UNITED STATES – MEASURES AFFECTING THE PRODUCTION AND SALE OF CLOVE CIGARETTES

(DS406)

Answers of the United States of America
to the First Set of Questions from the Panel to the Parties

January 6, 2011

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I. GENERAL CONSIDERATIONS

B. AS SUCH/ AS APPLIED CLAIMS

3. Both parties: In the event that Indonesia is raising "as applied" claims, should it be required to submit specific applications of a measure in order to properly raise an "as applied" challenge in accordance with Article 6.2 of the DSU?

1. Article 6.2 of the DSU requires a complaining Member to "identify the specific measures at issue." In the event that Indonesia is raising "as applied" claims, Indonesia should be required to provide specific applications of a measure in order properly to raise the claim.

D. INTERPRETATION

5. Both parties: Annex 1 of the *TBT Agreement* provides that the "terms presented in the sixth edition of the ISO/IEC Guide 2 1991, General Terms and Their Definitions Concerning Standardization and Related Activities, shall, when used in this Agreement, have the same meaning as given in the definitions in the said Guide taking into account that services are excluded from the coverage of this Agreement". Does the said Guide contain any definitions that are relevant in the present dispute? What is the relevance of the updated version of the ISO/IEC Guide?

2. As of this time, the United States has not identified any interpretive issues in this dispute that would call for reference to the 1991 ISO/IEC Guide. Given that the TBT Agreement specifically refers to the 1991 edition of the Guide, the United States is not aware of a reason to refer to subsequent editions.

6. Both parties: In the opinion of the parties, what is the legal value of paragraph 5.2 of the Doha Ministerial Decision on Implementation-related Issues and Concerns of 14 November 2001 (WT/MIN(01)/17)?

3. The Doha Ministerial Decision on Implementation-related Issues and Concerns is a decision of the Ministerial Conference. Its legal value is at most a means of supplemental interpretation within the meaning of Article 32 of the *Vienna Convention on the Law of Treaties* ("VCLT") that may be used to confirm the meaning of Article 2.12 based on an analysis of the ordinary meaning of the terms of that provision in their context and in light of the TBT Agreement's object and purpose in accordance with Article 31 of the VCLT.

4. While the Ministerial Decision may be used to confirm the meaning of the term "reasonable interval" it may not in and of itself be relied upon as the basis for concluding that that

term means not less than six months. As reviewed in the U.S. First Written Submission, the ordinary meaning of the term "reasonable" is "in accordance with reason; not irrational or absurd" and what is "reasonable" will necessarily vary based on the facts and circumstances of each case.[1]

5. While Article IX.2 of the Agreement Establishing the World Trade Organization ("Marrakesh Agreement") provides that the Ministerial Conference along with the General Council have "exclusive authority" to adopt interpretations of the WTO Agreement and sets out procedures for adopting such interpretations, the Ministerial Declaration is not such an interpretation. First, the Ministerial Decision does not purport to set forth an interpretation of the WTO Agreement. Nothing in the text of that decision refers to Article IX.2 of the Marrakesh Agreement nor indicates that the procedures set out in Article IX.2 for adopting such interpretations were followed. Second, as far as the United States is aware such procedures were not followed. In fact, the Ministerial Decision preceded the TBT Committee decision on this issue,[2] indicating that the Ministerial Conference did not act on a recommendation of the TBT Committee as Article IX.2 requires for the adoption of binding interpretations. Thus, the Ministerial Decision does not constitute a binding interpretation of the WTO Agreement, or of Article 2.12 of the TBT Agreement in particular.

7. Both parties: Could the parties please elaborate their views on the legal value of the TBT Committee decisions and recommendations cited by the parties in their first written submissions?

6. TBT Committee decisions, including the one on which Indonesia relies to support its Article 2.12 claim, cannot amend or provide binding interpretations of the TBT Agreement. In fact, the TBT Committee is not authorized to adopt amendments to the TBT Agreement nor is it authorized to issue binding interpretations of the TBT Agreement. This is made clear by Articles 13 and 15 of the TBT Agreement and Articles X and XI of the Marakesh Agreement.

7. Article 13 of the TBT Agreement establishes the TBT Committee. That article provides that the Committee shall meet "for the purpose of affording Members the opportunity of consulting on any matters relating to the operation of this Agreement or the furtherance of its objectives, and shall carry out such responsibilities as assigned to it under this Agreement or by the Members." Neither the TBT Agreement nor the Members has assigned the TBT Committee the responsibility of adopting amendments or interpretations of the TBT Agreement. In fact, Article 15.4 of the TBT Agreement makes clear that the TBT Committee does not have such authority. In particular, Article 15.4 provides that the Committee "shall review the operation and implementation of this Agreement ...with a view to *recommending* an adjustment of the rights and

[1] U.S. First Written Submission, paras. 300-301.

[2] The TBT Committee decision was adopted in May 2002 while the Ministerial Decision was adopted in November 2001. *See* G/TBT/M/26, 6 May 2002, para. 15; WT/MIN(01)/17, 20 November 2001.

obligations of this Agreement where necessary..." and "shall, where appropriate, submit *proposals* for amendments to the text of this Agreement to the Council for Trade in Goods."[3]

8. Article IX.2 of the Marakesh Agreement established that only the General Council and Ministerial Conference are authorized to adopt binding interpretations of the WTO Agreement, and any amendments of a covered agreement (such as the TBT Agreement) may only be made in accordance with the provisions set forth in Article X of the Marakesh Agreement. Thus, while the Committee may review the operation of the TBT Agreement and make recommendations, it is not authorized to amend or issue binding interpretations of the TBT Agreement, functions which are reserved for other WTO bodies.

E. EXPERTS

8. Both parties: At the first substantive meeting, the parties indicated that in their view the Panel did not need to consult experts at this stage of the proceedings. However, if the Panel were to decide to do so:

(a) Should the Panel ask the World Health Organization (WHO) to propose experts?

9. If the Panel were to consult with experts, it would be appropriate for the Panel to ask the WHO to propose those experts.

(b) On which specific issues should the experts be consulted? For example, would the Panel benefit from information on whether the various additives, including menthol, facilitate addiction among youth for instance by increasing palatability?

10. If the Panel were to consult with experts, the United States believes that key issues in this dispute involve matters of public health, such as the window of initiation for tobacco use, the attractiveness of clove cigarettes to young smokers, and the public health consequences of regular smoking. Also, if experts were consulted, it is important that any question asked of the experts respect the applicable burden of proof in this proceeding. In other words, the relevant questions for experts would involve whether Indonesia, as the complaining party, has met its burden of putting facts on the record that support the factual assertions that Indonesia makes in presenting its claims. For example, a relevant question on the public health issues might be:

> Based on the evidence on the record in this dispute, is there a basis for concluding that the products banned by Section 907(a)(1)(A), *i.e.*, cigarettes with a characterizing flavor other than tobacco or menthol (including clove cigarettes) are not used disproportionately by U.S. young people (*i.e.*, children and young adults

[3] TBT Agreement, Article 15.4 (emphasis added).

in the window of initiation (approximately the ages of 12-26)), when compared to older adult smokers?

11. In contrast, the example provided by the Panel does not appear to be a central question in this dispute that needs to be answered by an expert.

(c) What should be the procedure that the Panel should follow to choose the experts in particular: a) the number of experts and b) whether they should be individual experts or an expert?

12. While the United States believes it is not necessary to consult experts, were the Panel to do so, the United States submits the following procedures for the Panel's consideration. These procedures are drawn from the final expert procedures adopted by the panel in *Japan – Measures Affecting Agricultural Products* (DS76). As noted in the procedures themselves, the United States believes that it is preferable to nominate individual experts. The United States also believes that the number of individual experts chosen should depend on the number and types of issues on which advice is sought, as well as by the different areas on which each expert can provide expertise.

Proposed Expert Procedures Regarding Selection of Experts:

1. The Panel will seek expert advice from individual experts.

2. The Panel will solicit suggestions of possible experts from the Secretariat of the World Health Organization (WHO), and, subsequently, from the parties. The parties are asked not to engage in direct contact with the individuals suggested.

3. The Secretariat will seek a brief curriculum vitae from each individual suggested. These curricula vitae will be provided to the parties. Parties will have the opportunity to comment on and to make known any compelling objections to any particular expert under consideration.

4. The number of experts the Panel selects will be determined in light of the number and types of issues on which advice will be sought, as well as by the different areas on which each expert can provide expertise.

5. Experts will be appointed on the basis of their qualifications and the need for specialized scientific expertise.

6. The Panel will inform the parties of the experts it has selected.

II. FACTUAL ISSUES

9. Both parties: While Indonesia refers to the measure at issue as "Section 907" of the *Family Smoking Prevention and Tobacco Control Act* ("FSPTCA") in its Panel Request, in its first written submission Indonesia refers to the measure at issue as "Section 101(b)" of the FSPTCA. The United States refers to the measure as "Section 907(a)(1)(A)" of the FSPTCA. What is the correct way to refer to the measure at issue? Is the Panel correct in referring to it as Section 907(a)(1)(A)?

13. The measure is most properly referred to as section 907(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (as amended by the Family Smoking Prevention and Tobacco Control Act) or, as shorthand, section 907(a)(1)(A) of the FFDCA. It can also be referred to as 21 U.S.C. § 387g(a)(1)(A) (which is section 387g(a)(1)(A) of title 21 of the U.S. Code).[4] Unless the Panel prefers otherwise, the United States will refer to the measure as section "907(a)(1)(A) of the FFDCA" or simply "section 907(a)(1)(A)."

10. Both parties: It appears to be common ground between the parties that the effect of Section 907(a)(1)(A) is to establish a ban on the production and sale of certain kinds of cigarettes. However, Section 907(a)(1)(A) does not contain any explicit reference to a ban on production or sale. Is the ban on production and sale of cigarettes with a characterizing flavour implicit in Section 907(a)(1)(A)? Are there other provisions of US law that are relevant in this regard?

14. Section 907(a)(1)(A) of the FFDCA establishes a product standard for cigarettes sold in the United States. Such products cannot contain, as a constituent or an additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice that is a characterizing flavor. Cigarettes that do contain a banned characterizing flavor fail to conform with this product standard and are deemed to be "adulterated" under section 902(5) of the FFDCA. Under the FFDCA, adulterated products are not to be sold or held for sale in the United States. Under the FFDCA, adulterated products sold or held for sale in the United States may be subject to seizure under section 304 of the FFDCA. In addition, if a person violates section 907(a)(1)(A), FDA has the authority to initiate, among other actions, injunction actions and criminal prosecutions under sections 301, 302, and 303 of the FFDCA.

11. Both parties: Does the measure establish a complete ban on the sale and purchase of clove cigarettes within the United States? For example, does it ban the importation of small quantities of clove cigarettes for personal use?

15. As a result of section 907(a)(1)(A), it is unlawful to sell or to import clove cigarettes. There is no exception for small quantities for personal use.

[4] The United States notes that its First Written Submission provided the citation inaccurately at times, and regrets if any confusion resulted.

12. Both parties: The United States observes that "Indonesia agrees with the United States that the rates that clove cigarettes are consumed by young people versus adults is a key fact to determine in this case".[5]

(a) Does Indonesia agree with the US statement?

(b) It appears that neither party has explicitly defined what it means by "young people", "adolescents", "youth", "young adults", or "adults". Please clarify (i) which term should be used by the Panel and (ii) which is the age group at issue.

16. The United States sees the "window of initiation" for smoking as approximately between the ages of 12-26 (that is, from when an individual turns 12 until he or she turns 26), and the United States has been using both to "youth" and "young people" interchangeably to refer to people within this age range.[6] For greater clarity, the United States will use the term "young people" to describe individuals within this age range.[7]

17. Given that the scholarship and survey data on cigarette use is provided in different ways by different sources, the United States has also made references to other terms, and for purposes of this dispute attributes the following meanings to those terms: "children" (ages 17 and younger), "adolescents" (ages 13 through 17), "adults" (ages 18 and older), "young adults" (ages 18 through 25), and "older adults" (ages 26 and older).

(c) In addition, the parties sometimes formulate their conflicting assertions on this factual question in terms of cigarettes that "appeal" to youth, are "designed" and/or "marketed" for youth, are "used" by youth, and so forth. Please clarify.

18. **Appeal/Use**. For the purposes of the analysis in this dispute, the terms "appeal" and "use" are equivalent. This is simply because persons will "use" the cigarettes that "appeal" to them. So,

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[5] U.S First Written Submission, para. 244.

[6] *See* U.S. First Closing Statement, para. 6; Exhibit US-89.

[7] The United States notes that while different public health experts may use slightly different estimates for the upper range of the window of initiation (that is, some may say the window is 12-24 or 12-30), agreement exists that preventing people in their late teens and yearly twenties from initiating smoking is an important part of tobacco prevention efforts in the United States. *See, e.g.*, Wechsler, *et al.*, "Increased Levels of Cigarette Use Among College Students: A Cause for National Concern," Journal of American Medical Association (JAMA), vol. 280, no. 19, at 1677-78 (November 18, 1998) ("Increased Levels of Cigarette Use Among College Students"), Exhibit US-92; Ling & Glantz, "Why and How the Tobacco Industry Sells Cigarettes to Young Adults: Evidence from the Industry Documents," American Journal of Public Health, Vol. 92, No. 6, at 914 (June 2002) ("Why and How the Tobacco Industry Sells Cigarettes to Young Adults"), Exhibit US-93; Lantz, "Smoking on the rise among young adults: implications for research and policy," Tobacco Control 2003;12, at i69, Exhibit US-94.

for example, the phrase "disproportionate appeal/use" means that these products are used by a significantly higher percentage of young people (both children and young adults) than of older adults. The fact that some cigarettes disproportionately used by young people – and not used regularly by a large number of older adult smokers – is critical in understanding why the United States has banned non-tobacco, non-menthol flavored cigarettes.

