifying valid alternative measures, the Panel observed that a proposed measure may be a valid alternative even if it already exists in some form in the legal system of the responding Member. According to the Panel:

"[W]here it exists in the responding Member, albeit in a different form from that proposed by the complainant. In such a case, it is the variation proposed by the complainants as a substitute for the challenged measure that would be the subject of the comparative analysis under Article 2.2 of the TBT Agreement, including of whether that variation of an existing measure would make an equivalent contribution to the objective pursued by the responding Member".\textsuperscript{141}

71. The Panel explained that where such a variation is proposed, the responding Member will bear the burden of showing why such variation is not a valid alternative.\textsuperscript{142}

72. With respect to the degree of contribution that a proposed alternative must be apt to make, the Panel stated that a proposed alternative measure may achieve an equivalent degree of contribution in ways different from the technical regulation at issue. In the view of the Panel, what is relevant is the overall degree of contribution that the technical regulation makes to the objective pursued, rather than any individual isolated aspect or component of contribution.\textsuperscript{143}

73. With respect to assessing whether a proposed alternative makes an equivalent contribution to the objectives, the Panel stated that the time-frame within which the effects of a measure may be expected to arise could be pertinent in assessing the degree of contribution that a proposed alternative may make.\textsuperscript{144} It also suggested that a proposed alternative may not make an equivalent contribution to the challenged measure if the alternative entails greater risks of non-fulfilment of the relevant objectives.\textsuperscript{145}

74. Moreover, the Panel emphasized that, in assessing proposed alternative measures, regard must be had to the broader regulatory context in which the challenged measures exist, and how the challenged measures work together with other measures to achieve the desired objective.\textsuperscript{146} In this connection, the Panel stated:

"While different measures may have the capacity to contribute through various means to the same objective of reducing the use of, and exposure to, tobacco products, this does not imply that they would be interchangeable or substitutable, and thereby constitute ‘alternatives’ to each other, where each measure is intended to address a distinct aspect of a multifaceted problem, and where the comprehensive and complementary nature of the measures is an integral part of the approach pursued. In such a context, the removal of one element of the comprehensive policy may, as the Appellate Body has described it, weaken the policy by reducing the synergies between its components, as well as its total effect".\textsuperscript{147}

75. With respect to the reasonable availability of proposed alternatives, the Panel noted past Appellate Body jurisprudence that "undue burdens and prohibitive" costs may limit the availability of an alternative. The Panel further explained that:

"The relevant costs that may be taken into consideration include the enforcement and implementation costs incurred by the regulating Member, but may also include 'significant costs or difficulties faced by the affected industry, in particular where such

\textsuperscript{140} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1364.
\textsuperscript{141} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1682.
\textsuperscript{142} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1573.
\textsuperscript{143} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1454.
\textsuperscript{144} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1462.
\textsuperscript{145} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1528.
\textsuperscript{146} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1391.
\textsuperscript{147} Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1528.
costs or difficulties could affect the ability or willingness of the industry to comply with the requirements of that measure”.148

76. Summarizing its extensive discussion under Article 2.2, the Panel reiterated the following guidelines with respect to reviewing proposed alternative measures:

"[A] proposed alternative measure need not contribute to the objective to a degree that is identical to the measure at issue, and that a proposed alternative measure may achieve an equivalent degree of contribution in ways different from the technical regulation at issue. However, as discussed above, we do not understand this to imply that, where the concern being addressed is of a multifaceted nature and legitimately involves a multidimensional response, one aspect of a comprehensive strategy could be substituted for another, where they would address different aspects of the problem. In addition, a panel's 'margin of appreciation' in assessing equivalence should be informed by the risks that non-fulfilment of the technical regulation's objective would create, the nature of the risks and the gravity of the consequences arising from the non-fulfilment of the technical regulation's objective, the characteristics of the technical regulation at issue as revealed through its design and structure, the nature of the objective pursued, and the nature, quantity and quality of the evidence available".149

1.3.2.2.1 Burden of proof

77. The Appellate Body in US – COOL elaborated on the burden of proof under Article 2.2 of the TBT Agreement as follows:

"In order to demonstrate that a technical regulation is inconsistent with Article 2.2, the complainant must make a prima facie case by presenting evidence and arguments sufficient to establish that the challenged measure is more trade restrictive than necessary to achieve the contribution it makes to the legitimate objective, taking account of the risks non-fulfilment would create. A complainant may, and in most cases will, also seek to identify a possible alternative measure that is less trade restrictive, makes an equivalent contribution to the relevant objective, and is reasonably available. It is then for the respondent to rebut the complainant's prima facie case by presenting evidence and arguments showing that the challenged measure is not more trade restrictive than necessary to achieve the contribution it makes toward the objective pursued, for example, by demonstrating that the alternative measure identified by the complainant is not, in fact, "reasonably available", is not less trade restrictive, or does not make an equivalent contribution to the achievement of the relevant legitimate objective."150

