

Tobacco Control and Beyond: The Broader Implications of *United States—Clove Cigarettes* for Non-Communicable Diseases

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I. INTRODUCTION

As implementation of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) accelerates and states seek to address risk factors for non-communicable disease more broadly, tension has increased between the law of the World Trade Organization (WTO) and public health. For example, Indonesia recently brought a successful claim against a U.S. law that prohibits cigarettes with a characterizing flavor other than menthol or tobacco.¹ Indonesia succeeded in arguing that the regulation discriminates against clove-flavored cigarettes of Indonesian origin in favor of menthol-flavored cigarettes of U.S. origin.²

Also in the WTO context, the Dominican Republic, Honduras, and Ukraine have challenged an Australian law prohibiting the presence of branding on tobacco packaging other than product and variant names in a standardized location, font size, and style.³ This regulation, commonly referred to as “plain packaging,” is the first of its kind and may represent a turning point in the regulation of tobacco packaging.⁴

More broadly, the tobacco industry has launched a new wave of international litigation.⁵ Outside of the WTO, Philip Morris has also been active in using trade and investment agreements to challenge tobacco control measures directly. In 2010, Philip Morris launched a challenge to Uruguayan tobacco packaging measures under

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¹ Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/AB/R (Apr. 4, 2012).

² *Id.* ¶ 298.

³ See, e.g., Request for Consultations by Ukraine, *Australia—Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS434/1 (Aug. 17, 2012).

⁴ See *id.*

⁵ See generally BENN MCGRADY, WORLD HEALTH ORG. [WHO], CONFRONTING THE TOBACCO EPIDEMIC IN A NEW ERA OF TRADE AND INVESTMENT LIBERALIZATION (2012).

a bilateral investment treaty (BIT) between Switzerland and Uruguay.⁶ In 2011, the company launched a similar challenge to Australia's plain packaging legislation under the Australia-Hong Kong BIT.⁷ In 2012, Philip Morris lost a claim in Norwegian courts that challenged a prohibition on the display of tobacco products at the point of sale under the European Economic Area Agreement.⁸

This resistance to regulation comes at a time of heightened concern about risk factors for Non-Communicable Diseases (NCDs), as reflected in the recent Political Declaration of the High-Level Meeting of the General Assembly on the Prevention and Control of NCDs. Increasingly, states are also using the lessons learned in tobacco control to address other risk factors for NCDs, such as harmful alcohol use and poor diet. Some of these efforts, such as a move to graphic warning labels on alcoholic beverages in Thailand, have also proven controversial under WTO law.

This Article builds on earlier analysis of the implications of WTO law for regulations to address NCDs.⁹ More specifically, this Article examines the implications of *United States—Clove Cigarettes* and subsequent technical barriers to trade (TBT) disputes for tobacco control and control of NCDs associated with alcohol and poor diet. Part II of this paper describes the limited scope of the Agreement on Technical Barriers to Trade (the "TBT Agreement"), which may prove to be an important caveat to the implications of *United States—Clove Cigarettes* and other TBT disputes. Part III examines the principle of non-discrimination as applied in TBT disputes and the possible effects of this approach on domestic regulatory autonomy in the context of NCDs. Part IV examines how application of principles governing necessity may affect the issues.

II. THE SCOPE OF THE TBT AGREEMENT

The two provisions of the TBT Agreement most relevant to regulations addressing NCDs are Articles 2.1 and 2.2, which govern non-discrimination and necessity respectively.¹⁰ Before discussing these provisions in further detail in parts II and III of this paper, it is important to note that those provisions apply only to technical regulations.¹¹ Accordingly, it should not be assumed that the law as developed in *United States—Clove Cigarettes* and subsequent TBT disputes will affect *all* measures to address NCDs.

The phrase "technical regulation" is defined in Annex 1.1 of the TBT Agreement as a:

⁶ Request for Arbitration, *FTR Holdings S.A. v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7 (Feb. 19, 2010), <http://www.italaw.com/cases/460>.

⁷ Notice of Arbitration, *Philip Morris Asia Ltd. v. Australia*, UNCITRAL, PCA Case No. 2012-12 (Nov. 21, 2011), <http://www.italaw.com/sites/default/files/case-documents/ita0665.pdf>.

⁸ *Philip Morris Nor. AS v. Ministry of Health & Care Servs.*, 10-041388TVI-OTIR/02 (Oslo D. Ct. Sept. 14, 2012) (Nor.).

⁹ See BENN MCGRADY, *TRADE AND PUBLIC HEALTH: THE WTO, TOBACCO, ALCOHOL, AND DIET* (2011).

¹⁰ Agreement on Technical Barriers to Trade art. 2.1-2.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120 [hereinafter TBT Agreement].

¹¹ *Id.*

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.¹²

The heart of the definition is such that the document in question must lay down product characteristics in order to be a technical regulation. These characteristics may be in a negative form, such as a prohibition, or in a positive form, such as a compulsion.¹³

In the tobacco control context, there is a limited range of measures that constitute technical regulations. The most obvious examples are packaging and labeling requirements and requirements concerning the constituents of tobacco products. The TBT Agreement does not, however, ordinarily apply to taxes or to restrictions on marketing that are commonly used to reduce tobacco consumption but that do not lay down product characteristics.¹⁴

In the contexts of alcohol and diet, the question of scope is more complex. Article 1.5 of the TBT Agreement provides that the agreement does not apply to measures falling within the scope of the Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”).¹⁵ The SPS Agreement applies to a broad range of measures, including any measure “to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs.”¹⁶ The types of measures covered are described in the following way:

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.¹⁷

Accordingly, most product regulations in the food context, and food labeling measures, will fall within the scope of the SPS Agreement rather than the TBT Agreement.¹⁸

In the alcohol context, some measures fall outside the scope of the TBT Agreement and others fall within the scope of the SPS Agreement. Regulations governing the constituents of alcoholic beverages in order to reduce toxicity would

¹² *Id.* at Annex 1.

¹³ See Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 67, WT/DS135/AB/R (Mar. 12, 2001) [hereinafter Appellate Body Report, *EC—Asbestos*].

¹⁴ *See id.*

¹⁵ TBT Agreement, *supra* note 10, at art. 1.5.

¹⁶ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

¹⁷ *Id.* at Annex A.

¹⁸ For a more detailed discussion see MCGRADY, *supra* note 9, at 175-80.

appear to fall within the SPS Agreement. This includes bans on methanol and other substances that are widespread and have not proven controversial under WTO law.

A number of other alcohol control regulations would appear to lay down product characteristics and thereby fall within the scope of the TBT Agreement. Labeling measures are one example. Other examples include measures that prohibit the sale of “alcopops” (pre-mixed drinks targeted at young people) and regulations that prohibit pre-mixed drinks containing caffeine or other stimulants. In the case of pre-mixed alcopops, it might be argued that restrictions are aimed at addressing the risks associated with additives, such as flavorings and mixers. At their core, however, it appears such bans are not applied to address risks arising from additives but are more concerned with the attractiveness of the end product to specific groups. It is less clear whether the same can be said for drinks with caffeine or other stimulants. In the case of the United States, for example, the U.S. Food and Drug Administration (FDA) referred to caffeine as an additive so as to permit invocation of FDA regulatory powers.¹⁹

Notwithstanding the ordinary wording of the definition of SPS measures, in practice WTO Members have tended to raise concerns relating to measures affecting alcoholic beverages through the TBT Committee, suggesting that most Members view the TBT Agreement as being the applicable agreement.²⁰ This past practice also suggests that restrictions on alcopops, caffeinated beverages and alcoholic energy drinks are likely to be notified to and discussed in the TBT Committee.²¹

Despite the limitations on the scope of the TBT Agreement, it is worth noting that WTO case law tends to seek consistent approaches to interpreting rules restricting regulatory autonomy across different WTO covered agreements.²² Accordingly, the TBT disputes may still be relevant to interpretation of other agreements, including the SPS Agreement. This issue is discussed in Part III.

III. UNITED STATES—CLOVE CIGARETTES AND NON-DISCRIMINATION UNDER ARTICLE 2.1

In 2009, the United States prohibited cigarettes containing a constituent that is a characterizing flavor of tobacco or tobacco smoke, other than menthol or tobacco.²³ Indonesia brought a WTO complaint, which alleged the law violates Article 2.1 because it treats Indonesian clove flavored cigarettes less favorably than like U.S. menthol flavored cigarettes.²⁴

Article 2.1 of the TBT Agreement provides that: “Members shall ensure that in respect of technical regulations, products imported from the territory of any Member

¹⁹ *Caffeinated Alcoholic Beverages*, FDA, <http://www.fda.gov/Food/IngredientsPackaging/Labeling/ucm190366.htm> (last updated Mar. 10, 2011).

²⁰ Comm. on Technical Barriers to Trade, *Note by the Secretariat: Seventeenth Annual Review of the Implementation and Operation of the TBT Agreement*, at 24-25, G/TBT/31 (Mar. 2, 2012).

²¹ TBT notifications with respect to alcoholic beverages actually exceed those for tobacco. To search publicly available notifications, see *TBT Information Management*, WTO, <http://tbims.wto.org/> (last visited Mar. 15, 2013).

²² This issue is discussed in further detail below within the context of *United States—Clove Cigarettes*.

²³ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 907(a)(1)(A), 123 Stat. 1776, 1799 (2009).

