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

(DS406)

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

March 3, 2011

TABLE OF REPORTS

Australia – Apples (Panel)	Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R, adopted 17 December 2010, as modified by the Appellate Body Report, WT/DS367/AB/R
Australia – Apples (AB)	Appellate Body Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R, adopted 17 December 2010
Australia – Salmon (AB)	Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998
Brazil – Tyres (Panel)	Panel Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/R, adopted 17 December 2007, as modified by the Appellate Body Report, WT/DS332/AB/R
Brazil – Tyres (AB)	Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R, adopted 17 December 2007
Chile – Alcohol (AB)	Appellate Body Report, *Chile – Taxes on Alcoholic Beverages,* WT/DS87/AB/R, WT/DS110/AB/R, adopted 12 January 2000
EC – Aircraft (Panel)	Panel Report, *European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft*, WT/DS316/R, circulated 30 June 2010
EC – Asbestos (AB)	Appellate Body Report, *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/AB/R, adopted 5 April 2001
EC – Hormones (AB)	Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998
Indonesia – Autos	Panel Report, *Indonesia – Certain Measures Affecting the Automobile Industry,* WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R, and Corr.1 and 2, adopted 23 July 1998, and Corr. 3 and 4
Japan – Agricultural Products (AB)	Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999
Japan – Alcohol (AB)	Appellate Body Report, *Japan – Taxes on Alcoholic Beverages,* WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996

Korea – Alcohol (Panel)	Panel Report, *Korea – Taxes on Alcoholic Beverages,* WT/DS75/R, WT/DS84/R, adopted 17 February 1999, as modified by the Appellate Body Report, WT/DS75/AB/R, WT/DS84/AB/R
US – Wool Shirts and Blouses (AB)	Appellate Body Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R, adopted 23 May 1997, and Corr.1

I. FACTUAL ISSUES

80. Both parties: Indonesia indicates that it exported $15 million in clove cigarettes to the United States in 2008 (Indonesia's first written submission, paras. 29, 40, 112, 129, 139, 152). At footnote 148 of its first written submission, Indonesia cites to "U.S. International Trade Commission Data Web, 2008 Imports for HTSUS 24022010, viewed 29 August 2010." That figure is approximately the same as the figure found in the first table in Exhibit US-100. However, the information contained in Exhibit US-75 indicates that the value of clove cigarettes exported from Indonesia to the United States in 2008 was only $0.226 million, and that this comprised only 0.07% of Indonesia's cigarette exports in 2008. Please clarify.

1. The two exhibits are drawn from two different sources. Exhibit US-100 is drawn from U.S. Government import statistics. These statistics are based on actual entries of, and duties paid on, imports of clove cigarettes. The United States believes these figures to be accurate. As the Panel notes, Indonesia relies on the same data.[1]

2. In contrast, Exhibit US-75 is drawn from Indonesian Government export statistics. The record in this dispute does not indicate Indonesia's methodology for collecting its export statistics. As a general matter, however, the United States considers import statistics to be more reliable. Import statistics are based directly on customs forms, which are used for the purpose of assessing import duties and are subject to verification. In addition, the country of destination listed on an export declaration may reflect the initial, as opposed to the final, destination, of the shipment. Thus, to the extent that any Indonesian clove cigarettes are exported to the United States from a third country, those shipments are more likely to be reflected in U.S. import statistics than in Indonesia's export statistics.

3. In any event, the point the United States relies on Exhibit US-75 for, that Indonesian clove exports to the United States constitute a tiny portion of total exports of clove cigarettes, is true, regardless of which figures the Panel relies on.[2] Indonesia has not contested this fact.

81. Both parties: Is the Panel correct in its understanding that the only type of cigarettes that were imported from Indonesia to the United States before the entry into force of Section 907(a)(1)(A) were clove cigarettes?

4. Indonesia also has exported to the United States other tobacco cigarettes that do not include clove.

---

[1] Exhibit US-100 refers to data of the U.S. Department of Commerce. This data is generated originally by the U.S. International Trade Commission and then provided to the Department of Commerce for reporting purposes.

[2] U.S. Second Opening Statement, para. 108; U.S. First Written Submission, para. 211.

5. Indonesian cigarettes other than clove cigarettes constituted almost 20% of Indonesian exports of cigarettes to the United States in 1998. The statistics are provided as Exhibit US-134. It should be noted that the United States applied a lower tariff by weight and volume to "cigarettes containing clove," so it is unlikely that clove cigarette manufacturers would have mistakenly imported their cigarettes under the wrong subheading (Exhibit US-91). The vast majority of imported cigarettes – at least 95% – were not banned by section 907(a)(1)(A) and Indonesia continues to have the ability to export those cigarettes to the United States.

II. CLAIMS MADE BY INDONESIA

A. AS SUCH/AS APPLIED CLAIMS

82. Further to Indonesia's responses to Panel questions Nos. 2 and 3, it is the Panel's understanding that Indonesia is challenging Section 907(a)(1)(A) both "as such" and 'as applied".

(a) Indonesia: The Panel notes that Indonesia's response to Panel question No. 2 seems to be indicating Indonesia's desire that the Panel analyses first its claims "as applied". Could Indonesia confirm this? Please do so in light of the following jurisprudence: "as such" claim is that which challenges "laws, regulations, or other instruments of a Member that have general and prospective application, asserting that a Member's conduct - not only in a particular instance, but in future situations as well - will necessarily be inconsistent with that Member's WTO obligations"[3] ... "The fact that a panel makes a finding that a measure 'as such' is inconsistent with the covered agreements also covers every instance of application of the same measure."

(b) Indonesia: The United States in response to Panel question No. 3 indicates that "[i]n 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." How does Indonesia respond to this statement?

(c) United States: Does the United States agree that Indonesia has complied with Article 6.2 of the DSU requirements in respect of its "as applied" claims?

6. Indonesia has not submitted any legal basis or factual support for an "as applied" claim, in its panel request or at any point in this dispute. Indonesia's panel request challenges the measure on its face: it plainly cites "Section 907 of the *Family Smoking Prevention and Tobacco Control*

[3] *US – Oil Country Tubular Goods Sunset Reviews (AB)*, para. 172.

Act" as the "measure" that was subject to consultations and which forms the basis of the dispute. Indonesia's panel request challenges the measure on its face. The United States does not agree that any "as applied" claims are identified in the panel request, and therefore "as applied" claims are outside the Panel's terms of reference.

B. ARTICLE 2.1 OF THE TBT AGREEMENT AND ARTICLE III:4 OF THE GATT 1994

83. Both parties: In response to Panel question No. 27, Indonesia requested that the Panel first conduct a like product analysis of clove cigarettes, on the one hand, and both menthol- and tobacco-flavoured cigarettes produced in the United States, on the other hand, and, "only if that analysis does not lead to a determination of likeness, would it be necessary for the Panel to analyze the likeness of clove cigarettes, on the one hand, and menthol-flavored cigarettes produced in the United States, on the other hand".[4]

We note, however, that Indonesia's Panel Request appears to define the domestic like product as menthol cigarettes, and makes no reference to regular cigarettes. Specifically, the Panel Request states that "banning clove cigarettes in the United States while exempting menthol cigarettes from the ban is inconsistent with the following provisions of GATT 1994 ... Article III: 4 of the GATT 1994 because the measure provides treatment to an imported product, clove cigarettes, that is 'less favorable' than that accorded to a like domestic product, menthol cigarettes" (emphasis added). Likewise, the Panel Request states that the measure is inconsistent with "TBT Article 2.1 because the measure results in treatment that is 'less favorable' to imported clove cigarettes than that accorded to a like domestic product, menthol cigarettes"(emphasis added).

Would this mean that if the Panel were to conduct a like product analysis of clove cigarettes, on the one hand, and both menthol- and tobacco-flavoured cigarettes produced in the United States, on the other hand, we would be exceeding our terms of reference?

7. The United States considers that the panel request must identify the measure or measures at issue and the claims raised by the complaining party. Identifying a national treatment claim in a panel request would require a complaining party to identify the measure at issue and to allege that the measure violates a national treatment obligation under, for example, Article III:4 of the GATT 1994. The Appellate Body has distinguished between "claims" and "arguments" for purposes of

[4] *Colombia – Ports of Entry (Panel)*, para. 7.44, citing to *US – Oil Country Tubular Goods Sunset Reviews (AB)*, para. 172.

reviewing a panel request in light of the terms of Article 6.2 of the DSU.[5] The domestic products to be considered in the Article III like product analysis are elements of the disputing parties argumentation in support of (and in opposition to) the national treatment claim, and should be set out in the parties' written and oral submissions to the panel. The domestic products being used as the basis for the argument would thus not constitute part of a panel's terms of reference.

8. That said, it is telling that Indonesia keeps changing its like product analysis throughout this dispute. The fact that Indonesia keeps shifting its position on the fundamental like product analysis entailed in an Article III claim shows that Indonesia lacks a coherent theory about why Section 907(a)(1)(A) should be found in breach of the United States' WTO obligations.

84. Both parties: Also with respect to the likeness analysis:

(a) Were there any menthol-flavoured clove cigarettes imported/sold in the United States before the entry into force of Section 907(a)(1)(A)?

9. The United States does not have full information on possible variations in the flavors of clove cigarettes exported by Indonesia to the United States. The United States does note that one brand of clove cigarettes – Djarum – sold a flavor known as "L.A. Menthol," among its other additional flavors such as cherry, vanilla, Splash, and Bali Hai.[6] Aside from the name of the product, the United States does not have information on the degree to which any menthol added to this particular brand of clove cigarette might have affected its flavor and related characteristics. It appears that Djarum introduced a range of flavors as part of an effort to create new and different options for the mostly young people attracted to clove cigarettes.

(b) Would the existence of menthol-flavoured clove cigarettes be relevant to the like-product analysis in this dispute?

10. No, the possible existence of a clove cigarette with an additional menthol flavor would not be relevant to the like product analysis in this dispute. As the United States has explained, clove cigarettes are not "like products" to menthol and tobacco-flavored cigarettes. The possible existence of individual products that may be hard to characterize in no way undermines the existence of different categories of products.

11. Take for example, a national treatment claim involving two different species of animals, such as imported donkeys and domestic horses. In the context of a particular dispute, these two species might be found to be different products. The fact that there exists a hybrid of the two species (mules) would not alter the like product analysis.

---

[5] *See*, *e.g.*, *Korea – Beef (AB)*, para. 88.

[6] *See, e.g.*, Exhibit US- 63.

12. Moreover, as the United States understands Indonesia's arguments, Indonesia is not arguing that one specific brand of clove cigarettes (such as the above-mentioned Djarum "L.A. Menthol" brand of clove cigarette) is like tobacco or menthol flavored cigarettes. Rather, Indonesia is basing its national treatment claim on the theory that all clove cigarettes are "like products" to all other U.S. domestic cigarettes.

86. United States: At paragraph 74 of its second written submission, Indonesia contends that menthol and regular cigarettes also contain eugenol and coumarin. Does the United States agree?

13. No, the United States does not agree. The most recent data indicate that menthol-flavored and tobacco-flavored cigarettes do not contain eugenol or coumarin.

14. Indonesia relies on Exhibit US-71 in making the assertion that eugenol and coumarin are present in menthol and "regular" cigarettes. This exhibit – a study conducted by the U.S. Centers for Disease Control and Prevention ("CDC") – was published over ten years ago (in 1999). This study tested 68 different brands of menthol and "regular" cigarettes for a variety of flavor-related compounds. It found that a very small number (6) of the 68 brands contained eugenol, and that only 1 of the 68 brands contained coumarin. The study also does not indicate that these compounds were found at anywhere near the level as those contained in clove cigarettes. Thus, even this outdated study is not supportive of Indonesia's "like product" contentions.

15. Moreover, the United States has presented more recent data (from 2010) that reached different conclusions (Exhibit US-72). This research study, also conducted by the CDC, tested 17 "regular" cigarette brands, 17 menthol cigarette brands and 13 clove cigarette brands. It found that all 13 clove cigarette brands contained eugenol and 12 of the 13 clove cigarette brands contained coumarin. In contrast, none of the "regular" or menthol cigarette brands contained either coumarin or eugenol.

16. In conclusion, although coumarin and eugenol were found in a small number of "regular" and menthol cigarette brands in the past, this finding has not been repeated in more recent research. Moreover, as Indonesia has conceded in the past,[7] it is not surprising that eugenol is found in high quantities in clove cigarettes, as it derives from clove (as well as from other spices that may be included in the "secret sauce," such as cinnamon leaf and other plant oils).[8]

87. United States: At paragraph 69 of its second written submission, Indonesia argues that the addition of a "sauce" is not exclusive of clove cigarettes as "menthol and tobacco cigarettes each have their own flavouring agents, which are also referred to as 'sauce' or 'casing'". Does the United States agree?

---

[7] Indonesia Answer to Q28(b), para. 72.

[8] U.S. Answer to Q28(b), para. 67.

17. The United States does not agree that the special sauce used in Indonesian clove cigarettes is the same as the "casing" used in all cigarettes, including menthol and tobacco cigarettes.

18. The United States has presented evidence from Indonesian producers of clove cigarettes demonstrating that the "special sauce" is used to create a unique taste and experience. As PT Djarum explains:

> *It is not just the cloves that make kretek special, but also the secret sauce that adds to its enjoyment*. Blending the unique taste of tobacco, fruit and herb extracts, and other natural flavorings, some say the kretek sauce recipe is more closely guarded than that of Coca Cola. Known only by two or three members of each kretek company, the sauce is used to *soften* the bite of tobacco and the pungency of clove. And, to further enhance the flavor, the tip of the kretek is *sweetened*. All adds to a *richer and fruity* taste, *sweet-scented* aroma and *pleasant* aftertaste than any regular cigarettes, and well-appreciated by kretek connoisseurs.[9]

19. The sauce used in clove cigarettes is not a generic "casing" – it is a special recipe essential to the specific flavor of clove cigarettes. Nor is there any evidence that the description of the special sauce added to clove cigarettes is merely a transient or temporary marketing strategy;[10] rather, the flavor imparted by the sauce is part of the essential flavor and identity of the products. Indonesia has not presented evidence as to the ingredients and flavor of the sauce to rebut what its own industry contends.[11]

20. Instead, Indonesia submitted a single page from a report by the European Commission Scientific Committee on the Addictiveness and Attractiveness of Tobacco Additives.[12] The excerpt explains the manufacturing process of cigarettes and notes that cigarettes usually contain a casing.[13] However, this excerpt has no bearing on whether the casing of a clove cigarette is similar to the casing of a Winston, Camel or Kool cigarette – it simply notes that they all have a casing.