1.4 Article 2.3

78. In the context of interpreting Article 2.4 of the TBT Agreement, the Panel in EC – Sardines noted with respect to Article 2.3:

"The language of Article 2.3 suggests that Members are to eliminate technical regulations that no longer serve their purpose or amend them if the changed circumstances or objectives can be addressed in a less trade-restrictive manner. This requirement also applies to technical regulations that were enacted before the TBT Agreement came into force. Thus, Members would be under an obligation to periodically evaluate their technical regulations and either discontinue them if they no longer serve their objectives or change them if there is a less trade-restrictive manner in which to achieve the underlying objectives of the regulations."151

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148 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1709.
149 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.1722.
151 Panel Report, EC – Sardines, para. 7.81.
1.5 Article 2.4

1.5.1 General

1.5.1.1 Three-step analysis

152 Referring to the findings of the Panel and the Appellate Body EC – Sardines, the Panel in US – Tuna II (Mexico) considered the following three elements in its assessment of Mexico’s claim under Article 2.4 of the TBT Agreement: (i) the existence or imminent completion of a relevant international standard; (ii) whether the international standard has been used as a basis for the technical regulation; and (iii) whether the international standard is an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, taking into account fundamental climatic or geographical factors or fundamental technological problems.

1.5.1.2 Temporal scope of application

80. In EC – Sardines, the Appellate Body upheld the panel’s finding that Article 2.4 applies not only to the "preparation and adoption" of technical regulations, but also to the "application" of existing measures adopted prior to 1 January 1995, such as the EC regulations that were adopted in June 1989 and continued to exist. In reviewing the Panel’s reasoning, the Appellate Body agreed with the following analysis:

"Article 2.4 of the TBT Agreement starts with the language 'where technical regulations are required'. We construe this expression to cover technical regulations that are already in existence as it is entirely possible that a technical regulation that is already in existence can continue to be required. ... Moreover, we note that the first part of the sentence of Article 2.4 is in the present tense ('exist') and not in the past tense – '[w]here technical regulations are required and relevant international standards exist or their completion is imminent', Members are obliged to use such international standards as a basis. This supports the view that Members have to use relevant international standards that currently exist or whose completion is imminent with respect to the technical regulations that are already in existence. We do not consider that the word 'imminent', the ordinary meaning of which is 'likely to happen without delay', is intended to limit the scope of the coverage of technical regulations to those that have yet to be adopted. Rather, the use of the word 'imminent' means that Members cannot disregard a relevant international standard whose completion is imminent with respect to their existing technical regulations."

81. In EC – Sardines, the Appellate Body also agreed with the Panel that the Appellate Body’s findings in EC – Hormones with respect to the applicability of the SPS Agreement to measures enacted before 1995 that continue to be in force thereafter were relevant to its analysis.

82. In EC – Sardines, the Appellate Body further agreed with the Panel’s reliance on Articles 2.5 and 2.6 as relevant context in the interpretation of Article 2.4, supporting the conclusion that Article 2.4 is applicable to measures enacted before the TBT Agreement that continue to be in force thereafter. In this regard, the Panel had noted that Article 2.5 speaks of "preparing, adopting or applying" a technical regulation, while Article 2.6 states that Members are to participate in preparing international standards by the international standardizing bodies for products which they have either "adopted, or expect to adopt technical regulations."


157 Panel Report, EC – Sardines, paras. 7.75-7.76.
Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements”.\textsuperscript{158}

1.5.2 Relevant international standard

1.5.2.1 "International standard"

83. The Appellate Body in \textit{US – Tuna II (Mexico)} provided a number of clarifications with respect to the meaning of the concept of "international standard" in Article 2.4, based on the contextual elements of the TBT Agreement, the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities\textsuperscript{159} (the "ISO/IEC Guide 2: 1991"), and taking into account the TBT Committee Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5, and Annex 3 to the Agreement (the "TBT Committee Decision")\textsuperscript{160}.