²⁴ Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 3.1, WT/DS406/R (Sept. 2, 2011).

shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.”²⁵

Indonesia argued that although the technical regulation did not discriminate against imported products on its face, the effect was nonetheless discriminatory.²⁶ Indonesia’s argument was based on the fact that clove cigarettes consumed in the United States prior to implementation of the law were predominately Indonesian in origin, whereas menthol cigarettes consumed in the United States are predominately of U.S. origin.²⁷ The United States argued that the regulatory distinction drawn between clove and menthol cigarettes was based not on the foreign origin of clove cigarettes, but on the fact that clove cigarettes are a “starter product” used disproportionately by youth.²⁸ That is, youth and adults consume menthol cigarettes in similar proportions, whereas clove cigarettes were consumed predominantly by youth.²⁹

To establish that a technical regulation violates Article 2.1 on national treatment grounds, a complainant must establish that the products in question (clove and menthol cigarettes) are like products and that the imported products (clove cigarettes) are treated less favorably than the products of national origin (menthol cigarettes).³⁰

Prior to *United States—Clove Cigarettes*, the approach to be used in determining whether products are like under the TBT Agreement was not clear. The panel examined whether clove and menthol cigarettes were like in regulatory terms.³¹ That is, the United States was pursuing the objective of reducing youth smoking and in this light the panel examined whether clove and menthol cigarettes were like in terms of their effect on youth smoking.³² On the facts, the panel found the products to be like. The panel found that each type of cigarette imparts a characterizing flavor that reduces the harshness of tobacco, and that each is attractive to youth.³³

On appeal, the Appellate Body clarified that whether product categories are to be considered like is “a determination about the nature and extent of a competitive relationship between and among the products at issue.”³⁴ Under this approach, the fact that products may pose divergent risks to health will not in and of itself mean that they are not like products, but may be relevant to the question of competitiveness.³⁵ Despite interpreting the likeness test differently from the panel, the Appellate Body upheld the panel’s finding that clove and menthol cigarettes are like for purposes of this dispute.³⁶ The Appellate Body also noted that it is sufficient for a sub-group of the population (in this case youth) to treat the products as competitive in order for likeness to be established.³⁷

²⁵ TBT Agreement, *supra* note 10, at art. 2.1.

²⁶ Appellate Body Report, *supra* note 1, ¶ 54.

²⁷ *Id.* ¶ 53.

²⁸ *Id.* ¶ 19.

²⁹ *Id.*

³⁰ Peter Van den Bossche et al., *WTO Rules on Technical Barriers to Trade* (Maastricht Faculty of Law, Working Paper No. 2005-6, 2005), available at <http://www.worldtradelaw.net/articles/vandenbosschetbt.pdf>.

³¹ See Panel Report, *supra* note 24, ¶ 7.230.

³² *Id.* ¶¶ 7.231-232.

³³ *Id.* ¶ 7.182.

³⁴ Appellate Body Report, *supra* note 1, ¶ 120.

³⁵ *Id.* ¶ 129.

³⁶ *Id.* ¶ 160.

³⁷ *Id.* ¶¶ 143-144.

On the question of less favorable treatment, the panel sided with Indonesia.³⁸ On appeal, the Appellate Body sought to clarify the meaning of less favorable treatment. The Appellate Body clarified that mere detriment to some imported products will not satisfy the requirement.³⁹ The Appellate Body stated, “Article 2.1 should not be interpreted as prohibiting any detrimental impact on competitive opportunities for imports in cases where such detrimental impact on imports stems exclusively from legitimate regulatory distinctions.”⁴⁰ To determine whether a detrimental impact stems exclusively from legitimate regulatory distinctions, a panel must scrutinize “the design, architecture, revealing structure, operation and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed.”⁴¹

After elaborating this test, the Appellate Body upheld the panel’s finding that less favorable treatment had been established.⁴² In doing so, the Appellate Body relied on the fact that the prohibited products were primarily clove cigarettes from Indonesia, whereas the permitted products (menthol cigarettes) were primarily domestically produced.⁴³ The Appellate Body stated that it was not persuaded that the detrimental impact on competitive opportunities for imported cigarettes stemmed from a legitimate regulatory distinction.⁴⁴ Rather, the Appellate Body relied on the panel’s findings to the effect that menthol cigarettes had the same product characteristics as clove in terms of their effect on rates of youth smoking.⁴⁵

A. SIGNIFICANCE IN TERMS OF WTO LAW

United States—Clove Cigarettes was the first of three challenges to different U.S. technical regulations. In each of these three disputes, complaints were brought under both Articles 2.1 and 2.2 of the TBT Agreement.⁴⁶ Because there had been relatively few disputes touching on these principles of non-discrimination and necessity within the TBT context, *United States—Clove Cigarettes* marked an important point in development of the law. Prior to *United States—Clove Cigarettes*, disputes under the General Agreement on Tariffs and Trade (GATT 1994) had served to clarify the balance of rights (to regulate) and obligations.⁴⁷

The GATT 1994, which applies to trade in goods, establishes a rule-exception relationship between principles of non-discrimination and necessity. Where a measure is discriminatory in form or effect under Article III, it may nonetheless be lawful if justified in accordance with one of the general exceptions in Article XX, such as the necessity exception in paragraph (b).⁴⁸ Consequently, the need to balance the rights and obligations of Members in applying Article III of the GATT 1994 is

³⁸ *Id.* ¶ 9.

³⁹ *Id.* ¶ 192.

⁴⁰ *Id.* ¶ 174.

⁴¹ *Id.* ¶ 215; *see also id.* ¶ 182.

⁴² *Id.* ¶ 226.

⁴³ *Id.* ¶ 224.

⁴⁴ *Id.* ¶ 225.

⁴⁵ *Id.*

⁴⁶ *See, e.g.*, Appellate Body Report, *supra* note 1; Appellate Body Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/AB/R (May 16, 2012) [hereinafter *United States—Tuna II*].

⁴⁷ *See* Weihuan Zhou, *US—Clove Cigarettes and US—Tuna II (Mexico): Implications for the Role of Regulatory Purpose Under Article III:4 of the GATT*, 15 J. INT’L ECON. L. 1075 (2012).

⁴⁸ General Agreement on Tariffs and Trade 1994 art. XXII, Apr. 15, 1994, 1867 U.N.T.S. 187 [hereinafter GATT 1994].

limited because Article XX serves as a policy balancing mechanism preserving measures that, *inter alia*, are necessary to protect human life or health.

Article III:4 of the GATT 1994 prohibits WTO Members from treating imported products less favorably than like domestic products in respect of all laws, regulations, or requirements affecting their internal sale, offering for sale, purchase, transportation, distribution, or use.⁴⁹ Under this provision, whether products are like is also determined by reference to the nature and extent of a competitive relationship between them.⁵⁰ Whether imported products are treated less favorably also turns on whether the conditions of competition are modified to the detriment of imported products.⁵¹ A panel, however, is not required to ask whether the detriment to imported products is based solely on a legitimate regulatory distinction. Rather, a panel must look more generally at the explanations for the detrimental effect.⁵² As the Appellate Body has stated, “the existence of a detrimental effect on a given imported product resulting from a measure does not necessarily imply that this measure accords less favorable treatment to imports if the detrimental effect is explained by factors or circumstances unrelated to the foreign origin of the product.”⁵³

In the event that a measure violates Article III:4, the measure may nonetheless be justified under Article XX(b) on grounds that it is necessary to protect human life or health.⁵⁴ This exception is subject to a requirement set out in the chapeau that the measure not be “applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.”⁵⁵ This passage governs only how a measure is applied and not the form of a measure itself. When considering questions of application, the test is whether reasons given for discrimination in application of the measure bear a rational connection to the objective or go against that objective.⁵⁶

Because Article 2.1 of the TBT Agreement is not subject to general exceptions along the lines of those in Article XX, it was foreseeable that *United States—Clove Cigarettes* would alter the balance of rights and obligations reflected in the GATT 1994. To avoid this, the panel took a distinct approach to likeness by following the approach to interpretation used in investment treaties, which usually lack general exceptions along the lines of GATT Article XX.⁵⁷ The effect of this was to narrow the scope of the non-discrimination obligation relative to that in the GATT 1994. In rejecting the panel’s approach, the Appellate Body stated that under its approach the balance between rights and obligations in Article 2.1 of the TBT Agreement “is not, in principle, different from the balance set out in the GATT 1994, where obligations, such as national treatment in Article III, are qualified by the general exceptions provision of Article XX.”⁵⁸

⁴⁹ *Id.* at art. III.

⁵⁰ Appellate Body Report, *EC—Asbestos*, *supra* note 13, ¶ 117.

⁵¹ Appellate Body Report, *Dominican Republic—Measures Affecting the Importation and Sale of Cigarettes*, ¶ 93, WT/DS302/AB/R (Apr. 25, 2005).

⁵² *Id.* ¶¶ 95-96.

⁵³ *Id.* ¶ 96.

⁵⁴ GATT 1994, *supra* note 48, at art. XX(b).

⁵⁵ *Id.* at art. XXII.

⁵⁶ Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 227, WT/DS332/AB/R (Dec. 3, 2007) [hereinafter *Brazil—Retreaded Tyres*].

⁵⁷ See generally Nicholas DiMascio & Joost Pauwelyn, *Non-Discrimination in Trade and Investment Treaties: Worlds Apart or Two Sides of the Same Coin?*, 102 AM. J. INT’L L. 48 (2008).

