
**REACH REVISITED:
A FRAMEWORK FOR EVALUATING
WHETHER A NON-TARIFF MEASURE HAS
MATURED INTO AN ACTIONABLE
NON-TARIFF BARRIER TO TRADE**

LAWRENCE A. KOGAN*

I. INTRODUCTION	494
II. REACH-RELATED TRADE CONCERNS AT THE WTO 2004–2011	502
A. REACH IN A NUTSHELL.....	502
B. REACH UNDERGOES CONTINUAL REVIEW AND CONSULTATION AT THE WTO	509
C. SPECIFIC REACH-RELATED TRADE CONCERNS RAISED BY WTO TBT COMMITTEE MEMBERS 2004–2011	514
1. REACH’s Hazard-Based Registration Requirement Is Overly Complex, Burdensome, and Costly	514
2. EU Member States Engage in Inconsistent and	

* © 2012 Lawrence A. Kogan. Lawrence A. Kogan is founder and Managing Attorney of The Kogan Law Group, P.C., a New York City-based multidisciplinary professional services firm specialized in identifying and addressing emerging regulatory, policy, and trade risks posed to multinational company assets, operations, and supply chains. He is President/Director of the Institute for Trade, Standards and Sustainable Development (ITSSD), a Princeton, NJ-based nonprofit legal research, analytics, and educational organization. Mr. Kogan formerly advised the National Foreign Trade Council and its membership concerning the interplay between international trade rules and health and environmental regulations, including REACH, formerly served on the international trade committee of the Association of the Bar of the City of New York and as adjunct professor of international trade law and policy at the Seton Hall University Whitehead School of Diplomacy and International Relations, and currently serves on the international trade committee of the Inter-Pacific Bar Association. A much abbreviated version of this article will appear as a chapter titled *REACH and International Trade Law* in the book *THE EUROPEAN UNION REACH REGULATION FOR CHEMICAL SUBSTANCES: LAW AND PRACTICE* (Lucas Bergkamp ed.), to be published by Oxford University Press Publications© in 2013.

	Potentially Discriminatory Treatment of Substances (SVHCs) in Articles.....	515
3.	REACH's Monomer Registration Requirement Is Costly and Burdensome, Threatens IP, and Is Potentially Discriminatory.....	516
4.	Delayed and Confusing EU REACH Implementation Process Belies Lack of EU Institutional Capacity to Meet Regulatory Burdens.....	517
5.	Non-EU Manufacturers Would Be Competitively Disadvantaged if Forced to Choose Between Importer and "Only Representative" Registration to Protect Their IP.....	518
6.	REACH's Mandatory Data-Sharing and SIEF Membership Potentially Places Non-EU Manufacturers at a Competitive Disadvantage.....	519
7.	REACH's Extra-Territorial Vertebrate Animal Testing Prohibition Imposes Unnecessary Burdens and Costs on Non-EU Manufacturers.....	520
8.	REACH's Delegation of Direct Enforcement and Penalty Responsibilities to EU Member States Yields Inconsistent and Potentially Discriminatory Treatment of Non-EU Manufacturers.....	521
9.	EU's Adoption and Implementation of REACH May Not Satisfy EU's WTO Obligation to Accord Special and Differential Treatment to Developing Countries....	522
III.	ANALYSIS OF RECENT WTO TBT JURISPRUDENCE	524
	A. OVERVIEW AND PRELIMINARY CONSIDERATIONS	524
	B. ELEMENTS OF A POTENTIAL CAUSE OF ACTION UNDER KEY PROVISIONS OF THE TBT AGREEMENT	526
	1. Does the Disputed Measure Qualify as a "Technical Regulation" Within the Meaning of TBT Annex 1?	526
	a. Technical Regulation Three-Part Test.....	527
	2. Is the Disputed Technical Regulation Trade-Discriminatory and Thus Inconsistent with the National Treatment Obligation of TBT Article 2.1?	530
	a. Generally	530
	b. 'Like' Products Four-Part Test.....	532
	i. Compare the Physical Properties of Competing Products	534

ii. Identify the End-Uses of Competing Products ..	535
iii. Identify Consumer Tastes and Habits Regarding Competing Products	536
c. “Treatment No Less Favorable” Two-Part Test	538
i. Identify Comparable Product Scope of Imported and Domestic Products	538
ii. Compare All “Like” Imported Products with All “Like” Domestic Products to Determine Detrimental Less Favorable Treatment	539
3. Is the Disputed Technical Regulation Inconsistent with TBT Article 2.2 Because It Imposes an Unnecessary Obstacle to Trade That Is More Trade- Restrictive Than Necessary to Fulfill a Legitimate Objective Considering the Risks Non-Fulfillment Would Create?	547
a. Is the Disputed Technical Regulation “Trade- Restrictive”?	547
b. Does the Technical Regulation Pursue a “Legitimate” Objective?	549
i. Is the Identified Objective Indeed the Objective of the Regulation?	550
ii. How Can a Member Determine Whether the Regulation’s Objective Is “Legitimate”?	551
c. Does the Technical Regulation Fulfill the Identified Objective(s)?	552
d. Is the Technical Regulation More Trade- Restrictive Than Necessary to Fulfill the Objective(s) Concerned?	556
i. Is There a Less Trade-Restrictive Alternative Available?	557
ii. What Risks Are Engendered if the Available Less Trade-Restrictive Alternative Cannot Equally Fulfill the Identified Objectives?	558
4. Did the Technical Regulation’s Sponsor Fail to Take into Account Developing Country Needs When Preparing and Applying Such Measures, With a View to Ensuring That No Unnecessary Obstacles to Trade Were Created Within the Meaning of TBT Article 12.3?	561

a.	Developing Country “Special and Differential Needs” Three-Part Test	562
IV.	A FRAMEWORK FOR EVALUATING WHETHER THE EU REACH REGULATION IS A NON-TARIFF BARRIER TO TRADE	566
A.	TBT ANNEX 1 ANALYSIS OF REACH	567
1.	“Technical Regulation” Test	567
B.	TBT ARTICLE 2.1 ANALYSIS OF REACH	570
1.	“Like” Products Test	570
a.	SVHCs in Articles: “Like” Product Analysis	571
b.	Non-SVHC Substances on Their Own and in Preparations/Mixtures: “Like” Product Analysis	582
2.	“Treatment No Less Favorable” Test	584
a.	Potential EU Member State Discrimination Arising from Article Registration, Including Those Containing SVHCs	586
b.	Potential EU Member State Discrimination Arising from REACH Registration-Related Compliance Inspections and Enforcement Penalties	591
c.	Potential “Only Representative” (“OR”) Discrimination	598
d.	Potential SIEF Discrimination	601
C.	TBT ARTICLE 2.2 ANALYSIS OF REACH	605
1.	Technical Regulation’s “Trade-Restrictiveness”	605
2.	Technical Regulation’s “Objective”	605
3.	“Legitimacy” of Technical Regulation’s Objective	607
4.	Technical Regulation’s “Fulfillment” of Its Legitimate Objective	609
a.	Basis for Registration Data	612
b.	Quantity, Quality, and Types of Required Pre-Registration Data	613
c.	ECHA’s and EU Member States’ Capacity to Process/Use Pre-Registration-Related Data	616
d.	ECHA’s Capacity to Clearly Disseminate REACH Registration Data to Stakeholders	619
e.	ECHA’s Perfunctory and Infrequent Evaluation of Harmful Substances	623
f.	REACH Pre-Registration Process Design Flaws	

Impaired Phase-in Substance Identification	627
5. Whether the Technical Regulation Is “More Trade Restrictive Than Necessary” to Fulfill the Objective Concerned, Taking into Account the Risks Nonfulfillment Would Create	629
a. Demonstrating How REACH Is More Trade Restrictive Than Necessary	630
i. Human Resource–Related Costs	631
ii. ECHA Registration Costs	632
iii. Data Gathering, Supply-Chain Communication and Exchange, and IT-Related Costs	633
iv. Notification, Hidden and External Consultant Costs	636
v. Trade Impacts of REACH Registration Costs ...	637
b. Comparing REACH to a Reasonably Available Less Restrictive Alternative.....	641
i. Canada’s Risk Prioritization-Based Chemicals Management Plan	641
ii. Japan’s Risk Prioritization-Based Chemical Substance Control Law.....	649
c. Taking into Account the Risk(s) That a Reasonably Available Less Trade-Restrictive Alternative Will Not Fulfill the Legitimate Objective.....	654
D. TBT ARTICLES 12.3 AND 12.1 ANALYSIS OF REACH.....	657
1. Analyzing Whether the EU Considered Developing Country “Special Development, Financial, and Trade Needs” in Proposing, Adopting, and Implementing REACH.....	657
a. Developing Country Trade Concerns Summarized	657
b. European Union Response to Developing Country Trade Concerns.....	658
i. Establishing ECHA Help Desks	659
ii. Providing REACH Regulatory Guidance.....	659
iii. Providing International Funds for Technical Assistance and Capacity Building	660
iv. Rendering Bilateral Technical Assistance.....	660

v. Convening REACH Training-Based Webinars.....	661
c. Adequacy of the European Union Response	661
V. CONCLUSION	662
A. SUMMARY OF REACH TBT FINDINGS.....	662
B. LOOKING FORWARD	666

I. INTRODUCTION

This article outlines a possible analytical framework employing recent and relevant World Trade Organization (“WTO”) jurisprudence for evaluating whether technical regulations such as the European Union’s (“EU’s”)/European Community’s (“EC’s”)¹ regulatory regime for the Registration, Evaluation, Authorisation and Restriction of Chemicals (“REACH”),² as adopted and/or as applied, are WTO-consistent. The focus of this legal review is limited³ to two “covered”⁴ agreements: the Agreement on Technical Barriers to Trade (“TBT Agreement”)⁵ and General Agreement on Tariffs and Trade 1994 (“GATT 1994”).⁶ Both the GATT 1994 and the TBT

1. See UK FIN. SERVS. AUTH., A BRIEF GUIDE TO THE EUROPEAN UNION AND ITS LEGISLATIVE PROCESSES 5 (2011), available at http://www.fsa.gov.uk/pubs/other/guide_to_eu.pdf (discussing how the EU was “founded to enhance political, economic and social cooperation and how the EEC was renamed the EC to “reflect[] the determination of the Member States to expand the [EC’s] powers to non-economic domains”).

2. See Parliament and Council Regulation 1907/2006, 2006 O.J. (L 396) 1 [hereinafter REACH].

3. The reader is reminded that the analysis herein provided may need to be periodically updated over time to reflect the evolving nature of both the regulatory regime known as REACH and then-current WTO TBT jurisprudence.

4. See *Legal Texts: The WTO Agreements*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/ursum_e.htm (last visited Oct. 30, 2012) (outlining the summary of the Final Act of the Uruguay Round).

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

6. See General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]; Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154; see also Appellate Body Report, *Korea — Definitive Safeguard Measures on Imports of Certain Dairy Products*, ¶ 75, WT/DS98/AB/R (Dec. 14, 1999) (noting that GATT 1994 was incorporated in the WTO Agreements and “that the *WTO Agreement* is one treaty”).

Agreement are multilateral treaties⁷ that “form part of Annex 1A to the [Marrakesh Agreement establishing the World Trade Organization]”⁸ and may potentially apply to REACH. Whereas the GATT 1994 is concerned generally with trade in goods, the TBT Agreement is more specialized and establishes rules and procedures regarding the development, adoption, and application of mandatory technical regulations and voluntary standards for products and the procedures (such as testing or certification) for determining whether a particular product meets such regulations or standards (“conformity assessment procedures”).⁹ WTO jurisprudence holds that “when the GATT 1994 and another Agreement in Annex 1A appear *a priori* to apply to the measure in question, the latter should be examined on the basis of the Agreement that deals ‘specifically, and in detail,’ with such measures.”¹⁰ Consequently, if REACH is determined to constitute “a ‘technical regulation’ within the meaning of the TBT Agreement, then the latter [the TBT Agreement] would deal with the measure [REACH] in the most specific and most detailed manner.”¹¹

The TBT Agreement applies to all technical measures addressing industrial and agricultural products, except those properly

7. See *Plurilaterals: Of Minority Interest*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm10_e.htm (last visited Oct. 30, 2012) (listing the four plurilateral WTO Agreements: Trade in Civil Aircraft, Government Procurement, Dairy Products (terminated in 1997), and Bovine Meat (terminated in 1997)).

8. See Panel Report, *European Communities — Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 8.16, WT/DS135/R (Sept. 18, 2000) (citing Appellate Body Report, *European Communities — Regime for the Importation, Sale and Distribution of Bananas*, ¶ 204, WT/DS27/AB/R (Sept. 9, 1997) [hereinafter EC — Asbestos Panel Report] (explaining that after the relevant agreements to be applied are determined, the analysis then shifts to the order in which the agreements are applied).

9. See TBT Agreement, *supra* note 5, Annex 1, ¶ 3; see also *WTO Legal Texts*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/legal_e.htm#GATT94 (last visited Oct. 30, 2012).

10. EC — Asbestos Panel Report, *supra* note 8, ¶ 8.16.

11. *Id.* ¶¶ 8.17, 8.56 (indicating that, even if a regulation is not covered by the TBT Agreement, it may be subject to other provisions of the WTO Agreement such as Articles I, III, and/or XI); see *Multilateral Agreements on Trade in Goods: General Interpretive Note to Annex 1A*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/05-anx1a_e.htm (last visited Oct. 30, 2012) (detailing that, in the event of a conflict between GATT and another agreement establishing the WTO, the provision of the other agreement shall prevail).

characterized as sanitary and phytosanitary (“SPS”) measures,¹² or as specifications for government procurement,¹³ which are instead covered under separate WTO agreements.¹⁴ “[T]he object and purpose of the *TBT Agreement* is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members’ right to regulate.”¹⁵ One of the TBT Agreement’s primary objectives is to prevent WTO Members from using regulations as unnecessary barriers to trade while ensuring that they retain their sovereign right to regulate “for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels [they] consider appropriate.”¹⁶

The EU REACH regulation can be described as a behind-the-border¹⁷ technical measure intended to address regional health and environmental concerns and impacts. It can be appropriately classified¹⁸ as a type of non-tariff measure (“NTM”)¹⁹ that falls

12. See Agreement on Sanitary and Phytosanitary Measures art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 33 I.L.M. 1125 [hereinafter SPS Agreement] (covering technical regulations and standards addressing food product safety issues).

13. See Agreement on Government Procurement, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 4, 1915 U.N.T.S. 103 (describing a plurilateral agreement covering measures addressing government procurement); see also *The Plurilateral Agreement on Government Procurement (GPA)*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm (last visited Oct. 10, 2012) (relaying that the GPA is the only legally binding agreement found in the WTO focusing on government procurement).

14. See TBT Agreement, *supra* note 5, art. 1.4–1.5.

15. See Appellate Body Report, *United States — Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 174, WT/DS406/AB/R (Apr. 4, 2012) [hereinafter US — Clove Cigarettes Appellate Body Report].

16. See TBT Agreement, *supra* note 5, pmbl.

17. See CÉLINE CARRÈRE & JAMIE DE MELO, CERDI, NON-TARIFF MEASURES: WHAT DO WE KNOW, WHAT SHOULD BE DONE? 4 n.3 (2009), available at <http://hal.inria.fr/docs/00/55/35/99/PDF/2009.33.pdf> (conveying that behind-the-border measures are trade costs that do not result from trade policies).

18. See *generally id.* at 7–8, boxes 1–2 (summarizing the current and proposed classifications of non-tariff measures). See also SUDIP RANJAN BASU ET AL., UNITED NATIONS CONFERENCE ON TRADE AND DEV., EVOLUTION OF NON-TARIFF MEASURES: EMERGING CASES FROM SELECTED DEVELOPING COUNTRIES 9, 16 (2011), available at http://www.unctad.info/upload/TAB/docs/Research/itcdttab_53_Advance_unedited_jan2012.pdf.

19. See CARRÈRE & DE MELO, *supra* note 17, at 4, 7 box 1; ROBERT W. STAIGER, WORLD TRADE ORG. ECON. RESEARCH & STATISTICS DIV., NON-TARIFF MEASURES AND THE WTO 2 (2012), available at <http://www.wto.org/english/>

within the scope of the TBT Agreement because it arguably distorts and creates uncertainty surrounding international trade flows of chemical substance-based products.²⁰ As the WTO itself acknowledges, “While the application of NTMs does not always *restrict* trade, they often result in unnecessary restrictions or undue barriers, which explains” why they are frequently and interchangeably referred to as non-tariff barriers (“NTBs”).²¹ NTBs are “barriers to trade that are not tariffs,” which may, in certain instances, include health and consumer safety technical regulations to the extent they are misused.²²

The WTO Committee on Technical Barriers to Trade (the “TBT Committee”)²³ regularly compiles statistics²⁴ about GATT

res_e/reser_e/ersd201201_e.pdf (attempting to define non-tariff measures and identify the three broad categories of such measures). “There is no agreed definition in the WTO of what constitutes a ‘non-tariff measure’ nor a ‘non-tariff barrier’” WTO E-LEARNING, MARKET ACCESS FOR GOODS AND NON-AGRICULTURAL MARKET ACCESS (NAMA) NEGOTIATIONS 209 (2012), *available at* http://etraining.wto.org/admin/files/Course_258/CourseContents/NAMA-E-Print2.pdf; *see* BASU ET AL., *supra* note 18, at 15 (noting the WTO’s effort to keep a database of NTMs negotiated between countries).

20. *Cf.* WTO E-LEARNING, *supra* note 19, at 231 (explaining that application of the SPS Agreement depends on a measure’s objective and its direct or indirect effect on international trade).

21. *Id.* at 62–63, 209 (emphasis added).

22. *Glossary of Statistical Terms: Non-Tariff Barriers*, OECD, <http://stats.oecd.org/glossary/detail.asp?ID=1837> (last updated Mar. 10, 2003). At least one OECD study that employed a cross-survey analysis to ascertain the use and incidence of NTBs in different markets found that technical measures were consistently included among the highest (“top five”) ranked NTBs. *See* OECD TRADE POLICY STUDIES, LOOKING BEYOND TARIFFS: THE ROLE OF NON-TARIFF BARRIERS IN WORLD TRADE 22–24, 231 (2005) (recognizing that technical measures have the possibility of “effectively” serving as “border-protection instruments”).

23. *See* TBT Agreement, *supra* note 5, art. 13.1 (“A Committee on Technical Barriers to Trade is . . . established and shall be composed of representatives from each of the Members.”).

24. One OECD study analyzed the lists of WTO NTB notifications submitted by eleven OECD and twenty-one non-OECD countries during the period spanning from March 2003 through October 2004. *See* OECD TRADE POLICY STUDIES, *supra* note 22, at 233. The study found that, of the 1200 NTB notifications reviewed, “TBTs represent[ed] the NTB category with the highest incidence of notifications with 530 entries, or almost half of the total. . . . TBTs were the principal reported barrier for 12 of the 21 countries, and the second most reported barrier for five others. Almost half of the complaints in this area concerned technical regulations and standards (46%).” *Id.* at 233–34 (emphasis added).