21. The only evidence that Indonesia presents to attempt to draw a link between a casing and the special sauce in clove cigarettes is that a casing may be used "to tone down or mute the

---

[9] Exhibit US-39.

[10] *See*, *e.g., Korea Alcohol (Panel)*, para. 10.95 (noting that marketing strategies can change and therefore may not be evidence of whether products are directly substitutable).

[11] *See* Indonesia Answer to Q29, para. 74.

[12] Indonesia Second Written Submission, fn. 108, Exhibit IND-82.

[13] Exhibit IND-82 at 21.

harshness of the tobacco smoke."[14] However, an additive that mutes the harshness of tobacco smoke is not the same thing as an additive that imparts a characterizing flavor. No public health regulator has suggested that every such technique can be banned at once; the strategy, as advocated by the WHO, is to enact the most effective measures that can be achieved.[15] This requires regulators to draw reasonable lines based on what is appropriate for the public health. The United States is acting consistently with the public health consensus by banning characterizing flavors, which are particularly harmful as the appeal especially to young people.[16]

88. Both parties: Exhibit US-100 provides information on annual cigarette imports into the United States over the period 2000-2009. At paragraph 168 of its second written submission, the United States explains that "menthol-flavored cigarettes are classified with tobacco-flavored cigarettes" for the purpose of tracking annual cigarette imports to the United States. Is the Panel correct in its understanding that there is no information on the breakdown between imports of menthol cigarettes vs. imports of regular cigarettes?

22. The United States does not track separately data on imports of menthol cigarettes. As the United States has explained, the United States (as well as Indonesia) has different tariff lines for clove cigarettes and other cigarettes, but not different tariff lines for menthol cigarettes.[17]

23. However, the United States was able to obtain from other government sources data verifying that imported cigarettes containing menthol have been sold in the United States. The latest dates for which data is available, 2008 through part of 2009, show that at least 12 countries exported at least 28 different brands of menthol cigarettes to the United States.[18] None of these imported products were banned by section 907(a)(1)(A). Moreover, each of the menthol cigarette manufacturers also export brands of regular tobacco-flavored cigarettes to the United States, as well. It is not evident from the data how imports of menthol cigarettes breakdown as compared to imports of "regular" cigarettes.

89. United States: In its third party oral statement, Norway suggests that there is an internal contradiction in the United States explanation for banning clove cigarettes while not banning menthol: according to Norway, "some cigarettes are banned to promote public health, and other more popular cigarettes are

---

[14] Exhibit IND-82 at 21.

[15] U.S. Answer to Q19, paras. 49-54. Partial Guidelines to Article 9 and 10 of the WHO FCTC, FCTC/COP4(10) at 3.1.2.

[16] U.S. First Written Submission paras. 54-78; U.S. Second Written Submission paras. 41-78.

[17] The U.S. Schedule XX to the GATT 1994 and Harmonized Tariff Schedule separate "cigarettes containing clove" (2402.20.10) and "other" cigarettes (2402.20.90 and 2402.20.00). Exhibit US-91.

[18] U.S. Federal Trade Commission Data on Imported Menthol Cigarettes, Exhibit US-136, Exhibit US-137.

permitted, apparently also to promote public health". How does the United States respond?

24. Norway's comment – like similar comments by Indonesia in this dispute – indicates a fundamental misunderstanding of the objective of section 907(a)(1)(A). The sale of any cigarette, in any country, does not promote the public health. The challenge is how to appropriately address the public health burden of such a deadly, addictive product. Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") presents a comprehensive approach to this complex problem.

25. Cigarettes with characterizing flavors of candy, fruit, clove, etc. are banned under the challenged measure because these products appeal disproportionately to people within the window of smoking initiation, and thus present a particular public health concern. Banning these products benefits the public health by helping reduce smoking among young people, the critical age group for purposes of reducing overall smoking prevalence in the United States. Moreover, because so few people are addicted to this category of cigarettes and use such products exclusively, their elimination does not create any significant risk of negative consequences for the individual smoker, the U.S. health care system, or the society as a whole though an expansion of the black market. Such negative public health consequences could undermine the public health gains of banning the cigarettes in the first place. And, in fact, such negative public health consequences have not manifested themselves since section 907(a)(1)(A) entered into force.

26. The situation is much different for tobacco- and menthol-flavored cigarettes. Because tens of millions of people are addicted to these cigarettes, the precipitous ban of these products would risk producing negative consequences that would undermine the public health gains from the ban as well as cause other problems for the society at large.[19] In this regard, the United States is not taking the position that these heavily-used products do not present a public health concern. Indeed, they clearly do. But it does not follow that banning either or both of these types of cigarettes at the time of the enactment of the Tobacco Control Act would have benefits overall for the public health. As the U.S. Congress noted, banning these products might very well involve significant negative public health consequences that would undermine the public health benefits from the ban reducing their initiation and use. The Tobacco Control Act's provisions, including section 907(a)(1)(A), are the result of a pragmatic, reasonable weighing of those benefits and negative consequences in addressing the very difficult problem of smoking in the United States. The Tobacco Control Act generally, and section 907(a)(1)(A) specifically, results in a significant net gain for public health in the United States.

27. The testimony of public health experts before Congress prior to the enactment of the Tobacco Control Act support this public health analysis. For example:

[19] U.S. First Written Submission, paras. 21-26.

- Richard Land, D.Phil., President, The Ethics and Religious Liberty Commission of the Southern Baptist Convention, testified: "We do not advocate removal of tobacco from the market, but instead believe [U.S. Food and Drug Administration ("FDA")] regulation is the most significant means to protect public health. A tobacco ban could prompt contraband trafficking and black market sales of the prohibited tobacco products.[20]

- Elmer Huerta, M.D., M.P.H., President, American Cancer Society, testified: "Keeping tobacco products on the market clearly is not in the best interest of the public health. Unfortunately, there is no effective way to eliminate these products. As we learned during Prohibition, an outright ban would lead to the creation of a black market and all of the undesirable social side effects that black markets create. The fact is 45 million Americans are currently addicted to tobacco. The critical effort is to stop new smokers, who are mostly kids, from starting, to increase the access and affordability of cessation services and to give the public objectively reviewed, factual information about tobacco products. We also must stop the tobacco industry's misleading labeling and advertising, unsubstantiated health claims, and manipulation of their product in order to keep smokers smoking and getting new users to start. The proposed legislation is critically needed to protect the public health from the harms of tobacco."[21]

- Jack Henningfield, Ph.D., Vice President, Research and Health Policy, Pinney and Associates and Professor of Behavioral Biology at Johns Hopkins University School of Medicine, testified: "Although few in public health would probably disagree with the premise that the world would be better without tobacco products as they have been made, marketed and used, we have them and there is few viable ways to remove them in the near future. Most would probably also agree that the status quo is unacceptable. These are my positions as well ...

  This [bill] is an effort to address the reality that at least for the foreseeable future, I do not believe that banning tobacco is viable. FDA came to this conclusion itself in the development of its Tobacco Rule in the mid 1990s. These conclusions recognize that approximately 50 million Americans are current cigarette smokers. By some estimates, nearly 40 percent of all cigarettes may be smoked by people with other psychiatric problems including depression, anxiety, thought disorder, and other substance dependence disorders and science based medical interventions for addressing their tobacco use in the context of these other problems is in its infancy. Furthermore, for many people nicotine withdrawal is debilitating and is

[20] Senate Committee on Health, Education, Labor and Pensions ("HELP") Hearing, S.625, "The Need for FDA Regulation of Tobacco," at 204 (February 27, 2007) ("February 27, 2007 Senate HELP Hearing"), excerpted at Exhibit US-138.

[21] February 27, 2007 Senate HELP Hearing, at 200, Exhibit US-138.

> not compatible with their meeting occupational, social and family demands. This includes our military troops and many people in sensitive occupational positions that involve public safety. I believe that many of these people could be treated with existing pharmacological and behavioral treatments, but limitations in access to treatment prevent many in need of treatment from getting it.
>
> Many health care plans do not provide adequate coverage for existing treatment and tobacco addiction rates are highest among the lower income individuals who are least likely to have any health care coverage whether they are working or not (roughly 80 percent of the approximately 47 million person without health care do not work). For many of those with co occurring psychiatric disorder, there are still unresolved questions as to how best to treat their tobacco addiction along with other disorders. These are just the scientific, medical, and health care delivery obstacles to attempting to ban tobacco product in the near future. The social, political, and potential contraband market issues that would arise are additional issues. Much of this was discussed in a paper that was commissioned by the American Medical Association and that I co-authored a few years ago.[22] I note that the FDA, in its Tobacco Rule development came to a similar conclusion about banning tobacco products."[23]

28. There is no countervailing public health concern that provides any support for keeping cigarettes with characterizing flavors of candy, fruit, clove, liquor, etc. on the market. The overwhelming view of public health experts of those that testified before Congress was that the weight of the evidence argued against expanding the prohibition of section 907(a)(1)(A) to tobacco- and menthol-flavored cigarettes at that time. Nevertheless, the Tobacco Control Act presents a comprehensive approach to the address the harms of tobacco, and gives the U.S. FDA extensive authority to take further measures as appropriate to continue to make progress.

90. United States: In deciding to exclude menthol-flavoured cigarettes from the scope of Section 907(a)(1)(A) the United States referred to the high level of addiction within the smoking population, and thus the heavy burden on the health system and the potential appearance of a black market.

(a) The United States has explained that there were too many people addicted to menthol-flavoured cigarettes to prohibit that type of cigarette. How many people had to have been addicted to cigarettes with a given characterizing flavour in order for this exclusion to be justified from a public health perspective?

---

[22] Henningfield, *et al.*, "Reducing the addictiveness of cigarettes," Tobacco Control, 7:281-293 (1998), Exhibit US-139.

[23] February 27, 2007 Senate HELP Hearing, at 209-210, Exhibit US-138.

29. The U.S. Congress did not define a specific threshold in order for the number of people in the United States addicted to a particular tobacco product to be enough for that product's prohibition to cause negative consequences that would undermine the public gains of banning the product in the first place. The United States is unaware of any public health expert or authority that has ever attempted to define such a threshold. More to the point, no matter where the threshold may be defined, it is clear that in this case the number of smokers of the banned cigarettes (including clove cigarettes) is below that threshold since the number of such smokers was so low and the vast majority of all such smokers did not smoke clove cigarettes on a regular basis.

30. The approach adopted by the U.S. Congress was to analyze which products present a public health concern whose prohibition would not lead to negative public health effects. As the Report of the House of Representatives states, all of the banned cigarettes are lightly and irregularly used and thus their prohibition would not cause negative consequences.[24]

31. In contrast, roughly speaking, there are about 32 million regular smokers of tobacco-flavored cigarettes, between 14 and 17 million regular smokers of menthol-flavored cigarettes.[25] The situation with the regularly heavily-used tobacco- and menthol-flavored products pose different questions, simply because so many people are addicted to them, and the U.S. Congress took into account that the precipitous prohibition of these cigarettes may cause negative public health consequences that would undermine the public health benefits of their prohibition. In contrast, the U.S. Congress made the pragmatic, reasonable decision that the banning of cigarettes with characterizing flavors of candy, fruit, clove, etc. would benefit the public health by eliminating these trainer cigarettes from the market without producing any offsetting public health risks or problems.

32. The United States would also like to clarify that the question is not whether there is a "potential" for a black market for cigarettes in the United States. A sizable black market for cigarettes exists in the United States even without banning tobacco- or menthol-flavored cigarettes,[26] a point Indonesia has not contested. The question, in this regard, is whether a wider prohibition would tend to exacerbate this already existing black market. Numerous public health

---

[24] U.S. House of Representatives, Report of the Committee on Energy and Commerce, Rep't. No. 111-58, Pt. 1, at 38 (2009), Exhibit US-67.

[25] While the majority of tobacco- and menthol-flavored cigarettes are produced domestically, there are imports of both type of products. *See* U.S. Answer to Q88; *see also* Exhibit US-100. A significantly smaller amount of the banned cigarettes were produced for the U.S. market, either by U.S. or foreign cigarette companies. These brands included RJ Reynolds' "Signature Blends," Belgian-produced "Sweet Dreams," as well as Indian-produced bidis with a characterizing flavor, and Indonesian-produced clove cigarettes. *See* U.S. First Written Submission, paras. 48-52 (citing, among other exhibits, AC Nielsen 2008 Data on Flavored Cigarettes in the United States, Exhibit US-52); U.S. Second Written Submission, paras. 79-82; *see also Letter from Larry Sherman to Customers* (September 17, 2009), Exhibit IND-13. The evidence thus directly contradicts Indonesia's assertion that "in practice," section 907(a)(1)(A) "applies to only clove cigarettes from Indonesia." Indonesia Second Closing Statement, para. 6.

[26] *See* U.S. First Written Submission, paras. 24-26.

experts testified before Congress that a ban, for example, has the potential to exacerbate this black market. Thus:

- Richard Land, testified: "A tobacco ban could prompt contraband trafficking and black market sales of the prohibited tobacco products. Additionally, a tobacco ban lacks sufficient congressional and public support, partly due to our Nation's experience with a ban on alcohol. History shows that Prohibition in the 1920s and early 1930s was not sustainable largely because alcohol consumption was a personal habit very widespread among adults. Outlawing tobacco, also a widely used product, would receive a similar negative reaction from a minority of the public."[27]

- Jack Henningfield, testified: "I am concerned that [banning cigarettes] would foster contraband or 'black market' sales. Factors that fuel such markets are reduced access and substantially increased cost in the open market, while demand remains high. FDA regulation is expected to contribute to reduced demand and reduced consumption of tobacco products because its efforts should support prevention of initiation of use and encourage more users to quit. This should reduce pressures that foster contraband markets."[28]

33. Of course, the United States is not the only country to suffer from the illicit sale of cigarettes – it is a global problem. The WHO indicates that as much as a third of exported cigarettes are ultimately sold on the black market.[29] This significant trade in illicit cigarettes represents a serious public health concern. According to the WHO, the illicit trade in tobacco products:

---

[27] February 27, 2007 Senate HELP Hearing, at 204, Exhibit US-138. Other witnesses also drew the analogy to the United States' failed experiment of banning alcohol in the early 20th Century, a time referred to as "Prohibition." *See, e.g.*, *id.* at 200 (Elmer Huerta testifying that: "[u]nfortunately, there is no effective way to eliminate [cigarettes]. As we learned during Prohibition, an outright ban would lead to the creation of a black market and all of the undesirable social side effects that black markets create."); *id.* at 214 (Gregory Connolly, D.M.D., M.P.H., Professor, Harvard School of Public Health, former Director of the Massachusetts Department of Public Health's Tobacco Control Program, testifying that: "[t]he United States banned the sale of alcohol in the early part of the last century. The action did have a positive public health impact but also created unintended consequences of increased crime and other social problems. Given the fact that 45 million Americans smoke, *this history would argue against an immediate, total ban of cigarettes*.") (emphasis added).