⁵⁸ Appellate Body Report, *supra* note 1, ¶ 96.

Whether *United States—Clove Cigarettes* alters the balance between rights and obligations is open to question in light of conflicting case law under the GATT 1994. Whereas *United States—Clove Cigarettes* requires WTO Members to justify a detrimental impact on imported products as legitimate,⁵⁹ the extent to which Members must do this under the GATT 1994 is less clear. One line of case law suggests the legitimacy of a regulatory distinction between products is only evaluated under the chapeau of Article XX. For example, the Appellate Body's decision in *United States—Gasoline* held that a Member must establish the necessity of a measure as a whole and not the necessity of discrimination under Article XX(b).⁶⁰ Under this approach, a Member would not have to establish the legitimacy of a regulatory distinction between products in order to establish necessity (although the discrimination may be weighed and balanced in the analysis).⁶¹ Moreover, the chapeau only governs *application* of a measure and not the form of the measure itself (such as where an otherwise neutral measure is applied in a discriminatory manner).⁶² As a result, there is a very narrow range of circumstances in which a Member will have to justify regulatory distinctions between measures.

However, in a more recent dispute and without expressly referring to the earlier authority, the Appellate Body stated that where violation of Article III occurs, it is the discrimination that must be justified as necessary and not the measure.⁶³ The decision in *Thailand—Customs and Fiscal Measures on Cigarettes from the Philippines* suggests a respondent will have to justify a discriminatory regulatory distinction drawn between like products in order to establish the necessity of the measure.⁶⁴ In short, if this more recent approach to the GATT 1994 prevails, the Appellate Body's observation in *United States—Clove Cigarettes* that the balance between rights and obligations are similar under the GATT and TBT Agreement would appear to be correct. However, if the earlier approach prevails, the GATT 1994 might be more permissive than Article 2.1 of the TBT Agreement.

To add to the confusion, since *United States—Clove Cigarettes*, the Appellate Body has equated the concept of a legitimate regulatory distinction with compliance with the chapeau of GATT Article XX. In *United States—COOL*, the Appellate Body stated that a distinction would not be legitimate if it “is designed or applied in a manner that constitutes a means of arbitrary or unjustifiable discrimination.”⁶⁵ The notable distinction here is that this passage refers to regulations “designed or applied” whereas the chapeau only governs application of a measure.⁶⁶

⁵⁹ *Id.* ¶ 54.

⁶⁰ Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, at 16, WT/DS2/AB/R (Apr. 29, 1996) [hereinafter *United States—Gasoline*].

⁶¹ On this weighing and balancing issue, see Simon Lester, *What Aspect of a Measure Should Be Considered Under the GATT Article XX Sub-Paragraphs? Some Criticism*, INT'L ECON. L. & POL'Y BLOG (Feb. 24, 2013, 1:23 PM), <http://worldtradelaw.typepad.com/ielpblog/2011/06/what-aspect-of-a-measure-should-be-considered-under-the-gatt-article-xx-sub-paragraphs-some-criticism.html>.

⁶² *United States—Gasoline*, *supra* note 60, at 22.

⁶³ Appellate Body Report, *supra* note 1, ¶ 73.

⁶⁴ Appellate Body Report, *Thailand—Customs and Fiscal Measures on Cigarettes from the Philippines*, ¶ 177, WT/DS371/AB/R (June 17, 2011).

⁶⁵ Appellate Body Reports, *United States—Certain Country of Origin Labeling (COOL) Requirements*, ¶ 270, WT/DS384/AB/R, WT/DS386/AB/R (June 29, 2012) [hereinafter *United States—COOL*].

⁶⁶ *See id.*

B. APPLYING THE TEST TO MEASURES ADDRESSING NCDs

Leaving aside resolution of the prevailing approach, it is clear that demonstrating the legitimacy of regulatory distinctions will sometimes be challenging for regulators in the contexts of tobacco, alcohol, and diet. The legitimacy of a distinction must ultimately be based on an analysis of the risks posed by the relevant product categories. Unlike the SPS Agreement, however, the TBT Agreement offers no guidance on the issue of what type of risk assessment or evidence is adequate.⁶⁷ This poses a particular challenge in the context of NCDs like cancers, diabetes, or stroke because many risk factors are distal from, rather than proximate to, the onset of disease. These risk factors are often related to complex patterns of consumer behavior, such as an unhealthy diet over long periods.

Before considering the evidence used to justify regulatory distinctions in this context, it is worth noting that the burden of proof rests with the complainant to show that imported products are treated less favorably than like domestic products.⁶⁸ If the complainant adduces evidence and arguments to show that the measure is not even-handed, the burden then shifts to the respondent to show that the detrimental impact on imported products stems exclusively from a legitimate regulatory distinction.⁶⁹

Regulations drawing distinctions between products for purposes of addressing NCDs tend to be based on two types of evidence. First, a regulation may be based on evidence of the health risks associated with consumption of a particular product, for example, the risks associated with using an electronic cigarette. For distal causes of disease, this evidence is often collected through longitudinal cohort studies carried out over long periods of time.⁷⁰ While controlling for other factors, these studies compare the disease burden of different groups (cohorts) in order to evaluate the disease burden associated with particular products or product constituents, i.e., whether there was a positive association between consumption of electronic cigarettes and the onset of disease.⁷¹

Second, a regulation may be based on evidence of consumer behavior causing heightened risk. For example, in *United States—Clove Cigarettes*, the United States argued that clove cigarettes pose a greater health risk than menthol cigarettes due to the former being particularly attractive to young people.⁷² The panel failed to engage with the evidence on this issue by stating that each disputant presented conflicting evidence using different methodologies that did not permit a finding of fact.⁷³ Although the Appellate Body criticized this aspect of the decision,⁷⁴ the dispute does highlight how difficult it can be to provide compelling evidence of risk based on consumer behavior or preferences. In this respect, the Appellate Body went to lengths to explain a panel's obligation:

⁶⁷ See TBT Agreement, *supra* note 10.

⁶⁸ Appellate Body Report, *supra* note 1, ¶ 98.

⁶⁹ *United States—Tuna II*, *supra* note 46, ¶ 216.

⁷⁰ See, e.g., Panel Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶¶ 8.187-193, WT/DS135/R (Sept. 18, 2000) [hereinafter Panel Report, *EC—Asbestos*].

⁷¹ *Cf. id.*

⁷² Appellate Body Report, *supra* note 1, ¶ 67.

⁷³ Panel Report, *supra* note 24, ¶¶ 7.209-210.

⁷⁴ Appellate Body Report, *supra* note 1, ¶ 151.

We acknowledge that extracting meaningful information from surveys that differ considerably in terms of research parameters might not be an easy task. Likewise, we do not suggest that panels must always be capable of engaging in sophisticated statistical exercises to solve data discrepancies that ultimately cannot be resolved. However, the fact that evidence relied on by the parties may be difficult to compare cannot excuse the panel from examining it. A panel has the obligation to “consider *all* the evidence presented to it,” and it should at least attempt to extract potentially relevant information contained therein. It is only after such an examination that a panel might be able to provide “reasoned and adequate explanations” as to why it cannot or chooses not to rely on specific evidence submitted by the parties. In our view, a panel cannot determine *a priori* that some pieces of evidence are not reliable for the purposes of its analysis solely on the basis of a difference in the parameters and methodology used.⁷⁵

Leaving evidentiary difficulties concerning legitimacy to one side, there is an evidentiary question of how a respondent can show that detriment to imports is based *solely* on that regulatory distinction and not on other factors. The first question to consider here is what it means for detriment to be “based on” a regulatory distinction. Case law interpreting this phrase in the context of Article 5.1 of the SPS Agreement suggests that the regulation must be rationally related to the regulatory distinction.⁷⁶ In *United States—Tuna II*, however, the Appellate Body appeared to set the bar higher by examining whether the U.S. measure at issue was “calibrated” to the risks the United States was seeking to address.⁷⁷ By adopting this approach the Appellate Body appears to be using a proportionality standard. This view is reinforced by discussion in *United States—COOL*, where the Appellate Body concluded that the informational requirements imposed on meat producers were disproportionate to the level of information actually passed on to consumers.⁷⁸ It is worth noting that a proportionality test would be more difficult for a respondent to satisfy than a rational relationship test.

It is also worth noting that whether a distinction is legitimate is a separate question to whether the regulation is based on that distinction. The former was at issue in *United States—Clove Cigarettes*.⁷⁹ Although there was no standard articulated in that dispute against which the legitimacy of a regulation should be judged,⁸⁰ *United States—COOL* suggests that the issue may turn on a GATT Article XX chapeau standard.

The second question to consider is how a respondent could establish that a measure is based *solely* on a legitimate regulatory distinction. The Appellate Body has not given any guidance on how this term will be interpreted where a regulatory distinction is legitimate. In this respect, a number of commentators have argued that this fails to take account of “messy regulation,” where regulators and legislators adopt policies beneficial to the public interest but with mixed motives.⁸¹

⁷⁵ Appellate Body Report, *supra* note 1, ¶ 151 (internal citations omitted).

⁷⁶ Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶¶ 193-194, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC—Hormones*].

⁷⁷ *United States—Tuna II*, *supra* note 46, ¶ 282.

⁷⁸ *United States—COOL*, *supra* note 65, ¶¶ 347-349.

⁷⁹ See Appellate Body Report, *supra* note 1.