19. **Design**. Whether cigarettes are "designed" for young people is a separate (but related) issue from whether they appeal to, or are used by, young people. It is well established that the cigarette companies did "design" many of the banned cigarettes specifically to attract young people to these products.[8] Such design characteristics include what characterizing flavor to use and how the flavor is included within the product.[9] This issue provides background to the Panel regarding what the United States did, and is complementary of the survey and academic articles that support the fact that flavored cigarettes do disproportionately appeal to young people, and thus are properly considered "trainer" cigarettes.[10]

20. However, the issue of whether flavored cigarettes are "designed" to appeal to young people is not legally relevant in of itself. That is to say, Indonesia would not prove any element of its claim if it establishes that the cigarette companies did not in fact design their flavored products to appeal to young people. The question, rather, is what cigarettes were young people using in the years prior to the ban being enforced.

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[8] *See, e.g.*, Lewis & Wackowski, "Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands," American Journal of Public Health, Vol. 96, No. 2, at 1601-1608 (February 2006) ("A Look at Flavored Cigarettes Promoted by Mainstream Brands"), Exhibit US-33; Wayne & Connolly, "How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93," Tobacco Control 2002; 11 (Suppl I), at i35 ("How Cigarette Design Can Affect Youth Initiation"), Exhibit US-95. The Wayne and Connolly article notes that one of the key design changes that RJ Reynolds did to attract new young adult smokers was to introduce flavorings, including chocolate, vanilla, and licorice. The authors quote from a RJ Reynolds memo to a flavor developer that states:

> I would like to express my sincere appreciation for the exciting flavoring work you have done on Project XG. The chocolate/vanillin/licorice/tobacco enhancer is undoubtedly one of the most exciting and promising flavorants that has been developed during the last several years . . . As you know, this flavorant appears to have *significant appeal among the 18-24 year old smoker group and this is obviously the group that we desperately are after*.

Id. at i35 (emphasis added).

[9] *See, e.g.*, Carpenter, *et al.*, "New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies," Health Affairs, Vol. 24, No. 6, at 1607 (November/December 2005) ("New Cigarette Brands with Flavors that Appeal to Youth"), Exhibit US-40*; How Cigarette Design Can Affect Youth Initiation*, i34-i35, Exhibit US-95.

[10] *See* U.S. First Written Submission, paras. 54-55, 58-60 (citing to Exhibit US-53 and Klein, *et al.*, "Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005," Nicotine & Tobacco Research, vol. 10, No. 7 (July 2008) ("Klein Article"), Exhibit US-51); U.S. First Oral Statement, para. 16.

21. **Marketing**. The role of "marketing" in this dispute is similar to the issue of "design." It is well-established that cigarette companies have targeted U.S. young people for decades in the advertising and marketing of their products.[11] This targeted advertising and marketing is specifically addressed in a number of different contexts, including the Master Settlement Agreement ("MSA").[12] The United States considers this information to be helpful in understanding the larger context that existed at the time of the Tobacco Control Act's enactment. However, as is the case with the design of the products, Indonesia would not prove any element of any of its claims by establishing that cigarette companies have not targeted young people in their advertising and marketing.

(d) Concerning the burden of proof, must Indonesia prove that clove cigarettes do not appeal to youth? Or can Indonesia rather establish a prima facie case by asserting that there is no evidence proving that clove cigarettes appeal to youth?

22. To the extent that the Panel would find that any element of Indonesia's claims turns on the factual issue of whether clove cigarettes appeal to youth, then, yes, it would indeed be Indonesia's burden to prove this factual assertion. Moreover, Indonesia may not meet this burden by asserting a lack of evidence – to the contrary, such an assertion by Indonesia would amount to a concession that Indonesia cannot prove its claims. Put simply, if Indonesia asserts that clove cigarettes do not appeal to youth, Indonesia, as the complaining party, must support this assertion by submitting evidence on the record.

23. As the United States explained in the U.S. First Written Submission, the Appellate Body has stated in *US – Wool Shirts and Blouses*, and has repeated many times since then, that in order for the complaining Member to satisfy its burden of proof, it must "adduce[] *evidence* sufficient to raise a presumption that what is claimed is true."[13] Thus, a complaining Member does not satisfy its burden of proof through bare assertions – it must submit sufficient evidence to support its claims to satisfy its burden of proof. If the complaining Member does put forward sufficient evidence to establish a *prima facie* case, the responding Member has the opportunity to put forward evidence to rebut the *prima facie* case. If the responding Member is able to adduce

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[11] *See, e.g.*, *New Cigarette Brands with Flavors that Appeal to Youth*, at 1601-1608, Exhibit US-40; *Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 908-916, Exhibit US-93; Hendlin, *et al*, "'Acceptable rebellion': marketing hipster aesthetics to sell Camel cigarettes in the US," Tobacco Control, 2010;19: 213-222 ("Acceptable Rebellion"), Exhibit US-96; Biener & Albers, "Young Adults: Vulnerable New Targets of Tobacco Marketing," American Journal of Public Health, Vol. 94, No. 2, at 326-330 (February 2004) ("Young Adults: Vulnerable New Targets of Tobacco Marketing"), Exhibit US-97.

[12] *See* U.S. First Written Submission, paras. 82-88.

[13] *US – Wool Shirts and Blouses (AB)*, p. 14. The Appellate Body has repeated this standard many times. *See, e.g.*, *EC – Hormones (AB)*, paras. 97-98; *Japan – Apples (AB)*, paras. 153-157.

sufficient evidence, the claim fails.[14] The Appellate Body has further stated that the burden of proof is not to be allocated based on a comparison of the respective difficulties experienced by complainant and respondent in collecting information to prove a case.[15] It does not matter whether it is relatively straightforward or extremely difficult for the complaining Member to establish that the challenged measure is in violation, the complaining Member still has to prove its claim.[16]

24. Here, the United States has previously discussed why Indonesia's reliance on recent NSDUH surveys, the Western Watts survey, and its other sources is in error.[17] As such, Indonesia has failed to produce any reliable evidence that establishes that clove cigarettes do not appeal to young people in the United States. Moreover, the United States has put forth evidence that establishes that just the opposite is true. Clove cigarettes, like all cigarettes banned under section 907(a)(1)(A), not only appeal to young people, but appeal disproportionately to young people, and are, in terms of absolute numbers, used by relatively few older adults.[18]

(e) The parties have submitted some empirical evidence on this issue, including but not limited to several surveys (including the NSDUH, NYTS, and MTF surveys). The Panel assumes that the surveys and other information submitted to the Panel do not constitute all of the empirical research that exists, and that might shed some light on this issue. However, the Panel presumes that while there may be other research (whether of a scientific, statistical or other nature) that relates to the question of whether clove and/or other flavoured cigarettes appeal to youth, the surveys and other evidence submitted by the parties represent what they consider to be the most relevant information available. The Panel further understands the parties to be of the view that the Panel should conduct its objective assessment of this issue on the basis of this evidence. Is the foregoing correct?

25. Yes, the United States believes that the Panel should conduct its objective assessment of the issue based on the evidence submitted by the disputing parties.

26. The United States also notes that it has submitted the best and most relevant information to the Panel on the question of the use of clove cigarettes and other flavored cigarettes; in

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[14] *See US – Wool Shirts and Blouses (AB)*, p. 14; *see also EC – Hormones (AB)*, para. 104 ("[A] *prima facie* case is one which, in the absence of effective refutation by the defending party, requires a panel, as a matter of law, to rule in favor of the complaining party presenting the *prima facie* case.").

[15] *EC – Sardines (AB)*, para. 281.

[16] *EC – Sardines (AB)*, para. 281.

[17] U.S. First Oral Statement, paras. 18-19; U.S. First Written Submission, paras. 67-78.

[18] U.S. First Oral Statement, para. 16; U.S. First Written Submission, paras. 54-55, 61-78; Exhibit US-53, at 7.

particular the 2002 and 2003 NSDUH, as well as the National Youth Tobacco Survey ("NYTS") and the Monitoring the Future ("MTF") surveys.[19] Although other surveys may have asked questions about the use of clove cigarettes and other flavored cigarettes, they have not done so in a manner that approaches the rigor of these three nation-wide surveys.

13. Both parties: Among adult smokers today - i.e. those that smoke regularly because of an addiction to nicotine - are there studies that show what type of cigarette triggered the addiction in today's smoking population? Do the parties consider that the same patterns would apply to those starting to smoke today?

27. The United States is not aware of studies that would show what type of cigarette(s) triggered the addiction in today's smoking population. Moreover, the United states considers that it is unlikely that, in any case, the same patterns would apply today.

28. There are significant differences in the cigarette marketplace of the 1950s, 1960s and 1970s and the current marketplace. The regulatory landscape in the earlier decades was much different, with relatively few restrictions on the advertising and promotion of cigarettes, including relatively few restrictions on marketing techniques that target, either by design or effect, young people. Also, consumers were less aware of the dangers of smoking in the middle of the 20th century. As a result, smoking was more culturally accepted. As the United States describes in its First Written Submission,[20] awareness of the dangers of smoking increased in the last several decades and since the 1980s and 1990s, more stringent advertising regulations have been put in place in the United States. At the same time, cigarette manufacturers have innovated to develop more appealing cigarettes, in particular to attract young people to smoking.[21] So, for example, in the last ten years, there have been many more flavored cigarette brands on the U.S. market than in earlier decades. These brands are banned by section 907(a)(1)(A)), but were disproportionately used by young people while on the market.

29. Thus, while these newer products had no role in triggering addiction among those who began smoking in the mid-to-late 20th century, it is likely these products played a role in triggering addiction among those who began smoking in the 21st century. Indeed, cigarette companies acknowledged that flavored cigarettes were part of their campaign to recruit youth smokers,[22] and it is not unreasonable that the United States, based on data confirming this intended effect, would regulate accordingly.

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[19] *See* U.S. First Written Submission, section III.F; Exhibit US-53.

[20] U.S. First Written Submission, paras. 79-84.

[21] U.S. First Written Submission, paras. 43-53, 89-92, 101.

[22] U.S. First Written Submission, paras. 43-53, 101.

30. In addition, it should be noted that all cigarette products that contain nicotine are addictive, and surveys or other methods may not be able to ascertain a single "trigger" for addiction among users who have tried more than one product at the time they became regular smokers. As noted, young people today tend to try clove and other flavored cigarettes around the time that they are in the age-window of initiation (adolescent and young adult).

14. United States: Section 907(a)(1)(A) refers to "characterizing flavour":

(a) What is a "characterizing flavour"?
(b) Does this term have a technical meaning under US law?

31. Section 907(a)(1)(A) of the FFDCA explains that a "characterizing flavor" is present in a cigarette when the cigarette or any of its component parts contain, as a constituent or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Accordingly, the legislation makes clear that constituents or additives do not meet the definition of "characterizing flavor" *per se*, but meet the definition when they characterize the flavor of the tobacco product or the tobacco smoke.

32. The legislative history of this provision also is helpful in understanding this term. The relevant congressional committee report states that this provision "prohibits the use of any constituent or additive that causes a cigarette or its smoke to have a characterizing flavor other than menthol or tobacco."[23] It further explains that "[a] cigarette (including any component of the cigarette) or its smoke should not be determined to have a prohibited characterizing flavor based solely on the presence of an ingredient in the product or its smoke."[24] Senate commentary in the legislative record further clarifies that "[w]hile the term 'characterizing flavor' is undefined in the legislation, it is intended to capture those additives that produce a distinguishing flavor, taste, or aroma imparted by the product. Nothing in this section is intended to expressly prohibit the use of any specific ingredient that does not fall into this category."[25]

33. Cigarettes are a highly engineered product. Most aspects of a cigarette related to the user's experience are deliberately designed.[26] It has not been the experience of the United States that cigarettes unintentionally or unwittingly would contain a "characterizing flavor," as the taste of the cigarette and aroma of the smoke are among the specifically engineered aspects of a cigarette.

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[23] H.R. Rep. No. 111-58(I), at 37-38 (2009), Exhibit US-67.

[24] H.R. Rep. No. 111-58(I), at 37-38 (2009), Exhibit US-67.

[25] 155 Cong. Rec. S64111 (June 10, 2009), Exhibit US-98.

[26] *See* Hoffman, Djordjevic, Hoffman, "The Changing Cigarette," American Health Foundation, *Preventive Medicine* 26, Article No. PM970183 (1997), at 428-29, Exhibit US-99.

(c) Who decides when a cigarette has a characterizing flavour?

34. The FDA is recognized under the legislation as possessing "the scientific expertise needed to implement effectively all provisions" of the Tobacco Control Act.[27] Section 901(a) of the FFDCA affords the FDA authority to implement and enforce the provisions of the Tobacco Control Act, including the ban on certain characterizing flavors. For example, on the effective date of the provision, FDA published guidance on section 907(a)(1)(A).[28]

15. United States: Exhibit US-35 refers to sample legislation in some States to curb youth smoking. In particular, page 6 of the exhibit refers to sample legislation from the State of Minnesota. We note that the State of Minnesota defines the term "characterizing flavour" as a "distinguishable taste or aroma, other than tobacco, menthol, or clove, imparted either prior to or during consumption". Please explain why clove is specifically excluded from the prohibition. Would this mean that the State of Minnesota was of the view that clove and menthol cigarettes are alike? Would this mean that the State of Minnesota was of the view that clove cigarettes do not appeal to youth?

35. As general matter, the views behind a state measures are often not self-evident. This is true even among somewhat similar measures from state to state; specific objectives and considerations will vary in the different states. The United States would caution the Panel from drawing broad inferences from legislative measures at the state level.

36. With respect to the Panel's specific question, the legislation from Minnesota referenced in Exhibit US-35 was introduced in the Minnesota House of Representatives in March 2005 but was never enacted (the bill was not approved by a House committee and was not introduced in the state Senate). There were no similar bills on this topic introduced in the state subsequently. Thus, this bill does not reflect the views of the State of Minnesota.

16. Both parties: According to Indonesia, clove cigarettes "currently account" for 0.09 per cent of all cigarettes consumed in the United States.[29] Have clove cigarettes had a greater or lesser share of the US cigarette market over time, or did the market share remain generally flat at around 0.1 per cent? Please provide figures for the past 10 years.

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[27] *See* section 2(45) of the Tobacco Control Act, Exhibit US-7.

[28] Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2), issued September 22, 2009, and updated December 23, 2009, available at http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183228.htm.