[28] February 27, 2007 Senate HELP Hearing, at 211, Exhibit US-138; *see also id.* at 217 (Lisa Shames, Acting Director, Natural Resources and Environment Team, U.S. Government Accountability Office ("GAO"), testifying that the GAO has already "reported in 2004 that cigarette smuggling, particularly of counterfeit cigarettes, is a significant problem. However, because of the clandestine nature, the extent of cigarette smuggling into the United States is impossible to measure with any certainty.") (citing GAO, *Cigarette Smuggling: Federal Law Enforcement Efforts and Seizures Increasing*, GAO-04-641 (May 28, 2004), Exhibit US-140).

[29] WHO, *Illicit Trade in Tobacco Products*, Report of the Regional Workshop New Delhi, India, at 1 (September 15-16, 2008) ("WHO, *Illicit Trade in Tobacco Products*"), Exhibit US-141.

> undermines national pricing policies, deprives governments of revenue, permits tobacco companies to subvert and undermine international cooperation in tobacco control, makes top international brands available at affordable prices to low-income consumers and to image-conscious young people who often regard such products as sophisticated and fashionable. Above all, it undermines legal restrictions and health regulations such as those that deal with mandatory health warnings and sales to minors. Illicit trade in tobacco products contributes to making tobacco products cheaper and more accessible, resulting in increased consumption of these products which finally culminate in increased global death and disease burden. Illicit trade in tobacco products affects people who are more sensitive to price such as young people and the poor. It also allows cigarettes to be sold as singles instead of in packs, for instance, or at unregulated outlets that make them more accessible to the vulnerable groups.[30]

(b) Please provide the information, including relevant data, concerning the cost-benefit analysis which was used as a basis for the decision to exclude menthol-flavoured cigarettes from the ban.

34. Section 907(a)(1)(A) is a public health measure, not a measure of economic regulation. As such, a quantitative cost-benefit analysis in terms of, for example, increase in the growth of one industry versus the overall drag on the economy could not be calculated, and would not be appropriate.[31] As discussed in response to Question 89 and in prior U.S. submissions, the Tobacco Control Act's provisions, including section 907(a)(1)(A), are the result of a pragmatic, reasonable weighing of the public health benefits and potential negative public health consequences involved in addressing the very difficult problem of smoking in the United States.[32] In short, section 907(a)(1)(A) reflects fundamental public policy choices adopted by the U.S. Congress. Indonesia has presented no basis for a finding that these policy choices are in any way inconsistent with U.S. obligations under the WTO Agreement.

35. The effect of banning tobacco- and menthol-flavored cigarettes was discussed in testimony before Congress in the years that the Tobacco Control Act was considered by Congress. As

---

[30] WHO, *Illicit Trade in Tobacco Products*, at 1, Exhibit US-141; *see also* U.S. First Written Submission, para. 25 (discussing similar public health concerns related to the cigarette black market). The WHO also recognizes that the illicit trade in cigarettes creates other negative consequences that are not directly related to the pubic health. WHO, *Illicit Trade in Tobacco Products*, at 1 ("Smuggling of tobacco products also poses a significant law-and-order problem, as it is often carried out by organized crime and terrorist organizations, undermining national security and law and order."), Exhibit US-141; *see also* U.S. First Written Submission, para. 25 (discussing similar concerns regarding crime related to the cigarette black market).

[31] As discussed previously, Congress did take into account numerous scientific studies relating to smoking by young people. *See* U.S. Answer to Q61, para. 143 (citing to documents contained within the 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) ("October 2, 2007 HR Hearing"), Exhibit US-108).

[32] For further discussion, *see also* U.S. Second Written Submission, paras. 9-23.

discussed in response to Questions 89 and 90(a), any benefits gained by banning tobacco-flavored cigarettes, menthol-flavored cigarettes, or both, could be undermined by the negative consequences associated with the prohibition. For this reason, the overwhelming view of the testimony before the U.S. Congress by the public health experts was that the banning of all cigarettes is not a viable option. For example, Richard Bonnie, the Director of the University of Virginia's Institute of Law, Psychiatry, and Public Policy, testified:

> [C]learly with 45 million smokers smoking and otherwise using other products that are addictive, *it is clearly not feasible* to adopt a prohibition approach. Obviously you would have to take into account the cost of trying to enforce a prohibition, the inevitable development of illicit markets and so on.
>
> So I think nobody on the committee thought that for the foreseeable future that prohibiting these products is a feasible option. So the question then is what do you do. In order to eventually move in the direction of substantially reducing the use of the product, and there are only really two choices that we have.
>
> One is basically to continue the regulatory environment that we now have, and the other is to engage in aggressive measures to try to discourage the use of the substance and to reduce prevalence in the way that this bill proposes to do.[33]

Senator Edward Kennedy aptly summed up the prevailing view among U.S. public health authorities when he stated:

> Given the addictiveness of tobacco products, it is essential that the FDA regulate them for the protection of the public. Over 40 million Americans are currently addicted to cigarettes. *No responsible public health official believes that cigarettes should be banned*.[34]

91. United States: As regards consumer tastes and habits, at paragraph 61 of its second written submission, the United States says that of adolescents who smoke clove cigarettes, "most do so occasionally, and not as their primary cigarette" (citing Exhibit US-53, at p. 10, and United States' first written submission, paras. 182-189). If most adolescents who smoke clove cigarettes

[33] 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, at 49-50 (October 3, 2007) ("October 2, 2007 HR Hearing") (emphasis added), Exhibit US-108; *see also id.* at 118 (William V. Corr, Executive Director, Campaign for Tobacco-Free Kids, testifying that: "[a] 'safe and effective' standard would thus dictate a total ban on tobacco products, and with close to 50 million Americans addicted to tobacco use, *virtually all public health experts recognize this as infeasible and unproductive*.") (emphasis added); February 27, 2007 Senate HELP Hearing, at 209 (Jack Henningfield testifying that: "[t]his [bill] is an effort to address the reality that at least for the foreseeable future, *I do not believe that banning tobacco is viable*.") (emphasis added), Exhibit US-138.

[34] February 27, 2007 Senate HELP Hearing, at 5 (emphasis added), Exhibit US-138.

do so only occasionally and "not as their primary cigarette", i.e. they already smoke menthol or regular cigarettes most frequently, then how can clove cigarettes be considered "trainer" or "starter" cigarettes in respect of those smokers?

36. As an initial matter, it is important to clarify the concept of a "trainer" or "starter" cigarette as it pertains to the "age window of initiation," as Indonesia has presented certain misconceptions about this concept.

37. Clove cigarettes, and the other banned cigarettes are "trainer" cigarettes, and therefore pose a unique public health problem, because, when available, they are disproportionately used by young people within the age window of initiation. In other words, at the time when evidence show that most smokers transition from non- or occasional use to regular use – between the ages of 12 and 26 – clove and other banned flavors were used far more prevalently than they were used at later ages, when evidence shows that individuals largely have passed the vulnerable, "experimental" stage.[35] Public health officials have concluded that cigarettes that are used far more prevalently during this stage than at any other time are functioning as a "trainer" cigarette, meaning that they appeal particularly to inexperienced smokers.

38. Indonesia contends that a "trainer" cigarette must be the precise "trigger" of addiction[36] or the cigarette that most young people are smoking.[37] Such assertions misunderstand the process by which inexperienced smokers become addicted. First, it is often impossible to determine precisely what product triggers a specific addiction. While individuals can become addicted after one use of a cigarette,[38] it often takes more than one use, and for those who try different tobacco products it is not necessarily possible to determine precisely when addiction occurs. During the age window of initiation, individuals who become regular smokers tend to progress through phases from "trying" a cigarette to "experimenting" to eventually becoming a regular or established smoker.[39] The relevant point is that individuals in the experimental demographic – ages 12 to 26 – were using clove cigarettes more than older individuals were using them. This use at the vulnerable stage means that such cigarettes were facilitating the advancement toward

---

[35] 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 908-910 (June 2002) Exhibit US-93; Bernat, Erickson, *et al*., "Adolescent Smoking Trajectories: Results from a Population-Based Cohort Study," *Journal of Adolescent Health* 43 (2008) 334-340 at 336-338 ("Adolescent Smoking Trajectories") Exhibit US-142.

[36] Indonesia Oral Statement at the Second Substantive Hearing, para. 33.

[37] Indonesia Oral Statement at the Second Substantive Hearing, paras. 34-36.

[38] U.S. First Written Submission, para. 20, U.S. Second Opening Statement, para. 10. DiFranza, *et al.*, "Initial Symptoms of Nicotine Dependence in Adolescents," Tobacco Control 9, at 317 (September 2000), Exhibit US-21; DiFranza, *et al.*, "Symptoms of Tobacco Dependence After Brief Intermittent Use," Archives of Pediatric and Adolescent Medicine 161(7), at 705 (July 2007), Exhibit US-22.

[39] Why and How the Tobacco Industry Sells Cigarettes to Young Adults, Exhibit US-93; Adolescent Smoking Trajectories, Exhibit US-142.

regular use. For example, a young person may first be exposed to a "regular" tobacco-flavored cigarette. The young person may take to it immediately, or might find the flavor and feel disagreeable. In the latter case, that individual may not be inclined to try another cigarette. However, that young person may at another time be exposed to a clove cigarette, known for its sweeter taste and flavorful smoke, and that appeal might induce the young person to try it despite the initial negative experience with a regular cigarette. If the experience of smoking a clove cigarette is positive, that person is then more likely to try another tobacco product. Eventually, as the taste and experience of tobacco becomes familiar, the young person may be inclined to smoke tobacco- or menthol-flavored cigarettes. Indeed, the statistics show that once young consumers made the transition to becoming regular smokers, they were using tobacco or menthol flavored cigarettes as their regular cigarette.

39. Second, the fact that more young people were smoking tobacco and menthol cigarettes does not contradict the fact that clove and other banned flavored cigarettes were "trainer" cigarettes that posed a particular public health risk. Rather, the fact merely reflects that, in absolute terms, almost every smoker in the United States is smoking tobacco- or menthol-flavored cigarettes. In absolute terms, more young people and more older people are smoking regular and menthol flavored cigarettes. The relevant point with respect to clove flavored cigarettes is that young people between the ages of 12 and 25 were smoking them at much higher rates than older people were.[40] In terms of absolute numbers they were not as widely used as regular or menthol cigarettes; but based on how they *did* tend to be used – by young people during initiation – they posed a unique public health problem as "trainer" cigarettes. This is not the case with regular and menthol cigarettes; rates of use among young people and older adults are much more even.[41]

40. The United States also appreciates the opportunity to clarify the statement noted in the Panel's question. As the Panel notes, in paragraph 61 of the U.S. Second Written Submission, the United States explains the analytical weakness of Indonesia's suggestion that determining the use of clove cigarettes among adolescents (i.e., individuals under age 18) should focus on which cigarette adolescents report that they use "most often."[42] Indonesia's approach is flawed because, during the window of initiation (ages 12 through 26), evidence shows that, in general, individuals are transitioning from being non- or occasional smokers to being regular smokers. During this time, many adolescents and young adults do not yet have a cigarette that they smoke "most often" or as their regular cigarette. Therefore, the U.S. statement that the "vast majority of adolescents who smoke clove cigarettes [...] do so occasionally, and not as their primary cigarette" is meant to convey this point: young people in the age of initiation are, for the most part, still experimenting with tobacco products and have not yet taken up a habit associated with a particular brand or style.

---

[40] Exhibit US-53 at 7.

[41] "Regular" and menthol cigarettes also pose a specific public health problem, and, indeed, most of the Tobacco Control Act is geared toward reducing these numbers, through measures that severely restrict advertising, impose strict labeling requirements, and require approval of new products. U.S. First Written Submission, paras. 103-139.

[42] U.S. Second Submission, para. 61.

However, the wording of the statement should not be construed to suggest that adolescents already have a different, regular cigarette. To the contrary, the age range of 12 to 26 is the period in which nearly every person who becomes a regular smoker transitions from non- or occasional to regular use. Therefore, it is consistent with this statistic that some adolescents will have become regular smokers and likely attached to a brand, but in general this age range is the "experimental" range.

41. For those individuals who already are regular smokers and likely have attached themselves to a particular brand of cigarette (including some adolescents and young adults), clove cigarettes would no longer function as a "trainer" cigarette.

92. Both parties: The Panel would like to obtain the parties' views as to which are the relevant consumers that the Panel needs to consider in order to examine the consumers' tastes and habits criterion within its likeness analysis under Article 2.1 of the TBT Agreement:

(a) Should the Panel consider that the relevant consumers are smokers? If so, should the Panel consider smokers in general, or should it focus on particular age segments?

(b) Or should the Panel instead consider as the relevant consumers the "pre-smoking" youth population, i.e., youth that have not taken up the habit of smoking yet but could potentially experiment with cigarettes?

42. The United States considers that the relevant consumers for purposes of examining the consumers' tastes and habits criterion within the likeness analysis are all potential and current smokers in the United States. In this dispute, young people within the age window of initiation are "potential consumers" whose views of different cigarettes are particularly relevant to the like product analysis. That such individuals are more likely than adults to find clove-flavored cigarettes attractive is relevant. Such a disparity contrasts with the appeal of tobacco and menthol cigarettes, which are appealing both to young people and to older adults. This disparity is evidence that clove cigarettes are not interchangeable with menthol or tobacco cigarettes. It also accounts for why a different public health risk is posed by clove cigarettes than is posed by menthol and tobacco cigarettes.

93. We note that, in paragraphs 81-82 of its second written submission, Indonesia argues that clove cigarettes are substitutable with menthol and regular cigarettes. We also note that, in paragraph 113 of its second written submission, the United States argues that consumers do not view clove cigarettes as substitutable for tobacco or menthol cigarettes.

(a) Both parties: Should the Panel take into account brand loyalty in its examination of whether clove cigarettes are substitutable with menthol and/or regular cigarettes?