⁸⁰ *Id.*

⁸¹ See Simon Lester, *The Clove Cigarette Ban and the Impact of WTO Rules on Government Regulation*, INT’L ECON. L. & POL’Y BLOG (Feb. 24, 2013, 1:38 PM),

The practical significance of these issues in a regulatory context can be further illustrated by deeper exploration of specific examples in the contexts of tobacco, alcohol, and diet.

C. TOBACCO CONTROL

In the context of tobacco control, regulatory distinctions appear in a number of forms. For example, tobacco taxes sometimes apply different tax rates to different product categories.⁸² Similarly, packaging and labeling measures are often tailored to specific products or may include exemptions, such as for cigars sold as single sticks.⁸³ Most importantly, regulatory distinctions are drawn by product regulations including product bans and restrictions on additives and characterizing flavors. Regulatory distinctions are also drawn by regimes that treat tobacco products and cessation aids differently. An example of an outright product ban can be observed in the EU, where snus is prohibited (with the exception of in Sweden) but other tobacco products are permitted.⁸⁴ *United States—Clove Cigarettes* provides an example of a restriction on additives and flavors, as does a Brazilian regulation discussed below.⁸⁵

Tobacco product regulation occurs against a backdrop of controversy within the public health and scientific community concerning harm reduction. A number of emerging tobacco and nicotine products, such as electronic cigarettes, nicotine hand-creams and gels, and nicotine infused drinks and foods, have generated controversy. On the one hand, some argue that these products, like flavored cigarettes, are starter products that are particularly attractive to young people.⁸⁶ As the argument goes, in addition to the risks inherent in consuming these products there is a population health risk that these products will facilitate nicotine addiction and ultimately lead to increased tobacco consumption, morbidity and mortality.⁸⁷ On the other hand, it has also been argued that these products are likely to be less harmful to health than cigarettes because some other non-combustible products, such as snus, have a disease burden distinct from cigarettes.⁸⁸

In many countries, these emerging products fall within legislative or regulatory gaps. Many of the products fall outside the scope of tobacco control laws and regulations, as well as outside laws and regulations governing the marketing and sale of tobacco cessation aids. Expert advisory groups have advised taking a precautionary approach to products such as electronic cigarettes on the basis that long-term observational studies, such as longitudinal cohort studies, are required in order to assess risk, but cannot be conducted without permitting sale of the

<http://worldtradelaw.typepad.com/ielpblog/2009/06/the-clove-cigarette-issue-and-the-impact-of-wto-rules-on-government-regulation.html>.

⁸² See, e.g., 27 C.F.R. §§ 40.21-.32 (2012).

⁸³ Although packaging and labeling measures would fall within the scope of the TBT Agreement, only the GATT 1994 would govern taxes.

⁸⁴ Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001, art. 8, 2001 O.J. (L 194) 26, 31.

⁸⁵ See *infra* note 92-96 and accompanying text.

⁸⁶ See, e.g., *Flavored Tobacco Product Fact Sheet*, FDA, <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/ucm183198.htm> (last updated Dec. 1, 2011).

⁸⁷ See *id.*

⁸⁸ See generally Jonathan Foulds & Lynn Kozlowski, Comment, *Snus—What Should the Public-Health Response Be?*, 369 LANCET 1976 (2007); Coral E. Gartner et al., *Should the Health Community Promote Smokeless Tobacco (Snus) as a Harm Reduction Measure?*, 4 PLOS MED. 1138 (2007).

products.⁸⁹ It is implicit in this approach that some products may be prohibited outright for failure to gain regulatory approval as cessation aids. Given the state of the science on many emerging products, and the inherent limitations of scientific methods, drawing legitimate regulatory distinctions may be particularly difficult in this context if the evidentiary standard is set high.

For reasons relating to political economy, however, controversy has focused more on established products. For example, Brazil has introduced a regulation banning the use of additives other than sugar in the production of tobacco products.⁹⁰ A number of WTO Members have objected to the measure in the TBT Committee, arguing that the effect of the measure is to ban blended tobacco products that use additives to mask the harsh flavor of burley.⁹¹ These Members argue that the effect of the measure is to discriminate against imported products because the Brazilian tobacco market is comprised primarily of cigarettes containing flue-cured tobacco rather than blended tobacco.⁹²

How would the like products test apply to this example? The fact that likeness under Article 2.1 is about the nature and extent of a competitive relationship between products is significant. This, along with prior case law, suggests that different categories of tobacco products will ordinarily be considered like products for purposes of Article 2.1, irrespective of the relative risks to health posed by those products. Moreover, even if there is clear market segmentation between product categories, this will not preclude a finding of likeness if one segment of the population treats the products as interchangeable.⁹³

How would the less favorable treatment standard apply to this example? As discussed above, the application of this standard turns first on the effects of a measure on the competitive opportunities of imported products.⁹⁴ If it is assumed for the sake of argument that the majority of cigarettes with additives consumed in Brazil were of foreign origin, *United States—Clove Cigarettes* suggests that the burden would rest with Brazil to show that the effect on competitive opportunities for imported products is based solely on a legitimate regulatory distinction.

If the objective were to address the improved palatability of products containing additives, the first issue would be whether the regulation is proportional to that objective. In this respect, there appears to be quite a close relationship between the ban on additives and such an objective. The second question would be whether there is a legitimate regulatory distinction between products that do and do not contain additives. If a chapeau “rational relationship” standard were applied, there would be a fairly strong argument that the products are distinct based upon their palatability. However, if a higher standard were applied the issue might turn on evidence of consumer perceptions relating to palatability. In such a context, Brazil might need to produce qualitative evidence concerning the palatability of different products. This evidence would be most persuasive if collected in the Brazilian market itself. If this type of evidence were required, it would be implicit that Brazil ought to have based

⁸⁹ See generally WHO, TECHNICAL REPORT SERIES 955, WHO STUDY GROUP ON TOBACCO PRODUCT REGULATION: REPORT ON THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REGULATION: THIRD REPORT OF A WHO STUDY GROUP (2009).

⁹⁰ Brazil, *Notification to the Committee on Technical Barriers to Trade*, G/TBT/N/BRA/407 (Dec. 15, 2010).

⁹¹ Appellate Body Report, *supra* note 1, ¶¶ 131, 133.

⁹² Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 10-11 November 2011*, ¶¶ 127-141, G/TBT/M/55 (Feb. 9, 2012).

⁹³ Appellate Body Report, *supra* note 1, ¶¶ 142-143.

⁹⁴ See *supra* notes 49-53 and accompanying text.

its measure on a reasonably sophisticated assessment of the risks associated with different product categories. Like the requirement to base an SPS measure on a risk assessment under Article 5.1 of the SPS Agreement, a similar evidentiary requirement in the TBT Agreement could prove to be a barrier to regulation. More specifically, if the evidentiary requirement is interpreted too strictly, there is a risk that rational regulation of emerging products will not be permissible until after the predictable risks associated with those products have manifested and been studied. This would marginalize the role of precaution in policymaking in a context where the apparent risks are not merely theoretical but logically flow from the known risks associated with existing products with similar characteristics.

On the other hand, the limited analysis of the facts conducted at first instance by the panel in *United States—Clove Cigarettes* meant that the Appellate Body was left to draw comparisons between the objective features of clove and menthol cigarettes rather than to rely on a detailed factual record concerning consumption patterns. In this context, it might be argued that theoretical arguments about product characteristics will be sufficient. However, it remains to be seen how this will play out in future disputes.

D. ALCOHOL CONTROL

WTO Members draw regulatory distinctions between product categories of alcoholic beverages in a number of contexts. The most common regulatory distinction is found in graduated or differential tax schemes, which usually tax products with higher alcohol per volume at a higher rate than products with lower alcohol per volume.⁹⁵ The underlying goals of this approach are to reduce total consumption of alcohol at the population level and to reduce excessive consumption in a single sitting.⁹⁶ These goals may also be pursued through other measures, such as restrictions on the sale of certain products in particular types of stores.⁹⁷

Other common forms of regulation include the banning of certain product constituents or categories. For example, many WTO Members prohibit the presence of methanol, a known toxin, in alcoholic beverages.⁹⁸ More controversially, over recent years a number of WTO Members (or political sub-divisions thereof) have prohibited, or considered prohibiting, specific product categories such as “alcopops,”⁹⁹ caffeinated alcoholic beverages, and alcoholic beverages pre-mixed with stimulants, such as energy drinks.

For example, in June 2012, New Zealand notified the WTO that a new policy aimed to reduce “ready-to-drink” products could affect trade in products with an alcohol content of between six to fourteen percent.¹⁰⁰ The proposed regulations

⁹⁵ See LAW COMM’N, ALCOHOL IN OUR LIVES: CURBING THE HARM 289 (2010), available at <http://www.lawcom.govt.nz/project/review-regulatory-framework-sale-and-supply-liquor/publication/report/2010/alcohol-our-lives>.

⁹⁶ *Id.*

⁹⁷ For example, the Systembolaget in Sweden is a government monopoly for sales of everything above 3.5% by volume. See ALKOHOLLAG (Svensk författningssamling [SFS] 1994:1738).

⁹⁸ See, e.g., Karel Janicek, *Czech Republic Alcohol Ban: Country Bans Hard Liquor Sales Amid Wave of Methanol Poisonings*, HUFFINGTON POST (Sept. 15, 2012, 2:04 PM), http://www.huffingtonpost.com/2012/09/15/czech-republic-alcohol-ban-methanol-poisonings_n_1886735.html.