1994/WTO Member NTB notifications submitted pursuant to TBT Article 2.9.²⁵ “Transparency” is one of the core obligations imposed generally on all GATT 1994/WTO Members, and specifically for TBT Agreement Parties. Article 2.9 requires that “[w]henever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards,”²⁶ Members *must*:

prompt[ly] publi[sh proposed] laws, regulations, judicial decisions and administrative rulings affecting trade in such a manner as to enable governments and traders to become acquainted with them. In addition, some measures shall be published before their entry into force.²⁷ WTO Members are also required to inform the WTO and fellow-Members of specific measures, policies or laws through regular “notifications.”²⁸

TBT Committee statistics reflect, for the most part, a steady but growing global trend in NTB notifications of technical regulations and conformity-assessment procedures.²⁹ These statistics also reflect that TBT Committee Members have continued to reference in their notifications the same three public policy objectives as the primary basis for their regulatory proposals. For example, the protection of human health or safety and the prevention of deceptive practices and consumer protection were *the* two most frequently cited policy

25. See TBT Agreement, *supra* note 5, art. 2.9.

26. *Id.*

27. See *id.* art. 2.9.1; WTO E-LEARNING, *supra* note 19, at 60; GATT, *supra* note 6, art. X.

28. WTO E-LEARNING, *supra* note 19, at 60; see TBT Agreement, *supra* note 5, art. 2.9.

29. See World Trade Organization [WTO], Comm. on Technical Barriers to Trade, *Note by the Secretariat: Seventeenth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 1, fig.1, G/TBT/31 (Mar. 2, 2012) [hereinafter *Seventeenth Annual TBT Review*] (providing a bar graph illustrating the growth of TBT notifications since 1995); see also WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Sixteenth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 8, G/TBT/29 (Mar. 8, 2011) [hereinafter *Sixteenth Annual TBT Review*]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Fifteenth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 11, G/TBT/28 (Feb. 5, 2010) [hereinafter *Fifteenth Annual TBT Review*]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Fourteenth Annual Review of the Implementation and Operation of the TBT Agreement*, fig.1, G/TBT/25 (Mar. 4, 2009) [hereinafter *Fourteenth Annual TBT Review*].

objectives for each of the years 2003 through 2011, and the protection of the environment was among the top three most frequently cited policy objectives in six of these nine years.³⁰ Indeed, the TBT Committee's most recent (2011) Annual Review reflects that "[t]he most commonly stated objectives of the measures discussed relate to health and safety, and the protection of the environment."³¹

30. See Seventeenth Annual TBT Review, *supra* note 29, tbl.1 (identifying protection of human health, prevention of deceptive practices and consumer protection, and protection of the environment as the three policies most frequently cited); Sixteenth Annual TBT Review, *supra* note 29, tbl.1 (identifying protection of human health and prevention of deceptive practices and consumer protection as the two policies most frequently cited); Fifteenth Annual TBT Review, *supra* note 29, tbl.1 (identifying protection of human health and prevention of deceptive practices and consumer protection as the two policies most frequently cited); Fourteenth Annual TBT Review, *supra* note 29, ¶ 11 (identifying protection of human health, prevention of deceptive practices and consumer protection, and protection of the environment as the three policies most frequently cited); WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Thirteenth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 13, G/TBT/23 (Feb. 20, 2008) (identifying protection of human health, prevention of deceptive practices and consumer protection, and protection of the environment as the three policies most frequently cited); WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Twelfth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 11, G/TBT/21/Rev.1 (Apr. 4, 2007) (identifying protection of human health, prevention of deceptive practices and consumer protection, and protection of the environment as the three policies most frequently cited); WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Eleventh Annual Review of the Implementation and Operation of the TBT*, ¶ 12, G/TBT/18 (Feb. 17, 2006) (identifying protection of human health, protection of the environment, and prevention of deceptive practices and consumer protection as the three policies most frequently cited); WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Tenth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 10, G/TBT/15 (Mar. 4, 2005) (identifying protection of human health, prevention of deceptive practices and consumer protection, and protection of the environment as the three policies most frequently cited); WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Ninth Annual Review of the Implementation and Operation of the TBT Agreement*, ¶ 12, G/TBT/14 (Mar. 5, 2004) (identifying protection of human health and prevention of deceptive practices and consumer protection as the two policies most frequently cited).

31. Seventeenth Annual TBT Review, *supra* note 29, ¶ 19, fig.9. The TBT Committee's 2011 Annual Review reflects that the number of specific trade concerns has grown rather steadily since 1995, and has practically tripled between 2005 and 2011 with each specific trade concern raised, sometimes covering more than one issue. See *id.* ¶ 14, fig.4, n.15. It reveals that 1,154 specific concern-related issues were raised from January 1, 1995, through December 31, 2011, in

These statistics are significant because of the TBT Committee's constructive role as a forum in which WTO Members "discuss issues related to specific measures (technical regulations, standards, or conformity assessment procedures) maintained by other Members" known as "specific trade concerns."³² Specific trade concerns "relate variously to proposed measures notified to the TBT Committee in accordance with the notification requirements in the [TBT] Agreement or to measures currently in force."³³ Notifying WTO Members are expected to clearly explain the objective(s) of a given measure in its accompanying notification, or at the very least, shortly following the notification's triggering of specific trade concerns registered by other Members.³⁴ The raising of specific trade concerns is viewed as an early barometer of the perceived "trade-worthiness" of a given measure.

These statistics help to place TBT notifications submitted with respect to technical regulations like the EU's REACH, and WTO Members' reactions to them, into proper context. The EU first notified the TBT Committee about the REACH regulation on January 21, 2004.³⁵ Although the EU's 2004 notification designated three public policy objectives—the protection of human health or safety, trade facilitation, and the protection of the environment³⁶—it was subsequently discovered that "animal welfare" had actually played a very influential role in shaping the REACH regime.³⁷ The

connection with 549 specific trade concerns discussed by Members during said period. *See id.* figs.4–5. The three most frequently raised specific trade concern-related issues invoked by WTO Members from 1995–2011 were: i) the "need for more (further) information, or clarification about the measure at issue"; ii) unnecessary barriers to trade; and iii) transparency. *Id.* fig.5, ¶¶ 15–16. It also reveals that the regulatory measures most frequently raised for discussion in the Committee were those proposed and/or maintained by the EU, China, and the United States. *See id.* ¶ 22.

32. *Id.* ¶ 13

33. *E.g.*, WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Specific Trade Concerns Addressed in the TBT Committee*, 1 G/TBTGEN/74/Rev.8 (June 1, 2011).

34. *See* Seventeenth Annual TBT Review, *supra* note 29, ¶ 18.

35. *See* WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52 (Jan. 21, 2004) [hereinafter Jan. 21, 2004, TBT Committee Notification].

36. *Id.* at 1.

37. *See* Doaa Abdel Motaal, *Reaching REACH: The Challenge for Chemicals Entering International Trade*, 12 J. INT'L ECON. L. 643, 658–59 (2009) ("While

EU thereafter submitted eight additional notifications over the ensuing seven-year period reflecting several amendments, revisions, addenda, and implementation guidance that the EU has issued, and continues to issue, to the evolving REACH regulation.³⁸

The statistics also strongly suggest that the EU has recognized that the REACH's length and complexity and the new legal obligations it imposes present real compliance challenges for industries that have affected international trade in chemical substance-based products and, consequently, the operation of industry global supply chains. Indeed, as of November 10, 2011, thirty-four WTO Members had expressed specific trade concerns about the EU REACH regulation, designated as "European Communities – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (ID 88)," for a record twenty-seven times since the EC's initial REACH notification to the TBT Committee.³⁹ This statistic was

health and environmental concerns have certainly been major drivers of REACH, few expected that animal welfare considerations and the desire to minimize the testing of chemicals on animals would become so influential in shaping REACH.”)

38. See Mark Blainey, *REACH, Still Being Developed!*, 6 J. EUR. ENVTL. & PLAN. L. 51, 52 (2009); see also WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.1 (Mar. 10, 2003) (noting that the final date for comments is extended to June 21, 2004); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.2 (Aug. 17, 2006) (noting the Common Position on the REACH proposal was adopted by the Council on June 27, 2006); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.3 (Jan. 22, 2007) (establishing a European Chemical Agency and amending the approximation of laws relating to the classification concerning REACH); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.3/Rev.1 (Feb. 9, 2007) (informing of the adoption of two regulations proposed in the January 22, 2007, TBT Committee Notification); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.4 (June 13, 2007) (notifying the TBT Committee that documents have been prepared to assist industry under REACH); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.5 (Apr. 30, 2008) (informing TBT Committee members on regulation fees); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.6 (Oct. 30, 2009) (informing TBT Committee members of proposed amendments to REACH in regards to Annex XVII (dichloromethane, lamp oils and grill lighter fluids, and organostannic compounds)); WTO, Comm. on Technical Barriers to Trade, *Notification*, G/TBT/N/EEC/52/Add.7 (Apr. 21, 2010) (informing TBT Committee Members of the adoption of the amendment to Annex XVII).

39. See *Members Discuss 54 Technical Barriers, China's Final Review and Streamlined Work*, WORLD TRADE ORG. (Nov. 2011) (emphasis added) (“Raised

recently emphasized by the WTO Secretariat in a May 31, 2012, report discussing G20 trade measures, which cited REACH as “the [specific trade concern] most frequently raised by the greatest number of Members (over 30).”⁴⁰ Precisely because of REACH’s ongoing evolution, and the EU’s continued review of the REACH regulatory framework with an eye to further revising and/or adding to it in the future,⁴¹ it is very likely that more EU TBT Committee notifications with respect to the REACH will be forthcoming and trigger additional discussion by concerned WTO Members.

II. REACH-RELATED TRADE CONCERNS AT THE WTO 2004–2011

A. REACH IN A NUTSHELL

The EU REACH regulation was adopted in December 2006 and entered into force on June 1, 2007.⁴² “REACH encompasses over 140 different articles, 17 distinct annexes, almost 300 pages of text, and

*for a record-breaking 27th time were the EU’s Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) and Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).”); see also EU REACH Regulation Subject to Intense Debate in TBT Committee, HKTDC RES. (Nov. 30, 2007), <http://economists-pick-research.hktdc.com/business-news/article/Business-Alert-EU/EU-REACHRegulation.subject-to-intense-debate-in-TBT-committee/baeu/en/1/1X000000/1X005OQA.htm>; Herbert Smith, *EU’s REACH and Other Chemical Regulations Debated in the Technical Barriers to Trade Committee*, LEXOLOGY (Jan. 8, 2008), <http://www.lexology.com/library/detail.aspx?g=773fad90-10eb-4b06-9f46-beb37e49edc2>.*

40. WTO OMC, REPORT ON G-20 TRADE MEASURES ¶ 32 (2012) (emphasis added), available at <http://www.oecd.org/investment/investmentpolicy/50492978.pdf>. “This seventh Report reviews trade and trade-related measures implemented by G-20 economies in the period from mid-October 2011 to mid-May 2012.” *Id.* ¶ 1.

41. See, e.g., Frédéric Simon, *EU Prepares to Re-Open REACH ‘Can of Worms,’* EURACTIV, <http://www.euractiv.com/climate-environment/eu-prepares-open-reach-worms-news-507129> (last updated May 10, 2012); see also *Chemicals: Review of REACH 2012*, EUR. COMM’N, http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/index_en.htm (last visited Oct. 30, 2012).

42. See *REACH: History and Background—History of the Adoption Process for the New Chemicals Legislation*, EUR. COMM’N, http://ec.europa.eu/environment/chemicals/reach/background/index_en.htm (last visited Oct. 30, 2012).

hundreds of pages of guidance—with the latter figure expected to grow considerably as more guidance is issued.⁴³ The REACH regulation's primary stated objective is to “ensure a high level of protection” of health, safety, and the environment⁴⁴ through the creation of a single comprehensive system that covers all (existing as well as new) chemical substances. It also has an important claimed tertiary objective of limiting the use of vertebrate animals in chemicals testing.⁴⁵ The European Commission has described REACH as a response to the perceived inability of prior EC legislation to ensure the gathering and reporting of enough information about chemicals in industrial and commercial use to permit the relevant EU government institutions to properly identify, evaluate, and manage the known *and unknown risks* arising from such uses.⁴⁶ While the REACH regime is composed of several elements, its primary (and arguably most controversial) element is its registration/data-gathering requirement. It applies to each legal entity⁴⁷ within the EC that manufactures/formulates within or imports into the EU⁴⁸ one ton or more per year⁴⁹ of either existing⁵⁰ or new

43. Lynn L. Bergeson, *Chemical Management, North American Style: The Montebello Agreement*, ENVTL. QUALITY MGMT., Spring 2008, at 89, 91.

44. See REACH, *supra* note 2, art. 1.1 (emphasis added).

45. See EUR. CMTYS., RESPONSE FROM THE EUROPEAN COMMUNITIES SUBMITTED BY WTO MEMBERS UNDER G/TBT/N/EEC/52 5 (REGULATION CONCERNING THE REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS (KNOWN AS REACH – COM ((2003) 644 FINAL), available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/eu_wto_response_041028_en.pdf.

46. See WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 4 November 2004*, G/TBT/M/34 ¶¶ 14–15 (Jan. 5, 2005) [hereinafter TBT Committee Minutes for the Meeting of 4 November 2004]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 21 March 2007*, G/TBT/M/41 ¶ 24 (June 11, 2007) [hereinafter TBT Committee Minutes for the Meeting of 21 March 2007].

47. See EUR. CHEMS. AGENCY, GUIDANCE ON REGISTRATION VERSION 1.6 § 1.5.3.1 (Jan. 2011) [hereinafter GUIDANCE ON REGISTRATION VERSION 1.6], available at <http://www.safetyhitech.com/codddocumento/14/Registration%2520EN%2520.pdf>. Such legal entities include: EU manufacturer/formulator, EU importer, and EU “only representative appointed by a non-EU manufacturer/formulator.” See REACH, *supra* note 2, arts. 3(9), 3(11), 8(1); see also GUIDANCE ON REGISTRATION VERSION 1.6, *supra*, §§ 1.5.2.1, 1.5.3.3 (citing REACH art. 2(1)(d)).

48. See EUR. CHEMS. AGENCY, GUIDANCE ON REGISTRATION VERSION 2.0 § 2.1.2.1 (May 2012) [hereinafter GUIDANCE ON REGISTRATION May 2012 Draft], available at http://echa.europa.eu/documents/10162/13632/registration_en.pdf; see

substances,⁵¹ or articles containing more than one ton of substances per year.⁵² This requirement applies to substances on their own, in preparations, or in articles⁵³ unless otherwise fully or partially exempt *to the extent* covered by other primary EU legislation.⁵⁴ It is

also GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, § 1.5.3.4. Readers should note that there are seven prior versions and three subsequent draft versions of this guidance document currently available. *See id.* at 4 (providing a history of the prior version of the Guidance on Registration); *see also* EUR. CHEMS. AGENCY, GUIDANCE ON REGISTRATION DRAFT VERSION 2 (Mar. 2012) [hereinafter GUIDANCE ON REGISTRATION March 2012 Draft]; EUR. CHEMS. AGENCY, GUIDANCE ON REGISTRATION DRAFT VERSION 2 (Jan. 2012); EUR. CHEMS. AGENCY, GUIDANCE ON REGISTRATION DRAFT VERSION 2 (Sept. 2011) [hereinafter GUIDANCE ON REGISTRATION Sept. 2011 Draft].

49. *See* REACH, *supra* note 2, arts. 6(1), 6(3)(b), 17(1), 18(1), 23(1), 23(3), 28(1), 28(6), 41(5)(b).

50. *See id.* arts. 3(20), 12(1)(a), 23, 26–28.

51. *See id.* arts. 12(1)(a), 26–27.

52. *See id.* art. 7(1)(a).

53. *See id.* arts. 5–7.

54. *See id.* arts. 2(3), 2(5)(b), 2(6)(d), 2(7)–(8), 9 (listing the EC Regulations and Council Directives that fully or partially exempt REACH). An interesting issue arises with respect to the general REACH registration and data-gathering exemptions granted for foodstuff and feedstuff additives that have not also been granted to food contact materials falling within the scope of Regulation (EC) No 1935/2004, even though both are primarily regulated under the auspices of the European Food Safety Authority (EFSA) on “*food safety*” grounds and subject to risk assessment. REACH Articles 14(5)(b) and 56(5)(b) provide only limited exemptions to food contact materials *on environmental safety grounds*—e.g., a chemical safety report need not include consideration of *the risks to human health* with respect to food contact materials, and food contact materials are not subject to the REACH “authorization” requirement. *See id.* arts. 14(5)(b), 56(5)(b); *see also* Anna Gergely & Laurel Berzanskis, *Food Contact Materials Lie Within REACH*, CHEM. WATCH, Feb. 2012, at 13, *available at* http://www.stepto.com/assets/htmldocuments/Chemical%20Watch_Food%20contact%20materials%20are%20within%20REACH.pdf (“Compliance with REACH is a prerequisite to compliance with the [food contact materials] legislation.”). This dichotomy would seem to explain why the EU filed SPS notifications on proposed food contact materials regulations, characterizing them as primarily relating to a “food safety purpose,” notwithstanding their ancillary coverage under REACH. *See* WTO, Comm. on Sanitary and Phytosanitary Measures, *Notification*, G/SPS/N/EEC/410 (Aug. 16, 2011); WTO, Comm. on Sanitary and Phytosanitary Measures, *Notification*, G/SPS/N/EEC/388 (Oct. 4, 2010); WTO, Comm. on Sanitary and Phytosanitary Measures, *Notification*, 1 G/SPS/N/EEC/340 (Feb. 17, 2009). Similarly, since pharmaceuticals are otherwise covered by other primary EU health safety legislation, they are afforded certain exemptions under REACH. *See* COVINGTON & BURLING LLP, REACH AND ITS IMPACT ON PHARMACEUTICALS (2007), *available at* <http://www.cov.com/files/Publication/ed03bc97-89de-471d-9163-4f1a26899ba2/Presentation/PublicationAttachment/e60742d7-e808-45a9-bec6->

primarily dependent on production volume, which serves as a proxy for exposure,⁵⁵ is currently being implemented in phases,⁵⁶ and can entail significant costs and fees, some of which have been reduced for small and medium-sized enterprises (“SMEs”).⁵⁷

The registration/data-gathering requirement obliges all such entities:

- To gather information in the form of a technical dossier describing those intrinsic characteristics of each substance posing human health and/or environmental hazards⁵⁸ “through literature search, data sharing [and] if necessary testing,” but to generally avoid vertebrate animal testing;⁵⁹
- To use that information in generating exposure information,⁶⁰ in preparing chemical safety reports (“CSRs”)⁶¹ assessing the risks from identified uses,⁶² and for putting in place and recommending risk-management measures that would ensure

590676c12a9a/REACH%20-%20And%20Its%20Impact%20on%20Pharmaceuticals%20-%20January%202007.pdf.

55. See Eurostat, *The REACH Baseline Study* 26, 32 (Eurostat Working Paper, 2009), available at http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-09-003/EN/KS-RA-09-003-EN.PDF; see also EUR. COMM’N, QUESTIONS AND ANSWERS ON REACH 15 (2007), available at <http://ec.europa.eu/environment/chemicals/pdf/qa.pdf> (stating that while “[t]he risk of a chemical substance toward human health and the environment does not necessarily have a proportionate relationship with the volume of production,” it explained that “[v]olume is used as a proxy for exposure. It allows a clear, enforceable priority setting for registration which also gives legal certainty” (emphasis added)).

56. Specifically, the phases are pre-registration, late pre-registration, and potential/new registration. See EUR. CHEMS. AGENCY, GUIDANCE ON DATA SHARING VERSION 2.0 §§ 1.2.4, 3.1.1 (Apr. 2012) [hereinafter GUIDANCE ON DATA SHARING VERSION 2.0], available at http://www.echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf; see also REACH, *supra* note 2, arts. 23(1)–(3), 28(2), 28(6); GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, §§ 1.7.1.1, 1.7.2.