43. Like product analyses are fact specific and should be conducted on a case-by-case basis, and therefore "brand loyalty" may be relevant in some circumstances to determine whether products are substitutable.[43] In this case, the United States has not presented brand loyalty as a "likeness" consideration and considers that brand loyalty is relevant only to the extent that it is synonymous with physical characteristics and the specific flavor and experience of different cigarettes. Clove-flavored Kretek cigarettes are considered "different" and "unique" not because of their brand *per se*, but because of the flavor and experience imparted by their particular physical characteristics.

(b) United States: Is there a contradiction between the argument that clove cigarettes are not substitutable for menthol or regular cigarettes, and the argument that clove cigarettes are "starter" or "trainer" cigarettes?

44. Clove cigarettes are "trainer" cigarettes because they are used disproportionately by young people during the age window of initiation – the time during which young people are experimenting with different tobacco products, and have not yet settled on a regular cigarette (see Answer to Q91). Therefore, it is not a contradiction to note that clove cigarettes are a trainer cigarette and often used alongside other cigarettes during the period that young people are experimenting with tobacco products and becoming familiar with smoking, but are for the most part abandoned and not substitutable for regular or menthol cigarettes once adults become established smokers and become habituated to a primary cigarette. The data show that once young people transition to regular use, they tend to select either a regular or menthol brand of cigarette as their primary cigarette, and do not view clove cigarettes, as well the other banned flavored cigarettes, as a substitute. However, novice and inexperienced smokers are more apt to use clove cigarettes because their particular characteristics are more appealing to young people. This use acclimates novice smokers to the experience of consuming tobacco, and begins to establish an addiction to smoking, eventually making them more likely to transition to the harsher, mainstream brands.

94. Both parties: How did the price of clove cigarettes compare with the price of menthol and regular cigarettes? If possible, please provide data for the period 2000-2009.

45. The United States does not have data on either the retail or wholesale price of clove cigarettes sold in the United States. Perhaps Indonesia would be better positioned to obtain such information from the Indonesian industry. Data obtained from the AC Nielsen Company for the

[43] *See*, *e.g.*, *Indonesia – Autos (Panel)*, para. 14.173.

Tobacco Product Advisory Committee's review of menthol cigarettes show that the price-per-pack of menthol and non-menthol cigarettes in the United States has been roughly similar, with menthol packs consistently about 2-3% higher than non-menthol cigarettes.[44] Currently, the retail price-per-pack of non-menthol cigarettes is approximately $4.86 and the price-per-pack of menthol cigarettes is approximately $5.00.[45]

95. Both parties: At paragraph 118 of its second written submission, concerning "less favourable treatment", the United States submits that the treatment at issue in both Article 2.1 of the TBT Agreement and Article III:4 of the GATT 1994 is the treatment of "imported products" compared to the treatment of like domestic products.

(a) Is it the United States' position that the Panel should compare the treatment accorded to cigarettes imported from all countries, as opposed to focusing only on the treatment accorded to cigarettes imported from Indonesia?

(b) If yes, then please explain the legal basis for that view.

46. The United States considers that Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement require that imported products be accorded treatment no less favorable than that accorded to like domestic products. Where a measure is facially neutral, panels need to consider all relevant evidence, on a case-by-case basis, to determine whether a measure accords less favorable treatment to imported products compared to like domestic products on a *de facto* basis. Such a determination cannot be reduced to a single test. Fundamentally, the comparison of treatment concerns the broader principles of Article III, specifically whether a measure is applied so as to afford protection to domestic production. This principle is further confirmed by the second sentence of Article III:4, which allows the application of differential internal transportation charges that are which are not based "on the nationality of the product." The TBT Agreement is consistent with these principles as well, as it is designed to "further the objectives of the GATT 1994 " and specifically provides that Members may "lay down product characteristics."

47. As the United States noted in its Opening Statement at the Second Substantive Meeting with the Panel, in assessing whether a measure accords *de facto* less favorable treatment, panels and the Appellate Body in previous disputes have considered relevant how the measure applies to imported products compared to like domestic products.[46] So, for example, where a measure

---

[44] "Trends in Menthol Cigarette Sales, Price, and Promotion in the United States," RTI International, Presented to the Tobacco Product Scientific Advisory Committee to the Food and Drug Administration (November 18, 2010). Exhibit US-143 at 38 (it is not clear whether "non-menthol cigarettes" in this report would include clove cigarettes for the dates before the ban took effect).

[45] "Trends in Menthol Cigarette Sales, Price, and Promotion in the United States," Exhibit US-143 at 28.

[46] U.S. Second Opening Statement, paras. 48-50.

applies a higher tax to nearly 100% of imported products and a lower tax to nearly 100% of like domestic products, such a ratio is strong evidence of *de facto* less favorable treatment, especially absent any other evidence as to the objective of the measure, and whether it distinguishes between products because of their national origin.[47] It would not make sense to limit this comparison to only a portion of products that are imported or to only a portion of domestic products determined to be like.

48. The legal basis for this view is an interpretation of the ordinary meaning of the relevant provisions (Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement) in light of their context and in light of the object and purpose of the Agreements, in accordance with Article 31 of the Vienna Convention on the Law of Treaties. An interpretation of the ordinary meaning of these terms requires a comparison of the treatment of imported products to the treatment of domestic products. The United States considers that the existence of less favorable treatment must be assessed with reference to imported cigarettes in general versus domestic cigarettes in general because these articles prescribe no less favorable treatment of imported products as compared to like domestic products.

49. This view is consistent with previous panel and Appellate Body reports. The Appellate Body in *EC – Asbestos* affirmed that measures may distinguish among products determined to be "like," and that the relevant comparison in the *de facto* treatment analysis is between "groups" of imported products and "groups" of like domestic products.[48] Similarly, the reports in *Dominican Republic – Cigarettes* and *EC – Biotech* found that where an alleged detrimental effect on an imported product is not attributable to its foreign origin, but to some other factor, that effect is not evidence of less favorable treatment.[49]

50. At the same time, the United States recognizes that Article III:4 of the GATT 1994 speaks in terms of imports from "any Member" and thus it may be appropriate to focus on the treatment accorded to imports from one Member compared to the treatment accorded to like domestic products. Even there, though, if the treatment is to be considered the treatment accorded to "imported products" then the treatment should be based on the origin of the products and not on other, legitimate regulatory grounds.

96. Both parties: In its response to Panel question No. 47, Indonesia states that "a case-by-case analysis of likeness in the context of a different measure reasonably could conclude that all cigarettes are not like for the purpose of that particular measure" (emphasis added). At paragraph 24 of its opening statement at the first substantive meeting, the United States submits that in

---

[47] U.S. Second Opening Statement, paras. 48-53.

[48] U.S. Second Opening Statement, para. 50; *EC – Asbestos (AB)*, para. 100.

[49] U.S. First Written Submission, paras. 205-212; U.S. Second Written Submission, paras. 137-144; U.S. First Opening Statement, paras. 51-57; U.S. Second Opening Statement, paras. 48-53.

the context of analysing whether the products at issue in this case are "like products", a relevant factor in this case "is the degree to which differences among the regulated products directly relate to the public health objectives of Section 907(a)(1)(A) (emphasis added). Again at paragraph 27 of its statement, the United States reiterates that "those product differences that relate to these public health objectives are relevant to the 'like product' analysis" (emphasis added).

Should the Panel understand that both parties agree with the proposition that two products may be "like" products in the context of one measure, but not "like" products in the context of a different measure, depending on the purpose/objective of the measure at issue?

51. Yes. Determining "likeness" between and among products under Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement serves the ultimate purpose of evaluating the relative treatment accorded by a particular measure to the products it covers. Therefore, the measure at issue is relevant to determining which characteristics of likeness or difference are significant in the given circumstances. As the Appellate Body notes in *EC – Abestos*, the dictionary provides a starting point in defining "like," but leaves many interpretive questions open, and in particular "does not *indicate which characteristics or qualities are important*."[50] The four factors noted in the *Border Tax Adjustment* Report provide a framework for assessing likeness, but do not substitute for the analytical task of determining the importance of specific traits and characteristics. The specific aspects of a product that are most relevant in a likeness determination may differ as a result of the measure at issue.

52. Certain products may be considered like in certain contexts but not in others. For example, as the United States noted at the Second Substantive Meeting with Panel, cups made from paper, plastic and aluminum might be considered "like" products regardless of these physical differences with respect to a tax or other fiscal measure. They all serve the same end-use of holding liquids, and may be viewed as interchangeable by consumers in this context. The different materials used in the cups may be considered to be less important in the like product analysis in this situation. However, the same cups might not be considered "like" with respect to a measure regulating products that can be used safely in microwave ovens. In that case, the different materials used to make the cups would be more relevant, as aluminum may not be safely used in a microwave. This difference would effect whether consumers viewed each cup as suitable for use in a microwave and would be relevant to measures regulating which cups could be used in microwaves. In this context, the different materials used would be significant differences among the cups. The particular measure at issue is relevant to whether the different physical properties of the cup mean that one cup is not "like" another cup.

[50] U.S. Second Written Submission, paras. 108-111; *EC – Asbestos (AB)*, para. 92 (emphasis in original).

53. In the present case, the physical differences between clove cigarettes on the one hand and tobacco and menthol cigarettes on the other hand directly relate to different consumer tastes and habits and the relative appeal of those products to potential smokers in the age window of initiation compared to older smokers. Similarly, patterns of use of these different products are also relevant to the public health basis of the measure at issue. This approach is consistent with the Appellate Body's recognition that determining likeness between and among products must be done on a case-by-case basis, in light of all relevant evidence.

97. Both parties: Both parties have referred the Panel to the WHO Framework Convention on Tobacco Control (FCTC). During the fourth Conference of the Parties, held from 15 to 20 November 2010, the parties to the FCTC adopted "Partial Guidelines for Implementation of Articles 9 and 10 of the Convention". Indonesia argues that these Partial Guidelines are not relevant to the factual or legal issues before the Panel. The United States, on the contrary, contends that the FCTC in general, and the Partial Guidelines in particular, are evidence of the growing global consensus of the need to take action through international collaboration and at the national level, to address the harm caused by tobacco products. The United States further observes that it is one of the 172 signatories to the Convention and argues that the US Tobacco Control Act is consistent with the FCTC's purposes and recommendations. In addition, the United States submitted a WHO Report in Exhibit US-113 entitled "The scientific basis of tobacco products regulation".

Could the parties elaborate on their positions related to the Partial Guidelines, in particular with respect to the inclusion of both "herb and spices" and "menthol" in these Guidelines? More specifically, is the Panel correct in its understanding that the principal factual findings and recommendations contained in both the Guidelines and the Report apply equally to both clove-flavoured cigarettes and menthol-flavoured cigarettes?

54. As an initial matter, the United States notes that while the WHO Draft Guidelines and Scientific Report present factual findings and recommendations relevant to this dispute, the basis for section 907(a)(1)(A) and the other provisions of the Tobacco Control Act were evidence and factual findings pertaining to cigarette use in the United States. Therefore, the United States considers the legislative history, survey evidence and other facts presented in this dispute that pertain specifically to the United States to be the most relevant to the Panel's assessment of section 907(a)(1)(A). The WHO findings and recommendations do not specifically take into account the particular circumstances in the United States. Therefore, the United States considers these findings and recommendations do not apply specifically to the United States but are intended to provide general guidance and consensus on the harms of tobacco products. The United States also would note the WHO factual findings and recommendations do not state that they "apply equally" to clove flavored cigarettes and to menthol flavored cigarettes.

55. In the context of this dispute, the factual findings in both the Partial Guidelines and the WHO Scientific Report that are of particular relevance are those addressed to additives and characteristics that make tobacco products more attractive or palatable.[51] The United States agrees that, in general, the Guidelines and the Report find that flavors are harmful to the extent that they make cigarettes more attractive, and that this finding applies both to clove and menthol cigarettes, as well as to other flavors or additives that make cigarettes more appealing.[52]

56. The United States has stressed the relevance of this factual finding by the World Health Organization because Indonesia has maintained the extreme, unsupported view that clove cigarettes are different than other cigarettes with characterizing flavors, such as "candy-flavored" cigarettes, and that the public health concerns associated with flavored cigarettes do not apply to clove-flavored cigarettes.[53] For example, Indonesia claims that even the WHO Scientific Report issues different findings and recommendations with respect to clove and menthol flavored cigarettes than it does for "candy-flavored cigarettes."[54] This contention is utterly false, as the WHO Scientific report clearly includes both clove and menthol among its findings with respect to flavored cigarettes.[55] Indonesia's attempt to parse the findings on "flavors" in order to claim that there is no evidence with respect to clove cigarettes is unsupportable. That flavoring agents, including clove, make cigarettes more appealing is an established factual finding. Regulators cannot be expected to issue findings with respect to *every* possible flavor – from cherry, to liquor and spice and other herbs – in order to regulate the flavors as a group.

57. This factual finding leads to WHO recommendations that are consistent with the U.S. approach in section 907(a)(1)(A). The recommendations contained in the Partial Guidelines and in the WHO Scientific Report are not intended to apply equally to all flavors or other additives that make cigarettes more attractive. The recommendations are intended to set goals or guidelines that regulating authorities adapt to the particular circumstances of the populations they are regulating. The WHO recommendations are consistent with the approach taken by the United States to consider the patterns of use of different cigarettes, as well as countervailing public health challenges associated with different regulations.

---

[51] *See*, *e.g.* Partial Guidelines to Article 9 and 10 of the WHO FCTC, FCTC/COP4(10) at 1.2.1.1, 3.1.2.2; *WHO, The Scientific Basis of Tobacco Product Regulation*, at 25-40, Exhibit US-113.

[52] *See*, *e.g.* Partial Guidelines to Article 9 and 10 of the WHO FCTC, FCTC/COP4(10) at 1.2.1.1, 3.1.2.2; *WHO, The Scientific Basis of Tobacco Product Regulation*, at 25-40, Exhibit US-113.

[53] Indonesia Second Opening Statement, paras. 43, 45-47; Indonesia Second Written Submission, paras. 35, 56; Indonesia First Written Submission, para. 63.

[54] Indonesia Second Opening Statement, para. 43.

[55] *WHO, The Scientific Basis of Tobacco Product Regulation*, at 25-40 ("Kreteks" are noted specifically on pp. 31, 35 as part of the section of cigarette flavors, and "flavourings such as cherry and cloves" are referenced in the recommendations on p. 99). Exhibit US-113.