84. The Appellate Body began its analysis by observing that the composite term "international standard" is not defined in Annex 1 of the TBT Agreement. The Appellate Body noted, however, that Annex 1.2 to the TBT Agreement defines a "standard" as follows:

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

\textit{Explanatory note}

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.\textsuperscript{161}

85. The Appellate Body then turned to the definition of "international standard" in the ISO/IEC Guide 2: 1991 and observed:

"The introductory clause of Annex 1 to the \textit{TBT Agreement} provides that terms used in the \textit{TBT Agreement} that are also 'presented' in the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities (the 'ISO/IEC Guide 2: 1991') 'shall ... have the same meaning as given in the definitions in the said Guide'. The term 'international standard' is defined in the ISO/IEC Guide 2: 1991 as a 'standard that is adopted by an international standardizing/standards organization and made available to the public.' This definition suggests that it is primarily the characteristics of the entity approving a standard that lends the standard its 'international' character."\textsuperscript{162}

86. The Appellate Body noted that the use of the word "however" in the introductory clause of Annex 1 to the TBT Agreement indicates that the definitions contained in that Annex prevail to the


\textsuperscript{160} Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement, in WTO document G/TBT/1/Rev.10, Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995, 9 June 2011, pp. 46-48.

\textsuperscript{161} Appellate Body Report, \textit{US – Tuna II (Mexico)}, para. 350.

\textsuperscript{162} Appellate Body Report, \textit{US – Tuna II (Mexico)}, paras. 351-353.
extent that they depart from the definitions set out in the ISO/IEC Guide 2: 1991. Because the definition of a "standard" in Annex 1.2 of the TBT Agreement refers to a "body" and Annex 1.4 of the TBT Agreement defines an "international body or system", the Appellate Body found that "in order to constitute an 'international standard', a standard has to be adopted by an 'international standardizing body' for the purposes of the TBT Agreement". 

87. On the basis of other contextual elements of ISO/IEC Guide 2: 1991 and Article 1.5 of the TBT Agreement, the Appellate Body further considered that:

"[A] required element of the definition of an 'international' standard for the purposes of the TBT Agreement is the approval of the standard by an 'international standardizing body', that is, a body that has recognized activities in standardization and whose membership is open to the relevant bodies of at least all Members." 

88. With respect to the question of what it means for the activities of an international standardizing body to be "recognized", the Appellate Body observed that the definitions of the term "recognize" "fall along a spectrum that ranges from a factual end (acknowledgement of the existence of something) to a normative end (acknowledgement of the validity or legality of something)" and noted that the former "would appear to require, at a minimum, that WTO Members are aware, or have reason to expect, that the international body in question is engaged in standardization activities".

89. Regarding the requirement in Annex 1.4 of the TBT Agreement that the membership in an international standardizing body must be "open to the relevant bodies of at least all Members", the Appellate Body noted that:

"The term 'open' is defined as 'accessible or available without hindrance', 'not confined or limited to a few; generally accessible or available'. Thus, a body will be open if membership to the body is not restricted. It will not be open if membership is a priori limited to the relevant bodies of only some WTO Members." 

90. With reference to the TBT Committee Decision, which it considered to be a "subsequent agreement" within the meaning of Article 31(3)(a) of the Vienna Convention, the Appellate Body additionally clarified that:

"[I]n order for a standardizing body to be considered 'international' for the purposes of the TBT Agreement, it is not sufficient for the body to be open, or have been open, at a particular point in time. Rather, the body must be open 'at every stage of standards development'.

Moreover, the TBT Committee Decision clarifies that a standardizing body must be open 'on a non-discriminatory basis'. Thus, provisions for accession that de jure or de facto disadvantage the relevant bodies of some Members as compared to other Members would tend to indicate that a body is not an 'international' standardizing body for the purposes of the TBT Agreement." 

91. In applying this interpretation of the terms "international standard" to the case at hand, the Appellate Body in US – Tuna II (Mexico) concluded that the Panel had erred in finding that the AIDCP was open to the relevant bodies of at least all Members, on the ground that the invitation to accede to the AIDCP was not issued automatically to a WTO Member interested in joining but required instead a decision by consensus of the parties to the AIDCP. The Appellate Body also considered that the Panel had erred in finding that it had to consider whether the AIDCP standard

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169 The Agreement on the International Dolphin Conservation Program.
was adopted by an international standardizing "organization", rather than by an international standardizing "body". 171

92. In EC – Sardines, the Appellate Body upheld the Panel's conclusion that even if not adopted by consensus, a standard adopted by a "recognized body" of the international standardization community can constitute a "relevant international standard". 172 The Appellate Body agreed with the following interpretation by the Panel of the last two sentences of the Explanatory note to the definition of the term "standard" contained in Annex 1.2:

"The first sentence reiterates the norm of the international standardization community that standards are prepared on the basis of consensus. The following sentence, however, acknowledges that consensus may not always be achieved and that international standards that were not adopted by consensus are within the scope of the TBT Agreement. This provision therefore confirms that even if not adopted by consensus, an international standard can constitute a relevant international standard." 173

93. Based on its own textual interpretation of the Explanatory note to the definition of the term "standard" contained in Annex 1.2, the Appellate Body considered that consensus is not required for standards adopted by the international standardizing community. 174 The Appellate Body also found that the Panel's interpretation gave effect to the chapeau of Annex 1 to the TBT Agreement, which provides that the terms defined in Annex 1 apply for the purposes of the TBT Agreement if their definitions depart from those in the ISO/IEC Guide 2:1991. The Appellate Body observed that, as the definition of a "standard" in the ISO/IEC Guide includes a consensus requirement, "the omission of a consensus requirement in the definition of a "standard" in Annex 1.2 of the TBT Agreement was a deliberate choice on the part of the drafters of the TBT Agreement, and that the last two phrases of the Explanatory note were included to give effect to this choice". 175

1.5.2.2 "Relevant"

94. In EC – Sardines, the Panel adopted the following analysis of whether the standard at issue in that dispute (Codex Stan 94) was a "relevant" international standard:

"Having determined that Codex Stan 94 is an international standard, the analysis turns to whether Codex Stan 94 is a 'relevant' international standard in respect of the EC Regulation. We note that the ordinary meaning of the term 'relevant' is 'bearing upon or relating to the matter in hand; pertinent'. Based on the ordinary meaning, Codex Stan 94 must bear upon, relate to or be pertinent to the EC Regulation for it to be a relevant international standard." 176

95. Given that both the EC Regulation and Codex Stan 94 dealt with the same product, namely preserved sardines, the Panel in EC – Sardines found that Codex Stan 94 was a relevant international standard. 177 The Appellate Body agreed with the Panel's interpretation of the ordinary meaning of the term "relevant" and its conclusion that that Codex Stan 94 was a "relevant international standard" for purposes of Article 2.4 of the TBT Agreement in that dispute. 178

96. In US – COOL, the Panel noted the parties' disagreement on whether CODEX-STAN 1-1985 was a "relevant" international standard within the meaning of Article 2.4 and observed:

"In this context, we also recall that the SPS Agreement recognizes the relevance of the Codex Alimentarius Commission by acknowledging that for food safety, international standards, guidelines and recommendations are the ones established by the Codex

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174 Appellate Body Report, EC – Sardines, paras. 222-223
176 Panel Report, EC – Sardines, para. 7.68.
1.5.3 "Shall use them... as a basis for"

97. In EC – Sardines, the Appellate Body considered the European Union's argument on appeal concerning the finding by the Panel that the relevant international standard (Codex Stan 94) was not used as a basis for the technical regulation at issue (EC Regulation). The European Union argued on appeal that a rational relationship between an international standard and a technical regulation is sufficient to conclude that the former is used "as a basis for" the latter.

98. In the course of its analysis, the Panel had noted that Article 2.4 states that Members "shall use" international standards "as a basis" for their technical regulation and considered that the word "shall" denotes a requirement that is obligatory in nature and that goes beyond mere encouragement. While this statement by the Panel was not appealed, the Appellate Body recalled, at the outset of its own analysis, that "Article 2.4 of the TBT Agreement requires Members to use relevant international standards 'as a basis for' their technical regulations under certain circumstances". In reviewing the analysis conducted by the Panel, the Appellate Body agreed with the Panel's conclusion that an international standard is used "as a basis for" a technical regulation "when it is used as the principal constituent or fundamental principle for the purpose of enacting the technical regulation". Having noted other similar dictionary definitions of the word "basis", the Appellate Body observed:

"From these various definitions, we would highlight the similar terms 'principal constituent', 'fundamental principle', 'main constituent', and 'determining principle' – all of which lend credence to the conclusion that there must be a very strong and very close relationship between two things in order to be able to say that one is 'the basis for' the other."

99. Turning to the European Union's contention, the Appellate Body considered that, while it did not need "to define in general the nature of the relationship that must exist for an international standard to serve 'as a basis for' a technical regulation", there was also no support for the European Union's argument that the existence of a "rational relationship" is the appropriate criterion for determining whether something has been used "as a basis for" something else. The Appellate Body, however, opined as follows:

"In our view, it can certainly be said – at a minimum – that something cannot be considered a 'basis' for something else if the two are contradictory. Therefore, under Article 2.4, if the technical regulation and the international standard contradict each other, it cannot properly be concluded that the international standard has been used 'as a basis for' the technical regulation."