⁹⁹ The term alcopops describes a class of pre-mixed, sweetened or flavored alcoholic beverages that are typically appealing to youth.

¹⁰⁰ Isaac Davison, *Liquor Bosses Battle Alcopop Ban*, N.Z. HERALD (July 19, 2012), http://www.nzherald.co.nz/world-trade-organisation/news/article.cfm?o_id=251&objectid=10820640.

would prohibit the sale of higher-alcohol content products in liquor stores, making them only available in restaurants and bars.¹⁰¹ The treatment of different products would be based on their alcohol content and the number of standard drinks contained in a serving.¹⁰² These prohibitions have been justified on the grounds that alcopops are particularly appealing to young people, may serve as a “starter product” and are used heavily in binge drinking.¹⁰³

Similarly, the FDA took enforcement action concerning pre-mixed drinks containing caffeine, arguing that caffeine is an unsafe food additive.¹⁰⁴ The enforcement action came after estimates that the beverages were consumed regularly by thirty-one percent of twelve to seventeen year-olds and thirty-four percent of eighteen to twenty-four year-olds.¹⁰⁵ There are also studies showing higher rates of binge drinking and sexual assault in contexts where these drinks are consumed.¹⁰⁶

As the discussion in Part II suggests, restrictions on retail sale of the type contemplated by New Zealand are unlikely to be considered technical regulations.¹⁰⁷ On the other hand, outright prohibitions on the sale of particular product categories such as alcopops would be technical regulations. With this in mind, an outright prohibition on alcopops is worth examining as a case study. A WTO Member challenging the regulation might argue that it treats imported alcopops less favorably than other beverages produced domestically. These beverages might include spirits that are not premixed, or other beverages such as beer or wine. On the question of likeness, the relatively low threshold discussed above suggests that alcopops could be considered like any of the other products listed.¹⁰⁸ As such, the analysis would turn first to the question of how the conditions of competition between domestic and imported products are affected. In an extreme hypothetical, it might be the case that all alcopops are imported and the WTO Member in question otherwise has a strong domestic alcoholic beverage industry. For example, the Member might be a major wine producing country, as New Zealand is. In such a situation, there would be no doubt that the measure affects the competitive opportunities of importers negatively, meaning that lawfulness would turn on whether the regulation is based solely on a legitimate regulatory distinction.

The regulatory concern with respect to alcopops is the effect these products have on consumption patterns. In this instance, concerns relate to the appeal of the products to young people due to the flavor, the similarity with soft drinks, and the ease with which alcopops can be consumed.¹⁰⁹ The legitimacy of the regulatory distinction between alcopops and wine would thus turn on the strength of the evidence that alcopops are particularly attractive to a specific group of consumers. Additionally, a respondent would have to show that this particular attractiveness

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Caffeinated Alcoholic Beverages*, FDA, <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm190366.htm> (last updated Mar. 13, 2013).

¹⁰⁵ *Fact Sheets: Caffeinated Alcoholic Beverages*, CDC, <http://www.cdc.gov/alcohol/fact-sheets/cab.htm> (last updated July 20, 2010) [hereinafter *Fact Sheets*].

¹⁰⁶ *Id.*

¹⁰⁷ *See supra* Part II.

¹⁰⁸ This view is also supported by disputes such as Appellate Body Report, *Chile—Taxes on Alcoholic Beverages*, WT/DS87/AB/R, WT/DS110/AB/R (Dec. 13, 1999); Appellate Body Report, *Korea—Taxes on Alcoholic Beverages*, WT/DS75/AB/R, WT/DS84/AB/R (Jan. 18, 1999); and Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996).

¹⁰⁹ *Fact Sheets*, *supra* note 105.

results in some additional negative health outcome, such as increased binge drinking or increased drinking by that group (as opposed to pure substitution of one product for another). The question of greater concern in this example is how a Member would show that the regulation is based solely on this distinction. Although the regulation may be proportional to the objective, other factors could suggest a protectionist purpose and it remains to be seen how such a hypothetical would be resolved in practice.

E. DIET

In the context of diet, regulatory distinctions are drawn in a wide array of situations. Most often, distinctions are drawn between products based upon the threat to health posed by additives, contaminants, toxins or disease-causing organisms.¹¹⁰ This involves placing maximum limits on certain ingredients in foods or beverages and sometimes prohibiting those ingredients, or entire classes of foods or beverages, outright.¹¹¹ In the specific context of obesity prevention, regulatory distinctions are drawn to promote a balanced diet. These distinctions include differential or graduated taxation based, for example, on the fat content of products,¹¹² soda taxes, restrictions on the sale of soda in packages above a certain size,¹¹³ and outright product bans such as for high fat cuts of meat like turkey tails and mutton flaps.¹¹⁴

As was discussed above, these measures will ordinarily fall within the scope of the SPS Agreement.¹¹⁵ Article 5.5 of that agreement is the provision most relevant to the drawing of regulatory distinctions, and obliges each WTO Member to avoid arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate for different situations, if such distinctions result in discrimination or a disguised restriction on international trade.¹¹⁶ The application of this provision to obesity prevention measures has been discussed elsewhere.¹¹⁷ The important thing to note here is the parallel between the approach to determining when a regulatory distinction is legitimate and application of Article 5.5. As *United States—COOL* illustrates, a panel might use a similar test to determine whether a distinction is legitimate. Accordingly, many of the same issues considered above in the context of tobacco and alcohol may be relevant in the food context. One difference, however, is that the SPS Agreement contains more specific rules governing risk assessment and the circumstances in which a precautionary approach to policymaking is permissible.¹¹⁸

¹¹⁰ *EC—Hormones*, *supra* note 76, ¶ 182.

¹¹¹ *Id.* ¶ 84.

¹¹² See DANISH MINISTRY OF TAXATION, DANISH TAX REFORM 2010, at 11-12 (2009), available at www.skm.dk/public/dokumenter/engelsk/Danish%20Tax%20Reform_2010.pdf; see also Sinne Smed, *Financial Penalties on Foods: The Fat Tax in Denmark*, 37 NUTRITION BULL. 142 (2012).

¹¹³ N.Y.C., N.Y., HEALTH CODE § 81.53 (2012).

¹¹⁴ See, e.g., Michael Field, *Samoa Rewarded for Turkey Tail Turnaround*, STUFF.CO.NZ, <http://www.stuff.co.nz/business/world/6062457/Samoa-rewarded-for-turkey-tail-turnaround> (last updated Nov. 31, 2011, 2:12 PM).

¹¹⁵ See *supra* Part II.

¹¹⁶ SPS Agreement, *supra* note 16, at art. 5.5.

¹¹⁷ MCGRADY, *supra* note 9, at 170–214.

¹¹⁸ SPS Agreement, *supra* note 16.

F. CONCLUSION ON ARTICLE 2.1

The analysis above is not intended to suggest that regulations aimed at risk factors for NCDs will violate Article 2.1 of the TBT Agreement. Rather, the overarching point is that the test set out in *United States—Clove Cigarettes* tinkers with the balance of rights and obligations under WTO law. In doing so, the test raises questions about the evidentiary burden on WTO Members implementing health regulations. These questions appear most relevant in the context of measures to address NCDs, due to the nature of the evidence on which such measures are based. In this context, WTO panels and the Appellate Body need to be aware of the limitations of scientific evidence, and the methods used in this field of policymaking as the test develops incrementally through settlement of future disputes.

IV. NECESSITY UNDER ARTICLE 2.2

In addition to its successful claim under Article 2.1 already discussed,¹¹⁹ *United States—Clove Cigarettes* involved an argument by Indonesia under Article 2.2 of the TBT Agreement that the prohibition of clove cigarettes was more trade restrictive than necessary to protect human health.¹²⁰

Article 2.2 of the TBT Agreement provides:

Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products.¹²¹

Understood in these terms, Article 2.2 establishes a separate requirement that WTO Members ensure all technical regulations are not more trade restrictive than necessary to achieve a legitimate objective.¹²² Such legitimate objectives explicitly include, *inter alia*, the protection of human health.¹²³ Article 2.2 is an independent obligation applicable to all technical regulations, rather than an exception to be subsequently invoked if another TBT provision is violated. A finding of inconsistency under Article 2.1 does not prejudice the outcome of analysis under Article 2.2.¹²⁴

In *United States—Clove Cigarettes*, the panel rejected Indonesia's argument that the measure was more trade restrictive than necessary to fulfill the legitimate

¹¹⁹ See *supra* Part III.

¹²⁰ Panel Report, *supra* note 24, ¶ 2.1.

¹²¹ TBT Agreement, *supra* note 10, at art. 2.2.