58. For example, the Draft Guidelines note that "regulating ingredients aimed at reducing tobacco product attractiveness can contribute to reducing the prevalence of tobacco use and dependence among new and continuing users."[56] This statement establishes a basic fact that regulation should be aimed at reducing the attractiveness of tobacco products can contribute to reducing the prevalence of tobacco use. The Partial Guidelines recommend further that "Parties should regulate, by prohibiting or restricting ingredients that may be used to increase palatability in tobacco products"[57] and affirm that, with respect to ingredients, regulators should "aim to implement the *most effective measures that they can achieve*."[58] In other words, the recommendations broadly advocate restricting or eliminating ingredients that may make cigarettes more palatable, but recognize that, with that goal in mind, regulators should develop measures that are the most effective they can achieve in light of broader public health considerations. The recommendations do not advocate uniform measures with respect to all additives, but advocate measures aimed at reducing the prevalence of tobacco use and dependence among new and continuing users and that are the most effective that can be achieved. Effective measures to achieve these ends will vary from country to country, depending on the patterns of use of specific tobacco products.

59. The Partial Guidelines do not contemplate that a Party will be able to ban all additives that make cigarettes more attractive at once, and assumes that incremental measures will be taken. How those increments are devised depends on the circumstances of the population being regulated.

60. The WHO Scientific Report recommendations are consistent with this approach. For example, the Report states that:

> the regulation of these flavoured products is challenging. It is a basic public health principle that toxic consumer products should not be contaminated with substances that hide potential harm from the product's odour or taste, such as the addition of sugar to contaminated food products. [...] Regulatory strategies need to focus on outcomes at the population level as well as the individual level.[59]

Like the WHO Partial Guidelines, the WHO Scientific Report affirms the basic factual finding that flavors and other sweeteners make cigarettes more attractive. The Report also establishes, in light of the fact that "regulation of these flavored products is challenging," the general recommendation that regulators should consider outcomes on the population as a whole and not

---

[56] Partial Guidelines to Article 9 and 10 of the WHO FCTC, FCTC/COP4(10) at 3.1.2.1.

[57] Partial Guidelines to Article 9 and 10 of the WHO FCTC, FCTC/COP4(10) at 3.1.2.2.

[58] Partial Guidelines to Article 9 and 10 of the WHO FCTC, FCTC/COP4(10) at 3.1.2 (emphasis added).

[59] *WHO, The Scientific Basis of Tobacco Product Regulation*, at 27.

merely on individual users. The Tobacco Control Act generally, and section 907(a)(1)(A) in particular, employs this strategy.[60]

61. This focus on the "population as a whole" means that regulation should consider how cigarettes are used among the population subject to regulation, and what impact restrictions or a ban would have on the overall population. It is entirely consistent with these broad recommendations that the United States considers the overall impact of banning certain products – including possible negative public health consequences.

C. ARTICLE 2.2 OF THE TBT AGREEMENT

100. United States: In its submissions, the United States has stressed that 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 (e.g. United States' response to Panel question No. 60). According to the United States, "Indonesia asserts the objective is simply reducing youth smoking and ignores that section 907(a)(1)(A) also includes avoiding the potential negative consequences of banning cigarettes to which tens of millions of adults are addicted" (United States' second written submission, para. 152). According to the United States, "Indonesia repeatedly mischaracterizes the objective of section 907(a)(1)(A) as 'reducing youth smoking'", and that is a "gross oversimplification of the objective of section 907(a)(1)(A)" (United States' second written submission, para. 153).

For the purposes of the analysis of the measure under Article 2.2 of the TBT Agreement, what are the practical implications (if any) of defining the objective of the measure simply in terms of "reducing youth smoking"?

62. "Reducing youth smoking" appears to mis-state the objective of section 907(a)(1)(A) in two important ways. First, given the discussion the parties have already had, Indonesia's characterization of the objective seems to be to reduce smoking prevalence of only people age 17 and younger. For all the reasons discussed in response to Question 101, such a characterization would be incorrect. The objective is to reduce smoking of all people within the window of initiation (*i.e.*, people ages 12-26). Second, Indonesia's characterization of the objective leaves off the latter half of the objective, namely, the avoidance of negative consequences.

[60] For example, section 907(a)(3)(B) provides that in determining tobacco product standards, the FDA must consider "the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard." Exhibit US-7.

63. The practical implications of limiting the objective to simply reducing "youth" smoking, without consideration of possible negative consequences is that this limitation may result in a different pool of alternative measures with which the challenged measure is compared. The result, thus, could be that such an analysis would not produce an answer of the question that needs to be answered – namely, whether an alternative measure exists that fulfills the objective at the level the United States considers appropriate, is reasonably available, and is significantly less trade restrictive.

64. The objective of section 907(a)(1)(A) is to protect 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 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. This objective is confirmed by the text, design, architecture, and revealing structure of section 907(a)(1)(A) in accordance with the Appellate Body's reports in *Chile – Alcohol* and *Japan – Alcohol*.[61]

65. The text makes evident that the measure draws distinctions between products, banning some, and allowing others to continue to be sold in the United States. The measure thus represents a counter-balancing of benefits and negative consequences, which is entirely consistent with theories of sound public health policy-making in general and smoking prevention measures in particular. To ignore the second half of the objective (avoiding negative consequences) would be tantamount to ignoring the text of the measure, and the underlying reasons for not banning tobacco- and menthol-flavored cigarettes.

66. As also discussed at the Panel's second substantive meeting, the other provisions of section 907 confirm the conclusion that avoiding negative public health consequences is central to the objective of section 907(a)(1)(A).

67. Section 907 is entitled "tobacco product standards" and section (a)(1) provides two such product standards: (A) the characterizing flavor ban; and (B) a prohibition that any tobacco contain pesticide residues that are not approved under U.S. law. However, section (a)(2) authorizes FDA to revise the tobacco standards set forth in (a)(1) in accordance with section 907(c), which is the process FDA must use in establishing, amending, or revoking any tobacco product standard. As part of this, there must be a finding that the new standard is "appropriate for the protection of the public health."[62] That is to say, subject to the requirements in the remainder of section 907, FDA may alter the requirements of section 907(a)(1)(A) to prohibit, for example, the use of an additive, flavor, or herb or spice, *regardless* of whether the ingredient produces a characterizing flavor, or to exempt characterizing flavors, such as clove or chocolate, from the prohibition contained in (a)(1)(A). To produce such a new product standard, FDA must do so in

---

[61] *See* U.S. Second Written Submission, para. 154.

[62] Section 907(c)(2)(A) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

accordance with the requirements of the remainder of section 907, *i.e.*, 907(a)(3-6), 907(b), and 907(c).

68. The remainder of section 907 contains a variety of requirements, both substantive and procedural. Under 907(a)(3)(B), in making its determination that a tobacco product standard is appropriate for the public health, FDA must consider: the risks and benefits to the entire population (including non-smokers), cessation, and initiation.[63] If it makes this finding, FDA must then seek public comments on its proposal to establish, amend, or revoke a tobacco product standard.[64] In addition to considering the section 907(a)(3)(B) issues, section 907(b)(2) states that FDA:

> shall consider all other information submitted in connection with a proposed standard, including information concerning the *countervailing effects* of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the *creation of a significant demand for contraband* or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.

69. Accordingly, Congress has mandated that FDA, prior to increasing or relaxing the requirements of section 907(a)(1)(A), consider all possible countervailing effects, including those of the health of smokers as well as any effect the new standard would have on the black market.[65] The fact that Congress requires FDA to make such a consideration supports the U.S. view of the objective of section 907(a)(1)(A). Simply put, it is not credible for Indonesia to argue that the objective of section 907(a)(1)(A) does not include the avoidance of negative consequences when the statute requires FDA to make this very consideration when deciding whether to adjust the standards contained therein. The House of Representatives Report makes clear that the U.S. Congress considered section 907(a)(1)(A) to be appropriate for the protection of the public health. It discusses the measure's impact on reducing initiation and considers the potential of countervailing effects of the measure, such as the potential to exacerbate the black market problem.[66]

---

[63] Section 907(a)(3)(B)(i)(I-III) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[64] Section 907(c)(1), (4) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[65] The instructions of the U.S. Congress to the Tobacco Products Scientific Advisory Committee ("TPSAC") is similar. Section 907(e) requires the TPSAC, which is charged with evaluating the impact and the use of menthol in cigarettes on the public health, to also address the considerations listed in section (a)(3)(B) and section 907(b)(2).

[66] HR Rep't, at 38, Exhibit US-67.

70. Indonesia's position is not consistent with the text of section 907(a)(1)(A), nor the overall structure of section 907, which the challenged measure is a part of, or its legislative history.[67]

101. United States: In its response to Panel question No. 12(b), Indonesia observes that "Section 2 of the FSPTCA lists 49 findings by Congress regarding the use of tobacco, and '[f]ully one quarter of all these findings refer to tobacco use by 'youth,' 'adolescents,' 'minors,' 'children,' those 'underage,' and those 'under 18.'" How does the United States respond?

71. The objective of the measure cannot be determined by simply counting up references to a particular age group in one section of the statute. Rather, the objective must be determined from an analysis of the text, design, architecture, and revealing structure of the measure itself.[68] Such an analysis directly contradicts Indonesia's arguments.

72. The text of section 907(a)(1)(A) does not refer to any age group or groups, but does say initiation is the key consideration. The text makes clear that the provision eliminates from the U.S. market cigarettes with characterizing flavors of candy, fruit, clove, etc. The measure thus helps to protect *all* potential and novice smokers who would be attracted to these flavored cigarettes, which includes not only children and adolescents, but young adults as well.[69] As discussed at the Panel's second substantive meeting, the objective of the Tobacco Control Act generally, and section 907(a)(1)(A) specifically, is not simply to delay the age at which people begin smoking, but to deter people from smoking in the first place.

73. Children and adolescents are prominently referenced in the Tobacco Control Act and its legislative history because these age groups play a central role in reducing smoking rates.[70] But they are not the only people that are at risk for becoming addicted smokers. The data indicates that while the majority of regular smokers tried their first cigarette before their 18th birthday, a sizable portion of people who will eventually become regular smokers have not. In addition, many 17-year-olds are novice or experimental smokers and do not transition into regular, addicted

---

[67] Finally, we note that one of the purposes of the Tobacco Control Act (purpose #10) is "to strengthen legislation against illicit trade in tobacco products." Tobacco Control Act, sec. 3(10), Exhibit US-7. As discussed in response to Question 90(a), the banning of tobacco- or menthol-flavored cigarettes could very well lead to an expansion of the already existing black market for cigarettes, thus undermining one of the purposes of the Tobacco Control Act. Section 907(a)(1)(A) does not undermine this general purpose of the Tobacco Control Act because its objective includes an avoidance of negative consequences, which includes, among other things, exacerbating the black market for cigarettes.

[68] *Chile – Alcohol (AB)*, para. 62; *see also Japan – Alcohol (AB)*, at 27; U.S. Second Written Submission, para. 40 (citing same).

[69] U.S. Second Written Submission, paras. 33-40; NSDUH 2008 Table on Smoking Initiation, Exhibit US-89.

[70] *See* NSDUH 2008 Table on Smoking Initiation (noting that 86.6% of regular smokers tried their first cigarette prior to their 18th birthday), Exhibit US-89.

smokers until they are young adults.[71] The scholarship indicates that twice the number of 18- to 19-year-olds are in the early stages of smoking initiation than of 18-year-old established smokers.[72] Overall, the portion of people becoming regular smokers as young adults has risen over time.[73] In terms of absolute numbers, the United States estimates that at least 300,000 people ages 18-26 began smoking daily in 2009.[74]

74. Indonesia does not contest any of this. It does not contest that all people ages 12 to 26 are within the window of initiation and therefore at risk from becoming addicted smokers. It does not contest that a sizable portion of those at risk are people age 18 or older. And it does not contest that, in terms of absolute numbers, the data indicates that *hundreds of thousands* of young adults become nicotine addicts *each year* from smoking cigarettes.

75. Instead, Indonesia contends that the United States had no intention to protect these people from the harm of addiction based on other provisions in the Tobacco Control Act and isolated quotes from the legislative history.[75] In this regard, Indonesia refers to a variety of provisions in the Tobacco Control Act, as well as the FDA regulations, which were first issued in 1996 but did not take effect until the enactment of the Tobacco Control Act, that are explicitly directed at potential smokers ages 17 and younger.[76] All of these measures accomplish complementary, but different objectives from section 907(a)(1)(A), and none of them establish that an entirely different measure, section 907(a)(1)(A), has the same objective as the measures Indonesia references. In the end, Indonesia fails to tie its argument back to the text of section 907(a)(1)(A) and explain *how* the elimination of a product from the market protects one part of the class of people at risk for addiction and not the entire class. The fact is that by *eliminating* these products

---

[71] Only 64.1% of eventual daily smokers smoked daily before turning 18 years of age. NSDUH 2008 Table on Smoking Initiation, Exhibit US-89.

[72] U.S. Second Written Submission, n.39 (quoting 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 908 (June 2002), Exhibit US-93).

[73] U.S. Second Written Submission, n.39 (quoting Lantz, "Smoking on the rise among young adults: implications for research and policy," Tobacco Control 2003 12, at i66, Exhibit US-94).

[74] U.S. Second Written Submission, para. 35.

[75] In this regard, we have already discussed how nothing in the legislative history, on which Indonesia so heavily relies, supports its argument. *See* U.S. Second Opening Statement, para. 72. Specifically, the House of Representatives Report never states that reducing smoking by children and adolescents is the ultimate or only aim of section 907(a)(1)(A), but rather that it is a significant part of the overall intent. In particular, the House of Representatives Report states that the intent of the bill "includes" reducing the number of children and adolescents who smoke; the Report does not say this is the only intent of the bill. H.R. Rep. No. 111-58, Pt. 1, at 37-38 (2009), Exhibit US-67.

[76] *See* Indonesia Second Written Statement, paras. 21-22. For further explanation of FDA's 1996 rule, please see U.S. First Written Submission, paras. 103-106

from the market *entirely*, section 907(a)(1)(A) seeks to protect *all* people at risk of becoming smokers.[77]

76. The remainder of section 907 confirms that the objective of the challenged measure is to protect all people at risk for smoking. As discussed in response to Question 100, section 907 authorizes FDA to make new product standards or revise the tobacco standards set forth in section 907(a)(1) if the new standard is "appropriate for the protection of the public health" and FDA establishes the new standard in accordance with the remainder of section 907. To establish a new product standard, section 907(a)(3)(B)(i) states that FDA:

> shall consider scientific evidence concerning – (I) the risks and benefits to the population *as a whole*, including users and nonusers of tobacco products, of the proposed standard; (II) the increased or decreased likelihood that *existing users* of tobacco products will stop using such products; and (III) the increased or decreased likelihood that *those who do not use tobacco products* will start using such products.[78]

As is apparent, none of these considerations are limited to people aged 17 and below. Just the opposite is true – FDA must consider the risk and benefits of the new standard to the *entire* population, how the new standard will affect cessation rates of *all* smokers, and how the new standard will affect initiation rates of *all* nonsmokers. The statute also requires FDA to make the same broad analysis when considering any potential countervailing effects of the new product standard. Thus, section 907(b) mandates that FDA consider "the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, *adult* tobacco users, or *nontobacco* users . . ."