[29] Indonesia's First Written Submission, paras. 7 and 40.

37. The United States submits Exhibit US-100, which provides market share data for clove cigarettes for the years 2000-2009. As indicated, Exhibit US-100 compares clove imports to the total U.S. market based on the excise tax data collected by the U.S. Treasury Department's Alcohol and Tobacco Tax and Trade Bureau ("TTB").[30] This data includes both clove cigarettes without additional characterizing flavors and clove cigarettes that do contain additional characterizing favors, such as vanilla, chocolate, strawberry, and coconut.[31]

38. Comparing import data with the TTB data, the market share of cloves varied between 0.06% and 0.13% in the years 2000-2009. On average, 358,626,000 individual clove cigarettes were imported, at an annual average value of 11.36 million U.S. dollars in these years.[32]

39. The United States further notes that clove cigarette imports also constituted a small percentage of foreign produced cigarettes imported to the United States. Clove cigarette imports varied between 0.8% and 4.3% of total cigarettes imports in the years examined, and between 2.3% and 8.3% in terms of value.[33]

40. The vast majority of imported cigarettes are unaffected by the ban. The import data shows that in the period January-October 2010,[34] the United States imported a total of 8.12 billion cigarettes valued at US$155.7 million, which is only a slight decrease from imports during the same period in 2009 where the United States imported 8.76 billion cigarettes valued at US$156.7 million.[35]

17. Both parties: What was the market share of clove cigarettes in the United States at the time of the ban? What was the market share of 'candy flavoured' cigarettes in the United States at the time of the ban? If possible, please

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[30] As such, this market share data serves is an approximation of market share as there currently exists a black market for cigarettes in the United States where a certain number of cigarettes are sold without the payment of U.S. excise taxes. *See* U.S. First Written Submission, para. 24 (citing to TTB's Report to Congress on Federal Tobacco Receipts Lost Due To Illicit Trade and Recommendations for Increased Enforcement (February 4, 2010), Exhibit US-27).

[31] *See* U.S. First Written Submission, para. 37 (describing the types of clove cigarettes that were on the market in the years prior to the enactment of the Tobacco Control Act).

[32] The United States also notes that it has submitted evidence indicating that those who smoke clove cigarettes do so infrequently (typically, those who smoke clove cigarettes do not do so daily). For example, according to data from the 2002 and 2003 NSDUH, almost 90% of young people who smoke cloves do so fewer than 10 days per month. *See* Exhibit US-53, at 10. As a result, the percentage of individuals who smoke clove cigarettes will be much higher than the market share of clove cigarettes. It is the overall prevalence of use, especially among young people, that is the most relevant question.

[33] Exhibit US-100.

[34] Import data for the calendar year 2010 is not yet available.

[35] Exhibit US-100.

specify the total market share, the market share for adult smokers and the market share for youth smokers. Please provide figures for the past 10 years.

41. With regard to the market share of cloves, please see the U.S. response to Question 16.

42. With regard to the market share of "candy-flavored" cigarettes, the United States notes that section 907(a)(1)(A) bans all cigarettes with a characterizing flavor, except for menthol and tobacco flavored cigarettes. The ban thus covers a wide variety of characterizing flavors, including candy, fruit, spice, and liquor.

43. The United States has thus far been unable to attain market share data for all non-clove products banned under the section 907(a)(1)(A).[36] In part, the reason for this is these products, although popular among young people, were on the market for a relatively short period of time and represented a relatively small market share. As such, sales of cigarettes flavored with candy, fruit, spice, etc. were not routinely tracked separately by U.S. government or private market survey data firms.[37] We also know that the U.S. company that was marketing the vast majority of these flavored products, RJ Reynolds, was marketing its flavored products differently, some of which were being sold over a period of years at regular sales outlets, such as convenience stores and grocery stores, while other product lines were being marketed at bars, concert venues, and other places where RJ Reynolds believed it could best get its product into the hands of its target younger audience.[38] Some portion of these products were not sold at all, but were rather given away as part of promotional events.[39] Further, a number of these product lines were only intended to be marketed on a temporary basis, either for a particular season or event.[40] Accordingly, even if there are surveys that have tracked sales of non-menthol, non-clove flavored cigarettes over the last decade, such surveys may well underestimate the quantity of this class of product on the U.S. market the years preceding the ban.

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[36] The United States would further note that in any event there is no direct "market share" data for smokers under the age of 18 as it is illegal for such persons to purchase cigarettes. Accordingly, there would be no surveys that track actual *sales* of any type of cigarette to people under 18. There are surveys that have tracked the *use* of these products by persons under the age of 18 and the United States has presented that evidence. *See* U.S. First Written Submission, section III.F (citing in particular to Exhibit US-53 and the Klein Article, Exhibit US-51).

[37] For example, TTB does not collect information that categorizes cigarettes by particular flavors, such as menthol cigarettes, clove cigarettes, or cigarettes with other characterizing flavors, and thus does not have data that would provide the relative market shares for any of these products.

[38] *See, e.g.*, Sepe, *et al.*, "Smooth Moves: Bar and Nightclub Tobacco Promotions That Target Young Adults," American Journal of Public Health, Vol. 92, No. 3, at 414-419 (March 2002), Exhibit US-101; *Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 912, Exhibit US-93; *Acceptable Rebellion*, at 213, Exhibit US-96.

[39] *See, e.g.*, *A Look at Flavored Cigarettes Promoted by Mainstream Brands*, at 246, Exhibit US-33.

[40] *See* U.S. First Written Submission, para. 49.

44. In this context, the United States would also re-emphasize that the public health consequences of these products is greater than reflected in their share of the entire cigarette market. As explained, these flavored cigarettes were being used as trainer cigarettes by young, novice smokers and were, like clove cigarettes, usually not smoked exclusively.[41] These products were not necessarily intended for regular use; rather, once the novice smoker transformed into the regular smoker, that person would switch to the regular product of the company making the flavored product.

45. Finally, the United States would also reiterate that section 907(a)(1)(A) forced U.S. cigarette companies to permanently give up an entire line of products that had been researched for decades.[42]

18. United States: The United States submits that "[c]love cigarettes are at least as dangerous as non-clove cigarettes, if not more so".[43] However, the United States also submits that Indonesia's argument that clove cigarettes are no more dangerous than other types of cigarettes lacks any connection to the requirements of Article 2.2 and also misses the point of Section 907(a)(1)(A).[44] Could the United States please clarify its position on this issue?

46. The Panel's first reference is to the fact section of the U.S. First Written Submission where the United States described the physical properties of clove cigarettes, among other things.[45] The United States believes that all cigarettes are toxic, and thus dangerous. However, clove cigarettes do contain significant different physical attributes, such as the presence of eugenol and coumarin, that may give rise to unique health concerns. These concerns are discussed in the U.S. answer to Question 38.

47. The Panel's second reference is to a statement in the U.S. First Written Submission's TBT Article 2.2 section. As the United States discusses in response to Question 60, the objective of section 907(a)(1)(A) is protecting public health by reducing smoking of young people while avoiding negative consequences associated with banning products to which tens of millions of adults are chemically and psychologically addicted. The means by which Section 907(a)(1)(A) does this is to ban products that are disproportionately used by young people while not banning products to which tens of millions of adults are addicted. As such, it is *not* the objective of section 907(a)(1)(A) to protect public health by removing particularly toxic products from the

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[41] Exhibit US-53, at 10.

[42] *See* U.S. First Written Submission, section III.E.3; U.S. First Closing Statement, para. 9.

[43] U.S. First Written Submission, para. 40.

[44] U.S. First Written Submission, para. 274.

[45] See U.S. First Written Submission, 35-42.

market and allowing less toxic products to remain on the market. Section 907(a)(1)(A) does not make distinctions between products on such a basis.

48. Accordingly, the question of the relative toxicity of clove cigarettes versus other cigarettes (both banned and not banned) is not relevant to the key question to be answered in the TBT Article 2.2 claim – whether an alternative measure exists that fulfills the United States' legitimate objective that is reasonably available and is significantly less trade restrictive than section 907(a)(1)(A). Given that the toxicity of clove cigarettes is not relevant to this question, Indonesia's discussion of this issue in its TBT Article 2.2 claim does, in fact, miss the point.

19. Both parties: Both parties have referred the Panel to the WHO *Framework Convention on Tobacco Control* ("FCTC"). At the fourth Conference of the Parties, held from 15 to 20 November 2010 in Punta del Este, the parties to the FCTC adopted "Partial Guidelines for implementation of Articles 9 and 10 of the Convention". Are these Partial Guidelines relevant to any of the factual or legal issues before the Panel?

49. The United States views the FCTC in general, and the "Partial Guidelines for implementation of Articles 9 and 10 of the Convention" ("the Partial Guidelines") in particular, to be evidence of the growing global consensus of the need to take action through international collaboration and at the national level to address the harms caused by tobacco products. The United States is one of the 172 signatories to the Convention, and the U.S. Tobacco Control Act is consistent with the FCTC's purposes and recommendations. In this sense, they help to provide factual context.

50. The aim of the Partial Guidelines "is to assist Parties in meeting their obligations under Articles 9 and 10 of the WHO FCTC and to provide guidance for implementation of these Articles".[46] Articles 9 and 10 are contained in Part III of the FCTC, which addresses "Measures relating to the reduction of demand for tobacco." The Articles specify guidelines for the national regulation of the contents of tobacco products (Article 9) and for the national regulation of tobacco product disclosures (Article 10). Article 9, in particular, provides relevant factual context, as section 907(a)(1)(A) is a national regulation of the contents of a tobacco product.

51. Several aspects of the Partial Guidelines for Article 9 are particularly relevant. First, the Partial Guidelines expressly encourage Parties to adopt product content regulations to "reduce the attractiveness of tobacco products."[47] The Partial Guidelines further state that "[t]obacco products are commonly made to be more attractive in order to encourage their use. From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring

[46] FCTC/COP/4/DIV/6, p. 45.

[47] FCTC/COP/4/DIV/6, section 1.2.1, p. 47.

agents, which help make tobacco products attractive."[48] In other words, the Partial Guidelines affirm that regulations restricting or prohibiting contents that make tobacco products more attractive, such as flavors, are consistent with the goal of reducing demand. The U.S. requirement that cigarettes cannot contain a characterizing flavor other than tobacco or menthol is consistent with this guideline.

52. Second, the Partial Guidelines specifically recommend that Parties should "regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products."[49] The FCTC specifically recommends and sanctions a ban on ingredients, such as flavors, including spices and herbs, that make tobacco products more palatable. The United States considers that the Partial Guidelines recognize that cigarettes are differentiated by users based on their distinguishable flavors, and implicitly reject Indonesia's suggestion that all cigarettes are "like products" and that banning one characteristic in cigarettes means a Party must ban all cigarettes. The United States action to ban characterizing flavors that make tobacco more attractive is consistent with the Partial Guidelines.

53. Third, the Partial Guidelines recognize that implementation of product regulation will occur on an individual national level and should "aim to implement the most effective measures that they can achieve."[50] This statement recognizes that not all product regulation that might be desirable in the abstract (such as banning all cigarette additives or even all cigarettes) is actually achievable under every given circumstance. This recognition is significant, because Indonesia has offered at various points the misguided suggestion that if the United States were "serious" in its objective to reduce smoking, it would ban all cigarettes or all menthol cigarettes. However, consistent with the Partial Guidelines, the United States has concluded, based on available evidence at this time, that such a broad-scoped ban aimed at immediately eradicating smoking altogether, in fact, would not achieve the intended goal and likely could cause other negative consequences. To apply the terminology of the FCTC, such a ban appropriately was deemed by the United States not to be achievable at this time. On the other hand, a more narrowly-tailored and focused ban on characterizing flavors aimed at reducing demand for cigarettes, especially among youth and young adults, was appropriately deemed to be achievable at this time.

54. For the reasons just noted, the Partial Guidelines of the FCTC support the U.S. regulatory approach of banning characterizing flavors in cigarettes. The Guidelines expressly recognized that restricting or prohibiting ingredients that make cigarettes more attractive is an effective measure, and also recognize that countries will adapt measure to their particular circumstances and based on what they can achieve.

III. CLAIMS MADE BY INDONESIA

[48] FCTC/COP/4/DIV/6, section 1.2.1.1, p. 47.

[49] FCTC/COP/4/DIV/6, section 3.1.2.2, p. 53 (emphasis added).

[50] FCTC/COP/4/DIV/6, section 3.1.2, p. 52 (emphasis added).

A. CLAIMS UNDER THE SPS AGREEMENT

20. Both parties: Indonesia's Panel Request indicates that "[s]hould the United States assert that the flavored cigarette ban is an SPS measure, then it is Indonesia's view that the measure is inconsistent with Articles 2, 3, 5, and 7 of the SPS Agreement." Do the parties agree that Section 907(a)(1)(A) is not an SPS measure within the definition of Annex A.1 of the SPS Agreement?

55. The United States does not believe section 907(a)(1)(A) is an SPS measure as defined in Annex A.1 and has not responded to Indonesia's claims on this basis. The United States further notes that if Indonesia believes that section 907(a)(1)(A) is an SPS measure, it is Indonesia's burden to establish that section 907(a)(1)(A) fits within one of the subparagraphs of Annex A.1. The United States notes, however, that Indonesia has yet to even raise the issue.

B. CLAIMS UNDER THE GATT 1994 AND THE TBT AGREEMENT

21. Both parties: Indonesia has made claims under Articles 2.1, 2.2, 2.5, 2.8, 2.9, 2.10, 2.12, and 12.3 of the *TBT Agreement*. Indonesia has also made a claim under Article III:4 of the GATT 1994, and the United States has invoked Article XX(b) of the GATT 1994:

(a) Is there a particular order of the analysis that the Panel should follow?

56. The particular claims do not appear to call for any particular order of analysis.

(b) Can one or more of these claims/provisions be addressed together, e.g. Article 2.1 of the *TBT Agreement* / Article III:4 of the GATT 1994?