57. See REACH, *supra* note 2, art. 74; see also Commission Regulation 340/2008, 2008 O.J. (107/6) arts. 3(3), 4(4).

58. See REACH, *supra* note 2, arts. 10(a), 12(1)(a)–(b).

59. See *id.* arts. 13(1)–(2), 25, Annex VI; TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶ 26.

60. See REACH, *supra* note 2, art. 10(a)(x) (applying to “substances in quantities of 1 to 10 tonnes” per year).

61. See GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, § 1.8.1.

62. See REACH, *supra* note 2, arts. 12(1)(c), 14(1) (pertaining to situations in which more than ten tons of a substance is imported per year).

the safe use of each substance;⁶³

- To submit such information to a newly created centralized regulatory Agency known as the European Chemicals Agency (“ECHA”) for review,⁶⁴ and for inclusion within a newly created central chemicals database to be administered by ECHA;⁶⁵ and
- To share the gathered information with the rest of the manufacturing supply chain⁶⁶ through voluntary consortia and mandatory Substance Information Exchange Forums (“SIEFs”) for purposes of ensuring: a) the supply chain members’ safe use of such substance(s) and b) the submission of joint supply chain registrations that permit new supply chain registrants to refer to previously prepared studies which serves to minimize the likelihood of duplicative vertebrate animal testing.⁶⁷

Various levels of dossier information are required depending on the manufactured or imported volume of each such substance⁶⁸ and on whether the substance is characterized as dangerous or as persistent, bio-accumulative, and toxic.⁶⁹

Substances are prioritized for evaluation following registration if they are suspected of posing a risk to human health or the environment. Substance evaluation under REACH, which is carried out by EU Member States, is more extensive than a dossier evaluation⁷⁰ and is intended to clarify the presence and degree of risk posed. The ECHA has stated that “[t]he selection and eventual prioritisation of substances for evaluation is made according to risk-

63. *See id.* arts. 14(1), 14(3).

64. *See id.* arts. 6(1), 7(1), 20 (detailing ECHA’s multiple organs and functions, including EU Member State coordination tasks and review measures).

65. *See id.* art. 16(1).

66. *See id.* art. 11.

67. *See id.* art. 13(5).

68. *See id.* arts. 12, 14, Annex XI (i.e., tonnage band).

69. *See id.* Annex XIII.

70. *See* EUR. CHEMS. AGENCY, REACH FACT SHEET: SUBSTANCE EVALUATION (2011), available at http://echa.europa.eu/documents/10162/13644/substance_evaluation_fact_sheet_en.pdf (“Substance evaluation may involve an assessment of all registration dossiers from all registrants specific to the same substance as well as an assessment of any other sources of information available . . .”).

based criteria.”⁷¹ Substances to be evaluated are listed in a Community Rolling Action Plan (“CoRAP”), recently adopted on a consensus basis by EU Member State representatives.⁷² It currently includes ninety substances, forty-three of which are “substances of very high concern” (“SVHCs”).⁷³

Once SVHCs have been notified to the ECHA, they undergo a two-step regulatory process (including the substance evaluation process), after which they are placed on an “authorisation list” and may be found to qualify for authorization.⁷⁴ SVHCs cannot be placed on the market or used after a given date, unless ECHA authorization is granted for their specific use, or the use is exempted altogether from authorization.⁷⁵ The authorization process is “risk-based” and is intended to ensure that risks from SVHCs are adequately controlled, restricted, or substituted. It is only at this stage that a scientific risk assessment is performed and employed to determine whether actual identified SVHC health or environmental risks can be adequately controlled.⁷⁶ EU Commission authorizations shall be granted “if the applicant [is] able to demonstrate adequate control of risks” or “if there [is] no alternative substance or technology (even if the risks [are] not adequately controlled) and socio-economic benefits

71. *Id.*

72. See EUR. CHEMS. AGENCY, COMMUNITY ROLLING ACTION PLAN (CORAP) (Feb. 29 2012), http://echa.europa.eu/documents/10162/13628/corap_2012_en.pdf. The CoRAP is scheduled to be “updated and changes may be introduced for the substances . . . listed in 2012 . . . [b]y the end of February 2013 . . .” *Id.*

73. See *REACH: Substance Evaluation Starts*, EUR. TRADE UNION INST. (Apr. 4, 2012), <http://www.etui.org/Topics/Health-Safety/News/REACH-substance-evaluation-starts>; see also REACH, *supra* note 2, arts. 14(4), 31(1)(a)–(b).

74. Prior to being placed on an authorization list pursuant to Articles 57, 58, and Annex IV, substances are first placed on a “Candidate List” pursuant to Article 59(1). As of December 19, 2012, there are 138 SVHCs on the Candidate List. See EUR. CHEMS. AGENCY, CANDIDATE LIST FOR AUTHORISATION UPDATED WITH FIFTY-FOUR NEW SUBSTANCES OF VERY HIGH CONCERN (SVHCs), ECHA/PR/12/39 (Dec. 19, 2012), http://echa.europa.eu/view-article/-/journal_content/b5d76d7f-7b28-4081-bd5c-9500e01e1ab2; EUR. CHEMS. AGENCY, CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN FOR AUTHORISATION, <http://echa.europa.eu/web/guest/candidate-list-table> (last updated Dec. 19, 2012).

75. *Authorisation*, EUR. CHEMS. AGENCY, <http://www.echa.europa.eu/web/guest/regulations/reach/authorisation> (last visited Oct. 30, 2012).

76. See EUR. CMTYS., *supra* note 45, at 6 (explaining that “although hazard is the basis on which the decision is made to subject substances to the authorisation system, the authorisation themselves . . . are decided strictly on the basis of a consideration of risk”).

outweigh[] the risks.”⁷⁷ The risks of alternative substances (“substitutes”) are also taken into account.⁷⁸

The complete and satisfactory fulfillment of the REACH registration requirement is a condition precedent to receiving marketing authorization for a given manufactured or imported substance, or substance-containing article, which is otherwise known as the principle of “[n]o data, no market.”⁷⁹ In essence, the REACH registration/data-gathering requirement, consistent with the European Union’s Roman civil law precautionary principle,⁸⁰ reflects a regulatory paradigm shift that reverses the burden of proof (both the burden of production and the burden of persuasion) from the

77. TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶ 28; see REACH, *supra* note 2, art. 60(2)–(4) (providing that authorizations shall not be granted for substances meeting the criteria of REACH Article 57(a), (b), (c), or (f) for which a threshold cannot be determined; substances meeting the criteria of REACH Article 57(d) or (e); and substances identified in REACH Article 57(f) “having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties”).

78. See TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶ 28.

79. See REACH, *supra* note 2, art. 5.

80. See *id.* art. 1(3). The civil law precautionary principle is often referred to as “*in dubio pro natura*, a Roman law principle for environmental protection that asserts that in case of doubt, any decision should favour the protection of nature.” See Rolando Castro, *Protection of Sea Turtles: Putting the Precautionary Principle into Practice*, in BIODIVERSITY AND THE PRECAUTIONARY PRINCIPLE: RISK AND UNCERTAINTY IN CONSERVATION AND SUSTAINABLE USE 117, 117 (2005). “The concept of the precautionary principle is different in civil law and common law, which have different approaches to the relationship between science and law. In the USA the regulation is ‘science-based’ meanwhile, in Europe the rule of science is determined through a ‘policy-related’ way.” Maria Vittoria Lumetti, *Presentation at an Int’l Comm’n for Electromagnetic Safety Conference: The Precautionary EMF Approach: Rationale, Legislation and Implementation* (Feb. 2006); see François Ost, *The Philosophical Foundation of Environmental Law: An Excursion Beyond Descartes* (unpublished manuscript), available at <http://www.dhdi.free.fr/recherches/environnement/articles/ostenvlaw.pdf> (last modified Oct. 14, 2004) (“[I]t is up to those undertaking any activity likely to transform the environment to demonstrate the absence of negative effects.”). “Generally speaking, the precautionary principle says that *in dubio pro natura*. If in doubt, decide in favour of the environment. . . . *Ennaltavarautumisen periaate* or *varovaisuusperiaate* (in Finnish), *försiktighetsprincip* (in Swedish), *Vorsorgeprinzip* (in German), *principe de précaution* (in French), *principio de precaución* (in Spanish).” MARKO AHTEENSUU, *IN DUBIO PRO NATURA? A PHILOSOPHICAL ANALYSIS OF THE PRECAUTIONARY PRINCIPLE IN ENVIRONMENTAL AND HEALTH RISK GOVERNANCE* 1 n.1 (2008).

regulator to the manufacturer or importer on the basis of only a substance's hazardous properties, irrespective of the actual risk that such substance poses to human health or the environment.

B. REACH UNDERGOES CONTINUAL REVIEW AND CONSULTATION AT THE WTO

The EU REACH had already triggered international trade concerns among WTO Member governments and non-EU industries by the time the European Commission first notified the TBT Committee of REACH's proposed adoption.⁸¹ WTO Members have since continued to register their concerns⁸² at a record number of TBT Committee meetings, as recently as November 2011.⁸³

81. See, e.g., WTO, Comm. on Technical Barriers to Trade, *Minutes of the Meeting of 7 November 2003*, G/TBT/M/31 ¶¶ 23–33 (Dec. 9, 2003); NAT'L FOREIGN TRADE COUNCIL, INC., 'ENLIGHTENED' ENVIRONMENTALISM OR DISGUISED PROTECTIONISM? ASSESSING THE IMPACT OF EU PRECAUTION-BASED STANDARDS ON DEVELOPING COUNTRIES 66–86 (2004); NAT'L FOREIGN TRADE COUNCIL, INC., EU REGULATION, STANDARDIZATION AND THE PRECAUTIONARY PRINCIPLE: THE ART OF CRAFTING A THREE-DIMENSIONAL TRADE STRATEGY THAT IGNORES SOUND SCIENCE 17–27 (2003); NAT'L FOREIGN TRADE COUNCIL, INC., LOOKING BEHIND THE CURTAIN: THE GROWTH OF TRADE BARRIERS THAT IGNORE SOUND SCIENCE 82–111 (2003).

82. See LAWRENCE A. KOGAN, EXPORTING PRECAUTION: HOW EUROPE'S RISK-FREE REGULATORY AGENDA THREATENS AMERICAN FREE ENTERPRISE 11–12, 40–43 (2005) (pointing to several studies that demonstrate the losses these countries will sustain due to REACH); Lawrence A. Kogan, *Exporting Europe's Protectionism*, 77 NAT'L INTEREST 91, 95 (2004) (remarking that REACH does not take into account exposure data and requires the “industry to jump through needless hoops”); Lawrence A. Kogan, *Precautionary Preference: How Europe Employs Disguised Regulatory Protectionism to Weaken American Free Enterprise*, 7 INT'L J. ECON. DEV. 65, 213 (2005); Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European “Fashion” Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 493 (2008) (asserting that the EU has been targeting “the U.S. regulatory and free enterprise systems for fundamental restructuring”); Lawrence A. Kogan, *The Precautionary Principle and WTO Law: Divergent Views Toward the Role of Science in Assessing and Managing Risk*, 1 SETON HALL J. DIPL. & INT'L REL. 77, 78 (2004) [hereinafter Kogan, *Divergent Views Toward the Role of Science in Assessing and Managing Risk*] (noting the “disparate public views [between the United States and the EU] toward the role of science in risk assessment and risk management”).

83. See Seventeenth Annual TBT Review, *supra* note 29. See generally WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 23 March 2004*, G/TBT/M/32 (Apr. 19, 2004) 2–15 [hereinafter TBT Committee Minutes for the Meeting of 23 March 2004]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 1*

July 2004, G/TBT/M/33 (Aug. 31, 2004) 2–16 [hereinafter TBT Committee Minutes for the Meeting of 1 July 2004]; TBT Committee Minutes for the Meeting of 4 Nov. 2004, *supra* note 46, at 3–23; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 22–23 March 2005*, G/TBT/M/35 (May 24, 2005) 2–8; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 16–17 June 2005*, G/TBT/M/36 (Aug. 4, 2005) 2–9; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 2 November 2005*, G/TBT/M/37 (Dec. 22, 2005) 2–7; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 15 and 17 March 2006*, G/TBT/M/38 (May 23, 2006) 2–14; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 7–9 June 2006*, G/TBT/M/39 (July 31, 2006) 2–15; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 9 November 2006*, G/TBT/M/40 (Jan. 26, 2006) 2–15; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 21 March 2007*, G/TBT/M/41 (June 11, 2007) 2–20 [hereinafter TBT Committee Meeting Minutes for the Meeting of 21 March 2007]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 5 July 2007*, G/TBT/M/42 (Aug. 6, 2007) 2–16; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 9 November 2007*, G/TBT/M/43 (Jan. 21, 2008) 2–23 [hereinafter TBT Committee Meeting Minutes for the Meeting of 9 November 2007]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 20 March 2008*, G/TBT/M/44 (June 10, 2008) 3–24 [hereinafter TBT Committee Minutes for the Meeting of 20 March 2008]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 1–2 July 2008*, G/TBT/M/45 (Sept. 9, 2008) 2–38 [hereinafter TBT Committee Minutes for the Meeting of 1–2 July 2008]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 5–6 November 2008*, G/TBT/M/46 (Jan. 23, 2009) 2–33 [hereinafter TBT Committee Minutes for the Meeting of 5–6 November 2008]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 18–19 March 2009*, G/TBT/M/47 (June 5, 2009) 2–33 [hereinafter TBT Committee Minutes for the Meeting of 18–19 March 2009]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 25–26 June 2009*, G/TBT/M/48 (Sept. 29, 2009) 2–26 [hereinafter TBT Committee Minutes for the Meeting of 25–26 June 2009]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 5–6 November 2009*, G/TBT/M/49 (Dec. 22, 2009) 3–23 [hereinafter TBT Committee Minutes for the Meeting of 5–6 November 2009]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 24–25 March 2010*, G/TBT/M/50 (May 28, 2010) 2–18 [hereinafter TBT Committee Minutes for the Meeting of 24–25 March 2010]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 23–24 June 2010*, G/TBT/M/51 (Oct. 1, 2010) 2–11 [hereinafter TBT Committee Minutes for the Meeting of 23–24 June 2010]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 3–4 November 2010*, G/TBT/M/52 (Mar. 10, 2011) 2–11 [hereinafter TBT Committee Minutes for the Meeting of 3–4 November 2010]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes of the Meeting of 24–25 March 2011*, G/TBT/M/53 (May 26,

That REACH, thus far, has not been formally challenged at the WTO can perhaps be explained by reference to a number of factors:

- The EU's May 20, 2003, submission to the TBT Committee of an "early notification" under TBT Article 2.9.1 acquainting Members with the proposed REACH regulation;⁸⁴
- The EU's hosting of a public Internet-based consultation in 2003⁸⁵ that received up to 6500 comments in response to the REACH proposal;⁸⁶
- The EU's granting of a sixty-day extension to the original ninety-day REACH comment period;⁸⁷
- The EU's willingness to respond in writing and in person to WTO Members' concerns at the TBT Committee meetings⁸⁸ and to engage in private bilateral consultations with some WTO Members;⁸⁹

2011) 2–11 [hereinafter TBT Committee Minutes for the Meeting of 24–25 March 2011]; WTO, Comm. on Technical Barriers to Trade, *Note by the Secretariat: Minutes on the Meeting of 15–16 June 2011*, G/TBT/M/54 (Sept. 20, 2011) 2–62.

84. See WTO, Comm. on Technical Barriers to Trade, *Minutes of the Meeting Held on 2 July 2003*, ¶ 62 G/TBT/M/30 (Aug. 19, 2003).

85. See *Commission Communication—Towards a Reinforced Culture of Consultation and Dialogue – General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM (2002) 704 final (Dec. 11, 2002) 7 (“[The Interactive Policy-Making Initiative] is one of the tools that will help the Commission . . . respond more quickly and accurately to the demands of citizens, consumers and business.”); *IPM: Interactive Policy Making*, IDABC, http://ec.europa.eu/yourvoice/ipm/index_en.htm (last updated Nov. 2008); see also *REACH Regulation – Public Consultation*, EUR. COMM’N, http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/consultation/index_en.htm (last visited Oct. 30, 2012) (outlining the “essential features” of REACH).

86. See *REACH Background: Internet Consultation on Draft Chemicals Legislation (the REACH System)*, EUR. COMM’N, http://ec.europa.eu/environment/chemicals/reach/background/internet_cons_en.htm (last updated Sept. 14, 2012).

87. See EUR. CMTYS., *supra* note 45, at 1 (stating that the original ninety-day comment period, which commenced on the date of the EC’s formal TBT notification, January 21, 2004, would have expired on or about April 21, 2004, but for the sixty-day extension until June 21, 2004).

88. See *id.*; TBT Committee Minutes for the Meeting of 4 November 2004, *supra* note 46, ¶¶ 54–67; TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶¶ 23–59.

89. See EUR. CMTYS., *supra* note 45, at 1 (conveying “a series of bilateral meetings were held in Geneva between the Commission and some of the countries

- Considerable WTO Member government and non-EU industry lobbying;⁹⁰
- The EU's willingness to incorporate at least some of the comments and criticisms received into a partial revision of REACH prior to its adoption;⁹¹
- The passage of time deemed necessary for the purpose of accurately assessing whether the first applicable REACH provisions as adopted have been applied in a WTO-consistent manner irrespective of the EU's own conclusions concerning whether they are WTO-compliant;⁹²
- A dedicated cadre of academic, civil society, and industry advocates/lobbyists who have labored to defuse accusations of REACH WTO non-compliance;⁹³ and

and organisations that have commented" on REACH); TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶ 30.

90. See, e.g., Lawrence Kogan, *Claims of Improper US Lobbying Quite a REACH*, E.U. REP., May 2004, at 18 (plenary ed.); *REACH: Intensive Lobbying on Eve of Parliament Hearing*, EURACTIV, <http://www.euractiv.com/pa/reach-intensive-lobbying-eve-par-news-213161> (last updated May 4, 2007).

91. See *What Is REACH?*, ENVTL. CHEMOINFORMATICS, <http://www.eco-itn.eu/node/37> (last visited Oct. 23, 2012) ("REACH has been developed in a climate of transparency and consultation."); see also Wojciech Kosci, *Lukewarm Reception for Watered-down Regulation*, GREEN HORIZON (May 17, 2007), <http://www.greenhorizon-online.com/index.php/Insight/the-european-parliament-votes-to-enact-comprehensive-legislation-but-reach-fails-to-please-industry-lobbyists-and-green-organisations-alike.html> (declaring that, despite the revised version, green organizations and industry lobbyists are not satisfied with the end product).

92. See TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶¶ 34–35 ("REACH applied equally to EU and non-EU producers."); see also TBT Committee Minutes for the Meeting of 4 November 2004, *supra* note 46, ¶¶ 23–24 (explaining that an "extensive impact assessment" was conducted to evaluate REACH).