77. Indonesia's claim that section 907(a)(1)(A) is only intended to protect people ages 17 and under runs directly counter to what the statute requires FDA to consider when altering those very same requirements. As such, the requirements of section 907(a)(2-6) and (b) support the objective of section 907(a)(1)(A) as stated by the United States.

103. United States: With respect to the existence of a "material contribution":

(a) Is it the United States' position that, as a legal matter, the question of whether or not the measure makes a "material contribution" is legally irrelevant for the purposes of the analysis under Article 2.2 of the TBT Agreement?

---

[77] *See also* Lewis, "Dealing with an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands," American Journal of Public Health, vol. 96, no. 2, at 250 (February 2006) (noting that the ban on flavorings other than menthol "would protect not only youth but also other susceptible target groups such as young adults"), Exhibit US-33.

[78] Section 907(a)(3)(B)(I) (emphasis added) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

78. Yes. The text of Article 2.2 makes no mention of "material contribution" and it is therefore legally irrelevant to the question of whether section 907(a)(1)(A) is not inconsistent with Article 2.2. In other words, a measure is not inconsistent with Article 2.2 simply because it does not make a "material contribution" to its objective. Rather, the test of Article 2.2 is different – whether the measure is more trade restrictive than necessary to fulfill a legitimate objective. To establish that a measure is inconsistent with Article 2.2 the complaining party must prove that: (1) a reasonably available alternative measure exists; (2) that fulfills the objective of the measure at the level that the Member imposing the measure considers appropriate; and (3) is significantly less trade restrictive.[79]

79. However, as part of the analysis of whether the complaining party has established a *prima facie* case of inconsistency, the Panel will need to understand at what level the measure fulfills its objective. To do this, the Panel will need to understand what the measure contributes to its objective. While Article 2.2 does not require that the measure fulfill its objective, it is difficult to believe that a measure that fails to fulfill its objective *completely* – that is to say, a measure that does not even make a marginal contribution to its objective – could be found consistent with Article 2.2.

(b) Is it the United States' position that, as a factual matter, banning clove cigarettes actually makes a "material contribution" to the objective of reducing youth smoking? If so, please explain how prohibiting what Indonesia refers to as only a "tiny sliver" of the cigarettes smoked by youth the measure can make a material contribution to the objective of reducing youth smoking?

80. As a factual matter, section 907(a)(1)(A), which bans cigarettes with characterizing flavors other than tobacco and menthol, makes a material contribution to its objective in that the prohibition of these cigarettes that disproportionately appeal to young people will eliminate the option to potential and novice smokers of "training" to become regular, addicted smokers with these products. As such, the measure is apt to reduce smoking of young people while avoiding the possibility of negative consequences.[80] This general point about the class of products banned

---

[79] *See, e.g.*, U.S. Second Written Submission, para. 145; U.S. First Written Submission, para. 264.

[80] We also note that while Indonesia believes that the data discussed in the Klein Article does not support the view that cigarettes with characterizing flavors, such as chocolate, cherry, and vanilla, exacerbate smoking prevalence of young people, public health experts, including Sarah Klein and her co-authors, believe just the opposite. *Compare* Indonesia Second Opening Statement, para. 42, *with* Klein Article ("Findings from this study suggest these products will likely find their largest market share among adolescents and young adults. Virtually all tobacco users become addicted before they can truly understand the consequences. Adding flavorings to tobacco products to make what is admittedly a dangerous and addictive product more appealing would seem to be harm enhancing and should be prohibited."), Exhibit US-51; Lewis, *Dealing with an Innovative Industry*, at 244 (referring to the data studies discussed in the Klein Article and stating, "[t]hese data raise significant concerns regarding the implications of these products for smoking among youths and young adults"), Exhibit US-33; and WHO, *The Scientific Basis of Tobacco*

under section 907(a)(1)(A) holds true for each of the individual products banned under the measure as well. That is to say, the elimination of clove cigarettes from the market (as well as chocolate, vanilla, cherry, etc.) makes a material contribution to the challenged measure's objective in the exact same way that the elimination of the entire class of products does.[81]

81. Indonesia makes the unsupportable claim that section 907(a)(1)(A) does not make a material contribution as other measures that the United States could have applied, but did not, would have made a larger contribution to reducing smoking than section 907(a)(1)(A) does.[82] We have already discussed in some detail why prohibiting all cigarettes would not meet the objective of section 907(a)(1)(A),[83] is not required by the text of Article 2.2,[84] and undermines the ability of Members to regulate complex problems incrementally,[85] and we will not repeat those points here.

82. We do note, however, that Indonesia's argument is unsupported even under an assessment of "material contribution" as conducted in an Article XX analysis. This is without prejudice to the fact that Article 2.2 of the TBT Agreement does not call for an analysis similar to that under Article XX of the GATT 1994. In *Brazil – Tyres*, the Appellate Body judged whether the challenged measure made a material contribution on its own terms, not in comparison with alternative measures. In the Appellate Body's Article XX analysis, the comparison of the challenged measure to alternative ones is only done to "confirm" that the measure is "necessary," not to determine the extent to which the measure contributes to its objective.[86] That is a separate inquiry, and one that takes place prior to comparison of the measure with alternatives.[87]

Product Regulation, at 37 (citing the data discussed in the Klein Article and stating, "[p]ublished research strongly suggests that youth targeting through marketing and product modifications influences youth smoking behaviour. Flavoured tobacco products may play a crucial role in this process, promoting youth initiation and helping young occasional smokers to become daily smokers by reducing or masking the natural harshness and taste of tobacco smoke."), Exhibit US-113.

[81] *See also* Lewis, *Dealing with an Innovative Industry*, at 250 (noting that the ban on flavorings other than menthol "would protect not only youth but also other susceptible target groups such as young adults"), Exhibit US-33.

[82] *See, e.g.*, Indonesia Answer to Q18, para. 51 ("If clove cigarettes are not more dangerous and are not widely smoked by youth, Indonesia submits it cannot be necessary to ban them if it was not necessary to ban menthol- and tobacco-flavoured cigarettes.").

[83] *See* U.S. Second Written Submission, paras. 168-170.

[84] *See* U.S. Second Written Submission, paras. 156-163.

[85] *See* U.S. Second Written Submission, paras. 9-23.

[86] *Brazil – Tyres (AB)*, para. 156 ("In order to determine whether a measure is 'necessary' within the meaning of Article XX(b) of the GATT 1994, a panel must assess all the relevant factors, particularly the extent of the contribution to the achievement of a measure's objective and its trade restrictiveness, in the light of the importance of the interests or values at stake. If this analysis yields a preliminary conclusion that the measure is necessary, this result *must be confirmed by comparing the measure with its possible alternatives*, which may be less trade restrictive while providing an equivalent contribution to the achievement of the objective pursued.") (emphasis added).

[87] *Compare Brazil – Tyres (AB)*, paras. 134-155, *with id.* paras. 156-175.

83. In *Brazil – Tyres*, the question was whether the import ban of retreaded tyres made a material contribution to reducing the exposure to risks arising from the accumulation of waste tyres. The panel found that the import ban "is capable of making a contribution to the objective pursued by Brazil, in that it can lead to a reduction in the overall number of waste tyres generated in Brazil, which in turn can reduce the potential for exposure to the specific risks to human, animal, plant life and health that Brazil seeks to address."[88] In making this determination, the panel only looked at the contribution the measure is capable of making on its own terms,[89] a point the Appellate Body confirmed.[90] Accordingly, the approach in *Brazil – Tyres* was to "evaluat[e] the extent to which the Import Ban is likely to result in a reduction of the exposure to these risks," not whether it made more or less of a contribution than other measures may have done.[91]

84. Further, the Appellate Body recognized that in evaluating whether the measure makes a material contribution to its objective, it must be cognizant that "certain complex public health or environmental problems may be tackled only with a comprehensive policy comprising a multiplicity of interacting measures." The fact that the contribution is not immediately apparent does not mean that the measure has no contribution.[92]

85. Clove cigarettes, like the class of cigarettes to which it belongs, have been designed to provide a distinct taste and aroma, and one which makes the product more appealing to consumers, particularly those potential and novice smokers who are at risk for becoming regular,

---

[88] *Brazil – Tyres (AB)*, para. 136 (quoting panel report at para. 7.148).

[89] *See Brazil – Tyres (Panel)*, paras. 7.119, 7.142, and 7.148.

[90] Thus, at paragraph 151, the Appellate Body in *Brazil – Tyres* stated:

> In order to justify an import ban under Article XX(b), a panel must be satisfied that it brings about a material contribution to the achievement of its objective. Such a demonstration can of course be made by resorting to evidence or data, pertaining to the past or the present, that establish that the import ban at issue makes a material contribution to the protection of public health or environmental objectives pursued. This is not, however, the only type of demonstration that could establish such a contribution. Thus, a panel might conclude that an import ban is necessary on the basis of a demonstration that the import ban at issue is apt to produce a material contribution to the achievement of its objective. This demonstration could consist of quantitative projections in the future, or qualitative reasoning based on a set of hypotheses that are tested and supported by sufficient evidence.

[91] *Brazil – Tyres (AB)*, para. 149.

[92] *Brazil – Tyres (AB)*, para. 151, stating:

> In the short-term, it may prove difficult to isolate the contribution to public health or environmental objectives of one specific measure from those attributable to the other measures that are part of the same comprehensive policy. Moreover, the results obtained from certain actions – for instance, measures adopted in order to attenuate global warming and climate change, or certain preventive actions to reduce the incidence of diseases that may manifest themselves only after a certain period of time – can only be evaluated with the benefit of time.

addicted smokers. The WHO has endorsed the view that clove cigarettes disproportionately appeal to young people and therefore present the same public health concern as the other cigarettes banned under section 907(a)(1)(A).[93] The survey data tracking actual clove cigarette usage by young people confirms that, in fact, young people within the window of initiation disproportionately use clove cigarettes, as they do other characterizing flavors, such as chocolate, cherry, coconut, etc.[94] The elimination of these trainer products makes it that much harder for non-smokers and novice smokers to become regular smokers, and thus is likely to reduce the smoking prevalence of young people over the long term.[95] This material contribution is even more apparent when one views section 907(a)(1)(A) in context, *i.e.*, as one element of a comprehensive strategy against smoking, one which has been in development in the United States for the last half century.[96]

86. The fact that a particular trainer product, such as clove cigarettes, does not have a large market share does not change this calculation. Products that appeal disproportionately to young people have particular public health concerns, regardless of their market share, and the product's elimination will make a material contribution to a reduction in smoking of young people. If the analysis was otherwise, no Member would every be able to justify under GATT Article XX a ban of any flavored cigarette, including chocolate, cherry, or vanilla flavored ones, without banning all cigarettes.[97]

107. Both parties: Indonesia submits that the NSDUH survey for 2009 shows that there are more than ten times as many smokers over the age of 30 whose regular brand is clove as there are regular clove smokers under 18 (Exhibit IND-74; Indonesia's second written submission, para. 31). The United States submits that the NSDUH survey for 2002-2003 shows that the percentage of

---

[93] *See* U.S. Second Written Submission, paras. 46-49.

[94] U.S. First Written Submission, paras. 54-55; Exhibit US-53.

[95] *Cf. Brazil – Tyres (AB)*, para. 154 ("Over time, this comprehensive regulatory scheme is apt to induce sustainable changes in the practices and behaviour of the domestic retreaders, as well as other actors, and result in an increase in the number of retreadable tyres in Brazil and a higher rate of retreading of domestic casings in Brazil.").

[96] *See generally* U.S. First Written Submission, sections G-H.

[97] We would further note that, as we have previously, that Indonesia is wrong to contend that it "has shown that there were no candy-flavored cigarettes being sold when the measure went into effect." Indonesia Second Opening Statement, para. 60. Prior to the Panel's second substantive meeting, Indonesia had not provided any evidence as to what other flavored cigarettes were or were not on the market in 2009. *See* Indonesia Answer to Q17, para. 48. However, at the Panel's second substantive meeting, Indonesia conceded that not only did Indonesian producers export cherry- and vanilla-flavored clove cigarettes to the United States, but that Belgian producers exported chocolate-flavored cigarettes to the United States. *See also* Carrie M. Carpenter, *et al.*, "New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies," Health Affairs, Vol. 24, No. 6, at 1602 (Nov./Dec. 2005), Exhibit US-40; AC Nielsen 2008 Data on Flavored Cigarettes in the United States, Exhibit US-52. Of course, numerous cigarette companies, both domestic and foreign, produced cigarettes with characterizing flavors of candy, fruit, liquor, etc. for the U.S. market that are now banned under section 907(a)(1)(A). *See* U.S. First Written Submission, paras. 48-51; U.S. Second Written Submission, paras. 79-86.

smokers over the age of 26 who smoke clove-flavoured cigarettes is "too low to calculate" (Exhibit US-53, p. 7). What is the source of such a significant discrepancy?

87. The differing conclusions of the parties illustrate fundamentally different approaches to which surveys provide accurate data, how clove cigarettes are actually used, and proper statistical methodology. Specifically, the parties reach different conclusions on the use of clove cigarettes among different age groups because:

- Indonesia and the United States use different questions and surveys to determine clove cigarette smokers;
- Indonesia makes calculations from a survey with an extremely small number of clove smokers, which introduces significant error; and
- Indonesia focuses on the total number of clove cigarette smokers in each age group, while the United States focuses on the prevalence of clove cigarette use in each age group.

88. First, Indonesia's analyses are based on the National Survey of Drug Use and Health ("NSDUH") respondents from 2009 who answered that clove cigarettes are the type of cigarette that they smoke "most often." We have already discussed why Indonesia's reliance on this question is improper.[98] The data analyses of the United States, on the other hand, rely on individuals who responded in the 2002-2003 NSDUH that they smoked clove cigarettes in the past month. This is the proper question from which to analyze clove cigarette use, particularly in light of the patterns of use of clove cigarettes during the window of initiation. (As the United States has previously shown, clove cigarettes tend to be smoked infrequently, so it is important not to rely exclusively on a question that asks which cigarette is smoked "most often.") Given Indonesia's improper reliance on the 2009 NSDUH, which was not designed to estimate clove cigarette use, it is not surprising that Indonesia's conclusions differ so dramatically from the conclusions of the United States, which relies on survey data that was, in fact, designed to estimate such use.