¹²² See *id.*

¹²³ *Id.*

¹²⁴ Panel Report, *supra* note 24, ¶ 7.332.

objective of reducing youth smoking.¹²⁵ Indonesia did not appeal the panel's finding on the issue.¹²⁶

Three primary reasons were given for rejecting Indonesia's claims. First, Indonesia argued that the ban exceeded the level of protection sought by the U.S. (i.e., that it was disproportionate to the regulatory goal).¹²⁷ The panel, however, held that Indonesia had not provided sufficient evidence to establish the level of health protection pursued by the United States.¹²⁸ Hence, Indonesia could not establish that the ban exceeded that level of protection.¹²⁹

Second, Indonesia argued the ban on clove flavored cigarettes made no material contribution to the objective of reducing youth smoking.¹³⁰ The panel rejected this argument, stating that "this is a case in which the measure actually represents at least the majority view, and potentially the unanimous view."¹³¹ The Panel noted its understanding on the issue was reinforced by WHO FCTC Partial Guidelines on Articles 9 and 10—Regulation of the Contents of Tobacco Products and Regulation of Tobacco Product Disclosures.¹³² These Guidelines are one in a series developed by consultative processes and adopted by the FCTC's Conference of the Parties (COP) with the aim of assisting Parties to meet their obligations under the convention.¹³³ The panel stated that the Partial Guidelines "show a growing consensus within the international community to strengthen tobacco-control policies through regulation of the content of tobacco products, including additives that increase the attractiveness and palatability of cigarettes."¹³⁴ The potential significance of the Partial Guidelines for future disputes will be discussed further below.¹³⁵

Finally, Indonesia argued there were less trade restrictive alternative measures to the ban that were reasonably available to the United States.¹³⁶ The panel concluded Indonesia had simply listed a number of tobacco control measures relating to reducing youth smoking as alternatives, each of which involved a greater risk of non-fulfillment of the objective compared with the outright ban at issue.¹³⁷ As such, it was difficult to see how the measures could make an "equivalent" contribution to achievement of the objective, at the level of protection sought by the United States.¹³⁸ Even if Indonesia's listing of alternative measures was sufficient to establish a prima facie case, the Panel felt the United States had rebutted this by showing that many of the alternative measures proposed were already in place, suggesting these were complementary measures rather than true alternatives.¹³⁹

¹²⁵ *Id.* ¶ 7.417.

¹²⁶ See Appellate Body Report, *supra* note 1, at Annex I.

¹²⁷ Panel Report, *supra* note 24, ¶ 7.421.

¹²⁸ *Id.* ¶ 7.431.

¹²⁹ *Id.* ¶¶ 7.373-374.

¹³⁰ *Id.* ¶ 7.431.

¹³¹ *Id.* ¶ 7.401.

¹³² *Id.* ¶ 7.427.

¹³³ See *Adopted Guidelines*, WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL [FCTC], <http://www.who.int/fctc/protocol/guidelines/adopted/en/> (last visited Mar. 17, 2013).

¹³⁴ Panel Report, *supra* note 24, ¶ 7.414.

¹³⁵ See *infra* Part IV.B.

¹³⁶ Panel Report, *supra* note 24, ¶ 7.422.

¹³⁷ *Id.* ¶ 7.423.

¹³⁸ *Id.* ¶¶ 7.422-424.

¹³⁹ *Id.* ¶ 7.425.

A. SIGNIFICANCE IN TERMS OF WTO LAW

Although the panel report illustrates how Article 2.2 applies to a particular tobacco control regulation, the absence of an appeal by Indonesia suggests the decision may not be of great systemic importance. As mentioned in relation to Article 2.1, *United States—Clove Cigarettes* was the first of three challenges to different U.S. technical regulations decided in 2012.¹⁴⁰ For the first time, these disputes specifically analyzed issues of discrimination and necessity as they operate in relation to technical regulations.

Prior to this, context had been provided by similar language in the GATT 1994 in relation to general restrictions on trade in goods.¹⁴¹ In the case of Article 2.2, parallels can be drawn with the GATT Article XX(b) exception, allowing certain otherwise discriminatory measures to remain lawful where these are, *inter alia*, necessary to protect human health.

Without attempting to give a comprehensive summary of the significant jurisprudence developed under Article XX(b), some broad observations about the components of a necessity analysis conducted under that exception can be made. Analysis under Article XX(b) proceeds in four stages, the first of which involves determination of whether the measure violating the GATT could be described as a measure for the protection of human life or health.¹⁴² In a second stage, a panel weighs and balances a range of factors in order to make a preliminary determination of whether the measure is necessary to achieve the Member's regulatory goal.¹⁴³ Relevant considerations include the contribution of the measure to achievement of the goal and the measure's trade restrictiveness.¹⁴⁴ These factors are weighed in light of the importance of a Member's regulatory goal.¹⁴⁵ If a measure survives this preliminary determination of necessity, the third step may involve analysis to determine whether less trade restrictive, reasonably available alternative measures exist.¹⁴⁶ Lastly, a panel will examine compliance with the chapeau of Article XX, to check the measure is not "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination . . . or a disguised restriction on trade."¹⁴⁷

As it will be seen, similar considerations may be used by panels in a TBT context. This notwithstanding, important differences in structure, scope, and the relationship between Articles 2.1 and 2.2 compared to their GATT counterparts command consideration of their practical operation. In particular, the status of Article 2.2 as a freestanding obligation, and differences in relevant burden of proof may have important implications for legal analysis, and ultimately the outcome of any challenge to a given regulation.

Since *United States—Clove Cigarettes*, the Appellate Body has considered Article 2.2 in *United States—Tuna II* and *United States—COOL*.¹⁴⁸ In *United*

¹⁴⁰ See *supra* Part III.

¹⁴¹ Panel Report, *EC—Asbestos*, *supra* note 70, ¶ 8.55 ("We also note that the criteria on the preparation, adoption or application of technical regulations in Article 2.2 of the TBT Agreement are very similar to those in Article XX of the GATT 1994. The preamble to the TBT Agreement in fact repeats some of the wording of Article XX of the GATT.")

¹⁴² See, e.g., Appellate Body Report, *EC—Asbestos*, *supra* note 13, ¶¶ 156-163.

¹⁴³ *Id.* ¶¶ 164-175.

¹⁴⁴ *Brazil—Retreaded Tyres*, *supra* note 56, ¶ 182.

¹⁴⁵ See, e.g., *id.* ¶ 178.

¹⁴⁶ See Panel Report, *Canada—Measures Relating to Exports of Wheat and Treatment of Imported Grain*, ¶ 6.223, WT/DS276/R (Apr. 6, 2004).

¹⁴⁷ GATT 1994, *supra* note 48, at art. XX.

¹⁴⁸ *United States—Tuna II*, *supra* note 46; *United States—COOL*, *supra* note 65.

States—Tuna II, the Appellate Body largely confirmed the approach of the panel to Article 2.2, stating:

A panel should begin by considering factors that include: (i) the degree of contribution made by the measure to the legitimate objective at issue; (ii) the trade restrictiveness of the measure; and (iii) the nature of the risks at issue and the gravity of consequences that would arise from non-fulfilment of the objective(s) pursued by the Member through the measure.¹⁴⁹

The Appellate Body has also clarified that in determining the contribution of a regulation, it is not that the regulation “must meet some minimum threshold of fulfilment.”¹⁵⁰ Rather, “a panel must seek to ascertain to what degree, if at all, the challenged technical regulation, as written and applied, actually contributes to the legitimate objective pursued by the Member.”¹⁵¹ To this end, assessment will be made as to whether the regulation at issue is capable of achieving the legitimate objective.¹⁵² The Appellate Body added, “The degree of achievement of a particular objective may be discerned from the design, structure, and operation of the technical regulation, as well as from evidence relating to the application of the measure,” such that “a panel must assess the contribution to the legitimate objective actually achieved by the measure at issue.”¹⁵³

If a contribution does exist, the trade restrictiveness of the regulation will then be assessed.¹⁵⁴ Where a complainant makes out a prima facie case that a reasonably available alternative regulation exists, the burden will shift to the respondent to show this is not the case.¹⁵⁵ It will be relevant to consider whether the proposed alternative is less trade restrictive; whether it would make an equivalent contribution to the legitimate objective, taking account of the risks non-fulfilment would create; and whether it is reasonably available.¹⁵⁶

The relationship between Articles 2.1 and 2.2 of the TBT Agreement is one issue that remains to be clarified. It might be expected that a discriminatory measure in violation of Article 2.1 would be more trade restrictive than necessary under Article 2.2. That is, the discrimination could not be considered necessary unless based on a legitimate regulatory distinction. Of course, this assumes that discrimination can be equated with the concept of trade restrictiveness, which may not be the case. In *United States—Clove Cigarettes*, the regulation was ultimately held to violate Article 2.1, but not Article 2.2.¹⁵⁷ This stemmed from the fact that the panel examined not whether the discrimination was necessary, but whether the ban on clove cigarettes was necessary.¹⁵⁸ In *United States—Tuna II*, the Appellate Body reversed the panel by finding a violation of Article 2.1, but then found no violation of Article 2.2.¹⁵⁹ Although the decision on Article 2.2 was due largely to failings in the panel’s earlier approach,¹⁶⁰ the decision could be taken to suggest that it is the

¹⁴⁹ *United States—Tuna II*, *supra* note 46, ¶ 322.

¹⁵⁰ *United States—COOL*, *supra* note 65, ¶ 461.

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *United States—Tuna II*, *supra* note 46, ¶¶ 315-317.

¹⁵⁴ *See id.* ¶ 317.

¹⁵⁵ *Id.* ¶ 323.

¹⁵⁶ *United States—COOL*, *supra* note 65, ¶ 471.

¹⁵⁷ Panel Report, *supra* note 24, ¶ 8.1(b)-(c).

¹⁵⁸ *Id.* ¶ 8.1(c).

¹⁵⁹ *United States—Tuna II*, *supra* note 46, ¶ 407(b)-(c).

¹⁶⁰ *See id.* ¶ 225.

necessity of the technical regulation as a whole that must be examined under Article 2.2.