100. With regard to the requirement in Article 2.4 that Members use relevant international standards "or the relevant parts of them" as a basis for their technical regulations, the Appellate Body further observed:

"In our view, the phrase 'relevant parts of them' defines the appropriate focus of an analysis to determine whether a relevant international standard has been used 'as a basis for' a technical regulation. In other words, the examination must be limited to those parts of the relevant international standards that relate to the subject-matter of the challenged prescriptions or requirements. In addition, the examination must be broad enough to address all of those relevant parts; the regulating Member is not permitted to select only some of the 'relevant parts' of an international standard. If a
part is relevant, then it must be one of the elements which is a basis for the technical regulation.186

1.5.4 Ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued

1.5.4.1 "Legitimate objectives pursued"

101. In EC – Sardines, the Panel noted that the "legitimate objectives' referred to in Article 2.4 must be interpreted in the context of Article 2.2", which provides an illustrative, open list of objectives considered "legitimate".187 The Panel then considered that, while "it is up to the Members to decide which policy objectives they wish to pursue and the levels at which they wish to pursue them", panels are required to determine the legitimacy of those objectives.188 The Appellate Body agreed with the Panel that "the 'legitimate objectives' referred to in Article 2.4 must be interpreted in the context of Article 2.2" and also shared the Panel's view that Article 2.4 implies that there must be an examination and a determination on the legitimacy of the objectives of the measure.189

1.5.4.2 "Ineffective or inappropriate means"

102. In considering the meaning of the terms "ineffective" and "inappropriate", the Panel in EC – Sardines noted that "ineffective" refers to something which is not "having the function of accomplishing", "having a result", or "brought to bear", whereas "inappropriate" refers to something which is not "specially suitable", "proper", or "fitting".190 The Panel thus held that in the context of Article 2.4 of the TBT Agreement:

"[A]n ineffective means is a means which does not have the function of accomplishing the legitimate objective pursued, whereas an inappropriate means is a means which is not specially suitable for the fulfilment of the legitimate objective pursued. An inappropriate means will not necessarily be an ineffective means and vice versa. That is, whereas it may not be specially suitable for the fulfilment of the legitimate objective, an inappropriate means may nevertheless be effective in fulfilling that objective, despite its 'unsuitability'. Conversely, when a relevant international standard is found to be an effective means, it does not automatically follow that it is also an appropriate means. The question of effectiveness bears upon the results of the means employed, whereas the question of appropriateness relates more to the nature of the means employed."191

103. The Appellate Body agreed with the Panel's interpretation of the terms "ineffective" and "inappropriate" and "that it is conceptually possible that a measure could be effective but inappropriate, or appropriate but ineffective".192

104. In the context of its assessment of whether the relevant international standard (CODEX-STAN 1-1985) was an effective and appropriate means of fulfilling the objective pursued by the United States, the Panel in US – COOL followed the reasoning of the Panel in EC – Sardines and considered that "CODEX-STAN 1-1985 would be effective if it had the capacity to accomplish the objective, and it would be appropriate if it were suitable for the fulfilment of the objective".193 Applying this analytical framework, the Panel found that CODEX-STAN 1-1985 was ineffective and inappropriate for the fulfilment of the specific objective as defined by the United States because it did not "have the function or capacity of accomplishing the objective of providing information to consumers about the countries in which an animal was born, raised and slaughtered".194

188 Panel Report, EC – Sardines, paras. 7.120-7.121.
189 Appellate Body Report, EC – Sardines, paras. 7.120-7.121.
1.5.4.3 Burden of proof

105. In EC – Sardines, the Appellate Body disagreed with the Panel that the burden of proof to demonstrate that the relevant international standard is an "ineffective or inappropriate" means to fulfil the "legitimate objectives" pursued rests with the respondent.\textsuperscript{195} The Appellate Body criticised the Panel for not following the Appellate Body's reasoning in EC – Hormones on the allocation of the burden of proof under Article 3.3 of the SPS Agreement:

"Given the conceptual similarities between, on the one hand, Articles 3.1 and 3.3 of the SPS Agreement and, on the other hand, Article 2.4 of the TBT Agreement, we see no reason why the Panel should not have relied on the principle we articulated in EC – Hormones to determine the allocation of the burden of proof under Article 2.4 of the TBT Agreement. In EC – Hormones, we found that a 'general rule–exception' relationship between Articles 3.1 and 3.3 of the SPS Agreement does not exist, with the consequence that the complainant had to establish a case of inconsistency with both Articles 3.1 and 3.3. We reached this conclusion as a consequence of our finding there that 'Article 3.1 of the SPS Agreement simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement'. Similarly, the circumstances envisaged in the second part of Article 2.4 are excluded from the scope of application of the first part of Article 2.4. Accordingly, as with Articles 3.1 and 3.3 of the SPS Agreement, there is no 'general rule–exception' relationship between the first and the second parts of Article 2.4."\textsuperscript{196}