93. See, e.g., HENRIK SELIN, EUROPEAN OVER-REACH? EFFORTS TO REVISE EUROPEAN UNION CHEMICAL LEGISLATION AND REGULATION 22 (2005) (concluding that REACH is "guided by EU's commitment to sustainable development"); see also Christian Tietje & Sebastian Wolf, REACH REGISTRATION OF IMPORTED SUBSTANCES – COMPATIBILITY WITH WTO RULES 52 (2005) [hereinafter Tietje & Wolf, REACH REGISTRATION OF IMPORTED SUBSTANCES], available at <http://www.wirtschaftsrecht.uni-halle.de/Heft42.pdf> ("Thus far it has not been decided whether . . . every regulatory intervention in the market which leads to altered consumer and user expectations to be illegal under WTO law."); Christian Tietje & Sebastian Wolf, *Legal Opinion WTO-legal Admissibility of a Possible Inclusion of Substances in Products from Third*

- The EU's likely comprehensive review of and deemed compliance with the Panel and Appellate Body decisions in the WTO *Shrimp-Turtle* case,⁹⁴ pursuant to which the EU

Countries to the REACH Registration Obligations (Article 6 REACH), GER. PAINT INDUS. ASSOC. (2005); Sarah Harrell, *Beyond "REACH"? An Analysis of the European Union's Chemical Regulation Program Under World Trade Organization Agreements*, 24 WIS. INT'L L.J. 471, 472 (2006) (arguing that the United States will probably lose if it challenges REACH before the WTO); OKOPOL – Institut für Ökologie und Politik GmbH, *Analysis of the Implementation of the Requirements of Article 7 Imported Products in REACH (Discussion Paper)* (Analyse der Umsetzung der Anforderungen von Artikel 7 Unter REACH Bei Importierten Erzeugnissen), (Sept. 2008) at 3–4, http://www.reach-info.de/dokumente/Anhaenge/diskussionspapier_behoerden_workshop.pdf (concerning chemical substances in 'articles'); HEIKE LÜSKOW ET AL., ANALYSIS OF THE REALISATION OF OBLIGATIONS FROM ARTICLE 7 AND 33 UNDER REACH FOR IMPORTED ARTICLES, 18–19 (2010) (relaying that "specialist lawyers" scrutinized Article 7 of REACH and agree that it is WTO compliant); Noah M. Sachs, *Rescuing the Strong Precautionary Principle from Its Critics*, 2011 U. ILL. L. REV. 1285 (2011); *Bulldozing REACH – The Industry Offensive to Crush EU Chemicals Regulation*, CORP. EUR. OBSERVATORY (2005), available at <http://archive.corporateurope.org/docs/lobbycracy/BulldozingREACH.pdf> (criticizing the flawed studies used to combat REACH); MARCO CONTIERO, GREENPEACE, TOXIC LOBBY: HOW THE CHEMICALS INDUSTRY IS TRYING TO KILL REACH 5 (2006), available at <http://www.indymedia.be/files/toxic%20lobby.pdf> (arguing that we need REACH because of a lack of knowledge on the hazards of chemicals, the health risks of some of these chemicals, and the environmental risks some chemicals pose); ALICE PALMER, WORLD WILDLIFE FUND, REACH AND "PROPORTIONALITY" UNDER WTO RULES 5 (2004), available at http://www.wwf.org.uk/filelibrary/pdf/reach_prop_0604.pdf.

94. See Panel Report, *United States — Import Prohibition of Certain Shrimp and Shrimp Products*, ¶¶ 7.54–7.56, WT/DS58/R (May 15, 1998) (highlighting, in part, the obligation within the GATT 1994 Article XX chapeau of every WTO Member planning to *unilaterally* impose extra-territorial (environmental) measures with potential trade-distorting effects to undertake good faith diplomatic efforts to negotiate with other WTO Members, including those that have raised objections to the proposed measure, for the purpose of concluding bilateral or multilateral agreements that address the perceived (health, environmental, etc.) threat in a more consensual manner, *prior to enforcing* said measure); Appellate Body Report, *United States — Import Prohibition of Certain Shrimp and Shrimp Products*, ¶¶ 166–72, WT/DS58/AB/R (Oct. 12, 1998); Recourse to Article 21.5 of the DSU by Malaysia, *United States — Import Prohibition of Certain Shrimp and Shrimp Products*, ¶¶ 119, 122, WT/DS58/AB/RW (Oct. 12, 1998) (affirming that measures must be applied equally to all Member States); John H. Knox, *The Judicial Resolution of Conflicts Between Trade and the Environment*, 28 HARV. ENVTL. L. REV. 1, 37 (2004) (explaining how the Appellate Body interpreted the chapeau as "giving it broad powers to strike a balance, or draw a 'line of equilibrium,' between the environmental interests protected by the specific exceptions in Article

arguably endeavored, in “good faith,” to engage in bilateral and multilateral negotiations to elevate evolving international chemicals management standards as it simultaneously sought to explain REACH to WTO Members.⁹⁵

C. SPECIFIC REACH-RELATED TRADE CONCERNS RAISED BY
WTO TBT COMMITTEE MEMBERS 2004–2011

As noted previously, at least thirty-four non-EU WTO Members have expressed specific trade concerns about the EU REACH regulation, pertaining mostly to its registration/data-gathering and notification obligations. These concerns are described below.

1. *REACH's Hazard-Based Registration Requirement Is Overly Complex, Burdensome, and Costly*

At multiple TBT Committee meetings,⁹⁶ WTO Member representatives of Argentina, Canada, China, Chinese Taipei, India, Thailand, and the United States alleged that REACH's complex and detailed registration/data-gathering process requires the aggregation of massive amounts of data on a given chemical substance-based product⁹⁷ without evidence of the risks it poses to human health or the environment.⁹⁸ In their view, such treatment threatened to impose

XX and the trade interests furthered by what it called the ‘substantive’ provisions of GATT”).

95. The EU is likely to emphasize that it had engaged in prior efforts to ensure that REACH was complementary to “*international* initiatives, such as the International Council of Chemical Associations (ICCA) HPV Program and the Globally Harmonized System (GHS)” and that “REACH [had] implemented a large number of the SAICM objectives (Strategic Approach to International Chemicals Management).” See TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 46, ¶ 37. “[T]he REACH proposal does not negatively affect the OECD Screening Information Data Set (SIDS) programme and the USA’s HPV programme.” EUR. CMTYS., *supra* note 45, at 7.

96. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83; TBT Committee Minutes for the Meeting of 2–3 November 2010, *supra* note 83; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 82; TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83; TBT Committee Minutes for the Meeting of 23 March 2004, *supra* note 83.

97. Substance-based products include substances, substance mixtures, and substance-containing articles.

98. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 76; TBT Committee Minutes for the Meeting of 20 March 2008,

a “chilling effect”⁹⁹ on the use, sale, and ultimate availability of any such substance.¹⁰⁰ It would also impose significant burdens and costs upon non-EU manufacturers, formulators, and importers, especially SMEs, which could potentially render them noncompetitive in EU markets.¹⁰¹ They further emphasized that, although the ECHA regulation fees applicable to REACH compliance¹⁰² may have granted differential treatment to SMEs generally, they did not grant special and differential treatment to *developing country* SMEs.¹⁰³

2. EU Member States Engage in Inconsistent and Potentially Discriminatory Treatment of Substances (SVHCs) in Articles

WTO representatives of Japan and the United States alleged at several TBT Committee meetings¹⁰⁴ that the inconsistent treatment accorded by six EU Member States to imported SVHCs, including metal alloys, under REACH Article 7(2) was more burdensome and costly, and that it was also contrary to ECHA’s (and the EU Commission’s) stated interpretation of that provision.¹⁰⁵ They also

supra note 83, ¶ 89; TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶ 46.

99. See TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 112.

100. See *id.*

101. See TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 40; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 122; TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶¶ 35–36, 44; TBT Committee Minutes for the Meeting of 23 March 2004, *supra* note 83, ¶ 31, 36–37.

102. See Commission Regulation 340/2008, arts. 3(4), 4(4), 5(4), 6(4), 7(1)–(2), 8(3), 9(3), 10(2), 12, Annex I (tbl.2), Annex III (tbl.2), 2008 O.J. (107/6).

103. TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 108; Commission Recommendation 2003/361, Concerning the Definition of Micro, Small and Medium-Sized Enterprises, 2003 O.J. (L 124) Annex art. 2 (defining an SME).

104. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83.

105. See TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 38 (noting that Article 7(2) requires EU manufacturers and importers of articles to notify ECHA if articles containing more than 0.1% (by weight) of an SVHC placed on the candidate list are to be imported); EUR. CHEMS. AGENCY, GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES § 2.2 (May 2008), http://echa.europa.eu/documents/10162/13632/articles_en.pdf (setting forth the

sought clarification¹⁰⁶ regarding how these inconsistent interpretations would affect non-EU manufacturers' and importers' REACH Article 33 supply chain communications obligation, and how ECHA would prevent EU Member State authorities from unilaterally halting importation and international trade flows of non-EU products.¹⁰⁷ Meanwhile, at other TBT Committee meetings,¹⁰⁸ the WTO representatives of Chile, China, and the Russian Federation objected to uncertainty created¹⁰⁹ by EU Member States (such as Germany) requiring the separate registration of each metal component of an alloy or mixture and the registration of semi-finished steel slabs as "components" rather than as finished "articles," contrary to a EUROFER trade association analysis¹¹⁰ with which ECHA had agreed.¹¹¹

3. *REACH's Monomer Registration Requirement Is Costly and Burdensome, Threatens IP, and Is Potentially Discriminatory*

WTO representatives of China, India, Japan, and the United States

EU's interpretation of Article 7(2)).

106. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 46; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 45; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 58.

107. See TBT Committee Minutes for the Meeting of 24–25 March 2009, *supra* note 83, ¶ 148–49.

108. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83.

109. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 99.

110. According to EUROFER's reading of the ECHA *Guidance on Requirements for Substances in Articles Version 1.1* (May 2008), "slabs, bars, billets and blooms made of steel alloys have article status under REACH" and thus could possibly be exempt from registration. See EUR. CONFEDERATION OF IRON & STEEL INDUS [EUROFER], EUROFER POSITION PAPER DETERMINING THE BORDERLINE BETWEEN PREPARATIONS/ARTICLES FOR STEEL AND STEEL PRODUCTS (2008) [hereinafter EUROFER POSITION PAPER], available at <http://www.eurofer.org/index.php/eng/REACH/Documents-and-useful-web-links/EUROFER-position-papers/Borderline-between-preparations-articles-for-steel-and-steel-products> (click on the first PDF).

111. See GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES, *supra* note 105, at 81–85; see also Letter from Andreas Herdina, Director for Cooperation, Eur. Chem. Agency, to Danny Croon, EUROFER (Sept. 2, 2009) (responding to issues raised by EUROFER on the application of REACH to steel and steel products).

questioned the logic and scientific necessity of the EU's burdensome and costly requirement subjecting reacted monomers in polymers to registration under REACH Article 6(3) even though polymers themselves are exempt from registration under REACH Article 2(9).¹¹² Some of these objections had been raised despite the European Court of Justice's July 2009 decision upholding the REACH monomer requirement in the face of an unsuccessful challenge brought by several European companies.¹¹³ The representatives were concerned that such registration costs and the risks posed to confidential and proprietary monomer manufacturing information, their intellectual property ("IP"), would make it more likely that non-EU manufacturers concerned about their IP would withdraw from the EU market¹¹⁴ and that non-EU distributors would switch to registration-compliant EC polymer suppliers who would consequently derive a competitive trade advantage from such rules.¹¹⁵

4. Delayed and Confusing EU REACH Implementation Process Belies Lack of EU Institutional Capacity to Meet Regulatory Burdens

WTO representatives of Australia, Chile, Switzerland, and the United States observed how the EU institutions vastly underestimated the volume of data that would be submitted incident

112. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶¶ 76, 79, 88; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 42; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 119.

113. See TBT Committee Minutes for the Meeting of 3–4 Nov. 2010, *supra* note 83, ¶ 104; Case C-558/07, *The Queen v. Sec'y of State for the Env't., Food and Rural Affairs*, 2009 E.C.R. I-05783; Keith Nuthall, *European Court Limits Monomers Controlled by REACH*, PWR.COM (July 13, 2009), <http://www.prw.com/subscriber/headlines2.html?id=1247477244>; Nick Elliot, *The EU's ECJ Rejects First Legal Challenge to the Registration Requirements of the REACH Regulations*, REED SMITH ENVTL. L. RESOURCE (July 27, 2009), <http://www.environmentallawresource.com/tags/european-court-of-justice/>. The European Court of Justice (ECJ) found compelling a prior advisory opinion rendered by the ECJ's Advocate General. See KELLER & HECKMAN LLP, *THE CASE BEFORE THE EUROPEAN COURT OF JUSTICE ON REGISTRATION OF MONOMERS IN POLYMERS UNDER REACH* (2009), available at <http://www.khlaw.com/showpublication.aspx?Show=2669>.

114. KELLER & HECKMAN LLP, *supra* note 113.

115. See TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 140.

to the REACH registration process and the number of requests made by non-EU stakeholders for clarification and technical assistance with respect to the REACH's complex registration/data-gathering rules, including those relating to "only representatives."¹¹⁶ They emphasized that the EU Commission and ECHA were therefore vastly underprepared to respond to such requests for purposes of ensuring compliance with and implementation of REACH, and to utilize such data in fulfillment of its underlying public policy objectives.¹¹⁷

5. *Non-EU Manufacturers Would Be Competitively Disadvantaged if Forced to Choose Between Importer and "Only Representative" Registration to Protect Their IP*

WTO representatives of Australia, Canada, Chile, and the United States alleged that REACH's requirement that non-EU chemical substance-based products manufacturers must employ the services of either an EU-based importer (i.e., a customer) or an "only representative"¹¹⁸ to protect their intellectual property from EU competitors incident to registering their chemical substance-based products could place non-EU manufacturers at a "competitive disadvantage" in EU markets.¹¹⁹ They emphasized how the

116. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 55; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 46; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 64; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶¶ 158–59.

117. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 55; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 45; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 158.

118. "[An only representative is a] natural or legal person established outside the Community who manufactures a substance on its own, in preparation or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers under [Title II: Registration of Substances]." REACH, *supra* note 2, art. 8; see also GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 2.1.2 (explaining that an "only representative" is "established in the EU and appointed by a manufacturer, formulator or producer of an article established outside the EU to fulfil the obligations of importers (see section xx)").

119. See TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 46; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 51; TBT Committee Minutes for the Meeting of 5–6 November

requirement imposed added costs and burdens, especially upon SMEs, which, unlike multinationals, are less likely to have a European presence¹²⁰ or to know where to find a competent and reliable only representative,¹²¹ and which, consequently, are more inclined to navigate REACH alone or to abandon EU markets altogether.¹²²

6. *REACH's Mandatory Data-Sharing and SIEF Membership Potentially Places Non-EU Manufacturers at a Competitive Disadvantage*

WTO representatives of Canada, China, India, Japan, Thailand, and the United States described at several TBT Committee meetings¹²³ how REACH's SIEF participation requirement and REACH's EU-based legal entity requirement potentially rendered non-EU chemical substance-based product manufacturers, especially those from developing countries,¹²⁴ susceptible to exploitation and/or trade discrimination¹²⁵ by EU-based companies operating the SIEFs

2008, *supra* note 83, ¶ 160; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 82, ¶ 140.

120. See TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶¶ 153, 159, 176; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶¶ 127–28.

121. ECHA was unwilling to provide such guidance. See DORIS THIEMANN, EUR. CHEMS. AGENCY, THE ROLE OF AN “ONLY REPRESENTATIVE” ACCORDING TO THE REACH REGULATION 17 (2008), available at <http://www.eurofer.org/index.php/eng/Media/Files/The-role-of-an-Only-Representative-according-to-the-REACH-Regulation>; see also TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 47; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 160.

122. See TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 48.

123. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 144; TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 80; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 43; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 170; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 170; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 38; TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶¶ 41, 44.

124. See TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶ 35.

125. See TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 38.

and the “voluntary” consortia that non-EU-based companies must join to fulfill their REACH information-sharing obligation.¹²⁶ They also claimed that the absence of EU institutional oversight over the informal rules of the consortia¹²⁷ and over SIEF governance and proprietary data-sharing¹²⁸ and letter of access (“LoA”) negotiation protocols and procedures effectively provided lead SIEF EU-based registrants with control over the determination of testing costs, including vertebrate animal testing, and the costs of LoAs needed by non-EU SIEF participants to secure referral rights to robust study summaries for REACH registration purposes.¹²⁹

7. *REACH's Extra-Territorial Vertebrate Animal Testing
Prohibition Imposes Unnecessary Burdens
and Costs on Non-EU Manufacturers*

WTO representatives of Canada, China, and India expressed concerns about REACH's extra-territorial imposition of the EU's regional prohibition against vertebrate animal testing of chemical substances.¹³⁰ These representatives observed that such a registration-related obligation, when combined with the cost-intensive joint registration¹³¹ and SIEF information-sharing obligations, imposes unnecessary burdens and significant costs upon otherwise

126. See TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 51; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 183.

127. See TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶ 44.

128. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 47; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶¶ 44–45; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 59.

129. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 146; TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶¶ 80, 88–89; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 43.

130. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 147; TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 89; TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶ 45.

131. See TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 45; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶¶ 60, 76; TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 26.

competitive non-EU chemical substance-based product manufacturers, especially SMEs, not otherwise subject to such a high cost structure in their home country jurisdictions.¹³² In addition, skepticism was expressed about whether the EU's acceptance of the testing data provided by non-EU laboratories fulfilling ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories¹³³ would actually allow for the use within REACH registrations of data generated outside the EU.¹³⁴

8. REACH's Delegation of Direct Enforcement and Penalty Responsibilities to EU Member States Yields Inconsistent and Potentially Discriminatory Treatment of Non-EU Manufacturers

WTO representatives of China, Japan, Mexico, and the United States described how REACH's delegation of registration compliance and enforcement responsibilities to EU Member States had resulted in non-uniform inspections, registration/data-gathering and presentation standards, and penalty impositions.¹³⁵ They emphasized that these practices could potentially raise compliance burdens and costs for imports¹³⁶ and consequently provide EU-based companies operating in those markets with a competitive trade advantage.¹³⁷ For example, the United Kingdom and Poland had enacted different inspection procedures to confirm company compliance with REACH pre-registration requirements¹³⁸ and, during one large-scale inspection, had demanded more information than was legally required under REACH.¹³⁹ Meanwhile, one French

132. See TBT Committee Minutes for the Meeting of 1 July 2004, *supra* note 83, ¶ 45.

133. *Id.* ¶ 46.

134. *Id.* ¶ 44.

135. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 150; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 50; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 171; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 134.

136. See TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 176.

137. See TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶¶ 162–63.

138. See TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 57.

139. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra*

law established excessively high civil monetary and criminal sanctions for REACH non-compliance¹⁴⁰ that were arguably WTO-inconsistent.¹⁴¹

9. EU's Adoption and Implementation of REACH May Not Satisfy EU's WTO Obligation to Accord Special and Differential Treatment to Developing Countries

During TBT Committee meetings convened between March 2007 and March 2011, especially those immediately prior to the close of the first REACH pre-registration period for phase-in substances, fourteen developing country WTO Member governments alleged that the EU had failed to provide adequate REACH registration-related technical assistance.¹⁴² While eleven governments had framed the issue of technical assistance in terms of developing country "special and differential" circumstances,¹⁴³ Argentina,¹⁴⁴ Chile,¹⁴⁵ and Cuba¹⁴⁶

note 83, ¶ 150.

140. See TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 171.

141. See TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 55; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 73; see also Case C-265/10, Eur. Comm'n v. King of Belg., 2011 E.C.R., available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AC%3A2011%3A186%3A0008%3A0008%3Aen%3APDF> (demonstrating which infringements of REACH result in a failure to fulfill that charter's obligations); *REACH Penalties: Belgium Found Guilty*, ACTIO BLOG (May 9, 2011), <http://www.actio.net/default/index.cfm/actio-blog/reach-penalties-belgium-found-guilty/> (explaining that imposing particularly high REACH compliance fines can constitute a breach of REACH).

142. See TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 146; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 32.

143. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 97 (Venezuela); TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 48 (El Salvador); TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 192; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶¶ 146, 150, 156, 165, 167, 169 (Qatar, Egypt, Botswana, Indonesia); TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶¶ 35, 40, 52 (Mexico, China, South Africa); TBT Committee Minutes for the Meeting of 9 November 2007, *supra* note 83, ¶ 33 (Chinese Taipei); TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 46 (Brazil).

144. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 142; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 39; TBT Committee Minutes for the Meeting of 24–25 March

discussed this issue most extensively. In their view: 1) the complex explanatory guides, websites, and other information developed by the EC as REACH pre-registration implementation tools were not helpful;¹⁴⁷ 2) ECHA's and the EC's possible capacity limitations¹⁴⁸ gave rise to delayed and unsatisfactory responses to non-EC and developing country questions and technical-assistance requests;¹⁴⁹ and 3) consequently, such EU assistance and guidance did not satisfy

2010, *supra* note 83, ¶ 40; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 56; TBT Committee Minutes for the Meeting of 25–26 June 2009, *supra* note 83, ¶ 92; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 178; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 155; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 33; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 110; TBT Committee Minutes for the Meeting of 9 November 2007, *supra* note 83, ¶ 27.

145. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 55; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 47; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 64; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 161; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 41; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 132; TBT Committee Minutes for the Meeting of 9 November 2007, *supra* note 83, ¶ 34; TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 49.

146. See TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 49; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 45; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 189; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 48.

147. Argentina emphasized the barrier to trade and lack of transparency. See TBT Committee Minutes for the Meeting of 23 June 2010, *supra* note 83, ¶ 39; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 40; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 178. Chile described the regulation as complex and confusing, expressing similar concerns to Argentina. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 55; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 64. Cuba further noted the difficulty compliance poses for developing countries. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 96.

148. See TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 161 (Chile); TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 32 (Argentina).

149. See TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 178; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 155; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 32; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 110.

the EU's WTO obligation to accord special and differential treatment to developing countries and their industries.¹⁵⁰

III. ANALYSIS OF RECENT WTO TBT JURISPRUDENCE

A. OVERVIEW AND PRELIMINARY CONSIDERATIONS

During the past year, the WTO issued three decisions interpreting the nondiscrimination and unnecessary-obstacle-to-trade provisions of the TBT Agreement. In each of these “cases of first impression,”¹⁵¹ the complainants had alleged that behind-the-border NTMs, such as those related to public health and the environment, constituted NTBs.¹⁵² These three cases include: 1) *United States—Measures Affecting the Production and Sale of Clove Cigarettes (US—Clove Cigarettes)*;¹⁵³ 2) *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products, (US—Tuna II (Mexico))*;¹⁵⁴ and 3) *United States—Certain Country of*

150. See TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 189; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 155 (Argentina).

151. See Panel Report, *United States — Measures Affecting the Production and Sale of Clove Cigarettes (“US-Clove Cigarettes”)*, ¶¶ 7.80, 7.81, 7.631, WT/DS406/R (Sept. 2, 2011) [hereinafter US — Clove Cigarettes Panel Report]; Panel Report, *United States — Certain Country of Origin Labeling (COOL) Requirements*, WT/DS384/R, WT/DS386/R (Nov. 18, 2011) [hereinafter US — COOL Panel Report].

152. See OECD TRADE POLICY STUDIES, *supra* note 22, at 13 (explaining that NTBs can serve important regulatory purposes; however, the measures must be at appropriate levels such that trade is not restricted more than necessary).

153. See US — Clove Cigarettes Panel Report, *supra* note 151, ¶¶ 1.1, 2.6 (challenging the U.S. Family Smoking Prevention and Tobacco Control Act (“FSPTCA”), the policy objective of which is to reduce youth smoking rates across U.S. communities); 21 U.S.C. § 387(g) (2009) (endeavoring to achieve this objective by imposing a ban on the production and trade of cigarettes and component parts, including the tobacco, filter, or paper, containing a flavor, herb, or spice that provides a characterizing flavor to the product).

154. See Panel Report, *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/R (Sept. 15, 2011) [hereinafter US — Tuna Panel Report]. In *US—Tuna II (Mexico)*, Mexico challenged several U.S. measures collectively deemed a “technical regulation” for TBT Agreement purposes. See *id.* ¶ 7.24. These consisted of a U.S. federal statute (the U.S. Dolphin Protection Consumer Information Act (“DPCIA”)), U.S. federal regulations implementing the DPCIA (50 C.F.R. 216.91–92), and the 2007 U.S. federal case ruling in *Earth Island Institute v. Hogarth*, 494 F.3d 757 (9th Cir.

Origin Labelling (COOL) Requirements (US—COOL).¹⁵⁵ All three Panel decisions were subsequently appealed and resulted in final “clarifying” Appellate Body rulings.¹⁵⁶ Although these rulings have had mixed results for the governments involved—the United States losing important issues in all three cases—they provide valuable insights into how WTO tribunals perceive the evolving relationship between a sovereign WTO Member’s right to regulate and its simultaneous obligation to prevent the use of technical requirements as discriminatory or unnecessary barriers to trade.

In general, a measure may be challenged in a WTO dispute settlement proceeding “as such,” “as applied,” or in both manners.¹⁵⁷ A measure may be evaluated “as such” by reviewing the measure as written—“on its face”—to see whether the text of the measure itself

2007), (the “Hogarth Ruling”). *See id.* ¶ 2.1. The DPCIA’s objectives were to promote dolphin protection through encouragement of changed fishing areas and practices and to prevent against consumer deception caused by misrepresentative “dolphin-safe” labels being affixed to tuna products caught in a manner adversely affecting dolphins. *See id.* ¶¶ 7.407–7.408, 7.414.

155. *See* US — COOL Panel Report, *supra* note 151, ¶¶ 7.61, 7.620. In *US—COOL*, Canada and Mexico challenged several U.S. country-of-origin labeling (“COOL”) measures collectively deemed a “technical regulation” for TBT Agreement purposes, the objective of which was “to provide as much clear and accurate origin information as possible to consumers.” *See id.* ¶¶ 7.61, 7.620. They consisted of one federal statute (the Agricultural Marketing Act of 1946, as amended by the Farm Security and Rural Investment Act of 2002 (“Farm Bill 2002”) and the Food, Conservation, and Energy Act of 2008 (“Farm Bill 2008”)); one federal agency (the U.S. Department of Agriculture (“USDA”) Agricultural Marketing Service (“AMS”)) final implementing regulation; two of USDA AMS’s Food Safety and Inspection Service (“FSIS”) interim final implementing regulations; related further implementing guidance, directives, and policy announcements; and a letter from the U.S. Secretary of Agriculture to a member of industry recommending additional voluntary labeling. *See id.* ¶¶ 2.2–2.3, 7.9–7.10.

156. *See* US — Clove Cigarettes Appellate Body Report, *supra* note 15; 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 US — Tuna Appellate Body Report]; Appellate Body Report, *United States — Certain Country of Origin Labeling (‘COOL’) Requirements*, WT/DS384/AB/R, WT/DS386/AB/R (June 29, 2012) [hereinafter US — COOL Appellate Body Report].

157. *See* Appellate Body Report, *United States — Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, ¶ 156, WT/DS213/AB/R (Nov. 28, 2002); *see also* Appellate Body Report, *United States — Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, ¶ 82, WT/DS244/AB/R (Dec. 15, 2005) [hereinafter US — Japanese Steel Appellate Body Report].

violates WTO rules. Alternatively, or in addition, a measure may be evaluated “as applied” by reviewing the application of its text in practice, irrespective of whether the text itself is consistent with WTO law. The WTO analysis of a measure “as applied” initially focuses on two factors: 1) whether the measure’s application results in a legally binding obligation, such as a prohibition that bans the market authorization of foreign manufactured products unless certain preconditions are first satisfied; and 2) whether the facts demonstrate that the measure’s application is inconsistent with a provision of a WTO-covered Agreement (e.g., the TBT Agreement).¹⁵⁸

The discussion that follows is intended to serve as a preliminary template against which to apply the analytical framework that has been proposed for evaluating the EU REACH regulation introduced in the next section of this article. Practitioners should recognize that a significant amount of anecdotal, empirical, and statistical evidence is required to successfully challenge a disputed technical regulation at the WTO. When undertaking this type of investigation, it must be remembered that the objective of the TBT Agreement, the GATT 1994, or any of the other applicable covered WTO agreements “is not to remove these measures but to ensure that they are set at an appropriate level to achieve legitimate objectives with minimum impact on trade.”¹⁵⁹

B. ELEMENTS OF A POTENTIAL CAUSE OF ACTION UNDER KEY PROVISIONS OF THE TBT AGREEMENT

1. *Does the Disputed Measure Qualify as a “Technical Regulation” Within the Meaning of TBT Annex 1?*

A given measure will be subject to the provisions of the TBT Agreement if it qualifies either as a “technical regulation” or a “standard,” as defined by TBT Annexes 1.1 and 1.2. TBT Annex 1.2 provides that “technical regulations [are defined] as mandatory documents,” and standards as voluntary . . . documents.”¹⁶⁰ TBT Annex 1.1 describes a technical regulation as a “[d]ocument which lays down [either] product characteristics or their related processes

158. See US — Japanese Steel Appellate Body Report, *supra* note 157, ¶¶ 92–93.

159. OECD TRADE POLICY STUDIES, *supra* note 22, at 13.

160. See TBT Agreement, *supra* note 5, Annex 1.2.

and production methods, including the applicable administrative provisions, with which compliance is mandatory.”¹⁶¹

a. Technical Regulation Three-Part Test

A document must meet each of the following three criteria, “derived from the wording of the definition in Annex 1.1,” to fall within the definition of a technical regulation:

First, the document must apply to an “identifiable” product or group of products. The *identifiable* product or group of products need not, however, be expressly *identified* in the document. *Second*, the document must lay down one or more characteristics of the product. These product characteristics may be intrinsic or they may be related to the product. They may be prescribed or imposed in either a positive or negative form. *Third*, compliance with the product characteristics must be mandatory.¹⁶²

The first criterion has been recognized as underlying a WTO Member’s core obligation under TBT Article 2.9.2, namely, to notify other members “of the products to be covered” by a proposed technical regulation.¹⁶³ However, a document needn’t explicitly mention a product for that product to be identifiable. “The identifiable product coverage of a measure can also be determined according to the substance of the measure at issue.”¹⁶⁴

The second criterion has been interpreted as incorporating a rather broad scope of product characteristics. They can include any “definable ‘features’, ‘qualities’, ‘attributes’ or other ‘distinguishing mark’ of a product.”¹⁶⁵ This means that characteristics can relate directly to the “features and qualities intrinsic to the product itself,” as well as indirectly to the means by which products are identified, presented, and made to appear.¹⁶⁶ In addition, it is also helpful to

161. *Id.* Annex 1.1.

162. Appellate Body Report, *European Communities — Trade Description of Sardines*, ¶176, WT/DS231/AB/R (Sept. 26, 2002) (quotations added) [hereinafter EC — Sardines Appellate Body Report]; see also Appellate Body Report, *European Communities — Measures Affecting Asbestos and Asbestos-Containing Products*, ¶¶ 66–70 WT/DS135/AB/R (Mar. 12, 2001) [hereinafter EC — Asbestos Appellate Body Report]; US — Tuna Panel Report, *supra* note 154, ¶ 7.58; US — COOL Panel Report, *supra* note 151, ¶ 7.147.

163. See EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 70.

164. See US — COOL Panel Report, *supra* note 151, ¶ 7.201.

165. EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 67.

166. See *id.*

consider whether the provision that constitutes the essence of the measure addresses a product characteristic, and whether the obligations set out by the measure are closely related to an essential function.¹⁶⁷

For a measure to be considered “mandatory,” consistent with the third criterion, it must “lay down . . . set forth, stipulate or provide [the] characteristics,” (e.g., qualities or attributes) “of products in a binding or compulsory fashion” or “ha[ve] the effect of *prescribing* or *imposing*” them.¹⁶⁸ Because a measure may “include both prohibitive and permissive elements,” it must therefore be “examined as an integrated whole, taking into account, as appropriate, the prohibitive and the permissive elements that are part of it.”¹⁶⁹ In evaluating the mandatory nature of a given measure, it is also helpful to consider the following indicia:

- Whether the measure is composed of classic legal instruments that are legally binding under the law of the home country jurisdiction;¹⁷⁰
- Whether the measure uses the word “shall” in laying down its requirements;¹⁷¹
- Whether the measure is supported by an “enforcement” mechanism that foresees the possibility of imposing a fine/penalty in the event of noncompliance;¹⁷² *and*
- Whether the measure consistently refers to its core requirement as a “mandatory” requirement.¹⁷³

For example, the Panel in *US—COOL* concluded that a series of U.S. measures imposing country-of-origin labeling (“COOL”) requirements for meat products consisting inter alia of statutory and

167. See *US — COOL Panel Report*, *supra* note 151, ¶ 7.212.

168. *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶¶ 67–69.

169. *Id.* ¶¶ 64, 75.

170. See *US — COOL Panel Report*, *supra* note 151, ¶ 7.157.

171. *Id.* ¶ 7.158. As the *US—COOL* Panel noted, the use of the word “shall” is indicative of mandatory compliance. See *US — COOL Panel Report*, *supra* note 151, ¶ 7.160; *EC — Sardines Appellate Body Report*, *supra* note 162, ¶ 194, n.111.

172. See *US — COOL Panel Report*, *supra* note 151, ¶ 7.159.

173. *Id.* ¶¶ 7.160–7.161 (citing *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶ 72).

regulatory instruments¹⁷⁴ satisfied each of these criteria and, thus, qualified as a “technical regulation” within the meaning of TBT Annex 1. Notably, the United States did not indicate in its notification of appeal its intention to challenge this portion of the Panel’s decision.¹⁷⁵ Concerning the first criterion, the Panel found that, although the COOL measure “identifie[d] *inter alia* beef and pork as part of the covered commodities, [its] country of origin labelling requirement [was] also applied to and thus enforceable against . . . upstream suppliers of meat products [which was] indispensable for retailers’ effective compliance with the . . . COOL [measure’s] main country of origin labeling obligation.”¹⁷⁶ It also found that other provisions “explicitly reference[d] livestock in defining ‘beef’ as ‘meat produced from cattle’, and ‘pork’ as ‘meat produced from hogs.’”¹⁷⁷ Consequently, the Panel ruled:

[T]he COOL measure applies to an identifiable product or group of products within the meaning of [TBT] Annex 1.1 . . . namely (i) beef and pork, either as muscle cuts or in ground form; and (ii) livestock (i.e. cattle and hogs), which are the input products necessary to develop the beef and pork products explicitly covered by the COOL measure.¹⁷⁸

With respect to second criterion, the *US—COOL* Panel found that “country of origin labelling [was] the essence of the COOL measure” and “that the obligations set out by the COOL measure, including the information requirement . . . [were] closely related to this essential function.”¹⁷⁹ Its conclusion was in accord with a prior WTO Panel that had ruled that “an explicit requirement to indicate country of origin on the label of a product is indeed a labelling requirement for purposes of the definition of ‘technical regulation.’”¹⁸⁰

174. See *supra* text accompanying notes 170–173.

175. See Notification of an Appeal by the United States, *US — Certain Country of Origin (COOL) Labeling Requirements*, WT/DS384/12, WT/DS386/11 (Mar. 28, 2012); see also *USTR to Appeal WTO Country of Origin Labeling Ruling*, DELTA FARM PRESS (Mar. 23, 2012), <http://deltafarmpress.com/markets/ustr-appeal-wto-country-origin-labeling-ruling>.

176. *US — COOL* Panel Report, *supra* note 151, ¶ 7.205.

177. *Id.* ¶ 7.206.

178. *Id.* ¶ 7.207.

179. *Id.* ¶ 7.212.

180. *Id.* ¶ 7.213 (citing Panel Report, *European Communities — Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, Complaint by Australia*, ¶¶ 7.447–7.448, 7.452 WT/DS174/R (Mar. 15,

Lastly, the *US—COOL* Panel determined that the disputed COOL measure satisfied the third criterion because:

- The measure was “composed of classic legal instruments that [were] legally binding in US law”;¹⁸¹
- Its “core country of origin labelling requirement . . . us[ed] the word ‘shall’” and the “COOL statute also use[d] the word ‘shall’ in laying down the requirement for ‘any person engaged in the business of supplying a covered commodity to a retailer’ to provide country of origin information to retailers”;¹⁸²
- “[T]he COOL measure [was] supported by an ‘enforcement mechanism’ pursuant to which a ‘violation’ of the above obligations by a retailer or by any other person engaged in the business of supplying a covered commodity to a retailer . . . [could result in] the Secretary of Agriculture imposing a ‘fine’”;¹⁸³ and
- “[T]he COOL statute refers to the core country of origin labelling requirement as ‘the mandatory country of origin requirement’” and “the 2009 Final Rule (AMS) contains the word ‘mandatory’ in its very title, and consistently refers to the essence of the COOL measure as ‘mandatory COOL.’”¹⁸⁴

2. *Is the Disputed Technical Regulation Trade-Discriminatory and Thus Inconsistent with the National Treatment Obligation of TBT Article 2.1?*

a. *Generally*

TBT Article 2.1 provides:

Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.¹⁸⁵

2005)).

181. *Id.* ¶ 7.157.

182. *Id.* ¶¶ 7.157–7.158.

183. *Id.* ¶ 7.159.

184. *Id.* ¶ 7.161.

185. TBT Agreement, *supra* note 5, art. 2.1.

The WTO Appellate Body in *US—Clove Cigarettes* emphasized that TBT Article 2.1 must be interpreted in light of the TBT Agreement’s text and its overall purpose.¹⁸⁶ The Preamble to the TBT Agreement strongly suggests that “the object and purpose of the *TBT Agreement* is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members’ right to regulate.”¹⁸⁷ In the Appellate Body’s view, the TBT Agreement’s “fifth recital reflects the trade-liberalization objective of the *TBT Agreement* by expressing the ‘desire’ that technical regulations, technical standards, and conformity assessment procedures do not create unnecessary obstacles to international trade.”¹⁸⁸ Further, the Preamble’s sixth recital suggests that “Members have a right to use technical regulations in pursuit of their legitimate objectives, provided that they do so *in an even-handed manner* and in a manner that is otherwise in accordance with the provisions of the *TBT Agreement*.”¹⁸⁹ In other words,

Members’ right to regulate should not be constrained if the measures taken are necessary to fulfill certain legitimate policy objectives, and *provided that they are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade*, and are otherwise in accordance with the provisions of the Agreement.¹⁹⁰

Furthermore, the Appellate Body in *US—Clove Cigarettes* recognized that the TBT Agreement, by virtue of its second recital,¹⁹¹ is linked to the GATT 1994,¹⁹² which similarly strives to achieve a balance between Article III’s national treatment and other obligations and the general exceptions provision of Article XX.¹⁹³ However,

186. See *US — Clove Cigarettes Appellate Body Report*, *supra* note 15, ¶ 173.

187. *Id.* ¶ 7.174.

188. *Id.* ¶ 7.92.

189. *Id.* ¶ 7.95 (emphasis added).

190. *Id.* (emphasis added).

191. See *id.* ¶ 7.91.

192. See *id.* “The second recital of the preamble links the two Agreements by expressing the ‘desire’ ‘to further the objectives of the GATT 1994’” *Id.* ¶ 109.

193. See *id.* ¶¶ 7.96, 7.108. “The second recital indicates that the *TBT Agreement* expands on pre-existing GATT disciplines and emphasizes that the two Agreements should be interpreted in a coherent and consistent manner.” *Id.* ¶ 7.91.

TBT Article 2.1 has a much narrower focus than GATT Article III.¹⁹⁴

Article 2.1 of the TBT Agreement is recognized as containing both a national treatment *and* a most-favored nation treatment obligation.¹⁹⁵ A technical regulation will be deemed inconsistent with the national treatment obligation of TBT Article 2.1 if it accords *like* “products imported from the territory of any Member . . . *treatment less favourable than* that accorded to *like* products of national origin and to *like* products originating in any other country.”¹⁹⁶ The complainant bears the burden under TBT Article 2.1 of establishing *prima facie* that the treatment accorded to imported products is “less favorable” than that accorded “like” domestic products or “like” products originating in any other country.¹⁹⁷ This burden is satisfied with a showing that the disputed measure is not even-handed.¹⁹⁸

b. ‘Like’ Products Four-Part Test

The “likeness” of imported and domestic products should generally be determined on a case-by-case basis pursuant to four general criteria¹⁹⁹: “(a) the properties, nature and quality of the products; (b) the end-uses of the products; (c) consumers’ tastes and habits—more comprehensively termed consumers’ perceptions and behavior—in respect of the products; and (d) the tariff classification of the products.”²⁰⁰

194. TBT Article 2.1 “applies only in respect of technical regulations” *Id.* ¶ 7.97. “[T]echnical regulations are in principle subject not only to Article 2.1 of the *TBT Agreement*, but also to the national treatment obligation of . . . [GATT] Article III:4 . . . as ‘laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use’ of products.” *Id.* ¶ 7.100.