57. The national treatment analyses in this case under Article 2.1 of the *TBT Agreement* and Article III:4 of the GATT 1994 involve similar issues. Moreover, the interpretation of Article III:4 of the GATT 1994 has been substantially more developed through panel and WTO reports than Article 2.1 of the *TBT Agreement*. Accordingly, the United States considers that it would be appropriate to address the national treatment claims together to the extent the Panel considers it useful, bearing in mind that each claim is separate and the individual elements of each particular claim must be satisfied.

C. WHETHER SECTION 907(a)(1)(A) IS A "TECHNICAL REGULATION"

22. United States: In its first written submission, the United States "notes that it is Indonesia's burden to establish that Section 907(a)(1)(A) is a technical regulation".[51] In its opening statement, the United States indicates that "the

[51] U.S. First Written Submission, para. 213.

measure is a technical regulation" (p. 10, second line) Does the United States agree with Indonesia that Section 907(a)(1)(A) is a technical regulation within the meaning of Annex 1.1 of the *TBT Agreement*? If that is the case, what are the implications of this for the Panel's standard of review and for the burden of proof.

58. The U.S. view as to the status of section 907(a)(1)(A) as a technical regulation should not change the standard of review of the Panel, which is to make an objective assessment, based on the facts presented, as to whether the measure at issue is a technical regulation. Likewise, the U.S. view does not alter Indonesia's burden of proof to make a *prima facie* showing on each element of each of its claims.

23. Both parties: In *EC – Asbestos*, the Appellate Body explained that "[a] 'technical regulation' must, of course, be applicable to an *identifiable* product, or group of products".[52] Indonesia states that "the rule applies to an identifiable group of products - certain flavoured cigarettes, especially clove cigarettes".[53]

(a) Would it be correct to say that, while the only group of products *prohibited* by the measure is "certain flavoured cigarettes", strictly speaking the measure *is applicable* to all cigarettes?

59. It would be correct to say that the measure is applicable to all cigarettes. Section 907(a)(1)(A) places a restriction on cigarettes and their component parts – that they cannot contain, as a constituent or an additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice that is a characterizing flavor.

(b) The wording of Section 907(a)(1)(A) refers to cigarettes "or" any of their component parts. To what extent, if at all, are "parts" and "components" subsumed within the definition of "cigarettes" under US laws and regulations?

60. "Parts" and "components" are not necessarily subsumed within the definition of "cigarettes" under U.S. laws and regulations. Parts and components may be physically incorporated as part of a finished cigarette, or may be sold separately, and when they are sold separately they do not fall under the definition of a cigarette. Section 900(3) of the FFDCA defines cigarettes in the following manner:

"The term 'cigarette'-

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[52] *EC – Asbestos (AB)*, para. 111 (emphasis in original).

[53] Indonesia's First Written Submission, para. 47.

> (A) means a product that-
>
> (i) is a tobacco product; and
>
> (ii) meets the definition of the term 'cigarette' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and
>
> (B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco."

This definition refers to a provision of the Federal Cigarette Labeling and Advertising Act that defines the term cigarette as follows:

> "(1) The term "cigarette" means-
>
> (A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and
>
> (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A)."

61. "Parts" and "components" not physically incorporated into a finished cigarette are not included in the definition of "cigarette" under section 900(3) of the FFDCA. However, the tobacco standard under section 907(a)(1)(A) of the FFDCA applies to a cigarette or any of its component parts (including the tobacco, filter, or paper). Accordingly, section 907(a)(1)(A) also applies to, for example, rolling papers or filters for use in roll-your-own cigarettes.

24. Both parties: In *EC – Asbestos*, the Appellate Body explained that "[t]he definition of a 'technical regulation' in Annex 1.1 of the *TBT Agreement* also states that '*compliance*' with the 'product characteristics' laid down in the 'document' must be '*mandatory*'."[54] Are there specific provision(s) of US law that establish the "mandatory" nature of Section 907(a)(1)(A), such as provision(s) regarding criminal or other sanctions in the event of non-compliance?

62. The mandatory nature of section 907(a)(1)(A) is evidenced by the language "shall not contain." There also are specific provisions contained in the Tobacco Control Act to address non-compliance with section 907(a)(1)(A), but these are not necessary to establish whether section 907(a)(1)(A) is mandatory. Products that fail to comply with section 907(a)(1)(A) are deemed adulterated under section 902(5) of the FFDCA. Under the FFDCA, adulterated products sold or held for sale in the United States may be subject to seizure under section 304 of the FFDCA. In addition, under sections 301, 302, and 303 of the FFDCA, FDA has the authority to

[54] *EC – Asbestos (AB)*, para. 68 (emphasis in original).

initiate, among other actions, injunction actions and criminal prosecution to address violations of section 907(a)(1)(A) and other provisions of the FFDCA.

D. NATIONAL TREATMENT: ARTICLE 2.1 OF THE TBT AGREEMENT AND ARTICLE III:4 OF THE GATT 1994

26. Both parties: The Appellate Body has explained that "a determination of 'likeness' under Article III:4 is, fundamentally, a determination about the nature and extent of a competitive relationship between and among products".[55]

(a) Is the same true of a determination of "likeness" under Article 2.1 of the *TBT Agreement*?

(b) If yes, must the Panel consider the competitive relationship between the products at issue as relevant in its likeness analysis under Article 2.1 of the *TBT Agreement* in the absence of a reference to a similar general principle as imbedded in Article III:1 of the GATT 1994?

63. The United States understands that, yes, a determination of "likeness" under Article 2.1 of the *TBT Agreement* (like the determination of likeness under Article III:4) is fundamentally a determination about the nature and extent of a competitive relationship between and among products.

64. The United States understands part (b) of the question to ask how the TBT "likeness" analysis is affected by the fact that the *TBT Agreement* contains no direct analog to Article III:1, which the Appellate Body has found to be important context in support of its finding of a connection between a "competitive relationship" and "likeness" under Article III:4. The United States does not see the absence of an Article III:1 analog in the *TBT Agreement* to be a basis for adopting a fundamentally different view of "likeness" in the *TBT Agreement*. The wording of the national treatment obligations pertaining to "like" products and "treatment no less favourable" under different WTO Agreements, including the GATT and the *TBT Agreement,* is substantially similar and in fact nearly identical.[56] This textual consistency reflects consistency of principle, as articulated by the Appellate Body in *EC – Asbestos*: namely, products that are in a competitive relationship are those products that could be affected through treatment of imports that is less favorable than that treatment accorded to domestic products.[57] National treatment ensures no less

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[55] *EC – Asbestos (AB)*, para. 99.

[56] *See TBT Agreement*, Article 2.1 ("Members shall ensure that in respect of technical regulations, products imported from the territory of a Member shall be accorded treatment no less favourable than that accorded to like products of national origin").

[57] *EC – Asbestos (AB)*, para. 99.

favorable treatment to imported products, and that treatment can only be meaningfully compared as between and among imported and domestic products that are, minimally, in a competitive relationship.

65. That said, the *TBT Agreement* also provides important context for a like product analysis, which is relevant in both the "like product" analyses under the *TBT Agreement* and under the GATT. Where a claim arising from the same measure and same facts is brought under both agreements, the United States considers that each Agreement informs the interpretation of the other. For example, the Preamble to the TBT Agreement establishes the general right of Members to take measures to protect human health, even when those measures affect or even restrict international trade, so long as certain conditions are met. The specific context of the *TBT Agreement* should inform an analysis under Article 2.1 (and in this case Article III:4 of the GATT 1994, as well). In particular, the "like product" analysis should consider not only the nature of the competitive relationship among and between products but also the nature of the public health basis upon which the technical regulation at issue is based.

28. Both parties: Both parties have described clove cigarettes as containing ground/minced clove buds; however, the United States refers to clove oil as the flavouring agent:[58]

(a) Please clarify whether there is clove oil in the cigarettes as opposed to ground/minced cloves buds, or both.

66. A particular brand of clove cigarettes may contain clove buds, minced buds, clove oil, or some combination of them. Each of these additives (buds, minced buds, oil) can impart clove flavor to the taste of the cigarette or aroma of the smoke. Furthermore, each of these forms of clove contains eugenol. Additionally, a clove-flavored cigarette ("A Touch of Clove" brand) previously sold by the U.S. company Nat Sherman was made with clove flavor in the filter, rather than with cloves mixed into the tobacco.

(b) Please clarify whether clove oil is the same additive as eugenol or whether these are two different additives that clove cigarettes contain.

67. Clove oil is not the same as eugenol. Clove contains eugenol, but eugenol also is obtained from many other natural sources, including sources believed to be among the ingredients of the "special sauce" in clove cigarettes, such cinnamon leaf and other plants and oils.

30. United States: Please specify which are the 18 commonly used flavour compounds in cigarettes mentioned in paragraph 174 of the United States' first written submission. Please specify which of those 18 commonly used

[58] U.S. First Written Submission, para. 37.

flavour compounds are used in regular, menthol and clove cigarettes, respectively.

68. These flavour compounds are identified in that attached Exhibit US-102. The flavor compounds that were tested were selected by the U.S. Centers for Disease Control and Prevention because previous testing had revealed that they were commonly present in cigarettes with a characterizing flavor.[59] These compounds are used on their own or in combination to create a flavor sensation, such as cinnamon, plum, or sassafras.[60]

69. The CDC's test found that of the 17 regular tobacco cigarettes tested, none contained detectable levels of the 18 common flavor compounds; of the 18 menthol cigarettes tested, each cigarette contained only menthol and none of the other 17 flavor compounds; and of the 13 clove cigarettes tested, 12 contained detectable levels of five different flavor compounds.[61] This finding suggests that clove cigarettes contain additional "characterizing flavors" beyond cloves, which may be attributable to the "special sauce."

70. In short, this analysis demonstrates that clove cigarettes contain flavor compounds that are often used to create a characterizing flavor, while tobacco and menthol cigarettes do not contain these flavor compounds.

31. Both parties: What is the tobacco content of menthol cigarettes, and how does that compare with the tobacco content of regular cigarettes?

71. Detailed and specific information on the tobacco content of cigarettes, including menthol, flavored (including cloves), and "regular" is proprietary information that is generally not available to sources outside of the tobacco industry. Before the Tobacco Control Act went into effect, cigarette manufacturers were not required to list all ingredients on product labels. However, general facts can be ascertained with respect to tobacco content in terms of weight and type. In general, tobacco and menthol cigarettes are composed of approximately 90% tobacco by weight. With respect to the type of tobacco, both regular and menthol cigarettes typically are composed of a blend of Virginia, Maryland burley, oriental, and reconstituted tobacco.[62]

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[59] It should be noted that the flavor compounds tested are not the same thing as a sweetener such as sugar or vanilla, which are commonly used to mask the harshness and bitterness of tobacco but do not impart a distinct flavor. Sweeteners that do not impart a characterizing flavor are often found in "regular" cigarettes. Sweeteners are not usually "characterizing flavors" because they are not identifiable to the smoker, such as by imparting a distinguishing flavor, taste or aroma.

[60] *See* Table identifying the flavor sources characteristics associated with the tested flavor compounds, Exhibit US-102; *see also* Stanfill S, Duncan B, Yan X, Richter P, Watson CH, "Levels of 18 flavor analytes present in non-mentholated, mentholated and clove cigarettes products," (2010), Exhibit US-72.

[61] Exhibit US-72.

[62] *See* chart in response to Question 33; *The Design of Cigarettes*, Colin L. Browne, Ph.D. Celanese Fibers Company Technical Department Charlotte, North Carolina (1981) at 43. Exhibit US-103.

32. Both parties: What is the additive content of menthol cigarettes? Is it the case that the only additive that menthol cigarettes have is 1 per cent of menthol oil?

72. All cigarettes, including cloves and menthols, may contain a number of additives (that is material in addition to tobacco). Generally, the specific formula for each brand of cigarette is proprietary information that is not publicly available. Menthol brands vary in the amount of menthol per cigarette and in the amount of menthol per gram of tobacco; some menthol brands many have slightly more or less than 1% of menthol oil.

33. United States: What kind(s) of tobacco is used in clove cigarettes, and how does that compare with the tobacco content of regular cigarettes?

73. As noted, the specific formula for each brand of cigarette is proprietary information that generally is not publicly available. Accordingly, information on the particular types of tobacco used in particular cigarettes is not widely available to the public. However, general facts can be ascertained with respect to tobacco content in terms of weight and type.

74. With respect to weight, in general tobacco and menthol cigarettes are composed of approximately 90% tobacco by weight, and clove cigarettes are composed of approximately 60% to 80% tobacco by weight, with the additive of clove composing up to 40%.

75. With respect to different types of tobacco, generally speaking, there are significant differences in the types of tobacco used in regular and menthol cigarettes and clove cigarettes. Typically, regular and menthol "American-blend" cigarettes use a blend of Virginia, Maryland, burley, oriental, and reconstituted tobacco. Although data is sparser for clove cigarettes, it appears that clove cigarettes tend to use Java sun-cured tobacco as a major component of the product.

76. One example of the tobacco used in American-blend cigarettes and in clove cigarettes is provided in the table below:[63]

[63] Data compiled from: *The Design of Cigarettes*, Colin L. Browne, Ph.D. Celanese Fibers Company Technical Department Charlotte, North Carolina (1981) at 43. Exhibit US-103 and Keyser & Juita, "Smallholder Tobacco Growing in Indonesia: Costs and Profitability Compared with Other Agricultural Enterprises" HNP Discussion Paper, Economics of Tobacco Control Paper No. 27; The World Bank (2005) at 6, para. 28, Exhibit US-104.

Tobacco type	**Curing process**	**American-blend cigarettes**[64]	**clove cigarettes**[65]
Virginia	Flue-cured	32%	30%
Burley	Air-cured	20%	
Oriental	Sun-cured	10%	
Maryland	Air-cured	2%	
Reconstituted (Schweitzer method)		2%	
Java Sun-cured	sun-cured		30%
clove buds			40%

The table shows that clove cigarettes typically contain 40% cloves, 30% Java sun-cured, and 30% Virginia type tobacco. In comparison, the table shows that menthol and regular brands in the United States ("American-blend") typically contain a blend of Virginia, burley, Maryland, oriental, and reconstituted tobacco.[66]

34. Both parties: Do all clove cigarettes contain cocoa and coumarin?

77. The specific content of clove cigarettes is proprietary information to which the United States does not have access, although Indonesia may be able to provide this information to the Panel. However, evidence suggests that coumarin is prevalent in clove cigarettes.