106. The Appellate Body therefore found that, in the case at hand, it was for Peru – "as the complaining Member seeking a ruling on the inconsistency with Article 2.4 of the TBT Agreement of the measure applied by the European Communities" – to bear the burden of establishing that Codex Stan 94 had not been used "as a basis for" the EC Regulation, as well as establishing that Codex Stan 94 was effective and appropriate to fulfil the "legitimate objectives" pursued by the European Communities through the EC Regulation.\textsuperscript{197}

1.6 Article 2.5

1.6.1 General

107. The Panel in US – Clove Cigarettes noted that:

"Article 2.5 contains two sentences: a first sentence regarding the explanation that Members are to provide, at the request of another Member, about the justification for their technical regulations; and a second sentence, which establishes a rebuttable presumption of compliance with the first sentence of Article 2.2 for those technical regulations that are prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in Article 2.2, and that are in accordance with relevant international standards."\textsuperscript{198}

1.6.2 First sentence

108. The Appellate Body in EC – Sardines observed that Article 2.5 of the TBT Agreement "establishes a compulsory mechanism requiring the supplying of information by the regulating Member".\textsuperscript{199}

109. The Panel in US – Clove Cigarettes considered that the first sentence of Article 2.5 includes the following four elements: "(i) the Member in question is 'preparing, adopting or applying a technical regulation'; (ii) this measure 'may have a significant effect on trade of other Members'; (iii) there is a 'request of another Member'; and (iv) the Member in question is to 'explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4' of

\textsuperscript{195} Appellate Body Report, EC – Sardines, para. 282.
\textsuperscript{197} Appellate Body Report, EC – Sardines, para. 282.
\textsuperscript{198} Panel Report, US – Clove Cigarettes, para. 7.447.
\textsuperscript{199} Appellate Body Report, EC – Sardines, para. 277.
Article 2.2 The Panel found that "Indonesia did not make a request pursuant to the first sentence of Article 2.5 of the TBT Agreement." The Panel thus concluded that one of the necessary elements of Article 2.5 was missing, and rejected Indonesia's claim.

1.6.3 Second sentence

1.1 In Australia – Tobacco Plain Packaging (Cuba), the Panel considered in some detail the meaning of the second sentence of Article 2.5. The Panel noted that, although Articles 2.4 and 2.5 of the TBT Agreement are similarly worded, the latter is narrower in scope than the former (since it only applies to technical regulations that pursue one of the legitimate objectives explicitly mentioned in Article 2.2), and also requires a closer connection between the measure at issue and the relevant international standard (since Article 2.5 requires that the measure at issue be "in accordance with" the relevant international standard, rather than merely relying on "the relevant parts" thereof).

1.2. Despite these differences, the Panel held the guidance provided in previous cases concerning the meaning of the term "international standard" as used in Article 2.4 of the TBT Agreement would be "equally relevant" to the meaning of the term as used in Article 2.5. Thus, according to the Panel, for an instrument to be considered an "international standard" under Article 2.5, it would need to (a) constitute a "standard" under Annex 1.2 of the TBT Agreement, and (b) be "international", a condition primarily predicated upon whether it was adopted by an "international standardizing body".

1.3. With respect to point (a), the Panel emphasized that a clear and distinctive identification of all components of the instrument that comprise the standard is necessary to allow an assessment of whether a "standard" exists and whether a challenged measure is "in accordance with" it.

1.4. The Panel also noted that the burden rests on the party invoking the presumption to demonstrate that all of the conditions under the second sentence of Article 2.5 are satisfied.

1.7 Article 2.6

110. In EC – Sardines, the Panel referred to Article 2.6 as providing contextual support for its conclusion that Article 2.4 applied to existing technical regulations:

"Article 2.6 provides another contextual support. It states that Members are to participate in preparing international standards by the international standardizing bodies for products which they have either 'adopted, or expect to adopt technical regulations.' Those Members that have in place a technical regulation for a certain product are expected to participate in the development of a relevant international standard."