195. *See* US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 87; *see also* US — COOL Appellate Body Report, *supra* note 156, ¶ 267 (“The MFN treatment obligation prohibits discrimination through technical regulations among like products imported from different countries, while the national treatment obligation prohibits discrimination between domestic and imported like products.”).

196. TBT Agreement, *supra* note 5, art. 2.1 (emphasis added); *see also* US — Clove Cigarettes Panel Report, *supra* note 151, ¶ 7.74.

197. *See* US — Tuna Appellate Body Report, *supra* note 156, ¶ 216 (citing US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 182).

198. *See id.*

199. *See* EC — Asbestos Appellate Body Report, *supra* note 162, ¶¶ 102–03 (recognizing, however, that Panels possess and should exercise the authority and discretion to examine *all* “relevant” evidence).

200. US — Clove Cigarettes Panel Report, *supra* note 151, ¶¶ 7.121–7.123

However, prior to undertaking this examination, it is first necessary to identify the domestic and imported products that must be compared, which may in part be gleaned from the disputants' references to, identification of, and/or description of the products.²⁰¹ The Appellate Body in *US—Clove Cigarettes* advised Panels to construe the concept of “likeness” broadly to avoid excluding from comparison products that are in a sufficiently strong competitive relationship.²⁰²

In *US—Clove Cigarettes*, the Appellate Body found that the likeness of imported and domestic products, within the context of TBT Article 2.1, should be determined based on the competitive relationship between and among the products, and not based on the legitimate objectives and purposes of the technical regulation, which can distort that competitive relationship.²⁰³ Nevertheless, the Appellate Body also concluded, “the regulatory concerns underlying a measure, such as *the health risks associated with a given product, may be relevant to an analysis of . . . ‘likeness’ . . .* [under both GATT 1994 Article III:4 and TBT Article 2.1] . . . to the extent they have an impact on the competitive relationship between and among

(citing EC — Asbestos Appellate Body Report, *supra* note 162, ¶¶ 101–03); *see also* Report of the Working Party, *Border Tax Adjustments*, L/3464 (Dec. 2, 1970), GATT B.I.S.D. 18S/97; US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 189. In *Clove Cigarettes*, the Appellate Body took note that both clove and menthol cigarettes were classified under the same six-digit HS Subheading 2402.20. *See* US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 159 (citing US — Clove Cigarettes Panel Report, *supra* note 151, ¶ 7.239).

201. *See* US — Clove Cigarettes Panel Report, *supra* note 151, ¶¶ 7.124–7.131, 7.141.

202. *See* US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 116.

203. *Id.* ¶ 112. The Appellate Body reasoned that such an approach was justified for two reasons. First, “measures often pursue a multiplicity of objectives, which are not always easily discernible from the text or even from the design, architecture, and structure of the measure . . .” *Id.* ¶¶ 113–15. Second, by focusing on the objectives of a measure rather than on the nature of the competitive relationship between and among imported and domestic products, Panels would effectively narrow Member States’ autonomy to regulate, as they would be compelled eventually to choose which from among a given measure’s objectives should prevail in a “likeness” or “treatment no less favorable” determination. *Id.* ¶ 115. *But see id.* ¶ 117 (“[I]n concluding that the determination of likeness should not be based on the regulatory purposes of technical regulations, we are not suggesting that the regulatory concerns underlying technical regulations may not play a role in the determination of whether or not products are like.”).

the products concerned.”²⁰⁴ The first three of the four likeness criteria are discussed below.

i. Compare the Physical Properties of Competing Products

The physical characteristics of a product should be thoroughly examined to assess the extent to which products share common or display distinct physical properties that are likely to influence their competitive relationship in the marketplace.²⁰⁵ This means that, while each of the criteria must be separately analyzed, they can be and often are interrelated. For example, “the physical properties of a product may also influence how the product can be used, consumer attitudes about the product, and tariff classification.”²⁰⁶ “In *EC – Asbestos*, the Appellate Body found that, in examining whether products are like, panels must evaluate all relevant evidence, including evidence relating to the *health risks* associated with a product, which was the underlying [‘regulatory’] concern of the challenged measure in that dispute,”²⁰⁷ and which was ultimately found to influence consumer tastes and preferences.

EC—Asbestos involved a disputed French prohibition against asbestos and products containing asbestos.²⁰⁸ Said measure blocked importation of Canadian chrysotile asbestos fiber tiles but exempted “certain existing materials, products or devices containing chrysotile fibre . . . that pose[d] a lesser occupational health risk than chrysotile fibre to workers handling those materials, products or devices” while “provid[ing] all technical guarantees of safety corresponding to the ultimate purpose of the use thereof.”²⁰⁹ The Appellate Body reversed the Panel’s finding that the banned Canadian tiles and the exempted French non-asbestos fiber PCG²¹⁰ were “like” products within the meaning of GATT Article III:4 because of their perceived similar end-uses. The Appellate Body reasoned that the Panel had

204. *Id.* ¶ 119 (emphasis added) (citing *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶¶ 113–14, 122).

205. *See* *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶ 114.

206. *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶¶ 7.151–7.153.

207. *US — Clove Cigarettes Appellate Body Report*, *supra* note 15, ¶ 118 (emphasis added).

208. *See* *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶ 1.

209. *Id.* ¶ 2.

210. *See id.* ¶ 16. PCGs collectively refers to polyvinyl alcohol fibres, cellulose, and glass fibres. *See id.* ¶ 84.

erred because it had failed to “evaluate *all* relevant evidence” and, thus, to *fully* take into account the physical properties of the chrysotile asbestos tiles, *including* their “molecular structure, chemical composition, and fibrillation capacity”²¹¹ In the Appellate Body’s view, this product characteristic was “important because the microscopic particles and filaments of chrysotile asbestos fibres [had been shown to be] carcinogenic in humans, following inhalation.”²¹² Such a finding could *prove* “the product toxic or otherwise dangerous to health.”²¹³ Consequently, by “excluding *the health risks* associated with chrysotile asbestos fibres from its examination of the physical properties of that product,” the Panel had omitted “a highly significant physical difference” and “a defining aspect of the physical properties of chrysotile asbestos fibres.”²¹⁴

Furthermore, the Appellate Body in *EC—Asbestos* determined that, where evidence relating to the properties of compared products reflects that such products are quite physically distinct, the complainant bears a “higher burden” to overcome the “indication that [those] products are *not* ‘like’”²¹⁵ In that event, the complaining party must “establish that, despite the pronounced physical differences, there is a competitive relationship between the products such that *all* of the evidence, taken together, demonstrates that the products are ‘like’”²¹⁶ As a result, Canada was required, but was unable, “to show, under the second and third criteria, that the chrysotile asbestos and PCG fibres [were] in such a competitive relationship.”²¹⁷

ii. Identify the End-Uses of Competing Products

The “end-uses” of a product are often considered in relation to their influence on “consumer tastes and habits.” “End-uses” are defined by “the extent to which products are *capable* of performing

211. *See id.* ¶¶ 113–14.

212. *Id.* ¶ 114.

213. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 118.

214. EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 114–16 (emphasis added).

215. *Id.* ¶ 118.

216. *Id.*

217. *Id.*

the same, or similar functions,” whereas, “consumer tastes and habits” are defined as “the extent to which consumers are *willing to use* the products to perform these functions.”²¹⁸ While consumer preference may result in the use of fewer than all of a product’s multiple functions, it does not affect the capability of the product to perform those other functions. In other words, an end-use (performance capability) of a product does not cease to exist for likeness determination purposes merely because consumers choose, as a matter of preference, not to pursue it.²¹⁹ “[W]hat matters in determining a product’s end-use is that a product is *capable* of performing it, not that such end-use represents the principal or the most common end-use of that product.”²²⁰ In *US—Clove Cigarettes*, the Appellate Body counseled Panels against forming too narrow of a picture of the various end-uses of a product, as this could distort a product likeness determination. “[I]t is only by forming a complete picture of the various end-uses of a product that a panel can assess the significance of the fact that products share a limited number of end-uses.”²²¹

*iii. Identify Consumer Tastes
and Habits Regarding Competing Products*

The Appellate Body in *US—Clove Cigarettes* found that, although end-uses and consumer tastes and preferences are, in principle, distinct likeness criteria that should be examined separately, they could nevertheless be interrelated.²²² For example, the functional use of clove cigarettes could be, based upon consumer tastes, either to satisfy an addiction to nicotine or to create a pleasurable experience associated with the taste of the cigarette and the aroma of the smoke.

218. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 125 (second emphasis added); *see also* US — Clove Cigarettes Panel Report, *supra* note 151, ¶ 7.191.

219. *See* US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 125.

220. *Id.* ¶ 131.

221. *Id.* ¶¶ 128–29. Since the *US—Clove Cigarettes* Panel had not looked beyond “smoking” as the common function between menthol and clove cigarettes, the Appellate Body concluded that the Panel had failed to perform a comprehensive enough review of potential “end-uses” to provide sufficient guidance on the issue of “likeness” (though such determination was not ultimately found to be fatal to the Panel’s “likeness” determination). *See id.* ¶¶ 129–32, 158.

222. *See id.* ¶¶ 125–26.

The Appellate Body therefore found that evidence relating to these uses could be mutually substituted and potentially fall under one or both criteria.²²³ The “substitutability” of products comprises one aspect of consumer tastes and habits.

The Appellate Body in *US—Clove Cigarettes* ruled that products need not be substitutable for *all* consumers, and they need not *actually* compete in the *entire* market.²²⁴ It found that it is sufficient to demonstrate that comparable products are highly substitutable for some consumers but not for others, with the inference being that they actually compete directly *in at least one or more market segments*.²²⁵ However, in the Appellate Body’s view, the determination of whether competition needs to take place in the whole market or may be limited to a segment of the market, is to be considered separately from the determination of whether there is a necessary degree of competition in a given market segment required to satisfy the standards of “directly competitive or substitutable products” and “like products.”²²⁶

The Appellate Body in *US—Clove Cigarettes* noted how the Appellate Body in *EC—Asbestos* had ruled that “the *health risks* associated with chrysotile asbestos fibres [had] influenced the behaviour of both manufacturers (who incorporate fibres into another product) and ultimate consumers.”²²⁷ It also “noted that a manufacturer [could] not ignore the preferences of the ultimate

223. See *id.* ¶¶ 126–27. Furthermore, the Appellate Body in *US—Clove Cigarettes* found that the *US—Clove Cigarettes* Panel, by excluding adult smokers from its evaluation, had incorrectly confined its analysis of consumer tastes and habits only to young consumers and young potential smokers who were the target of the regulation, the objective of which was to reduce youth smoking. See *id.* ¶ 137. In the Appellate Body’s view, “the Panel should have assessed the tastes and habits of *all relevant consumers of the products at issue* [to evaluate the degree of substitutability among these products].” *Id.* ¶¶ 137–39 (emphasis added).

224. In light of the *US—Clove Cigarettes* Panel’s limited analysis of consumer tastes and habits, the Appellate Body in *US—Clove Cigarettes* considered the degree of substitutability necessary to ensure an overall finding of “likeness” between clove and menthol cigarettes under TBT Article 2.1. See *id.* ¶ 139.

225. See *id.* ¶ 142 (discussing Appellate Body Report, *Philippines — Taxes on Distilled Spirits*, WT/DS396/AB/R (Dec. 21, 2011)).

226. See *US — Clove Cigarettes* Appellate Body Report, *supra* note 15, ¶¶ 143–45, 157.

227. *Id.* ¶ 118, n.294 (emphasis added) (citing *EC — Asbestos* Appellate Body Report, *supra* note 162, ¶ 122).

consumers of a product and, [that] if the risks posed by a particular product [were] sufficiently great, the ultimate consumers [could] simply cease to buy that product.”²²⁸

c. “Treatment No Less Favorable” Two-Part Test

Once groups of “like” imported and domestic products have been identified, a disputed technical regulation must then be analyzed to determine whether it accords “less favorable treatment” to imported products than to “like” domestic products, taking into account the risk of nonfulfillment of the legitimate objective underlying the measure.²²⁹ The complaining party bears the burden of proof in establishing such treatment.²³⁰ The following subsections refer to the several elements of a “treatment no less favorable” analysis.

i. Identify Comparable Product Scope of Imported and Domestic Products

TBT Article 2.1 requires that a “treatment no less favorable” analysis broadly focus on comparing the “treatment accorded to products imported from the complaining Member . . . with that accorded to like domestic products and like products *of any other origin*.”²³¹ At the very least, “domestic products [must] stand in a sufficiently close competitive relationship with the products imported from the complaining Member to be considered ‘like’ products” for purposes of the “treatment no less favorable” test of TBT Article 2.1.²³² In addition, “the universe of domestic products that are like the products imported from the complaining Member” must also be ascertained, keeping in mind the “nature and extent of the competitive relationship between the products” in the regulating Member’s market.²³³

According to the Appellate Body in *US—Clove Cigarettes*, such a “universe” inquiry could, temporally speaking, extend back in time

228. *Id.*

229. *See* US — Clove Cigarettes Panel Report, *supra* note 151, ¶ 7.249.

230. *See* US — COOL Appellate Body Report, *supra* note 156, ¶ 272; US — Tuna Appellate Body Report, *supra* note 156, ¶ 216.

231. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 190 (emphasis added).

232. *Id.* ¶ 191 (internal quotations added).

233. *Id.* ¶ 192.

to enable a Panel to consider evidence pre-dating the Panel's establishment "to the extent such evidence informs the [P]anel's assessment of the consistency of the measure at that point in time."²³⁴ It observed that "[n]othing in Article 2.1 enjoins a [P]anel[]" from taking this approach, especially "in the case of a *de facto* discrimination claim where a [P]anel must base its determination on the totality of facts and circumstances before it, including the design, architecture, revealing structure, operation, and application of the technical regulation at issue."²³⁵

ii. *Compare All "Like" Imported Products
with All "Like" Domestic Products to Determine Detrimental Less
Favorable Treatment*

The Appellate Body in *US—Clove Cigarettes* recognized the unique nature of technical regulations as compared to other laws, regulations, and requirements in applying the "treatment no less favourable" standard of Article 2.1, which prohibits both *de jure* and *de facto* "less favorable treatment" for "like" imported products.²³⁶ It

234. *Id.* ¶ 206.

235. *Id.* The Appellate Body deemed such an approach valid because it would have effectively enabled the *US—Clove Cigarettes* Panel to consider evidence showing that the disputed U.S. measure had imposed a "chilling effect" upon foreign producers prior to its entry into force. *Id.*

236. See *US — Clove Cigarettes Appellate Body Report*, *supra* note 15, ¶ 175; *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶¶ 7.287, 7.299. The "treatment no less favorable" analysis under TBT Article 2.1 is largely consistent with that required by GATT Article III:4, while recognizing the unique nature of technical regulations as compared to "other laws, regulations and requirements." Both provisions contain a national treatment obligation that draws no distinctions between *de jure* (direct, explicit in law) and *de facto* (indirect/having the effect of) discrimination. See Thomas Cottier & Mathias Oesch, *Direct and Indirect Discrimination in WTO Law and EU Law 5* (NCCR Trade Regulation, Working Paper No. 2011/16, 2011), available at http://www.nccr-trade.org/fileadmin/user_upload/nccr-trade.ch/hi/CottierOeschNCCRWP16.pdf. Under GATT Article III:4, a "treatment no less favorable" analysis "must be grounded in a close *scrutiny of the 'fundamental thrust and effect of the measure itself'*" and "on a careful analysis of the contested measure *and* of its implications in the marketplace [Such analysis] *need not* be based on the *actual effects of the* contested measure in the marketplace." *US — COOL Panel Report*, *supra* note 151, ¶¶ 7.438–7.439 (emphasis added). In other words, "the absence of '*actual trade effects*' of a measure does not prevent a Member from bringing a successful claim of violation under the covered agreements." See *US — COOL Panel Report*, *supra* note 151, ¶ 7.440 (emphasis added).

ruled that TBT Article 2.1 does not prohibit regulatory distinctions between products found to be “like,” provided that the *group* of “like” products imported from the complaining “Member is treated no less favourably than the *group* of domestic like products.”²³⁷ TBT Article 2.1 will tolerate any type of regulatory distinction between like products “as long as treatment accorded to the *group* of imported products is no less favourable than that accorded to the *group* of like domestic products.”²³⁸

The Appellate Body reasoned that, since technical regulations, by their very nature, establish distinctions between products according to their characteristics and related process and production methods (“PPMs”), TBT Article 2.1 should not be interpreted to mean that just *any* regulatory distinction, particularly those based *exclusively* on product characteristics or related PPMs, provides less favorable treatment *per se*.²³⁹ Rather, “the ‘treatment no less favourable’ requirement of Article 2.1 only prohibits *de jure* and *de facto* discrimination against the *group* of imported products,” and it does not prohibit “*detrimental impact on imports that stems exclusively from a legitimate regulatory distinction.*”²⁴⁰ Where “the detrimental impact on imported products stems exclusively from a legitimate regulatory distinction, it follows that the challenged measure is not inconsistent with Article 2.1.”²⁴¹ However, “where a regulatory distinction is not designed and applied in an even-handed manner—for example, because it is designed or applied in a manner that constitutes a means of arbitrary or unjustifiable discrimination—that distinction cannot be considered legitimate and, thus, the detrimental impact will reflect discrimination prohibited under Article 2.1.”²⁴²

According to the Appellate Body, a “treatment no less favorable” analysis should focus on whether “a measure modifies the *conditions of competition* in the relevant market *to the detriment of* imported

237. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 194 (emphasis added).

238. *Id.* ¶¶ 193, 194 (quoting EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 100).

239. *See id.* ¶ 169.

240. *Id.* ¶¶ 174–75, 181–82 (emphasis added); *see also* US — Tuna Appellate Body Report, *supra* note 156, ¶ 215.

241. US — Tuna Appellate Body Report, *supra* note 156, ¶ 216.

242. US — COOL Appellate Body Report, *supra* note 156, ¶ 293.

products.”²⁴³ This implies a broad scope of inquiry concerning the differential treatment in question that concentrates on whether the measure affects a “market” composed of many “like” products as opposed to individual like products. “[A] Member may draw distinctions between products which have been found to be ‘like’, without, for this reason alone, according to the *group* of ‘like’ imported products ‘less favourable treatment’ than that accorded to the *group* of ‘like’ domestic products.”²⁴⁴ However, as observed by the Appellate Body in *EC—Asbestos*, “[i]f there is ‘less favourable treatment’ of the group of ‘like’ imported products, there is, conversely, ‘protection’ of the group of ‘like’ domestic products.”²⁴⁵

Lastly, the Appellate Body emphasized that a more extensive “treatment no less favorable” analysis will be required where a disputed technical regulation is origin-neutral on its face, such that it does not *de jure* discriminate but rather *de facto* discriminates against imports.²⁴⁶ The Article 2.1 inquiry in such cases will necessarily entail a careful scrutiny of “the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, [of] whether that technical regulation is even-handed, in order to determine whether it discriminates against the group of imported products.”²⁴⁷

The Appellate Body in *US—COOL*, having determined that the disputed COOL measure did not discriminate *de jure*, emphasized the need 1) to examine the operation of such a measure in the particular market(s) in which it was applied,²⁴⁸ and 2) to ascertain whether the operation of the measure in such a market “has a *de*

243. US — COOL Panel Report, *supra* note 151, ¶ 7.298 (second emphasis added); see US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶¶ 177–79; US — Clove Cigarettes Panel Report, *supra* note 151, ¶¶ 7.264, 7.268.

244. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶¶ 178, 193 (first and third emphasis added).

245. *Id.* ¶ 178 (citing EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 100).

246. See *id.* ¶¶ 182, 215; US — COOL Appellate Body Report, *supra* note 156, ¶¶ 229, 286 (“[T]he existence of a detrimental impact on competitive opportunities for the *group* of imported [products] vis-à-vis the *group* of domestic like products [will] not [always be] dispositive of less favourable treatment under Article 2.1.” (emphasis added)); US — Tuna Appellate Body Report, *supra* note 156, ¶ 225.

247. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶¶ 182, 215 (emphasis added).

248. See US — COOL Appellate Body Report, *supra* note 156, ¶ 269.

facto detrimental impact on the *group* of ‘like’ imported products.”²⁴⁹ This means that “all the relevant features of the market, [including, but not limited to,] the particular characteristics of the industry at issue, the relative market shares in a given industry, consumer preferences, and historical trade patterns,” must be closely scrutinized.²⁵⁰ It also means that “*any* adverse impact on competitive opportunities for imported products vis-à-vis like domestic products that is caused by a particular measure may potentially be relevant”²⁵¹ In other words, “[i]n every case, it is *the effect of the measure on the competitive opportunities in the market* that is relevant to an assessment of whether a challenged measure has a detrimental impact on imported products.”²⁵²

In *US—COOL*, the Panel found that the COOL regulation did not *de jure* discriminate against imported meat products.²⁵³ It then undertook a “treatment no less favorable” analysis that scrutinized the design, architecture, revealing structure, operation, and application of the COOL measure to determine whether the COOL measure was *de facto* discriminatory. In doing so, it focused on, among other evidence, the economic and econometric studies submitted by the parties for purposes of gaining a broad understanding regarding whether the COOL requirements had imposed *a priori* a relatively higher compliance and cost burden upon imported Canadian and Mexican “like” meat products.²⁵⁴ Such data included information about relative trade volumes,²⁵⁵ market share,²⁵⁶ and COOL measure-related costs,²⁵⁷ specifically compliance costs and²⁵⁸ segregation costs.²⁵⁹

Although the Panel observed that “the COOL measure [did] not

249. *Id.* ¶ 286 (second emphasis added).

250. *Id.* ¶ 269.

251. *Id.* ¶¶ 225, 286; *US — Clove Cigarettes Appellate Body Report*, *supra* note 15, ¶ 179 n.372 (noting that there must be a direct relationship between the disputed measure and its adverse impact on imported goods to support a “treated less favorably” assertion).

252. *US — COOL Appellate Body Report*, *supra* note 156, ¶ 270.

253. *See US — COOL Panel Report*, *supra* note 151, ¶ 7.301.

254. *See id.* ¶¶ 7.303–7.488.

255. *See id.* ¶ 7.454.

256. *See id.* ¶ 7.474.

257. *See id.* ¶ 7.486.

258. *See id.* ¶ 7.303.

259. *See id.* ¶¶ 7.265–7.268, 7.322–7.325.

explicitly require segregation, let alone the segregation of domestic and imported livestock,” the regulation’s “labelling requirements for muscle cuts of meat, namely beef and pork, at the retail stage, i.e. ‘at the final point of sale to consumers,’” mandated the “labelling of meat based on the origin of an animal from which meat [was] derived.”²⁶⁰ Furthermore, it determined that, to “accurately label muscle cuts under the COOL measure, a covered retailer need[ed] to possess origin information on where livestock processing steps occurred. The retailer had to also determine origin under the COOL measure with regard to each muscle cut,” which could “be obtained only from the upstream livestock and meat supply chain.”²⁶¹ Based on its review of such data, the Panel concluded that the COOL regulation effectively imposed segregation of cattle and livestock and meat products produced therefrom and created a cost structure.²⁶² That cost structure had the effect of discriminating in favor of domestic suppliers, “particular[ly] in regard to muscle cuts,” by incentivizing the processing of exclusively domestic livestock at relatively lower cost and disincentivizing the handling of imported livestock.²⁶³

The Panel ultimately determined that the COOL measure had imposed less favorable treatment on imported “like” muscle cuts than it had on domestic “like” muscle cuts. It explained that it had not reached its conclusion based on a detailed examination of “the actual trade effects of the muscle cuts and ground meat labels under the COOL measure,” but rather by “assessing segregation and the resulting cost implications of the COOL measure”²⁶⁴ In other words, it emphasized that it had arrived at its decision by focusing on “the fundamental thrust and effect of the measure itself.”²⁶⁵

The Appellate Body in *US—COOL* found that the Panel had “properly examined whether the COOL measure modifie[d] the conditions of competition in the US market to the detriment of

260. *Id.* ¶ 7.315.

261. *Id.* ¶ 7.316.

262. *See id.* ¶¶ 7.486–7.506.

263. *See id.* ¶¶ 7.420, 7.546; *see also* US — COOL Appellate Body Report, *supra* note 156, ¶ 287.

264. US — COOL Panel Report, *supra* note 151, ¶¶ 7.438, 7.445.

265. *Id.* ¶ 7.438.

imported livestock.”²⁶⁶ It agreed with the Panel’s findings that: 1) the COOL measure had created a scenario that compelled U.S. livestock and meat market participants to make a choice between producing domestic livestock exclusively or producing domestic and imported livestock together, which resulted in most participants choosing the former; and 2) but for the COOL measure, the market participants would not have chosen as they had.²⁶⁷ Consequently, the Appellate Body upheld the *US—COOL* Panel’s conclusion that “the COOL measure . . . as applied in the US livestock and meat market” had “modifie[d] the conditions of competition in the US market to the detriment of imported livestock” by “creating an incentive for US producers to segregate livestock according to origin, in particular by processing exclusively US-origin [domestic] livestock” and a “disincentive against handling imported livestock.”²⁶⁸

In *US—Clove Cigarettes*, the Appellate Body found that the Panel had not examined the “‘architecture, structure and design’ of Section 907(a)(1)(A) [U.S. Family Smoking Prevention and Tobacco Control Act (“FSPTCA”)], including the fact that it allow[ed] Indonesia to import and sell regular and menthol cigarettes in the United States.”²⁶⁹ It also found that the Panel had failed to clearly explain that the effect of banning non-menthol-flavored cigarettes was to impose costs on producers from other WTO Members, notably Indonesian producers, rather than upon domestic producers.²⁷⁰ Yet

266. *US — COOL* Appellate Body Report, *supra* note 156, ¶ 291.

267. *See id.* The Appellate Body reached this conclusion because it determined that the COOL measure was comparable to the Korean law that had established a dual retail system for beef, which required small retailers to sell either exclusively domestic beef or exclusively imported beef. In *Korea — Various Measures on Beef*, the Appellate Body had previously ruled that such a measure was inconsistent with GATT Article III:4 since it had a detrimental impact on imported beef. *Id.* ¶ 288 (citing Appellate Body Report, *Korea — Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶¶ 145–46, WT/DS161/AB/R (Dec. 11, 2000) [hereinafter *Korea — Beef* Appellate Body Report]). It determined that the measure’s detrimental impact flowed not only from the legal necessity of making a choice, but also from the “direct practical effect” that such legal requirement had had in “denying competitive opportunities to imports.” *Id.* While private Korean entrepreneurs had chosen to sell domestic beef based “on their own calculations of comparative costs and benefits,” the Korean measure’s effects on imports were, nevertheless, found to be “the result of . . . governmental intervention.” *Id.*

268. *US — COOL* Appellate Body Report, *supra* note 156, ¶¶ 289, 292.

269. *US — Clove Cigarettes* Appellate Body Report, *supra* note 15, ¶ 219.

270. *See id.* ¶¶ 219, 221 (pointing out that the only justification provided for the

the Appellate Body concluded that the Panel had not seriously erred in later finding that the disputed technical regulation was inconsistent with Article 2.1.²⁷¹

Apparently, the Appellate Body's examination of the nature, design, and effect of the FSPTCA revealed that the provision, by design, "prohibit[ed] all cigarettes with characterizing flavours other than tobacco or menthol."²⁷² It also focused on the Panel's factual record, which demonstrated "that 'virtually all clove cigarettes' that were imported into the United States in the three years prior to the ban came from Indonesia," that "the 'vast majority' of clove cigarettes consumed in the United States came from Indonesia," that during "the years 2000 to 2009, between 94.3 and 97.4 per cent of all [unbanned] cigarettes sold in the United States were domestically produced . . . , that menthol cigarettes accounted for about 26 per cent of the total US cigarette market," and "that three domestic brands dominate[d] the US market for menthol cigarettes."²⁷³ The Appellate Body concluded that, although the Panel failed to connect all of the dots to show that the disputed U.S. measure had resulted in detrimental treatment of Indonesian clove cigarettes that amounted to discrimination, the factual record spoke for itself.²⁷⁴

Moreover, the Appellate Body found, based on the factual record, that the detrimental impact of the FSPTCA on the competitive opportunities for imported Indonesian clove cigarettes did not derive exclusively from a legitimate regulatory distinction.²⁷⁵ It noted that, although the measure's stated objective was to reduce youth smoking, menthol flavoring of the same character as that contained in the banned clove cigarettes, used to mask the cigarettes' tobacco and otherwise harsh flavor to make smoking more pleasant, had remained present in the cigarettes not banned by the regulation.²⁷⁶ The Appellate Body concluded that this inconsistency militated against a finding that the regulation's "detrimental impact on

conclusion that the ban would not affect domestic producers was that, at the time of the ban, only menthol cigarettes were on the U.S. market).

271. *See id.* ¶ 222.

272. *See id.*

273. *Id.* ¶¶ 222–23.

274. *See id.* ¶ 224.

275. *See id.* ¶ 225.

276. *See id.*

competitive opportunities for imported clove cigarettes stemmed from a legitimate regulatory distinction.”²⁷⁷

In its view, had the United States been genuinely concerned about the health risks associated with youth smoking, it would have acted differently.²⁷⁸ For example, its regulation would not have focused as it did on peppermint or any other ingredient exclusively present in menthol cigarettes.²⁷⁹ Rather, it would have focused primarily on nicotine, the addictive ingredient in menthol cigarettes that was also present in regular cigarettes, the group of products likewise permitted under the disputed regulation.²⁸⁰ Consequently, the Appellate Body held that the disputed technical regulation violated TBT Article 2.1 because it operated “in a manner that reflect[ed] discrimination against the *group* of like products imported from Indonesia.”²⁸¹

277. *Id.*

278. *See id.*

279. *See id.*

280. *See id.* (concluding that it was disingenuous for the United States to claim that menthol cigarettes had to remain on the market to avert catastrophic costs the U.S. healthcare system allegedly would bear *as the result of* treating “‘millions’ of menthol cigarette smokers affected by withdrawal symptoms” and due to the black market and smuggling that would have developed “to supply the needs of menthol cigarette smokers”).

281. *See id.* ¶¶ 227, 233 (emphasis added). In *US—Tuna II (Mexico)*, the Appellate Body found that the Panel had “applied an incorrect approach to assessing whether the measure at issue [was] inconsistent with [TBT] Article 2.1” because it had failed to conduct an analysis of the design, architecture, revealing structure, operation, and application of the disputed DPCIA measure. *See US — Tuna Appellate Body Report, supra* note 156, ¶¶ 225–27, WT/DS381/AB/R (May 16, 2012). Such an analysis would have revealed that regulatory distinctions based on different “fishing methods” or “geographical location,” as well as “national origin” per se, *can* “be relevant in assessing the consistency” of the disputed DPCIA measure with Article 2.1. *See id.* ¶ 225. The Appellate Body reasoned that the Panel should have considered, *inter alia*, whether the disputed DPCIA measure had the effect of exerting pressure on Mexico to modify its fishing practices, although, “[t]his alone . . . would not be sufficient to establish a breach of Article 2.1.” *See id.* ¶ 226.

3. Is the Disputed Technical Regulation Inconsistent with TBT Article 2.2 Because It Imposes an Unnecessary Obstacle to Trade That Is More Trade-Restrictive Than Necessary to Fulfill a Legitimate Objective Considering the Risks Non-Fulfillment Would Create?

TBT Article 2.2 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.²⁸²

The first sentence of Article 2.2 reflects the general principle set forth within both the TBT Agreement Preamble's fifth recital and TBT Article 2.5, namely the "desire" that technical regulations "*not create unnecessary obstacles to trade.*"²⁸³ The second sentence of Article 2.2 sets forth an "obligation" to fulfill the general principle contained in the first sentence of Article 2.2.²⁸⁴ This obligation consists of several elements that raise a number of questions, which will be addressed below.²⁸⁵

a. Is the Disputed Technical Regulation "Trade-Restrictive"?

GATT 1994 jurisprudence reflects that the term "restriction" entails some kind of "limitation on action or a limiting condition or regulation," and that the term "restrictive" implies some kind of impact of a measure on the "competitive opportunities available to imported products" rather than on the "trade" of imports.²⁸⁶ The

282. TBT Agreement, *supra* note 5, art. 2.2 (first emphasis added).

283. *See* US — COOL Panel Report, *supra* note 151, ¶ 7.551 (emphasis added).

284. *See id.* ¶ 7.552.

285. *See id.* ¶¶ 7.554–7.557.

286. *Id.* ¶¶ 7.570–7.572 (citing Panel Report, *India — Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, ¶ 5.128, WT/DS90/R (Apr. 6, 1999)); *see also* Panel Report, *India — Measures Affecting the Automotive*

Panel in *US—COOL* found that the term “trade-restrictive” was sufficiently broad in scope and that its focus for purposes of TBT Article 2.2 should similarly be on “the competitive opportunities available to imported products” rather than on “the demonstration of any *actual* trade effects.”²⁸⁷ Because the COOL regulation was shown by complainants to have “affect[ed] the competitive conditions of imported livestock,” the *US—COOL* Panel concluded that the measure was “trade-restrictive” within the meaning of TBT Article 2.2. The Panel arrived at this conclusion without rendering a finding as to the “level” of trade-restrictiveness.²⁸⁸

The Appellate Body in *US—Tuna II (Mexico)* and *US—COOL*, however, observed that “[a]s used in Article 2.2 in conjunction with the word ‘trade’, [‘trade-restrictive’] means something having a limiting *effect* on trade.”²⁸⁹ The Appellate Body also found “that the reference in Article 2.2 to ‘unnecessary obstacles’ implies that ‘some’ trade-restrictiveness is allowed”²⁹⁰ The Appellate Body in *US—Clove Cigarettes* adopted a similar approach to evaluating whether product distinctions established exclusively by a challenged technical regulation can be deemed to provide less favorable treatment to “like” products in violation of Article 2.1.²⁹¹ Because it is in the nature of technical regulations both to establish product distinctions based on their characteristics or PPMs²⁹² and to have effects on trade, the Appellate Body apparently concluded that not all distinctions and/or trade restrictions will be deemed to violate TBT Articles 2.1 and 2.2.²⁹³

Sector, ¶ 7.269-7.270, WT/DS146/R (Dec. 21, 2001); Panel Report, *Colombia — Indicative Prices and Restrictions on Ports of Entry*, ¶¶ 7.236, 7.241, WT/DS366/R (Apr. 27, 2009); Panel Report, *Argentina — Measures Affecting the Export of Bovine Hides and the Import of Finished Leather*, ¶ 11.20, WT/DS155/R (Dec. 19, 2000).

287. See *US — COOL* Panel Report, *supra* note 151, ¶ 7.572 (emphasis added).

288. See *id.* ¶ 7.575.

289. *US — Tuna* Appellate Body Report, *supra* note 156, ¶¶ 319; see *US — COOL* Appellate Body Report, *supra* note 156, ¶ 375.

290. *US — COOL* Appellate Body Report, *supra* note 156, ¶ 375.

291. See *US — Clove Cigarettes* Appellate Body Report, *supra* note 15, ¶ 169.

292. See TBT Agreement, *supra* note 5, Annex 1.1; *US — COOL* Appellate Body Report, *supra* note 156, ¶ 268.

293. See *US — COOL* Appellate Body Report, *supra* note 156, ¶ 268.

b. *Does the Technical Regulation Pursue a “Legitimate” Objective?*

The *objective* of a technical regulation is distinguishable from the technical regulation itself, “including the alleged intent behind the enactment of the particular technical regulation,” since “it is the objective that leads to a Member’s determination to adopt a technical regulation” and it is typically the objective that precedes the establishment of the regulation to be adopted or maintained.²⁹⁴ TBT Article 2.3 confirms this distinction by providing that “[t]echnical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.”²⁹⁵ This means that “‘circumstances’ or ‘objective(s)’ are not identical to technical regulations and logically precede the adoption of technical regulations.”²⁹⁶ Furthermore, the TBT Agreement Preamble’s sixth recital not only explicitly recognizes every Member’s “right to regulate in order to pursue certain *legitimate* objectives,”²⁹⁷ but also “acknowledges the right of every WTO Member to establish for itself the objectives of its technical regulations.”²⁹⁸

TBT Article 2.2 requires that complaining Members identify the objective pursued by the government sponsor of a disputed technical regulation on the basis of information they obtain prior to or during the dispute settlement proceeding.²⁹⁹ The Appellate Body has noted that the “*TBT Agreement* affords a complainant adequate opportunities to obtain information about the objectives of technical regulations or the specific considerations that may be relevant to the assessment of their appropriateness.”³⁰⁰ Typically, the objective of a disputed technical regulation can be identified in the “notification” that a Member submitted to the WTO TBT

294. US — COOL Panel Report, *supra* note 151, ¶¶ 7.597–7.599, 7.602, 7.609, 7.615, 7.617 (emphasis added).

295. TBT Agreement, *supra* note 5, art. 2.3 (emphasis added).

296. US — COOL Panel Report, *supra* note 151, ¶¶ 7.598–7.599.

297. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶¶ 94–95 (emphasis added).

298. US — COOL Panel Report, *supra* note 151, ¶ 7.584.

299. *See id.* ¶ 7.592.

300. *Id.* ¶ 7.593 (quoting EC — Sardines Appellate Body Report, *supra* note 162, ¶ 277).

Committee pursuant to TBT Article 2.9, which enjoys a rebuttable presumption of truthfulness and good faith consistent with international law.³⁰¹

i. Is the Identified Objective Indeed the Objective of the Regulation?

To discern whether a technical regulation's stated objective is, indeed, the regulation's actual objective, it is necessary to evaluate the regulation's text as well as its design, architecture, and structure. In addition, the significance of statements made by various legislators during the legislative process surrounding a disputed measure may also be evaluated, although the Appellate Body has deemed such an inquiry unnecessary and unadvisable given the difficulties of ascertaining and second-guessing the intent behind a measure that has multiple objectives.³⁰²

Although the Panel in *US—COOL* found that the COOL measure did not expressly state its objective, the Panel nevertheless concluded that said measure's objective was to provide consumer information on origin, as the United States had declared, because it was "devoted exclusively to the labelling requirements on origin."³⁰³ When reviewing COOL's design and structure, the Panel noted its broad scope and product coverage.³⁰⁴ It also observed that the measure's incorporation of exclusions for certain domestically produced food products and commodity ingredients, as well as small domestically located retail establishments and sales entities, was neither unusual nor exceptional, as such exceptions "might be justifiable for practical reasons and simply facilitate [its] implementation."³⁰⁵ Furthermore, after having examined all of the evidence proffered by the parties concerning statements made by individual legislators, some of which revealed protectionist sentiments, the Panel concluded that, on

301. See TBT Agreement, *supra* note 5, arts. 2.9.1–2.9.2; US — COOL Panel Report, *supra* note 151, ¶¶ 7.605–7.606.

302. See US — COOL Panel Report, *supra* note 151, ¶ 7.686 (citing Appellate Body Report, *Japan — Taxes on Alcoholic Beverages*, ¶¶ 27–28, WT/DS8/AB/R (Oct. 4, 1996)); see also Appellate Body Report, *Chile — Taxes on Alcoholic Beverages*, ¶ 62, WT/DS87/AB/R (Dec. 13, 1999).