89. Second, the 2009 NSDUH is an improper survey to estimate nation-wide usage of clove cigarettes given that the sample size of clove cigarette smokers is so small in this survey (in part because of the reliance on the "most often" formulation of clove use). In order to draw conclusions from survey data, there must be robust sample sizes in each category of respondents in order to ensure that small fluctuations in the number of people who respond to a question do

[98] *See* U.S. Second Written Submission, paras. 53-58; U.S. First Opening Statement, paras. 18-19; and U.S. First Written Submission, paras. 67-77.

not unduly affect the results.[99] For example, the CDC uses a minimum of 100 respondents in each category for making statistical estimates in the Youth Behavioral Risk Surveillance System.[100]

90. However, Indonesia bases all of its conclusions on the responses of just 65 people who responded to the 2009 NSDUH that they smoked clove cigarettes "most often," as follows:

Age	**Number of Cigarette Smokers Who Have Smoked Clove Cigarettes "Most Often" in the Past Month**	**Weighted Count[101]**
Total	65	218,665.99
<18	4	6,868.75
18-29	52	133,366.15
30+	9	78,431.09

91. These very small numbers (just nine smokers over the age of 30 and just four individuals under the age of 18 reported that they smoked clove cigarettes most often) are then combined with the "weights" used in the selection of subjects to generate weighted counts of clove smokers for the entire population. Indonesia then appears to divide the weighted number of clove smokers over the age of 30 with the weighted number of clove smokers under the age of 18 to reach the ratio of 10.

92. However, relying upon small sample sizes for estimates to make the conclusions that Indonesia does is subject to undue effects by small fluctuations in the data and is thus flawed. For example, if only two more individuals age 17 and younger (out of the thousands surveyed by NSDUH) had answered affirmatively to the use of clove cigarettes, then Indonesia's estimate of clove smoking of this age group would have increased by 50%. Such an approach is absurd on its face, and is not in accordance with sound statistical methodology.[102]

93. In addition to these two errors, Indonesia commits a wholly different kind of error when it compares the total number of clove smokers over the age of 30 to the total number of clove cigarette smokers under the age of 18. It is no surprise that there is a greater number of clove cigarette smokers in the 30 and over age group; as the United States has previously said, there are

---

[99] Van Belle, *Statistical Rules of Thumb: Wiley Series in Probability and Statistics* (2002), Exhibit US-144.

[100] U.S. Centers for Disease Control and Prevention, "Methodology of the Youth Risk Behavior Surveillance System," MMWR 2004;53 (No. RR-12), Exhibit US-145.

[101] This column was weighted according to standard NSDUH methodology.

[102] The import statistics makes plain just how small of a sample 65 individuals really is. In 2009, the United States imported 213,012,000 clove cigarettes worth US$7.7 million. Exhibit US-100. In 2008, the United States imported almost double the amount of clove cigarettes (427,214,000 clove cigarettes worth US$14.8 million) than it did in 2009, yet only 60 people responded to the 2008 NSDUH that they smoked clove cigarettes "most often."

many more people in that age group and thus many more smokers. As a result, it is not surprising that Indonesia could find data to support the claim that there are "ten times as many smokers over the age of 30 whose regular brand is clove as there are regular clove smokers under 18" (even if the data is unreliable). As the United States has previously explained, given that the numbers of individuals in each age group differ so radically, the appropriate measure is to compare the prevalence of clove use among younger smokers to the prevalence of clove use among older smokers. This is especially true given that initiation of smoking behavior occurs almost exclusively in young people.

94. In contrast to Indonesia's approach, the United States avoids the errors outlined above.

95. First, the United States uses a question ("During the past 30 days, did you smoke part or all of a clove cigarette," from the 2002-2003 NSDUH) that reflects how clove cigarettes are used.

96. Second, the United States relies upon data that is drawn from a sufficient sample size to make reliable conclusions. The conclusions stated by the United States on the prevalence of use of clove cigarettes are based on the 1,015 smokers aged 12-25 in the 2002-2003 NSUDH who responded that they had smoked clove cigarettes in the past month and the 127 smokers aged 26 and older who also did so.[103] These numbers are ten times larger than the numbers used by Indonesia in its calculations, and are of a sample size large enough to permit formal statistical analyses.

97. As the Panel notes, the sample size in some of the smaller age breakdowns of the 26 and older age group were too small to permit calculations of prevalence, consistent with the standard practice of the CDC. For the 2002-2003 NSDUH reports, the following sample sizes reported smoking clove cigarettes in the last month: 81 smokers aged 26-34, 41 smokers aged 35-49, 4 smokers age 50-64, and 1 person older than 64. This is why the United State stated the prevalence of use by those smaller age groups was "too low to calculate."

98. Finally, the United States makes the appropriate and relevant comparison, which is the prevalence of use of clove cigarettes in younger smokers to the prevalence of use of clove cigarettes in older smokers. This comparison, based on the 2002-2003 NSDUH, demonstrates that 5.5% of younger people (age 12-25) smoked clove cigarettes in the past month while only 1.0% of those age 26 and older reported that they had.[104]

99. In conclusion, in contrast to Indonesia's approach which has three key errors, the United States has applied scientifically valid methodology to estimate clove smoking in the United States and, as such, avoids the erroneous conclusions that beset Indonesia's analysis.

---

[103] The United States would like to emphasize that these are unweighted numbers.

[104] Exhibit US-53, at 7.

108. Both parties: At paragraph 270 of its first written submission, the United States observes that Indonesia "simply lists" a number of alternative measures that the United States could have adopted. At paragraph 164 of its second written submission, the United States submits that Indonesia continues to make "vague references" to dozens of different alternative measures. How much argumentation and evidence must a complaining party present with respect to the proposed alternative measure(s) in order to establish a violation of Article 2.2 of the TBT Agreement?

100. As the United States has previously discussed, Indonesia bears the burden of proof of whether an alternative measures exists that proves that section 907(a)(1)(A) is more trade-restrictive than necessary.[105] To make such a showing, Indonesia must adduce sufficient evidence to raise the presumption that an alternative measure: (1) is reasonably available; (2) fulfills the challenged measure's legitimate objective; (3) at the level the United States finds appropriate; and (4) that the alternative measure is significantly less trade restrictive than the challenged one.[106]

101. The Appellate Body's analysis of the complaining party's burden in the analogous provision, Article 5.6 of the SPS Agreement, is instructive in this regard. Relying on its previous decision in *US – Wool Shirts and Blouses*, the Appellate Body recently stated in *Australia – Apples*:

> Overall, the totality of the evidence identified and/or adduced by the complainant will have to be sufficient to establish a presumption that the alternative measure would meet the appropriate level of protection. Whether such evidence suffices to meet the burden of establishing a *prima facie* case will necessarily vary from measure to measure and from case to case. A panel's assessment of whether this burden has been met is a matter of legal characterization and not a scientific assessment of risk that must conform to the first three paragraphs of Article 5.[107]

---

[105] U.S. First Written Submission, para. 271.

[106] *US – Wool Shirts and Blouses (AB)*, p. 14.

[107] *Australia – Apples (AB)*, para. 366; *see also Australia – Apples (Panel)*, para. 7.1137 ("Bearing in mind the standard rules on burden of proof, applicable also in SPS disputes, the Panel will assess whether New Zealand has 'establish[ed] a *prima facie* case of inconsistency [with Article 5.6],' in particular as regards the second condition of the Article 5.6 test. In other words, the standard rules on burden of proof, as articulated by the Appellate Body in *US – Wool Shirts and Blouses*, apply here. Accordingly, the Panel will assess whether New Zealand has adduced sufficient evidence to raise a presumption that the proposed alternative measure would achieve Australia's ALOP. If New Zealand succeeds in raising this presumption, then the burden of proof shifts to Australia, who must adduce sufficient evidence to rebut the presumption. If Australia fails to rebut this presumption, then, as a matter of law, New Zealand will have satisfied the second prong of the Article 5.6 test.") (quoting Appellate Body Report on *EC – Hormones (AB)*, para. 98, and citing *Japan – Agricultural Products II (AB)*, para. 122).

102. Indonesia has not provided *any* evidence that an alternative measure exists that fulfills even one of the four elements.[108] Indonesia does not meet the *US – Wool Shirts and Blouses* standard by merely making reference to possible alternative measures.

103. The United States would further note that because all of the measures Indonesia refers to in paragraphs 106-110 of its First Written Submission allow trainer cigarettes with characterizing flavors of candy, fruit, liquor, etc. to remain on the market, none of these measures would fulfill the objective of section 907(a)(1)(A) at the level the United States considers appropriate. The United States already imposes significant restrictions on the advertising, marketing, and sale of cigarettes, and has applied section 907(a)(1)(A) as an additional, and more comprehensive, restriction.[109] In paragraphs 166-173 of the U.S. Second Written Submission, the United States discussed three alternative measures that would eliminate trainer cigarettes with characterizing flavors of candy, fruit, liquor, etc. and why these alternative measures do not prove section 907(a)(1)(A) to be more trade-restrictive than necessary.

109. United States: In its second written submission, the United States reiterates that Indonesia has failed to meet its burden of proof with respect to the existence of a reasonably available "alternative" measure.

(a) How does the United States respond to the argument advanced by Indonesia at paragraphs 157-162 of its oral statement at the first meeting with the Panel?

104. In paragraphs 157-162 of Indonesia's opening statement at the Panel's first substantive meeting, Indonesia contends that whether an alternative measure exists is "moot" because "the measure bears no rational relationship to the objective" and therefore does not fulfill the objective.[110] As the United States discussed at the Panel's second substantive meeting, it is highly unlikely that whether an alternative measure exists will ever be "moot," and it is certainly not so in this case.

---

[108] For example, Indonesia has yet to provide *any* evidence that even one of the many measures it refers to would actually reduce smoking of young people while avoiding potential negative consequences (*i.e.*, element #2).

[109] *See* U.S. First Written Submission, paras. 251-253 (quoting the HR Report and finding 6 of the Tobacco Control Act); *see also* Tobacco Control Act, sec. 2, finding 15 ("Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use."), Exhibit US-7; U.S. Second Written Submission, para. 165.

[110] Indonesia's First Opening and Closing Statement, para. 157-159. As an initial matter, it is difficult to understand how Indonesia can maintain that the measure, as it applies to clove cigarettes, has "no rational relationship" to the reduction of smoking at all given that the survey data establishes that clove cigarettes appeals to young people, a point the WHO explicitly recognizes. World Health Organization, "The Scientific Basis of Tobacco Product Regulation," WHO Technical Report Series 945, at 99 (2007) ("[T]he dependence-causing effects of nicotine can be increased by contents and designs that increase the free base fraction of nicotine, and flavourings such as cherry and cloves can be used to appeal to target populations."), Exhibit US-113.

105. Indonesia has not established that section 907(a)(1)(A) fails to fulfill its objective at any level. As the United States has discussed previously, the public health scholarship, the WHO, and the survey data all support the U.S. view that the banned cigarettes, including clove cigarettes, present a public health concern because the characterizing flavoring appeals to young people.[111] By eliminating from the market trainer cigarettes that disproportionately appeal to young people and not those cigarettes to which tens of millions of people are addicted, the measure fulfills its objective at the level the United States considers appropriate. Accordingly, the burden remains on Indonesia to establish – through sufficient evidence – the existence of an alternative measure that proves that section 907(a)(1)(A) is more trade-restrictive than necessary.[112]

(b) If a panel were to find that a challenged measure was not apt to make any material contribution to the achievement of the objective pursued, would it not necessarily follow that the simple removal of that measure (i.e. subjecting clove cigarettes to the same treatment as menthol and regular cigarettes) would be a less trade-restrictive measure providing an equivalent contribution to the achievement of the objective pursued?

106. As the United States has discussed, the text of Article 2.2 makes no mention of "material contribution" and it is therefore not the test to determine whether a Member has acted consistently with Article 2.2.

107. If a measure that restricts trade completely and utterly fails to fulfill its objective, then it would follow that there would be an alternative measure that did fulfill the objective at the same level and that was less trade restrictive. But, of course, that is not the case here, and so the Panel does not need to reach this issue in order to resolve this dispute. The evidence establishes that not only do clove cigarettes appeal to young people, they do so disproportionately. As such, any alternative measure that does not ban clove cigarettes would not fulfill the objective of the challenged measure at the level the United States considers appropriate because it leaves a trainer product on the market whose prohibition would not cause negative consequences.

---

[111] U.S. Second Written Submission, paras. 41-49.

[112] We further fail to see how paragraph 123 of the Appellate Body's report in *Australia – Salmon* "seems to acknowledge" Indonesia's position. Indonesia's First Opening and Closing Statement, para. 158. Paragraph 123 discusses the proper meaning of "likelihood" for purposes of interpreting what a "risk assessment" must constitute, and appears to be completely irrelevant to the matters before the Panel. The relevant section of the report does not even begin until paragraph 179. There, the Appellate Body explained the elements that the complaining party would need to prove to establish a violation of SPS Article 5.6. *Australia – Salmon (AB)*, para. 180. As discussed previously, the Appellate Body's discussion in this regard provides highly relevant guidance to the Panel as to what elements Indonesia must prove to sustain its claim under Article 2.2, the analogous provision to SPS Article 5.6. *See* U.S. First Written Submission, paras. 262-264.

(c) The United States has indicated that some of the potentially alternative measures proposed by Indonesia are already in place in the United States (United States' first written submission, footnote 316; United States' second written submission, para. 165). Please clarify which of the potentially alternative measures listed by Indonesia at paragraphs 106-110 of its first written submission are already in place in the United States.

108. As an initial matter, the United States notes that it is Indonesia's burden to adduce sufficient evidence that an alternative measure exists that would prove that section 907(a)(1)(A) is more trade restrictive than necessary to fulfill its legitimate objective.