78. As described in the U.S. First Written Submission,[67] a 2007 study found that coumarin was detected in 19 of the 33 clove cigarette brands tested, with levels ranging from 9.2 to 215 microg/cig. These detected levels are significantly higher than the levels found in commercial cigarette brands available in the United States.[68]

79. Results from the more recent research conducted by U.S. Centers from Disease Control and Prevention on common flavor compounds, described in more detail in response to Question 30, confirmed the presence of coumarin in clove cigarettes; 12 of 13 clove cigarettes tested

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[64] *The Design of Cigarettes*, Colin L. Browne, Ph.D. Celanese Fibers Company Technical Department Charlotte, North Carolina (1981) at 43, Exhibit US-103.

[65] Keyser JR, Juita NR, "Smallholder Tobacco Growing in Indonesia: Costs and Profitability Compared with Other Agricultural Enterprises" HNP Discussion Paper, Economics of Tobacco Control Paper No. 27; The World Bank (2005) at 6, para. 28, Exhibit US-104.

[66] Exhibit US-103; *see also The Changing Cigarette*, Exhibit US-99.

[67] U.S. First Written Submission, para. 166.

[68] U.S. First Written Submission, para. 166; Exhibit US-46.

contained detectable levels of coumarin.[69] In contrast, none of the regular or menthol cigarettes tested contained coumarin.[70] In an earlier study, only one of 68 non-clove cigarettes contained a detectable level of coumarin.[71] No studies have been published to show the prevalence of cocoa in clove cigarettes.

35. Both parties: What was the tobacco content of the "candy-flavoured" cigarettes? What were the additives included in the "candy-flavoured" cigarettes?

80. The United States would note as an initial matter that the term "candy-flavored" cigarettes is too narrow to describe the range of products banned under section 907(a)(1)(A). Section 907(a)(1)(A) applies to cigarettes with a characterizing flavor other than tobacco or menthol, including artificial and natural flavors and herbs and spices. The range of products banned under the legislation includes flavors such as cinnamon, clove, cola, coffee, and other "characterizing" flavors that are not necessarily associated with candy.

81. In addition, there is no precise definition of which flavors would be characterized as "candy" flavors, and information on the content and type of tobacco and the additives in non-clove, non-menthol cigarettes with characterizing flavors is proprietary information that is not easily available. To the extent that these products generally were made by American manufacturers (such as RJ Reynolds), the tobacco content was likely similar to other American-blend cigarettes, as described above**.**

36. Both parties: Is the toxicity of cigarettes an aspect of the "physical properties" of cigarettes?

82. Yes, the toxicity of cigarettes is an aspect of their physical properties. The Appellate Body expressly recognized in *EC – Asbestos* that the toxicity of a product is an element of a product's physical composition.[72] As the United States discusses further in its response to Question 40, the important question is not whether toxicity is a physical aspect of cigarettes, but whether, and to what extent, that physical attribute is relevant to the like product determination in this case.

83. The relative toxicity of asbestos and PCG fibres was a distinguishing physical characteristic of particular relevance in *EC – Asbestos*, because the Appellate Body considered that it was a health risk upon which consumers would differentiate the products. Moreover, the relative toxicity of the products in this case is not a basis for the public health distinctions drawn

[69] Exhibit US-72.

[70] Exhibit US-72.

[71] U.S. First Written Submission, para. 166; Exhibit US-71.

[72] *EC – Asbestos (AB)*, paras. 122, 128, 136.

between them, as it was in *EC – Asbestos*. In this case, trends of use and consumer choices are more relevant than relative toxicity.

37. Both parties: Is the level of addiction caused by regular, menthol and clove cigarettes the same?

84. In analyzing the human health effects of various types of cigarettes, it is important to examine separately two distinct issues: (1) the health effect on an individual of smoking cigarettes, and (2) the overall public health consideration, which turns in substantial part on how likely a specific type of cigarette will cause an increase in the use, by the population as a whole, of cigarettes and other tobacco products.[73] As the United States has explained, the distinctions in Section 907(a)(1) were based on public health considerations.

85. Thus the answer to Question 37 has two parts. With respect to the addictive effects of regular, menthol and clove cigarettes, all of these products contain nicotine and are thus addictive. Some data indicates that the levels of nicotine in clove cigarettes are higher than those of regular or menthol cigarettes.[74] If Indonesia believes that higher levels of nicotine in clove cigarettes have no impact on addictiveness, this would be Indonesia's burden to prove.

86. With respect to the public health considerations, there important differences in how regular, menthol and clove cigarettes are used among the U.S. population. One example of these differences, as the United States has explained, is that because of the attractive characterizing flavor of clove cigarettes, they are disproportionately used by young people and thus serve as trainer cigarettes.

38. Both parties: Is there any ingredient in clove cigarettes that:

(a) makes them more addictive than menthol or regular cigarettes?

87. Please see the response to Question 37.

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[73] In adopting a tobacco product standard, FDA must find that it is appropriate for the protection of the public health, taking into account, for example, the risks and benefits to the population as a whole, and must consider information concerning the countervailing effects of the standard on both tobacco users and nonusers. Section 907(a)(3)(B) and 907(b) of the FFDCA.

[74] *See, e.g.,* CDC, "Epidemiologic Notes and Reports Illnesses Possibly Associated with Smoking Clove Cigarettes," MMRW Weekly, 34(21), 297-9 (May 31, 1985), Exhibit US-37; Guidotti, *et al*, "Clove Cigarettes: the Basis for Concern Regarding Health Effects," The Western Journal of Medicine (August 1989), Exhibit US-38; Malson, *et al.*, "Clove Cigarette Smoking: Biochemical, Physiological, and Subjective Effects," Pharmacology Biochemistry and Behavior 74(3): 739-45 (February, 2003), Exhibit US-44; Polzin, *et al.*, "Determination of eugenol, anethole, and coumarin in the mainstream cigarette smoke of Indonesian clove cigarettes," Food & Chemical Toxicology 45(10): 1948-53 (October 2007), Exhibit US-45.

(b) makes them more harmful for health than menthol or regular cigarettes?

88. As the United States noted above in response to Question 37, it is important to examine separately two distinct issues in analyzing the human health effects of various types of cigarettes: (1) the health effect on an individual of smoking cigarettes, and (2) the overall public health consideration.

89. With respect to the first issue, the United States considers that all cigarettes are harmful and that smoking them is inherently unsafe. Whether smoking a given number of certain types of cigarettes is more harmful than smoking a given number of other types is the subject of various studies, and it is difficult to draw broad conclusions.

90. Nevertheless, some evidence shows that clove cigarettes contain ingredients that make them more harmful than menthol or tobacco cigarettes. If Indonesia believes that clove cigarettes are no more dangerous than other types of cigarettes, Indonesia would have the burden of proving this.

91. Compared to conventional (menthol or regular) cigarettes, clove cigarettes deliver more tar, nicotine, and carbon monoxide under machine-smoked conditions.[75] Clove cigarettes also may have greater than 1 mg of nicotine per cigarette, which is higher than the 1 mg standard recognized by the World Health Organization.[76]

92. Eugenol, a primary component in clove, is used as an anesthetic in dental procedures[77] and may have harmful effects on smokers, as identified during the 1980s. During a surge of popularity for clove cigarettes in the 1980s, eugenol was suspected of causing aspiration pneumonia or direct lung toxicity in 13 or more previously healthy young people.[78] The indirect toxic effect of eugenol is that by anesthetizing the back of the throat, it predisposes to aspiration, a

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[75] *See, e.g.,* CDC, "Epidemiologic Notes and Reports Illnesses Possibly Associated with Smoking Clove Cigarettes," MMRW Weekly, 34(21), 297-9 (May 31, 1985), Exhibit US-37; Guidotti, *et al*, "Clove Cigarettes: the Basis for Concern Regarding Health Effects," The Western Journal of Medicine (August 1989), Exhibit US-38; Malson, *et al.*, "Clove Cigarette Smoking: Biochemical, Physiological, and Subjective Effects," Pharmacology Biochemistry and Behavior 74(3): 739-45 (February 2003), Exhibit US-44; Polzin, *et al.*, "Determination of eugenol, anethole, and coumarin in the mainstream cigarette smoke of Indonesian clove cigarettes," Food & Chemical Toxicology 45(10): 1948-53 (October 2007), Exhibit US-45.

[76] *See* Knaresborough K., *Health effects of interaction between tobacco use and exposure to other agents*. Geneva, Switzerland: World Health Organization, 1999, Exhibit US-105.

[77] U.S. First Written Submission, para. 38.

[78] CDC, "Epidemiologic Notes and Reports Illnesses Possibly Associated with Smoking Clove Cigarettes," MMRW Weekly, 34(21), 297-9 (May 31, 1985), Exhibit US-37; Guidotti, *et al*, "Clove Cigarettes: the Basis for Concern Regarding Health Effects," The *Western Journal of Medicine* (August 1989), Exhibit US-38; Guidotti & Laing, "Clove Cigarettes," The *Western Journal of Medicine* (August 1992), Exhibit US-41.

condition in which the throat cannot keep vomit or regurgitated stomach contents from entering the trachea and lung. Because stomach acid is very damaging to lung tissue, aspiration sets up a serious, life-threatening initially sterile pneumonia which quickly becomes infected and may form an abscess. Several of the young people showed signs of aspiration pneumonia and at least two are known to have developed abscesses. Aspiration does not occur in healthy young people.

93. There are additional concerns about the health impact of coumarin. As the United States has previously stated, coumarin has been banned as an flavoring agent in food due to concern over toxicity.[79] Though conclusive research has not been performed on the impact of inhaling coumarin from clove cigarettes to allow definitive conclusions to be drawn, there is concern that inhaled coumarin may also present health risks.

94. With respect to the public health consideration, there are important differences in how regular, menthol and clove cigarettes are used by the U.S. population. As the United States has explained, because of the attractive characterizing flavor of clove cigarettes, they are disproportionately used by young people and thus serve as trainer cigarettes.

(c) masks the harshness of tobacco better than menthol cigarettes?

95. The United States is not aware of published research that compares masking of harshness by ingredients in clove cigarettes with masking of harshness by ingredients in menthol cigarettes. However, the two additives are not the same. Eugenol, which is a component of clove, is such a strong topical anesthetic that it is used to alleviate dental pain. Menthol is a milder topical anesthetic that creates a cooling sensation.

96. Research studies comparing the subjective experiences of smoking clove cigarettes to menthol or regular cigarettes contain information relevant to this question. According to one survey of youth in the state of Massachusetts who smoked clove cigarettes, 86% reported that clove cigarettes taste good.[80] And a small survey of smokers found that subjects preferred the taste of clove cigarettes to their usual brand.[81] These findings may indicate that ingredients in clove cigarettes effectively mask the harshness of tobacco.

39. Both parties: Is eugenol a component in clove cigarettes that enhances addiction?

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[79] *See* U.S. First Written Submission, para. 166.

[80] Soldz S., Dorsey E., "Youth Attitudes and Beliefs Toward Alternative Tobacco Products: Cigars, Bidis, and Kreteks," *Health Educ Behav* (2005) 32:549, Exhibit US-106.

[81] Malson, *et al.*, "Clove Cigarette Smoking: Biochemical, Physiological, and Subjective Effects," Pharmacology Biochemistry and Behavior 74(3): 739-45 (February, 2003), Exhibit US-44.

97. The United States is not aware of evidence showing whether on a cigarette-by-cigarette basis, the eugenol in clove cigarettes results in a different level of addiction than other cigarettes. However, as the United States has discussed, clove cigarettes have a different impacts on public health than other types of cigarettes. With respect to the eugenol element of clove cigarettes, eugenol has been used as a dental anaesthetic, and eugenol may numb the throat and thus mask the harsh taste of tobacco for beginner smokers. Compounds that make it easier to begin smoking may facilitate addiction.

40. United States: In paragraph 89 of its opening oral statement, Indonesia submits that the "relative toxicity of clove cigarettes is not an issue". Does the United States agree?

98. No, the United States does not agree. As the United States noted above, it is important to examine separately two distinct issues in analyzing the human health affects of various types of cigarettes: (1) the health effect on an individual of smoking cigarettes, and (2) the overall public health consideration. The United States understands the "relative toxicity" question to relate primarily to the first issue – the health affects on an individual of smoking a given quantity of cigarettes. Under the U.S. view of a proper like product analysis, the relative toxicity is not a key factor, but still must be considered – and Indonesia has the burden of proof on the issue.

99. All cigarettes are harmful and their use is inherently unsafe. The particular health measure at issue, section 907(a)(1)(A), is premised on the fact that all cigarettes are harmful and focuses on how cigarettes are used, in particular the prevalence of use among young people compared to adults. The relative toxicity of clove cigarettes is not an issue with respect to why clove cigarettes meet the criteria to be banned under section 907(a)(1)(A). The relevant factors with respect to section 907(a)(1)(A) are public health factors, primarily epidemiological in nature, focusing on patterns of use. The U.S. Congress also considered other, non-epidemiological factors, such as the potential for a black market, but the health considerations were premised on the understanding that all cigarettes are harmful and that public policy should consider trends and effects of use.

100. The United States would not agree, however, that the relative toxicity of clove cigarettes compared to tobacco or menthol cigarettes is "not an issue" with respect to whether the cigarettes are "like products." As the Appellate Body recognized in *EC – Asbestos,*[82] toxicity can be a distinguishing physical attribute of a product for purposes of determining likeness. The like product analysis considers an accumulation of factors, and relative toxicity is among them.

101. In this case, however, the United States has not emphasized relative toxicity as a "likeness" factor because it is not the health factor specifically at issue in the given regulatory context, and therefore is not the physical characteristic most relevant to the question of "likeness."

[82] *EC – Asbestos (AB)*, para. 122, 128, 136.

41. Both parties: Could it be argued that *regular* use is different from *occasional* use and that these are two different end-uses?