1.8 Article 2.8

1.8.1 Object and purpose

111. The Panel in US – Clove Cigarettes considered that the object and purpose of Article 2.8 is to avoid the creation of unnecessary obstacles to trade by requiring that product requirements be laid down in "functional" terms, wherever appropriate:

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201 Panel Report, US – Clove Cigarettes, para. 7.460.
203 Panel Report, Australia – Tobacco Plain Packaging (Cuba), paras. 7.270-7.289.
204 Panel Report, Australia – Tobacco Plain Packaging (Cuba), paras. 7.272 and 7.275.
206 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.286.
207 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.286.
208 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.286.
209 Panel Report, Australia – Tobacco Plain Packaging (Cuba), para. 7.286.
210 Panel Report, EC – Sardines, para. 7.76.
"[T]he object and purpose of Article 2.8 is to avoid the creation of unnecessary obstacles to trade by requiring that product requirements be laid down in functional terms wherever appropriate. For example, an ISO/IEC Directive explains that:

'Whenever possible, requirements shall be expressed in terms of performance rather than design or descriptive characteristics. This approach leaves maximum freedom to technical development. Primarily those characteristics shall be included that are suitable for worldwide (universal) acceptance.'

Along the same lines, a Decision taken by the TBT Committee in 2000 reflects the understanding of WTO Members that:

'In order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics.'

1.8.2 "Wherever appropriate"

In US – Clove Cigarettes, the United States (respondent) did not dispute that the technical regulation at issue was specified in terms of "design or descriptive characteristics", and not in terms of "performance". The Panel considered whether it would be "appropriate" to specify the ban on clove cigarettes imposed by that technical regulation in terms of "performance", rather than in terms of "design or descriptive characteristics". Relying on the ordinary meaning of the word "appropriate", as reflected in prior case law, the Panel considered that the relevant question before it was "whether Indonesia ha[d] demonstrated that it would be 'proper', 'fitting', and 'suitable' to formulate the technical regulation in Section 907(a)(1)(A) in terms of 'performance'". The Panel ultimately rejected Indonesia's claim under Article 2.8 because Indonesia had failed to demonstrate that it was "appropriate" to formulate the technical regulation in question in terms of "performance".

1.9 Article 2.9

1.9.1 "May have a significant effect on trade of other Members"

In US – Clove Cigarettes, the Panel concluded that the technical regulation had "a significant effect" on Indonesia's trade in clove cigarettes because it prohibited the importation of those cigarettes into the United States. In reaching that conclusion, the Panel provided the following interpretation of the phrase "may have a significant effect on trade of other Members":

"We observe that the wording of this second condition for the applicability of Article 2.9 is that the technical regulation 'may have a significant effect on trade of other Members' as opposed to 'will have a significant effect' or 'has a significant effect'. 'May' is used to express a possibility as opposed to a certainty. We therefore interpret these terms to mean that Article 2.9 of the TBT Agreement does not require proving actual trade effects. Rather, this condition encompasses situations in which a technical regulation may have a significant effect on trade of other Members.

We further observe that Article 2.9 of the TBT Agreement refers to a 'significant' effect. Significant means 'sufficiently great or important to be worthy of attention; noteworthy'.

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211 Panel Report, US – Clove Cigarettes, paras. 7.481-7.482.
212 Panel Report, US – Clove Cigarettes, para. 7.491.
We thus agree with the United States that a 'significant effect' encompasses all non de minimis effects on trade."^214

1.9.2 Article 2.9.2

114. In US – Clove Cigarettes, the Panel found that the United States had acted inconsistently with Article 2.9.2 by failing to notify the technical regulation at issue. In the course of its analysis, the Panel made the following observations regarding the scope of the obligation under Article 2.9.2:

"We note that Article 2.9.2, unlike Article 2.9.3, does not link the obligation to notify to the request of a Member.

We also note that Article 2.9.2 of the TBT Agreement applies to 'proposed' technical regulations. Along the same lines, the French version of Article 2.9.2 of the TBT Agreement uses the terms 'le règlement technique projeté', and the Spanish version of Article 2.92 of the TBT Agreement uses the terms 'el reglamento técnico en proyecto'. 'To propose' can be defined as 'to put forward [a technical regulation] for consideration by others'. Article 2.9.2 of the TBT Agreement therefore applies to what we would refer to as legal instruments falling within the definition of a technical regulation that would still be in 'draft' form, i.e., not yet adopted or in force. The language of the second sentence of Article 2.9.2 of the TBT Agreement reinforces this conclusion as it indicates that the notification must take place 'at an early appropriate stage, when amendments can still be introduced and comments taken into account'. Therefore, since the provision foresees the possibility of amendments and comments, the technical regulation at issue cannot have been enacted or adopted before the notification takes place. In our view, Article 2.9.2 (as it is also the case with Article 5.6.2 for conformity assessment procedures) is at the core of the TBT Agreement's transparency provisions: the very purpose of the notification is to provide opportunity for comment before the proposed measure enters into force, when there is time for changes to be made before 'it is too late'.'^216