To some extent, this may seem inconsistent with the Appellate Body's more recent approach under the GATT of examining the necessity of discrimination rather than the necessity of a measure.¹⁶¹ However, that approach is understandable in the context of the GATT where Article XX functions as an exception used for purposes of justifying a violation (such as discrimination). Because Article 2.2 is a freestanding obligation, a narrow approach to trade restrictiveness may apply whereby the test focuses not on the necessity of discrimination, but on whether the impact of a regulation on market access is more trade restrictive than necessary.

Taken as a whole, these decisions suggest that greater deference may be granted to a WTO Member to pursue product regulation under Article 2.2 than 2.1. In fact, it appears that there has been some migration of policy-balancing mechanisms into Article 2.1 due to the absence of an exception to that provision.

As with Article 2.1, a deeper understanding of how this approach to Article 2.2 may affect future regulation can be gained from further examples within the specific tobacco, alcohol, and diet contexts.

B. TOBACCO CONTROL

In the context of tobacco control particularly, the decision in *United States—Clove Cigarettes* highlights the difficulty of a challenging member in establishing that different types of tobacco control regulations are truly less trade restrictive alternatives. In an era where comprehensive programming practices are now widely accepted as the “gold standard” in tobacco control, WTO Members are likely to have little difficulty in arguing that different types of measures are complementary or cumulative components that operate synergistically to reduce tobacco-related harm, rather than those easily substituted for reasonably available, less trade restrictive alternatives.¹⁶²

Also noteworthy in the *United States—Clove Cigarettes* decision was the Panel's treatment of the FTC Guidelines. Although neither disputant explicitly asked the panel to consider whether the Guidelines (or specifically, the Partial Guidelines to Articles 9 and 10 in that case) constituted international standards per se, repeated references within the panel report allude to the potential utility of such documents in determining the lawfulness of tobacco product regulations in future TBT disputes.¹⁶³

Under the TBT Agreement, WTO Members are obliged to use relevant international standards as the basis for technical regulations except where these would be ineffective or inappropriate to achieve an objective in the circumstances, for example, because of fundamental technological problems.¹⁶⁴ In fact, Article 2.5 of the Agreement creates a presumption that health measures in accordance with relevant international standards do not create unnecessary obstacles to international trade for the purposes of Article 2.2.¹⁶⁵

Annex 1 to the TBT Agreement defines a “standard” as a “[d]ocument approved by a recognized body, that provides, for common and repeated use, rules, guidelines

¹⁶¹ See Panel Report, *supra* note 24, ¶ 7.260.

¹⁶² See, e.g., *Brazil—Retreaded Tyres*, *supra* note 56, ¶ 172.

¹⁶³ See Panel Report, *supra* note 24, ¶¶ 7.229-231, 7.414.

¹⁶⁴ TBT Agreement, *supra* note 10, at art. 2.4.

¹⁶⁵ See *id.* at art. 2.5.

or characteristics for products or related processes and production methods, with which compliance is not mandatory.”¹⁶⁶ The phrase “international standard” is not defined in the TBT Agreement.¹⁶⁷ Accordingly, the phrase is to be interpreted in accordance with ISO/IEC Guide 2 as a “standard that is adopted by an international standardizing/standards organization and made available to the public.”¹⁶⁸

In the current absence of a specific determination on the status of the FCTC Guidelines, the recent Appellate Body Report in *United States—Tuna II* elucidates several relevant criteria. For a particular rule to qualify as an international standard under the TBT Agreement, it must, *inter alia*, be adopted by a body that (i) has recognized activities in standardization and (ii) is open (in terms of membership) to the relevant bodies of at least all WTO Members.¹⁶⁹

Within the context of tobacco control, the requirement of “voluntariness” of standards suggests that mandatory provisions of the FCTC fall outside the definition of international standards. However, non-mandatory guidelines do appear to meet the definition.¹⁷⁰ Even if the Conference of the Parties to the WHO FCTC does not have recognized activities in standardization, which it may, the WHO does.¹⁷¹ If recognized as international standards, technical regulations in accordance with the guidelines would benefit from a presumption of lawfulness, or necessity, under Article 2.2.

It is not entirely clear how closely a regulation must be related to an international standard in order to meet the presumption of lawfulness (a measure which clearly contradicts a standard, for example, may be easy to rule out, but “in accordance with” may be harder to define). Nor is it entirely clear how specific an instrument must be in order to constitute an international standard. This notwithstanding, the FCTC Partial Guidelines to Articles 9 and 10 are likely to provide comfort to WTO Members, including Brazil in relation to the proposed additives ban already discussed above.¹⁷² Similarly, in the case of Australia’s plain packaging of tobacco products, relevant FCTC Guidelines to Article 11 and 13 could be expected to play a greater role in supporting Australia’s regulation under any challenge under Article 2.2.¹⁷³

Ultimately, resolution of the Guidelines’ status and relevance cannot be made until a direct analysis and determination are made by the Appellate Body. Until then,

¹⁶⁶ *Id.* at Annex 1.

¹⁶⁷ *See id.*

¹⁶⁸ Panel Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶¶ 7.663-665, WT/DS381/R (Sept. 15, 2011).

¹⁶⁹ *United States—Tuna II*, *supra* note 46, ¶¶ 357-358.

¹⁷⁰ Benn McGrady, US—Tuna: *International Standards and Plain Packaging of Tobacco Products*, TRADE, INVESTMENT & HEALTH BLOG (May 16, 2012), <http://www.oneillinstituteblog.org/us-tuna-international-standards-and-plain-packaging-of-tobacco-products/>; *see also* Lukasz Gruszczynski, *The WHO Framework Convention on Tobacco Control as an International Standard Under the TBT Agreement?*, 9 TRANSNAT’L DISP. MGMT., no. 5, Nov. 2012, available at <http://www.transnational-dispute-management.com/article.asp?key=1874#citation>.

¹⁷¹ Constitution of the World Health Organization art. 2(u), July 22, 1946, 14 U.N.T.S. 185.

¹⁷² *See* WHO FCTC, PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (2012).

¹⁷³ *See* WHO FCTC, GUIDELINES FOR IMPLEMENTATION OF ARTICLE 11 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (PACKAGING AND LABELLING OF TOBACCO PRODUCTS) (2008); WHO FCTC, GUIDELINES FOR IMPLEMENTATION OF ARTICLE 13 OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL (TOBACCO ADVERTISING, PROMOTION AND SPONSORSHIP) (2008).

the decision in *United States—Tuna II* seems to confirm how broad the definition of international standards is within the TBT regime.

Recognition of the FCTC Guidelines as international standards would be favorable for domestic regulatory autonomy, providing WTO Members with space to enact tobacco control regulations that offer a high level of health protection. Within a WTO regime where concern has been raised about industry-influenced or privately created standards, such recognition may also be seen by the public health community as endorsement of global health priorities and integration of the international trade and health regimes.

C. ALCOHOL CONTROL

As the NCD agenda gains heightened global awareness, states are increasingly using lessons learned in tobacco control to address other common risk factors for these conditions, including harmful alcohol use.

In an area where there exists no binding FCTC equivalent, Thailand's proposed graphic warning labels on alcohol provide a good example of potential challenges within WTO law. In 2010, as part of a package of alcohol reform, Thailand proposed implementation of graphic warnings on both imported and locally produced alcohol in an attempt to tackle rapidly rising harm associated with increased alcohol consumption.¹⁷⁴ Specifically, Thailand's proposed regulation involves colored graphic labels accompanied by warning statements to be rotated at 1000-package intervals, similar in form to those gaining international favor in the tobacco context, in which Thailand was also an early adopter.¹⁷⁵ The suggested content of these warnings is varied: from matters commonly accepted in annals of international medicine, i.e., "Drinking alcohol causes hypertension liver cirrhosis," to broader and potentially more categorical claims, i.e., "Drinking alcohol leads to unconsciousness and even death."¹⁷⁶

As a regulation likely to affect trade, and one arguably not based on any relevant international standard, Thailand provided notice to other WTO Members of its intention under Article 2.9 of the TBT Agreement.¹⁷⁷ As of January 2013, despite international discussion in several rounds of TBT Committee meetings, it appears Thailand has made little progress in implementation of the regulation.¹⁷⁸

WTO members' concerns with the proposed regulation relate principally to Article 2.2. A primary concern is the legitimacy of Thailand's regulatory objective. Comments of WTO Members, including the EU, Chile, and Mexico, challenge the legitimacy of the warnings on the basis that they suggest *any* level of drinking could lead to health problems.¹⁷⁹ These Members argue that it is not drinking per se, but excessive drinking that is the problem, implying that regulation should properly be directed only at *harmful* alcohol use.¹⁸⁰ Thailand has so far suggested several

¹⁷⁴ Thailand, *Notification to the Committee on Technical Barriers to Trade*, G/TBT/N/THA/332 (Jan. 21, 2010).

¹⁷⁵ These regulations were first approved in the Royal Gazette in 2009. *Picture Based Cigarette Warnings: Thai Cigarette Warnings*, PHYSICIANS FOR SMOKE-FREE CAN., <http://www.smoke-free.ca/warnings/Thailand%20-%20warnings.htm> (last visited Jan. 11, 2013).

¹⁷⁶ See Thailand, *supra* note 174.

¹⁷⁷ TBT Agreement, *supra* note 10, at art. 2.9.