102. Regular and occasional use of cigarettes could be described as different "end-uses" in the United States, and also represent different cigarette markets within the United States. Cigarettes have different end-uses that are fulfilled by clove cigarettes and tobacco or menthol cigarettes in varying degrees.

103. The United States does not dispute that cigarettes are used to smoke tobacco and to deliver nicotine to the body. However, this is not the end of the story. If it were, all cigars, pipes and cigarettes would be like products, which we doubt even Indonesia would suggest. Cigarette use is a cultural and ritualized activity. It is commonly understood that using cigarettes is a means by which individuals form social identities, both through group identification or differentiation.[83] For example, it is not an accident that certain cigarette types and brands are heavily preferred within social or cultural groups.[84] The regular market in the United States is dominated by tobacco and menthol cigarettes, and has been for at least 50 years.

104. In addition to this "regular" market, there is also what could be called an "occasional" cigarette market in the United States. This is not a formal distinction, but describes the different way that different cigarettes are used in the United States. The "occasional" cigarette market refers to the cigarettes that are smoked less prevalently, and often by both novice and established young smokers as something "different." "Occasional" cigarettes seek to appeal, and do appeal, to uninitiated smokers and to regular young smokers by creating the impression of a "special" or "indulgent" smoking experience. They seek to be, and are understood as, out of the ordinary. One way this "specialness" is created is by specific or characterizing flavors. As intended, smokers of flavored cigarettes, including cloves, tend to feel a unique "pleasure" in smoking these cigarettes. Flavored cigarettes, including clove-flavored cigarettes, are examples of "occasional" use cigarettes. These cigarettes tend not to be used on a regular basis, but are used by a small portion of the population, mostly novice smokers within the age window of initiation.

105. Cigarettes associated with the "occasional" market in the United States do not typically compete directly with cigarettes associated with the "regular" market, and were not viewed by consumers as interchangeable. Before section 907(a)(1)(A) went into effect, clove cigarettes were sold in head shops and tobacco shops and other specialty stores, in effect trading accessibility for an aura of "mystique" and rarity. Indonesia has not suggested or provided evidence to show that clove cigarettes competed to increase their market share or to be used as a "regular" cigarette. It should be noted, as well, that the relatively small market share held by clove cigarettes in the United States was in no way affected by government measures. In fact, as noted in the U.S. First Oral Statement, the United States accorded *better* tariff treatment to clove cigarettes than to other

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[83] *See*, *e.g.*, *Acceptable Rebellion,* Exhibit US-96.

[84] *See*, *e.g.*, DiFranza JR, Eddy JJ, Brown LF, Ryan JL, Bogojavlensky A; Tobacco acquisition and cigarette brand selection among youth. Tobacco Control (1994) 3: 334-338, Exhibit US-107.

cigarettes in its WTO tariff bindings. Indonesia has not alleged a "latent" market for clove cigarettes in the United States. The fact is – as Indonesia has not contradicted – clove cigarettes were used as a special cigarette, and not a regular cigarette, in the United States.

106. The United States would emphasize, however, that the fact that clove and other flavors were used only occasionally and tobacco and menthol cigarettes are used more regularly does not indicate that clove and other flavored cigarettes did not have a significant role in initiation and facilitating addiction. "Occasional" cigarettes are especially appealing to youth and thereby help to familiarize young people with the experience of smoking tobacco, for example the experience of lighting, holding, and inhaling a cigarette. By making cigarette smoking familiar and comfortable, these occasionally-used cigarettes help to facilitate further use and addiction. As discussed in the response to Question 43 below, clove and other flavored cigarettes were used as "trainer" cigarettes among the U.S. population and therefore were significant from a public health perspective, even if not as significant in terms of the absolute number of smokers who used them.

43. Both parties: Are menthol cigarettes "starter" cigarettes for youth in the United States?

107. The brief answer to this question is "no."

108. As explained in the U.S. First Written Submission, Section 907 is addressed to cigarettes disproportionately used by young people in the stages of initiation at the time they are progressing from being non- or occasional smokers to a being regular, addicted smokers.[85] The United States has variously used the terms "starter", "gateway", or "trainer" cigarettes to describe this product category. For greater clarity, the United States will use the single term "trainer" cigarette.

109. Trainer cigarettes may be the first cigarette a young person picks up, or may be used experimentally or occasionally in addition to other cigarettes, but in either case have the effect of making cigarettes and the experience of smoking more familiar and acceptable to the user. It is not merely coincidental that trainer cigarettes such as cloves and cigarettes with characterizing flavors banned by section 907(a)(1)(A) are used disproportionately by young people and by very few older adults, in terms of absolute numbers; these cigarettes are especially enticing, and inexperienced smokers are drawn to them. They are "trainers" to the extent that, as the statistics show, young people do not keep using them or adopt them as their brand of choice, but rather move on to the common cigarettes on the market, *i.e.*, tobacco or menthol flavored cigarettes.

44. Both parties: Should the Panel confine its evaluation of consumers' tastes and habits to US consumers?

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[85] *See Why and How the Tobacco Industry Sells Cigarettes to Young Adults*, at 909-911 (discussing the multi-step process an individual goes through from trying the first cigarette to becoming a daily smoker), Exhibit US-93.

110. Yes – the tastes and habits of consumers outside of the United States are not relevant to deciding any of the factual or legal questions at issue in this dispute.[86] Section 907(a)(1)(A) arises specifically from circumstances of use within the United States, and should be evaluated in that context. As a legal matter, the Appellate Body has recognized that, for purposes of national treatment, a directly competitive or substitutable relationship must be present within the market at issue and "consumer responsiveness to products may vary from country to country."[87] The Appellate Body noted only a few limited circumstances in which evidence of consumer behavior outside the United States might be relevant.[88] However those circumstances are not present here. For example, in *Korea – Alcoholic Beverages*, the Appellate Body considered that it was not inappropriate for the panel to consider market evidence from Japan in order to evaluate "latent" or "potential" demand for a Japanese alcohol in Korea, because Japan had raised the allegation that Korean measures may have frozen demand in favor of the domestic product.[89] Such an allegation has not been raised in this case, and no other circumstances are present to which evidence from other markets would appear to be relevant.

46. United States: Does the United States accept that the measures at issue constitute "laws, regulations or requirements" within the meaning of Article III:4 of the GATT 1994?

111. The United States considers that it is the complaining Member's burden to prove the elements of its claims, including the status of the measure or measures at issue in the dispute. That said, the United States does not contest that section 907(a)(1)(A) is a law of the United States.

50. Both parties: Please provide figures on the value and quantity of the imports of clove cigarettes from Indonesia to the United States for the past 10 years.

112. Please see the response provided to Question 16 above.

52. United States: The United States argues that Indonesia has failed to meet its burden under Article III:4 of the GATT 1994 or Article 2.1 of the *TBT Agreement* to show that Section 907(a)(1)(A) accords less favourable treatment to clove cigarettes than tobacco or menthol cigarettes "based on the national origin" of the products.[90] Does the United States consider that only those measures that are not origin-neutral are capable of affording "less

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[86] The United States also notes that Indonesia has not suggested that consumer tastes and habits outside the United States are relevant, or put forth evidence to that effect.

[87] *Korea – Alcoholic Beverages (AB)*, para. 137.

[88] *Korea – Alcoholic Beverages (AB)*, para. 137.

[89] *Korea – Alcoholic Beverages (AB)*, para. 137.

[90] U.S. First Written Submission, para. 218.

favourable treatment" within the meaning of Article III:4 of the GATT 1994 and Article 2.1 of the *TBT Agreement*?

113. At the outset, the United States notes that Article III:4 of the GATT 1994 and Article 2.1 of the *TBT Agreement* only prohibit treatment of imported products that is less favorable than for *like* domestic products. Accordingly, these provisions are all about the question of comparing the treatment accorded by a measure to imported products with the treatment accorded to domestic products. In order to reach the question of what treatment is accorded to imported versus domestic cigarettes, it is first necessary to determine whether Indonesia has met its burden to prove that the imported and domestic cigarettes at issue are "like" products in the given context. Indonesia has not decided which cigarettes are in fact being compared, let alone demonstrated that clove cigarettes are like domestic cigarettes such that the obligation to accord no less favorable treatment applies.

114. The starting point to interpret Article III:4 of the GATT 1994 and Article 2.1 of the *TBT Agreement* is the text of the provisions. Article III:4 requires that imported products "shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements[.]" Similarly, Article 2.1 of the *TBT Agreement* ensures that, in respect of technical regulations, imported products "shall be accorded treatment no less favorable than that accorded to like products of national origin." The United States considers that the treatment at issue in both provisions is the treatment of imported products *compared to* the treatment of like domestic products. In other words, the national treatment obligations under the GATT 1994 and the *TBT Agreement* fundamentally concern an analysis of the treatment accorded by a measure to products based on the national origin of the products.

115. In deciding national treatment claims under Article III:4 of the GATT 1994, panels and the Appellate Body have considered whether the measure at issue accords less favorable treatment to imports as compared to like domestic products, either on the face of the measure itself or by the effect of the measure. The central inquiry is the relative treatment of imports *compared to* domestic products.[91] In this case, section 907(a)(1)(A) is facially neutral and, in effect, accords equal treatment to all cigarettes regardless of their national origin.

116. Indonesia claims, however, that even though section 907(a)(1)(A) sets a product standard that applies equally to all cigarettes, the measure in fact accords less favorable treatment to Indonesian cigarettes as compared to U.S.-produced cigarettes because clove cigarettes – the main type of cigarette produced in Indonesia – fall under the ban. To maintain that such occurrence is evidence of less favorable treatment, Indonesia refuses to engage crucial facts which demonstrate that, in fact, section 907(a)(1)(A) is neutral with respect to imported and domestic products. In

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[91] *See*, *e.g.*, *Korea – Beef (AB)*, paras. 130-151 (determining that a measure which establishes different distribution systems for imported and domestic beef does not *per se* accord less favorable treatment to imports but does so in effect). *Mexico – Soft Drinks (Panel)*, paras. 8.115-1222 (concluding that a soft drink and distribution tax in fact treated imports less favorably compared to domestic products).

particular, Indonesia ignores, and seeks to minimize, the fact that domestic cigarettes also fall under the ban, and that the vast majority of imported cigarettes are still permitted for sale in the United States.[92] In other words, Indonesia seeks to subtract from the analysis of Article III:4 under the GATT 1994 and Article 2.1 of the *TBT Agreement* relevant evidence to the central comparison at issue under the provision: the treatment of imported products as compared to domestic products.

E. ARTICLE 2.2 OF THE TBT AGREEMENT

54. Both parties: The United States observes that "Indonesia agrees with the United States that the rates that clove cigarettes are consumed by young people versus adults is a key fact to determine in this case".[93] If the evidence were to show that clove cigarettes do not actually appeal to youth, as Indonesia contends, would it not necessarily follow that Section 907(a)(1)(A) is more trade-restrictive than necessary to achieve the objective and therefore inconsistent with Article 2.2 of the *TBT Agreement*? Conversely, if the evidence were to show that clove cigarettes do actually appeal to youth, as United States contends, would it not necessarily follow that Section 907(a)(1)(A) is not inconsistent with Article 2.2 of the *TBT Agreement*? In other words, how central is this "key fact" to the evaluation of the measure under Article 2.2 - is this fact in and of itself decisive?

117. The fact that all banned flavored cigarettes (including cloves) appeal to young people (and, in fact, disproportionately appeal to young people) is evidence that section 907(a)(1)(A) fulfills its legitimate objective.

118. With regard to the Panel's first question, Indonesia has not met its burden of showing that clove cigarettes do not appeal to youth smokers. Moreover, although not the U.S. burden to establish this fact, the United States has submitted convincing evidence on the issue.

119. That said, this key fact would not be decisive or sufficient to meet Indonesia's burden. Even if Indonesia were to establish that clove cigarettes were not disproportionately used by youth smokers, section 907(a)(1)(A) would still discourage youth smoking. In this counterfactual world, section 907(a)(1)(A) would still amount to a step towards fulfillment of the U.S. objective, although it would be a less targeted measure than the measure adopted in the actual world (where clove cigarettes *are* disproportionately used by youth smokers). In the counterfactual presented in the first sentence of the Panel question, Indonesia would still have the burden of proving that the measure was more trade restrictive than necessary.

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[92] Exhibit US-100.

[93] U.S. First Written Submission, para. 244.

120. The Panel's second question asks whether Indonesia could prevail on its Article 2.2 claim in the situation that the United States believes reflects the state of the record in this dispute: namely, where the record shows that clove cigarettes disproportionately appeal to young people. In these circumstances, the United States does not understand how Indonesia could establish that a reasonably available alternative measure exists that fulfills the United States' legitimate objective and is less trade restrictive, and notes that Indonesia has yet to even attempt to articulate such position.

55. United States: Indonesia submits that the test that has been developed under Article XX(b) of the GATT 1994 is equally applicable to the second sentence of Article 2.2 of the *TBT Agreement*. The United States disagrees, and terms this a "radical approach".[94] In *Brazil - Retreaded Tyres* the Appellate Body developed a framework for determining whether a measure is "necessary to protect human, animal or plant life or health" under Article XX(b) of the GATT 1994. What in the United States' view are the precise aspects of the Appellate Body's Article XX(b) analysis in *Brazil - Retreaded Tyres* that are inapplicable to Article 2.2 of the *TBT Agreement*?

121. No aspect of the Appellate Body's GATT Article XX(b) analysis in *Brazil – Retreaded Tyres* is applicable to a TBT Article 2.2 analysis.

122. To establish a breach of Article 2.2 of the TBT Agreement, a complaining party must establish that the measure at issue is "more trade-restrictive than necessary to fulfil a legitimate objective." As reviewed in the U.S. First Written Submission, interpreting Article 2.2 in accordance with customary rules of interpretation of public international law, a measure is "more trade-restrictive than necessary to fulfill a legitimate objective" if (1) there is a reasonably available alternative measure (2) that measure fulfills the objectives of the measure at the level that the Member imposing the measure has determined is appropriate and (3) is significantly less trade-restrictive.[95] It would not be appropriate to apply the same interpretive approach the Appellate Body in *Brazil – Retreaded Tyres* undertook in Article XX of the GATT 1994 in analyzing whether a measure is "more trade restrictive than necessary" within the meaning of Article 2.2 of the TBT Agreement.