1.9.3 Article 2.9.3

115. In US – Clove Cigarettes, the Panel rejected a claim under Article 2.9.3 on the grounds that while there was a request to provide particulars or copies of the technical regulation, it was not made until after the technical regulation had been enacted. Accordingly, the Panel found that the situation fell outside the scope of Article 2.9.3, which applies only to "proposed" technical regulations:^217:

"We note that, unlike the case of Article 2.9.2 of the TBT Agreement, the obligation to provide particulars or copies of a proposed technical regulation imposed by Article 2.9.3 of the TBT Agreement is only triggered by the request of a Member. However, as is the case with Article 2.9.2 of the TBT Agreement, such an obligation is limited to 'proposed technical regulations', i.e., technical regulations which are still in draft form and thus, as explained above, amendments can still be introduced and comments taken into account.^218

1.10 Article 2.10

1.10.1 Relationship with Article 2.9

116. In US – Clove Cigarettes, the Panel observed that "Article 2.10 of the TBT Agreement allows WTO Members to omit the requirements imposed by Article 2.9 of the TBT Agreement with respect

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^218 Panel Report, US – Clove Cigarettes, para. 7.545.
to proposed technical regulations, where certain urgent problems arise or threaten to arise". 219 The Panel further noted that:

"[T]he obligations under Article 2.10 of the TBT Agreement are only applicable when a Member omitted the steps enumerated in Article 2.9 of the TBT Agreement because 'urgent problems of safety, health, environmental protection or national security arise or threaten to arise'. In our view, the fact that Article 2.10 of the TBT Agreement only applies when a Member is departing from the general obligations established in Article 2.9 of the TBT Agreement entails that these two provisions have two distinct and separate scopes. Indeed, we see no situation in which a WTO Member's actions would fall within the scope of both obligations at the same time. Either the Member in question follows the general requirements under Article 2.9 of the TBT Agreement, or it decides to omit those requirements owing to any of the listed 'urgent problems' described in Article 2.10 of the TBT Agreement." 220

1.11 Article 2.12

117. In US – Clove Cigarettes, the Appellate Body agreed with the Panel that paragraph 5.2 of the Doha Ministerial Decision constitutes a subsequent agreement between the parties, within the meaning of Article 31(3)(a) of the Vienna Convention, on the interpretation of the term "reasonable interval" in Article 2.12 of the TBT Agreement. 221 The Appellate Body thus interpreted Article 2.12, taking into account paragraph 5.2 of the Doha Ministerial Declaration:

"Thus, we consider that, taking into account the interpretative clarification provided by paragraph 5.2 of the Doha Ministerial Decision, Article 2.12 of the TBT Agreement establishes a rule that 'normally' producers in exporting Members require a period of 'not less than six months' to adapt their products or production methods to the requirements of an importing Member's technical regulation." 222

118. With regard to the interests of the importing Member, the Appellate Body observed:

"[T]he Doha Ministerial Decision tempers the obligation to provide a 'reasonable interval' of not less than six months between the publication and the entry into force of a technical regulation by stipulating that this obligation applies 'except when this would be ineffective in fulfilling the legitimate objectives pursued' by the technical regulation. Thus, while Article 2.12 of the TBT Agreement imposes an obligation on importing Members to provide a 'reasonable interval' of not less than six months between the publication and entry into force of a technical regulation, an importing Member may depart from this obligation if this interval 'would be ineffective to fulfil the legitimate objectives pursued' by the technical regulation." 223

119. Regarding the burden of proof under Article 2.12, the Appellate Body explained:

"In sum, under Article 2.12 of the TBT Agreement, as clarified by paragraph 5.2 of the Doha Ministerial Decision, a complaining Member is required to establish a prima facie case that the responding Member has failed to allow for a period of at least six months between the publication and the entry into force of the technical regulation at issue. If the complaining Member establishes such a prima facie case, the burden rests on the responding Member that has allowed for an interval of less than six months between the publication and the entry into force of its technical regulation to establish either: (i) that the 'urgent circumstances' referred to in Article 2.10 of the TBT Agreement surrounded the adoption of the technical regulation at issue; (ii) that producers of the complaining Member could have adapted to the requirements of the technical regulation at issue within the shorter interval that it allowed; or (iii) that a period of 'not less than'..."
six months would be ineffective to fulfil the legitimate objectives of its technical regulation."^{224}

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^{224} Appellate Body Report, *US – Clove Cigarettes*, para. 290.