¹⁷⁸ Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 20-21 March 2012*, ¶¶ 77-79, G/TBT/M/56 (May 16, 2012).

¹⁷⁹ Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 3-4 November 2010*, ¶¶ 234-248, G/TBT/M/52 (Mar. 10, 2011).

¹⁸⁰ See *id.*

objectives of the proposed regulation, including not only prevention of alcohol-related harm, but also prevention of alcohol consumption broadly, as well as provision of information to consumers about risk.¹⁸¹ Unlike members with historically high but stable patterns of consumption such as the EU, Thailand argues there is no such thing as “risk-free drinking” within its domestic context.¹⁸² Compared with limited evidence of cardiovascular benefit in France, for example, Thailand refers to a lack of beneficial association with *any* level of consumption in low- and middle-income countries.¹⁸³ It also points to the Thai population’s recent and rapidly increasing patterns of use, particularly high disease burden, and the role of marketing and packaging as a critical vector for the epidemic within its borders.¹⁸⁴

Characterization of Thailand’s regulatory objective would then shape analysis of whether the regulation is more trade restrictive than necessary under Article 2.2. It is the contribution of the regulation to the objective that must be assessed. Several Members have questioned the scientific basis of both the form and content of the proposed labels.¹⁸⁵ In this respect, evidence would need to be brought of the contribution of graphic warning labels to the regulatory objective. This contribution would be weighed against trade restrictiveness, which arguably should not be concerned with the *content* of the health message involved, but only the imposition of requirements different or more onerous to other countries that may therefore create a barrier to market access. By this view, TBT analysis by a panel would ask whether warnings are more trade restrictive than necessary to protect health, but would not be concerned with the content of the warnings themselves.

Consideration may also be given to the availability of less trade restrictive reasonably available alternatives. Some Members have so far listed alternatives such as education and information campaigns.¹⁸⁶ However, Thailand already implements many of these, suggesting they may be complementary or cumulative regulations, rather than reasonably available alternatives.¹⁸⁷ There would also be a question as to whether such measures would achieve Thailand’s objective.

Accepting that other factors such as domestic politics or budgets may also be at play, Thailand’s apparent stall in legislative developments despite the evident health burdens associated with alcohol, highlights the potential of WTO proceedings (real or threatened) in creating regulatory chill. Interestingly, several of the WTO Members expressing objection to Thailand’s proposal, including Australia, already employ similar graphic warning labels on tobacco.¹⁸⁸ Several objecting Members also have prominent alcohol industries.¹⁸⁹ While not necessarily of direct relevance

¹⁸¹ See *id.* ¶¶ 245-248.

¹⁸² See THAKSAPHON THAMARANGSI & AREEKUL PUANGSUWAN, WHY THAILAND SHOULD HAVE THE PICTORIAL WARNING LABEL ON ALCOHOLIC BEVERAGE PACKAGES? 7 (2010), available at <http://ihppta.gov.net/publication/attachresearch/257/chapter1.pdf>.

¹⁸³ See *id.* at 1.

¹⁸⁴ Comm. on Technical Barriers to Trade, *supra* note 179, ¶¶ 234-248.

¹⁸⁵ See Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting 24-25 March 2011*, ¶¶ 229-230, G/TBT/M/53 (May 26, 2011).

¹⁸⁶ See, e.g., Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 24-25 March 2010*, ¶ 5, G/TBT/M/50 (May 28, 2010).

¹⁸⁷ Comm. on Technical Barriers to Trade, *supra* note 179, ¶ 248.

¹⁸⁸ See, e.g., *Plain Packaging of Tobacco Products*, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH & AGEING, <http://www.health.gov.au/internet/main/publishing.nsf/content/tobacco-plain> (last updated Mar. 15, 2012).

¹⁸⁹ See, e.g., Robin Room, *EU and Alcohol Policies Internationally*, ADDICTION & LIFESTYLES IN CONTEMP. EUR. REFRAMING ADDICTIONS PROJECT (Apr. 20, 2012, 9:04 AM), <http://www.alicerap.eu/blog/59-eu-and-alcohol-policies-internationally.html>.

to any potential legal analysis, such factors highlight the reality of complex and potentially competing interests of WTO Members in both exercising their own domestic regulatory autonomy, and respecting that of others.

In the absence of an equivalent legal framework to the WHO FCTC and its Guidelines in the alcohol context, it appears unlikely that countries such as Thailand would be able to support the lawfulness of regulation based on international standards. Although the World Health Assembly endorsed the adoption of a non-binding Global Strategy to Reduce the Harmful Use of Alcohol (Global Strategy) in 2010,¹⁹⁰ it is unclear whether such a document would constitute an international standard gaining the benefit of an Article 2.5 presumption. Although explicitly intended to give guidance for global action and recognizing the right of countries to make health regulations that may have trade implications,¹⁹¹ it is open to question whether the broad portfolio of policies contained by the Global Strategy are sufficiently specific to act as standards capable of common and repeated use.

Assuming the current absence of relevant international standards, the decisions in *United States—Clove Cigarettes* and *United States—Tuna II* may still provide guidance for future development of international instruments in an alcohol context. Those interested in ensuring a degree of regulatory autonomy for states to take public health measures more likely to withstand WTO scrutiny may prefer such instruments are developed with attention to the definition of international standards offered in *United States—Tuna II*, and any future decisions concerning the status of WHO FCTC guidelines.

D. DIET

As was mentioned above in the discussion of Article 2.1, the TBT Agreement does not apply to most regulations addressing diet because the SPS Agreement takes precedence.¹⁹² Although the SPS Agreement includes a necessity requirement similar to that found in Article 2.2 of the TBT Agreement,¹⁹³ the implications of *United States—Clove Cigarettes* for interpretation of that provision appear to be minimal. There is a well-established body of case law on the SPS Agreement, and disputes tend to focus on compliance with the obligations in Article 5, rather than on the general obligations concerning necessity.¹⁹⁴

V. CONCLUSION

United States—Clove Cigarettes was the first in a series of three intriguing TBT disputes. Because the Appellate Body had not clarified application of the TBT Agreement before these disputes were afoot, each of the panels approached the issues differently from the way subsequently preferred by the Appellate Body. This left holes in the factual records that forced the Appellate Body to work with the information available. This was most evident in *United States—Clove Cigarettes*, where the Appellate Body ruled that there was no legitimate regulatory distinction

¹⁹⁰ WHO, GLOBAL STRATEGY TO REDUCE THE HARMFUL USE OF ALCOHOL (2010), available at http://www.who.int/substance_abuse/alcstratenglishfinal.pdf.

¹⁹¹ *Id.* at 6-7.

¹⁹² See MCGRADY, *supra* note 9, at 175-80.

¹⁹³ *Id.* at 202.

¹⁹⁴ See, e.g., *id.* at 183-94.

between clove and menthol cigarettes without reference to evidence of consumption patterns.¹⁹⁵

This incomplete factual record, along with the fact that neither the United States nor Indonesia knew the test to be applied when their pleadings were made, suggests that it is necessary to approach the outcome with some caution. Future disputes will be decided in light of fuller factual records with better-informed disputants.

That is not to say that the law itself is now clear. Under Article 2.1 there remains some uncertainty concerning the substantive tests to be applied, as well as the standards of proof in question. It is known that detriment to the competitive opportunities of imported products must be based solely on a legitimate regulatory distinction. It also appears that a regulation must be proportional to the objective to be “based on” it. Similarly, it appears from disputes subsequent to *United States—Clove Cigarettes* that the legitimacy of a regulatory distinction will be judged in line with the GATT Article XX chapeau standard of arbitrary or unjustifiable discrimination.

Two further issues remain unclear. First, how to determine whether a regulation is based *solely* on a legitimate regulatory distinction, as opposed to on other factors, has not been clarified. In such a situation a panel will no doubt exercise a high degree of discretionary judgment, sometimes referred to as a smell-test.¹⁹⁶ Second, it remains to be seen how high the standard of proof will be set when determining the legitimacy of a regulatory distinction. Although the Appellate Body has pointed to the GATT Article XX chapeau standard,¹⁹⁷ this does not necessarily mean that the same approach to interpretation will be used (as is evident by the use of a proportionality standard in interpreting the phrase “based on”). In the context of reducing risk factors for NCDs, this is important because the evidence base for regulation is often dependent on longitudinal cohort studies or on evidence relating to consumer demand.

The analysis of Article 2.2 suggests that the provision, like GATT Article XX(b), is quite permissive. This seems even more so in light of the approach taken in *United States—Tuna II* with respect to international standards. In some respects, policy-balancing mechanisms traditionally used in analysis under Article XX(b) are migrating to the analysis of non-discrimination. This is not in itself problematic, and can be viewed as positive in a context where there is no exception to the prohibition on non-discrimination under Article 2.1. Nonetheless, there is a risk that the balance between rights and obligations will be upset in the process. WTO panels and the Appellate Body will have to be particularly attuned to this in the context of regulation to reduce risk factors for NCDs. In this context, WTO Members need space sufficient to permit rational regulation in a context where the legitimacy of regulatory distinctions can be difficult to assess and the effects of technical regulations may not be known in the short-term.

¹⁹⁵ Appellate Body Report, *supra* note 1.

¹⁹⁶ Robert E. Hudec, *GATT/WTO Constraints on National Regulation: Requiem for an “Aim and Effects” Test*, 32 INT’L LAW. 619 (1998).

¹⁹⁷ GATT 1994, *supra* note 48, at art. XX.