123. In particular, the term "necessary" is used in GATT Article XX in a very different context than in TBT Article 2.2. Under TBT Article 2.2, a panel is inquiring as to whether a measure that fulfills a legitimate objective is "more trade restrictive than necessary" to fulfill that objective. On the other hand, under GATT Article XX, the question is whether it is "necessary" to breach the GATT 1994 to protect human, animal or plant life or health or public morals or to secure compliance with laws or regulations. Thus, the alternatives that are being compared under TBT

[94] U.S. First Written Submission, fn 310.

[95] U.S. First Written Submission, paras. 264-265.

Article 2.2 are two alternatives that are WTO-consistent, while the alternatives being compared under GATT Article XX are an alternative that is WTO-inconsistent and another that is WTO-consistent. Moreover, the question under GATT Article XX is whether the measure itself is necessary, whereas under TBT Article 2.2 the question is whether the amount of trade-restrictiveness is necessary. And, unlike under Article XX, it is the complaining party that has the burden of establishing that the measure is "more trade-restrictive than necessary" under Article 2.2.

124. Further, there is no textual basis to apply the panel and Appellate Body's interpretive approach to GATT Article XX to TBT Article 2.2. Under the VCLT, the terms of a treaty must be interpreted based on their ordinary meaning in their context in light of the object and purpose of the treaty. The interpretation of TBT Article 2.2 based on the VCLT is outlined in the U.S. First Written Submission,[96] and does not support reading the word "necessary" in the phrase "more trade-restrictive than necessary to fulfil a legitimate objective" in TBT Article 2.2 to have the same meaning as the word "necessary" in GATT Article XX(a), (b) or (d). In light of the different context in which the word "necessary" appears in TBT Article 2.2 as compared to GATT Article XX and the different circumstances surrounding conclusion of those provisions, it would not be appropriate to apply the same meaning or interpretive approach to both provisions.

125. Accordingly, given that GATT Article XX(b) involves an entirely separate inquiry from the TBT Article 2.2, many of the aspects of the *Brazil – Retreaded Tyres* analysis would make no sense in the TBT Article 2.2 context.[97] For example, it would not be appropriate for a panel to ever evaluate the importance of the Member's objective in a TBT Article 2.2 analysis. Technical regulations can be applied for an innumerable number of reasons, and the text of TBT Article 2.2 recognizes this by leaving open the list of possible legitimate objectives. Not every technical regulation will be about life or death, but that does not mean that Members are afforded less discretion to make policy choices when applying technical regulations regarding consumer information as opposed to product safety.[98] There is simply no room in the text of TBT Article 2.2 for panels to second guess the policy choices of Members in that way. What panels can do, and in fact are obligated to do, is to inquire as to whether another measure exists that is reasonbly available that fulfills the policy objective of the challenged measure, but in a less trade restrictive way.

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[96] U.S. First Written Submission, paras. 259-268.

[97] The United States would also note that it has significant concerns with many of the aspects of the Appellate Body's analysis in *Brazil – Retreaded Tyres* as it applies to GATT Article XX(b).

[98] In this regard, the United States notes that there is no inquiry into the importance underlying the challenged SPS measure in an SPS Article 5.6 analysis – the inquiry is limited to evaluating whether "there is an SPS measure which: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member's appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the SPS measure contested." U.S. First Written Submission, para. 264 (quoting *Australia – Apples (AB)*, para. 194).

56. Both parties: The United States relies on footnote 3 to Article 5.6 of the SPS Agreement to argue that the appropriate standard to be applied under Article 2.2 of the *TBT Agreement* is whether an alternative measure exists that is "significantly" less restrictive to trade. Does a different legal standard apply under Article XX(b) of the GATT 1994?

126. While the analsyes of whether a measure is inconsistent with Article 2.2 of the TBT Agreement and whether a measure is justified under Article XX of the GATT 1994 may both look at the availability of an alternative measure, they are doing so to answer different questions. As discussed above, the question under a TBT Article 2.2 analysis is whether a measure restricts trade more than is necessary to fulfill an objective such as protecting human health. Answering the question under Article 2.2 involves analyzing whether an alternative measure is reasonably available that is significantly less trade- restrictive that fulfills the Member's legitimate objective. Such an analysis requires comparing the trade-restrictiveness of the challenged measure verses an alternative measure, and whether the proposed alternative measure is significantly less trade-restrictive. As elaborated in the response to Question 57 below, the need to review whether the alternative measure is significantly less trade restrictive is base on the particular context of that provision and confirmed by the letter from the Director-General of the GATT regarding TBT Article 2.2.

127. In contrast, the question under GATT Article XX(b) is whether it is necessary to breach the GATT to protect human, animal or plant life or health. Answering this question involves comparing the challenged measure (which was found to be WTO-inconsistent) with an alternative measure (which is WTO-consistent) and determining whether the alternative measure would make an equivalent contribution to the particular object pursued by the WTO-inconsistent measure such that it would not be "necessary" for the Member to breach its obligations under the GATT to fulfill that objective. Whether the WTO-consistent measure restricts trade less, or significantly less, is not relevant to this inquiry.

57. Both parties: Assuming *arguendo* that there is a difference between a "significantly less trade restrictive" standard and "less trade restrictive" standard, is that difference of any practical relevance in the present case? Would the application of one versus the other standard in the present case have any practical consequences for the evaluation of whether Section 907(a)(1)(A) is consistent with Article 2.2 of the *TBT Agreement*?

128. As noted in the U.S. First Written Submission, the United States considers that a measure would not breach of Article 2.2 where the complaining Member adduces sufficient evidence that an alternative measure fulfills the responding Member's legitimate objective and is less trade restrictive than the challenged measure by only insignificant margins. This view is supported by the December 15, 1993 letter from the Director-General of the GATT, which stated that while:

> it was not possible to achieve the necessary level of support for a U.S. proposal [concerning a clarifying footnote to Article 2.2 and 2.3 of the TBT Agreement] . . . it was clear from our consultations at expert level that participants felt it was obvious from other provisions of the [TBT] Agreement that the Agreement does not concern itself with insignificant trade effects nor could a measure be considered more trade restrictive than necessary in the absence of a reasonably available alternative.[99]

129. It is also supported by the context of Article 2.2: Article 5.6 of the SPS Agreement, which sets out a similar obligation to TBT Article 2.2 and makes clear in a footnote that establishing a breach of Article 5.6 involves putting forth an alternative that is "significantly" less trade restrictive.[100] It is also consistent with the TBT Agreement, which, for example, in Article 1.6, 2.9, and 5.6 indicates Members' concern with measure that have a significant effect on trade.[101]

130. That said, this issue would not appear to arise in this dispute where the challenged measure is an import ban and Indonesia adduces sufficient evidence that an alternative measure exists that does not ban its product, although the United States notes that to date Indonesia has failed to do so.

131. Finally, the United States would note that not every alternative measure would be less restrictive. For example, the possible alternative measure that the Panel refers to in question 53 (banning all flavored cigarettes except for tobacco-flavored) would not be less trade restrictive than section 907(a)(1)(A) – to the contrary, it would cover more imported products and would be more trade restrictive.[102]

58. Both parties: Both parties have made assertions about the "level of protection" sought by the United States. Article 5.6 of the SPS Agreement refers to the "level of protection" pursued by the Member in question. Article 2.2 of the *TBT Agreement* does not. Please clarify:

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[99] Letter from Peter D. Sutherland, Director-General of the GATT, to Ambassador John Schmidt, Chief U.S. Negotiator (December 15, 1993), Exhibit US-79. As noted in footnote 305 of the U.S. First Written Submission, the Director-General's letter provides supplemental means of interpretation within the meaning of Article 32 of the VCLT, in particular as circumstances of the TBT Agreement's conclusion, that confirms the meaning derived from the ordinary meaning, in context, and in light of the object and purpose of the TBT Agreement.

[100] U.S. First Written Submission, para. 263.

[101] Article 1.6 provides: All references in this Agreement to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments thereto and any additions to the rules or the product coverage thereof, except amendments and additions of an insignificant nature." Articles 2.9 and 5.6 set out members' obligations to publish and modify proposed measures that have a "significant effect on trade."

[102] Question 53. **Indonesia:** How is the exclusion of menthol cigarettes from the scope of the ban relevant to Indonesia's additional claim under Article 2.2 of the *TBT Agreement*? Could a finding of inconsistency with Article 2.2 of the *TBT Agreement* be remedied by extending the scope of the ban to also cover menthol cigarettes?

(a) What is the legal basis for considering the "level of protection" as part of the analysis under Article 2.2 of the *TBT Agreement*?

132. As the Panel correctly notes, the term "level of protection" is not used in Article 2.2 of the TBT Agreement nor elsewhere in the TBT Agreement. The preamble to the TBT Agreement, however, states that a Member should not be prevented from taking measures *inter alia* to protect human life or health *at the level the Member considers appropriate*. Article 2.2 states that technical regulations shall be no more trade-restrictive than necessary to fulfill a legitimate objective and explicitly includes protecting human health or safety as a legitimate objective. The preamble informs the interpretation of Article 2.2, in particular by making clear that a Member may adopt technical regulations to fulfill legitimate objectives such as protecting human life or health at the levels it considers appropriate. As the panel in *EC – Sardines* stated, "it is up to the Member[] to decide which policy objectives [it] wish[es] to purse and the levels at which [it] wish[es] to pursue them."[103]

(b) Why does the Panel have to make a finding on the "level of protection" in order to determine if the measure is consistent with Article 2.2 of the *TBT Agreement*?

133. A finding on the "level of protection" is not necessary in order to determine if a measure is inconsistent (or not inconsistent) with Article 2.2 of the TBT Agreement. As noted in response to (a), "level of protection" is not a term used in the TBT Agreement. However, as also noted in response to (a), the preamble to the TBT Agreement makes clear that Article 2.2 allows Members to decide for themselves which legitimate objectives to pursue and at what levels to pursue them.

134. However, evaluating the Member's level of protection may be helpful in analyzing whether a measure is more trade restrictive than necessary to fulfill a legitimate objective. For example, if the measure at issue goes beyond the chosen level of protection, there may be a case where a less trade restrictive measure may likewise fulfill the Member's legitimate objective.

135. In this dispute, the objective of section 907(a)(1)(A) is protecting public health by reducing smoking prevalence among young people while avoiding the potential negative consequences associated with banning products to which tens of millions of adults are chemically and psychologically addicted due to the potential but unknown consequences for the health of the individual users or the overall population. The means by which section 907(a)(1)(A) does this is to ban products that are disproportionately used by young people while not banning products to which tens of millions of adults are addicted. The level at which the United States considers appropriate to protect public health is to eliminate from the market, not simply restrict access to, those products that are disproportionately used by young people but not to eliminate from the market those products to which tens of millions of adults are addicted, and whose precipitous withdrawal from the market may cause negative public health consequences.

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[103] *EC – Sardines (Panel)*, para. 7.120.

(c) The "level of protection" is not expressly identified in the FSPTCA. Please clarify how the "level of protection" underlying the measure at issue should be ascertained by the Panel.

136. As noted in (a), it is for a Member to decide its own legitimate objectives and the level at which to pursue them. The level at which section 907(a)(1)(A) seeks to protect public health is drawn from the text of measure itself and confirmed by its legislative history as reviewed in paragraphs 251-252 of the U.S. First Written Submission. The Panel may confirm that the level at which section 907(a)(1)(A) seeks to protect public health is as the United States represents by reviewing these same sources.

(d) Do the parties consider that the Panel should attempt to identify the "level of protection" sought by the United States on the basis on inferences?

137. As noted in response to part (a), a finding on the "level of protection" is not necessary in order to determine if Section 907 is consistent with Article 2.2 of the TBT Agreement. Should the Panel make a finding on this issue, the Panel should do so based on the text of measure itself, as confirmed by its legislative history.

59. Both parties: Is the Panel correct in its understanding that there is no relevant "international standard" within the meaning of the second sentence of Article 2.5 of the *TBT Agreement*?

138. Yes, the United States considers that the Panel is correct in its understanding that there is no relevant "international standard" within the meaning of the second sentence of Article 2.5 of the *TBT Agreement*.

60. Both parties: Each party has provided a number of slightly different formulations of the "objective" of the measure at issue. Please clarify how the "objective" of Section 907(a)(1)(A) should be expressed.

139. The objective of section 907(a)(1)(A) is protecting public health by reducing smoking prevalence among young people while avoiding the potential negative consequences associated with banning products to which tens of millions of adults are chemically and psychologically addicted due to the potential but unknown consequences for the health of the individual users or the overall population. The means by which section 907(a)(1)(A) does this is to ban products that are disproportionately used by young people while not banning products to which tens of millions of adults are addicted.

61. Both parties: The last sentence of Article 2.2 of the *TBT Agreement* provides that in assessing the risks that non-fulfilment of the objective would create,

"available scientific and technical information" are relevant elements of consideration. Have the parties provided the Panel with any "available scientific and technical information" for the purposes of the fourth sentence of Article 2.2?

140. Yes, as explained below.

141. Article 2.2 provides, in relevant part, that "... technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. ... 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."

142. The final clause of the second sentence ("taking account...") requires Members in adopting a technical regulation to take into account the risks of non-fulfillment, and the fourth sentence requires that in doing so a Member consider among other things available scientific and technical information. In this case, not fulfilling the objective would result in the smoking rates of young people remaining unchanged. As discussed in the U.S. First Written Submission, if smoking rates among adolescents remain unchanged, more than 19 million individuals who are currently under 18 in the United States will grow up addicted to cigarettes, and more than 6 million of them will die prematurely from smoking, a significant risk indeed.[104] Congress was well aware of the risks that smoking poses to the U.S. population and it was fear of those severe risks that motivated Congress to enact one of the strictest anti-smoking laws that any Member has applied. For example, Congress made a finding in the Tobacco Control Act that:

> Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.[105]

143. In addition, the legislative history indicates that in the consideration of the Tobacco Control Act generally, Congress took into account numerous scientific studies related to smoking of young people.[106]

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[104] U.S. First Written Submission, para. 18 (citing Exhibit US-17).