109. In paragraphs 106-110 of its First Written Submission, Indonesia refers to various measures, some of which are already part of U.S. law:

- Paragraph 106. The measures referred to are, as Indonesia indicates, part of U.S. law.[113]

- Paragraph 107. These two measures are not part of U.S. law. In fact, FDA is barred, by law, from imposing either of them.[114]

- Paragraph 108. The 2006 Consent Agreement is not part of U.S. law, but is rather an agreement between 40 states and one U.S. tobacco company, RJ Reynolds;[115] The measure referenced in the last sentence of the paragraph, which appears

[113] One of the measures, regarding outdoor advertising, is the subject of pending rulemaking. 75 Fed. Reg. 13,241 (March 19, 2010). Another, regarding black-and-white text only advertising, was ruled unconstitutional in a court challenge and the U.S. government has appealed this decision to a higher court. *Commonwealth Brands v. United States*, 678 F.Supp.2d 512 (W.D. Ky. 2010), appeal pending sub. nom. *Discount Tobacco City & Lottery, Inc. v. United States*, No. l0-5234-35 (6th Cir. 2010).

[114] *See* Section 906(d)(3)(A)(ii) of the FFDCA, as amended by the Tobacco Control Act (prohibiting FDA from setting a minimum age of sale of tobacco products to persons older than 18), Exhibit US-7; *Id.* at section 906(d)(3) (mandating that FDA may not prohibit the sale of cigarettes in face-to-face transactions by a specific category of retail outlet).

[115] U.S. First Written Submission, paras. 89-95; 2006 Consent Agreement, Exhibit US-61. The 2006 Consent Decree limits RJ Reynolds in its marketing and sale of any future cigarettes with certain flavor-related words or images used in their name, packaging or advertising to adult-only venues. We note that FDA can enact restrictions on the advertising and promotion of tobacco products, but to do so the agency must first determine the restriction would be appropriate for the protection of the public health, the same standard that served as the basis for section 907(a)(1)(A). Section 906(d)(1) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7; *see, e.g.*, U.S. Second Written Submission, paras. 11 and 143.

unrelated to the 2006 Consent Agreement, is similar to measures currently part of U.S. law.[116]

- Paragraph 109. The United States has adopted measures along the lines of most of the foreign measures Indonesia refers to, which appear to be somewhat repetitive of the measures listed in paragraph 106.[117]

- Paragraph 110. Of the measures referred to in the five bullets, many were already described by Indonesia in paragraphs 106 and 109, and all but the second bullet are part in U.S. law.[118]

110. As discussed in response to Question 108, measures that continue to allow trainer cigarettes with characterizing flavors of candy, fruit, liquor, etc. to remain on the market do not fulfill the objective of section 907(a)(1)(A) at the level the United States considers appropriate.[119] The failure to fulfill section 907(a)(1)(A)'s objective at the level the United States considers appropriate is particularly clear with measures that are already part of U.S. law.[120] While the

[116] In reviewing new tobacco product applications, FDA must determine whether the marketing of the product is appropriate for the protection of the public health. Section 910(c)(2)(A) and (c)(4) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7. In issuing an order that allows marketing of a new tobacco product, FDA may restrict the product's advertising and promotion to the same extent FDA can impose such restrictions on tobacco products generally. Section 910(c)(1)(B) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7.

[117] U.S. law includes several restrictions on advertising, event sponsorship, free giveaways in conjunction with the purchase of cigarettes/smokeless tobacco products. *See, e.g.*, 21 C.F.R. Part 1140, Exhibit US-146. U.S. law also restricts the use of self-service displays and requires health warnings. *See, e.g.*, 15 U.S.C. 1333, as amended by the Tobacco Control Act, Exhibit US-147. U.S. law allows FDA to impose penalties on retailers for selling to underage buyers including imposing no-tobacco-sale orders. *See, e.g.*, section 303(f)(8) and (9) of the FFDCA, as amended by the Tobacco Control Act, Exhibit US-7. U.S. law already requires that cigarettes be sold/distributed in a package size of at least 20 cigarettes. 21 C.F.R. sec. 1140.16(b), Exhibit US-146.

[118] *See* 21 C.F.R. 1140.16(c) (restrictions on the use of self-service displays that permit a consumer to remove a cigarette without the retailer's direct assistance and restricting the use of vending machines), Exhibit US-146; *id*. at 1140.16(d) (restrictions on the distribution of free samples); and *id*. at 1140.16(b) (restricting the sale of single cigarettes and, with limited exceptions, requiring a minimum package size of 20 cigarettes).

[119] *Cf. Brazil – Tyres (AB)*, para. 211, where, in terms of Article XX, the Appellate Body noted that many of the potential measures put forward by the complaining party "cannot be considered real alternatives to the Import Ban" because they are merely "complementary to the Import Ban; indeed, they constitute mutually supportive elements of a comprehensive policy to deal with waste tyres."

[120] We would further note that among the many things that Indonesia has not established with regard to these alternative measures, it has not established that these alternative measures are "reasonably available" to the United States. For example, Indonesia describes one alternative measure as "bann[ing] almost all tobacco advertising." Indonesia First Written Submission, para. 109. The U.S. Supreme Court has long held that advertising is speech protected under the U.S. Constitution. While federal, state, and local governments may place certain restrictions on corporate speech, their authority to do so under the U.S. Constitution is not unlimited. It is clear, for example, that these governments may not prohibit advertising of an industry entirely. Of course, the United States would consider any measure that was inconsistent to the U.S. Constitution to not be "reasonably available" to the United States. Again, it is Indonesia's burden to prove all the elements of its claim, including whether an alternative measure is

United States maintains significant restrictions on the advertising, marketing, and sale of cigarettes, these restrictions have failed to reduce significantly smoking prevalence among young people. Additional measures were clearly needed. Section 907(a)(1)(A) imposes an entirely different type of measure, one that does not limit access or visibility of a product, but eliminates the product from the market entirely, and thus represents a type of "comprehensive" restriction that Congress found was needed to make further gains against the threat of smoking.[121] Narrowing the scope of such a measure – or removing it from U.S. law entirely – weakens the overall smoking strategy of the United States and does not support the U.S. objective to reduce smoking in the United States.

110. Both parties: At paragraph 109 of its first written submission, Indonesia asserts that "New South Wales, Australia, and Singapore have all banned candy-flavored cigarettes, but not clove cigarettes" (emphasis original) Please provide the Panel with additional information on the number of WTO Members that have banned certain types of flavoured cigarettes, and which types of flavoured cigarettes have been banned.

111. The United States would note that Indonesia did not submit evidence to support its contention that New South Wales, Australia, and Singapore have banned "candy-flavored" cigarettes, but not clove flavored cigarettes.

112. Based upon a review of available legislation on tobacco product legislation enacted by WTO Members, it appears that countries (or their states) including Canada, France, Australia and Thailand have enacted prohibitions on certain types of flavors in cigarettes. None of these countries apparently ban menthol flavored cigarettes.[122] Canada's legislation includes a ban on clove-flavored cigarettes, as it bans additives including "spices, seasonings, and herbs."[123] Based on the text of the other laws, it is not clear whether clove-flavored cigarettes are prohibited or allowed.[124] For example, Australian legislation varies among states, but generally prohibits

---

"reasonably available."

[121] *See* U.S. First Written Submission, paras. 250-254 (quoting the HR Rep't and the findings of Tobacco Control Act). The *Brazil – Tyres* panel and the Appellate Body came to a similar conclusion in the Article XX context, rejecting the EC's alternative measures that were already part of Brazilian law. *See Brazil – Tyres (AB)*, para. 172 ("In fact, like the Import Ban, these measures already figure as elements of a comprehensive strategy designed by Brazil to deal with waste tyres. Substituting one element of this comprehensive policy for another would weaken the policy by reducing the synergies between its components, as well as its total effect. We are therefore of the view that the Panel did not err in rejecting as alternatives to the Import Ban components of Brazil's policy regarding waste tyres that are complementary to the Import Ban.").

[122] Framework Convention Alliance, Product Regulation: The Facts at 2 Exhibit US-148.

[123] Cigarette Bans Enacted by Other WTO Members, Exhibit US-149.

[124] Cigarette Bans Enacted by Other WTO Members, Exhibit US-149..

cigarettes with a sweet, fruity or confectionary taste.[125] This description could apply to clove-flavored cigarettes. Thailand also bans fruity and confectionary cigarettes, and it is not clear from the face of the measures whether clove cigarettes are permitted.[126]

D. ARTICLE 2.8 OF THE TBT AGREEMENT

111. United States: In its response to Panel question No. 64, Indonesia submits that there is an established process for determining the thresholds at which flavours can be detected (set forth in "ASTM E679 - 04 Standard Practice for Determination of Odor and Taste Thresholds By a Forced-Choice Ascending Concentration Series Method of Limits"), and that a performance standard could use this established method to determine the concentrations of flavours that reach a threshold where they are recognizable by taste and odour and are, thus, "characterizing". Does the United States agree?

113. No, the United States does not agree. As discussed in at the Panel's second substantive meeting, the standard referred to – but not provided – in Exhibit IND-70 does not establish that the requirement of section 907(a)(1)(A) could be written in terms of performance, nor does it establish that it would be "appropriate" to do so.[127]

114. As a threshold matter, the United States is not clear that the standard referred to in Exhibit IND-70 is applicable to cigarettes at all, and Indonesia has made no showing that it is. But even if it were, the United States fails to see how a measure that incorporates this standard, which only purports to provide a particular means of testing, establishes that the challenged measure could be written in fundamentally different terms, and what those terms would be.

115. An example of a performance requirement would be a technical regulation for chairs, for example, that set a requirement that the chair must support a person of at least 130 kilograms, rather than in terms of the components of the chair (*i.e.*, if made of wood then the wood must be of a certain thickness and the nails must be of a certain length).[128] A performance requirement is thus one that regulates the performance of the product, as opposed to one that describes the design or the inputs of the product. An example of such a measure for cigarettes is the requirement that cigarettes be "fire safe." "Fire safe" cigarettes are those that are designed to self-extinguish when they are lit but not being smoked.

116. The requirement of section 907(a)(1)(A) is written in terms of the effect of certain additives and/or constituents of the cigarette. Indonesia purports that the standard referred to in

---

[125] Cigarette Bans Enacted by Other WTO Members, Exhibit US-149.

[126] Cigarette Bans Enacted by Other WTO Members, Exhibit US-149.

[127] *See* U.S. Second Opening Statement, paras. 92-100.

[128] U.S. Second Opening Statement, para. 95.

Exhibit IND-70 tests what concentration of an additive is needed to give the product a characterizing flavor of that additive. Thus, the standard Indonesia refers to would not be a performance standard – it is not a standard as to how a cigarette is to perform. Nor would it replace the standard in section 907(a)(1)(A). Instead, it merely purports to provide a particular means of testing whether that standard is met. Providing a test of when the standard of the measure, which is written in descriptive terms, is met does not mean that it is possible to put the requirement in the fundamentally different terms of performance, nor why it would be "appropriate" to do so.[129]

E. ARTICLE 12.3 OF THE TBT AGREEMENT

112. United States: Indonesia argues that the United States' interpretation of Article 12.3 would, in the light of Article 2.9.4 of the TBT Agreement, render Article 12.3 redundant (Indonesia's opening statement at the first meeting with the Panel, para. 185; Indonesia's response to Panel question No. 73, para. 146). How does the United States respond?

117. The U.S. view does not render Article 12.3 redundant of Article 2.9.4 as Indonesia claims.[130] The obligation of Article 2.9.4 is only one of a set of obligations contained in Article 2.9. If the conditions contained in the Article 2.9 chapeau are satisfied, then the transparency mechanism described in the subparagraphs of Article 2.9 are triggered. Article 12.3 is not so conditioned and does not specify a particular mechanism to facilitate the communications. In this regard, Article 12.3 is a broader obligation than the one provided in Article 2.9.4. The fact that in certain circumstances, Article 12.3 could be satisfied by satisfying Article 2.9.4 does not mean that Article 12.3 is inutile.

118. Critically, Indonesia is unable to articulate the legal standard that Article 12.3 imposes. It is not sufficient to simply say that "something" more than what the United States has done is required. As discussed previously, nothing in Article 12.3 requires the "something" more that Indonesia claims it does.[131] In particular, Article 12.3 does not require the developed country Member to accept every recommendation presented by the developing country Member.[132] Yet the United States cannot understand Indonesia's Article 12.3 claim as anything other than Indonesia's complaint that the United States in fact did not agree with the arguments it put forward to U.S. Government officials prior to the enactment of the Tobacco Control Act. Such a

---

[129] The United States would further note that the amount of flavoring necessary in any given cigarette to create a characterizing flavor will vary considerably based on the size of the cigarette, what type of tobacco is used, and what other ingredients are used. It is because of that variability that the section at issue focuses on banning cigarettes with ingredients that create a characterizing flavor rather than prohibit certain levels of certain ingredients.

[130] U.S. Second Opening Statement, para. 110.

[131] U.S. Second Opening Statement, paras. 106-109.

[132] U.S. First Written Submission, para. 309.

subjective standard cannot be what the Members intended Article 12.3 to mean. Rather, the best interpretation of what "take account" means for purposes of Article 12.3 is that the importing Member must *consider* the special needs of the developing country. This the United States certainly did – a point that even Indonesia does not appear to contest.

List of Exhibits

US-136	Chart of Menthol Cigarette Brands Imported to the United States
US-137	U.S. Federal Trade Commission Data on Imported Menthol Cigarettes
US-138	Senate Committee on Health, Education, Labor and Pensions ("HELP") Hearing, S.625, "The Need for FDA Regulation of Tobacco," at 204 (February 27, 2007)
US-139	Henningfield, *et al.*, "Reducing the addictiveness of cigarettes," Tobacco Control, 7:281-293 (1998)
US-140	U.S. Government Accountability Office, *Cigarette Smuggling: Federal Law Enforcement Efforts and Seizures Increasing*, GAO-04-641 (May 28, 2004)
US-141	World Health Organization, *Illicit Trade in Tobacco Products*, Report of the Regional Workshop New Delhi, India (September 15-16, 2008)
US-142	Bernat, Erickson, *et al*., "Adolescent Smoking Trajectories: Results from a Population-Based Cohort Study," *J Adolescent Health* 43 (2008) 334-340
US-143	"Trends in Menthol Cigarette Sales, Price, and Promotion in the United States," RTI International, Presented to the Tobacco Product Scientific Advisory Committee to the Food and Drug Administration (November 18, 2010)
US-144	Van Belle, *Statistical Rules of Thumb: Wiley Series in Probability and Statistics* (2002)
US-145	U.S. Centers for Disease Control and Prevention, "Methodology of the Youth Risk Behavior Surveillance System," MMWR 2004; 53 (No. RR-12)
US-146	21 C.F.R. pt. 1140
US-147	15 U.S.C. 1333
US-148	Framework Convention Alliance, Product Regulation: The Facts
US-149	Cigarette Bans Enacted by Other WTO Members