[105] Tobacco Control Act, sec. 2, finding 14, Exhibit US-7.

[106] For example, the October 3, 2007 U.S. House of Representatives hearing on the proposed law provides numerous references to scientific data. *See* Hearing Before the Subcommittee on Health of the Committee on Energy and Commerce of the U.S. House of Representatives on H.R. 1108, serial no. 110-69 (October 3, 2007), Exhibit US-108. Among the scientific data discussed at the House Hearing and among the pages on which they are discussed are the following: the 2007 Institute of Medicine report "Ending the Tobacco Problem: A Blueprint for the Nation," at 32, 33, 35; the 2006-2007 President's Cancer Panel Annual Report, at 115; the 2004 U.S. Surgeon

63. United States: The United States claims in paragraph 66 of its opening oral statement that menthol cigarettes were not banned by Section 907(a)(1)(A) because tens of millions of adult smokers are addicted to them. Did the United States consider the possibility of those adult smokers switching to regular cigarettes? If yes, what were the conclusions reached on this issue? In particular, did the United States consider any data concerning the percentage of menthol cigarette smokers that would have switched to regular cigarettes? If so, could the United States provide such data to the Panel?

144. No country in the world has ever tried to ban menthol cigarettes. In fact, with the exception of Bhutan, no country has ever tried to ban institute a broad ban on cigarettes.[107] As a result, the United States was not able to draw reasoned conclusions from the experiences of other Members. Furthermore, in the United States, many times individual states act as laboratories for the development of new U.S.-wide public health strategies. However, no state within the United States had banned menthol cigarettes, or any tobacco product used by so many people, so no U.S. specific data was available.

145. During the course of their meetings, the TPSAC has grappled with this very question and found the amount of information on the behavior of menthol smokers lacking. Two studies that were presented to TPSAC followed smokers over time and looked at whether menthol smokers switched to regular cigarettes and whether regular smokers switched to menthol cigarettes.[108] One of them, relying on recently gathered data, found that, over the course of the study period, 12% of study participants switched from menthol to non-menthol cigarettes while 11% switched from

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General's report "The Health Consequences of Smoking," at 38; the 2005 Harvard School of Public Health Study "New Cigarette Brands with Flavors That Appeal to Youth: Tobacco Marketing Strategies," at 69; and the 2005 NSDUH, at 69. The witnesses that testified before the H.R. Subcommittee included: Richard Bonnie, Director, Institute of Law, Psychiatry, and Public Policy, University of Virginia; Fred Jacobs, M.D., Commissioner, New Jersey Department of Health and Senior Services; Alan Blum, M.D., Director of the Center for Study of Tobacco and Society, College of Community Health Sciences, University of Alabama; Risa Lavizzo-Mourey, M.D., President and Chief Executive Officer, Robert Wood Johnson Foundation; Scott Ballin, Steering Committee Member, Alliance for Health, Economic, and Agriculture Development; and William V. Corr, Executive Director, Campaign for Tobacco-Free Kids.

[107] The United States will discuss the Bhutan experience in greater detail in its Second Written Submission. However, for purposes here, it is sufficient to note that in 2004 Bhutan enacted a national sales ban on cigarettes. Individual consumption of tobacco was allowed along with a 100% sales tax and 100% import tax if the tobacco was imported into Bhutan for personal use. Tobacco imported from India was subject only to the 100% sales tax due to a free trade agreement with Bhutan. The consequences of the law have included a robust black market, significant tobacco smuggling, continued smoking in entertainment venues, and continued smoking by some segments of the population, particularly young people. *See* Givel, *Tobacco Use Policymaking and Administration in Bhutan* (November 2009), Exhibit US-109.

[108] Pletcher, *et al.*, "Menthol Cigarettes, Smoking Cessation, Atherosclerosis, and Pulmonary Function: the Coronary Artery Risk Development in Young Adults (CARDIA) Study," Archives of Internal Medicine, Vol. 166, at 1915-1922 (September 25, 2006), Exhibit US-110.

non-menthol to menthol cigarettes. The second paper followed African-American smokers for 4.5 years and found that 15% switched from non-menthol to menthol cigarettes while only 4% switched from menthol to non-menthol.[109]

146. Based on the available data, the United States understands that for each adult menthol smoker, a number of outcomes could occur if menthol cigarettes were banned. Each smoker could: switch to regular cigarettes (or another tobacco product), successfully quit smoking, continue to smoke menthol cigarettes (obtained through the black market or another means), switch to other mentholated tobacco products, or self-mentholate their cigarettes. The United States did not have data indicating how many smokers would enter each of these pathways at the time of passage of the Tobacco Control Act; the limited studies referred to above do not present data from which reliable conclusions could be drawn.

147. Given the paucity of information, the fact that approximately 18 million adults smoke menthols, and the potential for negative consequences to occur, the United States refrained from enacting a precipitous ban on menthol cigarettes and directed FDA and TPSAC to further study the issue, so that actions specifically taken with respect to menthol would be appropriate for the protection of the public health. The TPSAC Report is pending. After the report is issued, FDA will consider the issue further. Congress recognized FDA as having particular expertise in this area,[110] gave FDA tools to better understand these issues,[111] and gave FDA adequate authority to address them.[112]

G. ARTICLES 2.5, 2.9, 2.10 AND 2.12 OF THE TBT AGREEMENT

67. United States: In responding to Indonesia's claim under Article 2.5, the United States points to the minutes of the November 2009 TBT Committee meeting. Was there anything else in written form that the United States can provide to the Panel, or were all of the United States' explanations of the justification of the measure only provided verbally?

148. At this time, we are not aware that the United States, or any representative thereof, provided any written responses to Indonesia on this issue.

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[109] Sidney, *et al.*, "Mentholated Cigarette Use among Multiphasic Examinees, 1979-86," American Journal of Public Health, Vol 79, No. 10, 1415-1416 (1989), Exhibit US-111. Yet another publication relevant to this topic found that 60% of menthol smokers would pay more money for a menthol cigarette than a non-menthol cigarette. Hymowitz, *et al.*, "Menthol cigarette smoking in African Americans and whites," Letter to the Editor, Tobacco Control 1995; 4: 194-195, Exhibit US-112.

[110] *See* Tobacco Control Act, sec. 2(44) and sec. 2(45). Exhibit US-7.

[111] *See, e.g.*, FFDCA, sec. 904(a) and (b), as amended by the Tobacco Control Act, Exhibit US-7.

[112] *See, e.g.*, Tobacco Control Act, sec. 3(2), Exhibit US-7; FFDCA, sec. 907, as amended by the Tobacco Control Act, Exhibit US-7.

69. Both parties: What is the meaning of the term "significant effect on trade" within the context of Article 2.9 of the *TBT Agreement*?

149. The United States does not view the term "significant effect on trade" as requiring a large amount of trade to be affected before Article 2.9 is triggered. Rather, the United States views the term "significant effect" to mean to encompass all non de minimis effects on trade.[113]

71. United States: Did the United States notify other Members through the Secretariat of the measure in accordance with Article 2.9.2 and/or 2.10.1 of the *TBT Agreement*? Please answer with a yes or no.

150. The United States did not notify the measure to the WTO Secretariat.

72. Both parties: It appears that both parties agree that for the purposes of Article 2.12 of the *TBT Agreement*, the date of "publication" of the technical regulation was the date the FSPTCA became law, and that the date of "entry into force" was the date, three months later, that Section 907(a)(1)(A) took effect. Is the Panel's understanding of the parties' positions correct? What was the exact date on which Section 907(a)(1)(A) took effect?

151. The U.S. Congress passed the Tobacco Control Act on June 11, 2009. The President signed the Act into U.S. on June 22, 2009. The Act, as signed by the President, was publicly available (published on the U.S. government website for legislation) as of June 22, 2009. September 22, 2009 is the day that section 907(a)(1)(A) took effect.

H. ARTICLE 12.3 OF THE TBT AGREEMENT

73. Both parties: The Panel in *EC – Approval and Marketing of Biotech Products* examined a claim under Article 10.1 of the SPS Agreement, which it described as the "equivalent provision" to Article 12.3 of the *TBT Agreement*.[114] Are there any aspects of that Panel's interpretation of Article 10.1 of the SPS Agreement that can be transposed to Article 12.3 of the *TBT Agreement*?

152. Based on the similarities between the provisions, SPS Article 10.1 provides relevant context for the interpretation of TBT Article 12.3.[115] Accordingly, past WTO reports examining

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[113] *See also* U.S. Answer to Question 57.

[114] *EC – Biotech*, fn 1330.

[115] TBT Article 12.3 obligates developed country Members to "in the preparation and application of technical regulations...take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations...do not create unnecessary obstacles to exports..." Similarly, SPS Article 10.1 obligates developed country Members to "in the preparation and application of sanitary and phytosanitary measures...take account of the special needs of developing country Members..."

the meaning of SPS Article 10.1, such as the *EC – Biotech* report, may be instructive to the Panel in this dispute.

153. When examining a claim under SPS Article 10.1, the *EC – Biotech* panel concluded that the developing country Member had the burden of demonstrating that the developed country Member did not take its special needs into consideration.[116] In addition, the *EC – Biotech* panel clarified that a developed country Member is not required to adopt every suggestion put forward by the developing country Member, but rather may balance the developing country Member's views with the views of other interested parties.[117] The *EC – Biotech* panel also concluded that the developed country Member is not required to provide the developing country Member with special and differential treatment vis-à-vis other developed country exporters.[118]

154. The Panel in this dispute should adopt a similar interpretation of TBT Article 12.3 as the *EC – Biotech* panel adopted for SPS Article 10.1. Based on this interpretation, Indonesia has clearly failed to establish that the United States has breached TBT Article 12.3 since Indonesia has failed to even identify what its special needs are or to adduce evidence to show that it made the United States aware of these special needs.[119]

75. Both parties: Does a developing country invoking Article 12.3 of the *TBT Agreement* have to prove that they communicated their special development, financial and trade needs to the developed country enacting a technical regulation in order to trigger the protection of this provision?

155. Indonesia has the burden of proof for this claim, and has not satisfied its burden as explained in the U.S. First Written Submission.[120] To establish a claim under Article 12.3, Indonesia, assuming *arguendo* it is a developing country, must identify what "special development, financial [or] trade needs" it had that the United States failed to take into account. Indonesia has not provided evidence that it identified any such needs during the legislative process, nor has it done so in it submissions to the Panel in this dispute.

77. Both parties: What kind of evidence would be sufficient to show that a Member implementing a technical regulation did "take account of" the special

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[116] *EC – Biotech*, para. 7.1622 (stating that "it is incumbent on Argentina as the Complaining Party to adduce evidence and argument sufficient to raise a presumption that the European Communities has failed to take into account Argentina's special needs as a developing country Member.").

[117] *EC – Biotech*, para. 7.1621 (stating that "[t]here is nothing in Article 10.1 to suggest that in weighing and balancing the various interests at stake, the European Communities must necessarily give priority to the needs of Argentina as a developing country.").

[118] *EC – Biotech*, para. 7.1621.

[119] *See* U.S. First Written Submission, para. 305-310.

[120] *See* U.S. First Written Submission, para. 305-310.

needs of developing country Members under Article 12.3 of the *TBT Agreement*?

156. The United States notes that it is Indonesia that has the burden of proof for this claim. Accordingly, and assuming *arguendo* that Indonesia is a developing country Member, it Indonesia that must identify what "special development, financial and trade needs" it has and how the United States did not take those needs into account "with a view to ensuring that such technical regulations . . . do not create unnecessary obstacles to exports from developing country Members."

157. To the best of our understanding, Indonesia has never identified any needs that are unique to a developing country (as opposed to a developed one). And even if Indonesia has identified such special needs, Indonesia has never established that the United States has not taken into account those needs "with a view to ensuring that such technical regulations . . . do not create unnecessary obstacles to exports from developing country Members. "

158. Article 12.3 only obligates the developed Member to take the developing Member's needs into account, that is consider them; not to modify the measure on account of them. Thus, Indonesia would need to establish that, assuming Indonesia establishes its particular development needs in this context, the United States did not consider them. Given that Indonesia had the opportunity to communicate its concerns to various U.S. government officials over a multi-year period, Indonesia cannot establish that the United States has acted inconsistently with Article 12.3.[121]

I. UNITED STATES' DEFENCE UNDER ARTICLE XX OF THE GATT 1994

78. United States: Is the United States invoking Article XX of the GATT as a defence for the claims raised by Indonesia under the *TBT Agreement*?

159. The United States is not invoking Article XX of the GATT as a defense for the claims raised by Indonesia under the *TBT Agreement*.

79. Both parties: Could the parties provide the Panel with their views about the possibility of raising a defence under Article XX of the GATT 1994 to justify a violation of a provision of the *TBT Agreement.*

160. Given the U.S. response to question 78, the United States understands that the Panel does not need to make a finding on this legal issue.

[121] *See* U.S. First Written Submission, para. 308.

Exhibit List

US-92	Wechsler, *et al*, "Increased Levels of Cigarette Use Among College Students: A Cause for National Concern," Journal of American Medical Association, Vol. 280, no. 19, 1673-1678 (November 18, 1998)
US-93	Ling & Glantz, "Why and How the Tobacco Industry Sells Cigarettes to Young Adults: Evidence from the Industry Documents," American Journal of Public Health, Vol. 92, No. 6, 908-916 (June 2002)
US-94	Lantz, "Smoking on the rise among young adults: implications for research and policy," Tobacco Control 2003;12
US-95	Wayne & Connolly, "How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93," Tobacco Control 2002; 11 (Suppl I)
US-96	Hendlin, *et al*, "'Acceptable rebellion': marketing hipster aesthetics to sell Camel cigarettes in the US," Tobacco Control, 2010;19: 213-222
US-97	Biener & Albers, "Young Adults: Vulnerable New Targets of Tobacco Marketing," American Journal of Public Health, Vol. 94, No. 2 (February 2004)
US-98	155 Cong. Rec. S64111 (June 10, 2009)
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