303. See US — COOL Panel Report, *supra* note 151, ¶¶ 7.680, 7.685.

304. See *id.* ¶ 7.684.

305. See *id.* (noting that complainants had alleged that such domestic exceptions reflected a trade protectionist intent).

balance, that evidence wasn't helpful to its inquiry into the objective of the COOL measure.³⁰⁶

ii. How Can a Member Determine Whether the Regulation's Objective Is "Legitimate"?

"[T]he legitimacy of a given objective must be found in the 'genuine nature' of the objective, which is 'justifiable' and 'supported by relevant public policies or other social norms.'"³⁰⁷ A complaining WTO Member bears the burden of establishing that the objective of a disputed regulation is *not* legitimate within the meaning of Article 2.2.³⁰⁸ TBT Article 2.2 sets forth a non-exclusive open list of legitimate objectives, which include, 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.³⁰⁹ This indicates that a wide range of objectives could potentially fall within the scope of legitimate objectives under Article 2.2 and that "a policy objective pursued by a technical regulation [need not] be specifically linked in nature to those objectives explicitly listed in Article 2.2."³¹⁰

Although "consumer information" is not expressly listed as a "legitimate objective" in the text of Article 2.2, the Panel in *US—COOL* determined that "consumers generally are interested in having information on the origin of the products they purchase" and that, consequently, "providing consumer information on origin is a legitimate objective within the meaning of Article 2.2."³¹¹ It found that many WTO Members, including the complainants and third-party amici, had "maintain[ed] some form of mandatory country of

306. *See id.* ¶¶ 7.686–7.691 (arriving at this conclusion, in part, because the legislation was enacted for a variety of purposes and because the panel was not in a position to second-guess legislative intent).

307. *Id.* ¶ 7.632 (second emphasis added).

308. *See id.* ¶¶ 7.629–7.631 (highlighting that, under the ordinary meaning of the term "legitimate," a measure's objective will generally be deemed legitimate if it is "conformable to law or principle," "justifiable and proper," or "conformable to a recognized standard type").

309. *See id.* ¶¶ 7.632–7.634.

310. *See id.* ¶¶ 7.634, 7.637 ("[T]o [have] conclude[d] that consumer information and preventing consumer confusion [were] not legitimate objectives would [have] suggest[ed] that none of these regimes was adopted to achieve a legitimate objective.").

311. *Id.* ¶¶ 7.650–7.651.

origin labelling for food and other products intended for human consumption” that “apply to food products at the retail level.”³¹² This “suggest[ed] that consumer information on country of origin [was] considered by a considerable proportion of the WTO Membership to be a legitimate objective under the TBT Agreement.”³¹³

The Panel also recognized that “Members have certain policy space in determining their objectives” and “may decide to adopt particular regulations even in the absence of a specific demand from their citizens, *and may do so without in fact shaping consumer expectations through regulatory intervention.*”³¹⁴ In response to Canada’s subsequent appeal of this determination,³¹⁵ the Appellate Body found that “the objective of providing consumers with information on origin as related to the objective of preventing deceptive practices” was not improperly linked to “the objective of consumer protection” because, in its view, “providing accurate and reliable information may protect consumers from being misled or misinformed.”³¹⁶ Consequently, the Appellate Body upheld the *US—COOL* Panel’s finding that the COOL labeling measure’s objective of providing information to consumers about where livestock were born, raised, and slaughtered was a legitimate objective within the meaning of TBT Article 2.2.³¹⁷

c. Does the Technical Regulation Fulfill the Identified Objective(s)?

The ordinary meaning of the word “fulfill” governs the analysis of whether the requirements of TBT Article 2.2 have been satisfied. It means that a measure must “carry out and perform” its underlying

312. *Id.* ¶ 7.637.

313. *Id.* ¶ 7.638.

314. *Id.* ¶ 7.649 (emphasis added). Apparently, the Panel, in considering evidence demonstrating that there had been consumer demand for and support of the COOL program incident to the legislative and administrative rule-making processes, acknowledged the risk that Members could also use such processes to shape consumer expectations. “Members, by shaping consumer expectations through regulatory intervention in the market, would be able to justify thereafter the legitimacy of that very same regulatory intervention on the basis of the governmentally created consumer expectations.” *Id.* ¶¶ 7.643–7.647 (citing EC — Sardines Appellate Body Report, *supra* note 162, ¶ 7.127).

315. *See* US — COOL Appellate Body Report, *supra* note 156, ¶¶ 443–48.

316. *Id.* ¶ 451.

317. *See id.* ¶ 453.

objective.³¹⁸ The Appellate Body previously construed the term “fulfill” in the context of GATT Article XX(b) to mean simply that “a measure makes a contribution to the objective pursued” and has “considered that a contribution exists when there is a genuine relationship of ends and means between the objective pursued and the measure at issue.”³¹⁹ This interpretation was adopted by the US—COOL Panel for purposes of TBT Article 2.2.³²⁰ The Appellate Body has since clarified the meaning of the term “fulfill” in *US—Tuna II (Mexico)* and *US—COOL*. According to the Appellate Body, the determination of whether a measure “fulfills” its objective under Article 2.2 does not necessitate a finding that the measure “must meet some minimum threshold of fulfillment.”³²¹ Rather, such a determination “is concerned with *the degree of contribution* that the technical regulation makes towards the achievement of the legitimate objective,” which “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.”³²²

In *US—COOL*, the Appellate Body concluded that, although the COOL measure did not completely satisfy the identified objective because its complex and confusing design and operation may have actually served to undermine that objective in some instances,³²³ the

318. See *US — COOL Panel Report*, *supra* note 151, ¶ 7.692.

319. *Id.* ¶ 7.693 (emphasis added).

320. *Id.* ¶¶ 7.692–7.693 (noting, however, that panels are not required to apply a specific methodology when assessing whether a measure contributes to an objective).

321. See *US — COOL Appellate Body Report*, *supra* note 156, ¶ 461.

322. *Id.* (emphasis added).

323. See *US — COOL Panel Report*, *supra* note 151, ¶ 7.695. The *US—COOL* Panel found that since the COOL regulation failed to convey meaningful origin information to consumers with respect to muscle meat products, the COOL labeling measure did not fulfill the underlying regulation’s identified objective, within the meaning of Article 2.2. See *id.* ¶¶ 7.719–7.720. “[The Panel found that] the different and complex categories of labels under the COOL measure and the operation of the COOL regime based on the commingling provisions render[ed] the origin information contained in [the ‘B’ and ‘C’] labels inaccurate and confusing.” *Id.* ¶¶ 7.713–7.715. While the “B” and “C” labels may have provided consumers with *more* information about country of origin of meat products than they had received previously under the pre-COOL regulatory regime, it did not help to provide as much *clear and accurate* meat origin information as possible. See *id.* ¶ 7.715. The complex and confusing design may have actually undermined COOL’s stated objective. For example, the different “B” and “C” categories of COOL labels for beef, lamb, and pork muscle cuts were found to be confusing and

measure did contribute to the overall objective of providing consumer information about the countries where the livestock from which meat was produced was born, raised, and slaughtered.³²⁴ Because the Panel had not focused “on ascertaining the degree of contribution achieved by the [COOL] measure,” and had ignored its own findings in concluding that the COOL measure did not fulfill its objective, the Appellate Body in *US—COOL* held that the Panel erred both “in its interpretation of Article 2.2” and “in its analysis under Article 2.2,” and reversed the Panel’s finding on this issue.³²⁵

In *US—Tuna II (Mexico)*, the Panel found that the design and operation of the U.S. Dolphin Protection Consumer Information Act’s (“DPCIA”) “dolphin-safe” labeling provisions could potentially undermine their policy objective.³²⁶ For example, the labeling measure failed to ensure against the U.S. market being used to encourage fishing techniques that adversely affected dolphins *outside* the Eastern Tropical Pacific (“ETP”), as labels could be

to not clearly convey the actual country of origin of the meat product as required under the COOL regulation. A label stating “Product of the US, Mexico” did not describe what “the US and Mexico” means as far as origin of the meat was concerned. The origin labels referred to and were differentiated based on information about the places where animals from which meat was derived were born, raised, and slaughtered. A meat product falling within the scope of categories “B” and “C” was required to carry a “B” or “C” label that indicated multiple countries of origin. The order in which the country name appeared on the label was determined by whether animals were raised in the United States (Label “B”) or whether they were imported right before slaughter (Label “C”). *See id.* ¶¶ 7.697–7.702. Furthermore, the Label “B” and “C” descriptions of origin did not deliver origin information as prescribed by the measure or as consumers would understand it, because the final federal regulations (the 2009 Final Rule (AMS)) had permitted the interchangeable use of labels “B” and “C” for commingled categories of meat. If commingling were to take place at multiple stages of the meat production process (e.g., at the processing packing and/or retail levels), the resulting labels affixed to these products would be even less accurate in terms of the origin of such products as defined by the COOL regulation. *See id.* ¶¶ 7.702–7.704. Although the *US—COOL* Panel recognized that these COOL regulation flexibilities reflected the U.S. government’s effort to strike a balance between industry cost and consumer information concerns, it found that such implementation actually served to *undermine* the regulation’s legitimate objective. *See id.* ¶¶ 7.704, 7.711.

324. *See US — COOL Appellate Body Report, supra* note 156, ¶ 466 (holding that, for the COOL labeling requirement to fulfill the regulation’s overall objective, it would have to be capable of conveying clear and accurate information on origin).

325. *See id.* ¶ 468.

326. *See US — Tuna Panel Report, supra* note 154, ¶ 7.599.

affixed to tuna caught pursuant to methods other than “setting on dolphins”³²⁷ *outside* the ETP without a certification indicating that a dolphin may have been killed or seriously injured in the process.³²⁸ In addition, the labeling regulation could possibly encourage fishing fleets to secure access to U.S. markets by refocusing more of their future activities *outside* the ETP, where they would not be monitored to avoid the regulation’s restrictions altogether.³²⁹

However, the Panel also found that the DPCIA’s “dolphin-safe” labeling provisions were “capable of protecting dolphins by ensuring that the US market [was] not used to encourage fishing practices that may kill or seriously injure dolphins *only within* the ETP.”³³⁰ Consequently, the Panel concluded that the DPCIA “dolphin-safe” labeling provisions, as well as related “dolphin-protection” provisions,³³¹ were *at least partially* able to fulfill their stated objective “of ensuring that consumers [were] not misled about whether tuna was harvested by a method that adversely affects dolphins.”³³² The Appellate Body did not dispute these findings because they apparently reflected the degree, however minimal, to which the disputed measures contributed to their underlying objective.³³³

327. “[T]he fishing technique known as setting on dolphins [entails] intentional deployment on or encirclement of dolphins with purse seine nets.” *Id.* ¶ 2.3 n.2 (referencing 16 U.S.C. § 1385(g)(1) (2009)); *see also* Dolphin-safe Labeling Standards, 50 C.F.R. § 216.91 (2009). In other words, “setting on dolphins” entails the “chasing and encircling [of] dolphins with a net in order to catch the tuna associating with them.” WTO Dispute Settlement, *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, ¶ 172 n.355, DS381 (June 13, 2012); *see also* NOAA Form 370, *Fisheries Certificate of Origin*, <http://swr.nmfs.noaa.gov/psd/noaa370.pdf> (last visited Oct. 30, 2012) (“Section 5.B.2: DOLPHIN SAFE STATUS . . . *Tuna harvested using a purse seine net outside the Eastern Tropical Pacific Ocean (ETP), with valid documentation by the captain of the vessel certifying that no purse seine net was intentionally deployed on or to encircle dolphins during the fishing trip.*” (emphasis added)).

328. *See* US — Tuna Panel Report, *supra* note 154, ¶ 7.597.

329. *See id.* ¶ 7.598 (finding that the measure permitted the “dolphin-safe” labeling of tuna caught by techniques adversely affecting dolphins *outside* the ETP while it simultaneously prohibited their use pursuant to the controlled conditions of the AIDCP [Agreement on the International Dolphin Conservation Program] *inside* the ETP).

330. *See id.* ¶ 7.599 (emphasis added).

331. *See id.* ¶¶ 7.590–7.592, 7.599 (noting that the success of dolphin-protection provisions were dependent upon dolphin-safe provisions).

332. *See* US — Tuna Panel Report, *supra* note 154, ¶ 7.592.

333. *See* US — Tuna Appellate Body Report, *supra* note 156, ¶ 329.

d. *Is the Technical Regulation More Trade-Restrictive Than Necessary to Fulfill the Objective(s) Concerned?*

The question of whether a *measure* is more trade-restrictive than “necessary” was previously addressed by the Appellate Body in the context of GATT 1994 Articles XX(b) and XI:2(a). In *Korea—Various Measures on Beef*,³³⁴ the Appellate Body analyzed the trade restrictiveness of *the challenged measure* in the context of GATT Article XX and concluded that “the word ‘necessary’ refers . . . to a range of degrees of necessity,” depending on the connection in which it is used.³³⁵ “At one end of this continuum lies ‘necessary’ understood as ‘indispensable’; at the other end, is ‘necessary’ taken to mean as ‘making a contribution to.’”³³⁶ In *China—Publications and Audiovisual Products*,³³⁷ the Appellate Body similarly analyzed the “trade-restrictiveness” of *the challenged measure* in terms of “necessity” in the context of Articles XI:2(a) and XX(b).³³⁸ In citing its prior analysis in *Brazil—Retreaded Tyres*,³³⁹ the Appellate Body observed that *the “necessity” of a measure* depends on “the importance of the interests or values at stake, the extent of the contribution made by the measure to the achievement of the relevant objective, the measure’s trade restrictiveness,” and the availability of “possible alternatives” with which the measure can be compared “in the light of the importance of the interests or values at stake.”³⁴⁰

The *US—Tuna II (Mexico)* Panel found this analysis helpful but concluded that it did not reflect the different context of TBT Article

334. See *Korea — Beef Appellate Body Report*, *supra* note 267.

335. *Id.* ¶ 161.

336. *Id.*

337. Appellate Body Report, *China — Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, WT/DS363/AB/R (Dec. 21, 2009) [hereinafter *China — Publications & Audiovisual Products Appellate Body Report*].

338. See *China — Publications & Audiovisual Products Appellate Body Report*, *supra* note 337, ¶¶ 241–42; Panel Report, *Brazil — Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (Dec. 3, 2007) [hereinafter *Brazil — Retreaded Tyres Panel Report*].

339. *China — Publications & Audiovisual Products Appellate Body Report*, *supra* note 337, ¶ 241 (citing *Brazil — Retreaded Tyres Panel Report*, *supra* note 338, ¶ 178).

340. *China — Publications & Audiovisual Products Appellate Body Report*, *supra* note 337, ¶ 241.

2.2. In the Panel's view, "the aspect of the measure to be justified as 'necessary' [in the context of TBT Article 2.2] is its *trade restrictiveness* rather than the necessity of the measure [itself] for the achievement of the objective."³⁴¹ Stated differently, "an assessment of whether any trade-restrictiveness arising under [a given] measure[] . . . is 'necessary' within the meaning of Article 2.2 must be understood as an enquiry into *whether such trade-restrictiveness is required* to fulfill the legitimate objectives pursued by the Member *at its chosen level of protection*."³⁴²

The Appellate Body in *US—Tuna II (Mexico)* concurred with and further refined the Panel's analysis.

In the context of Article 2.2, the assessment of "necessity" involves a relational analysis of the trade-restrictiveness of the technical regulation, the degree of contribution that it makes to the achievement of a legitimate objective, and the risks non-fulfilment would create. [A]ll [of] these factors provide the basis for the determination of what is to be considered "necessary" in the sense of Article 2.2 in a particular case.³⁴³

Thus, in its view, "Article 2.2 does not prohibit measures that have *any trade-restrictive effect*"; rather, "Article 2.2 is . . . concerned with restrictions on international trade that exceed what is necessary to achieve the degree of contribution that a technical regulation makes to the achievement of a legitimate objective."³⁴⁴

i. Is There a Less Trade-Restrictive Alternative Available?

To determine whether a disputed measure's "trade-restrictiveness" is required to fulfill the measure's legitimate objectives under TBT Article 2.2, it must be compared to other reasonably available alternatives. In this regard, the *US—Tuna II (Mexico)* Panel reasoned that, "[t]o the extent that a measure is capable of contributing to its objective, it would be more trade-restrictive than necessary if an alternative measure that is less trade-restrictive is reasonably available, that would achieve the challenged measure's objective *at the same level*."³⁴⁵ The complaining party bears the burden of

341. US — Tuna Panel Report, *supra* note 154, ¶ 7.460 (emphasis added).

342. *Id.* (first emphasis added).

343. US — Tuna Appellate Body Report, *supra* note 156, ¶ 318.

344. *Id.* ¶ 319 (emphasis added).

345. US — Tuna Panel Report, *supra* note 154, ¶ 7.465 (emphasis added).

identifying a reasonably available alternative that is capable of achieving the objective pursued by the disputed measure at the same level of protection, taking into account the risks non-fulfillment would create.³⁴⁶

The Appellate Body in *US—Tuna II (Mexico)* further refined this analysis. It explained that a number of factors must be evaluated to determine whether a technical regulation is “more trade-restrictive than necessary” within the meaning of Article 2.2. These factors 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 as well as the gravity of consequences that would arise from non-fulfillment of the objective pursued by the Member through the measure.³⁴⁷

The Appellate Body also stated that “[i]n most cases, a comparison of the challenged measure and possible alternative measures should [also] be undertaken.”³⁴⁸ According to the Appellate Body, such a comparison should consider whether the proposed alternative measure: a) is “less trade restrictive”; b) “would make an equivalent contribution to the relevant legitimate objective, taking account of the risks non-fulfillment would create”; and c) “is reasonably available.”³⁴⁹

ii. What Risks Are Engendered if the Available Less Trade-Restrictive Alternative Cannot Equally Fulfill the Identified Objectives?

When evaluating the trade-restrictiveness of a measure, “the risks that non-fulfillment would create” must also be taken into account.³⁵⁰ This means that a Panel must consider “the likelihood and the gravity of potential risks (and any associated adverse consequences) that might arise in the event the legitimate objective being pursued would

346. *See id.* ¶ 7.468.

347. US — Tuna Appellate Body Report, *supra* note 156, ¶ 322; *see* US — COOL Appellate Body Report, *supra* note 156, ¶ 471.

348. US — Tuna Appellate Body Report, *supra* note 156, ¶ 322.

349. *Id.*

350. *See* US — Tuna Panel Report, *supra* note 154, ¶ 7.466.

not be fulfilled.”³⁵¹ In assessing such risks, the second sentence of TBT Article 2.2 permits the use of “relevant . . . available scientific and technical information, related processing technology, or intended end-uses of products,” among other tools.³⁵² It also implies that “an alternative means of achieving the objective that would entail greater ‘risks of non-fulfilment’ would not be a valid alternative, even if it were less trade-restrictive,” as is consistent “with the fact that each Member is entitled, as expressed in the preamble of the TBT Agreement . . . to define its own level of protection.”³⁵³

In *US—Tuna II (Mexico)*, the only one of the three TBT cases to undertake this analysis,³⁵⁴ the Panel concluded that Mexico had identified a reasonably available alternative measure that did “not seem to create greater risks to dolphins *in* the ETP than those accepted by the United States under the challenged measures in relation to other fishing techniques used *outside* the ETP.”³⁵⁵ It also concluded that the alternative measure identified by Mexico “would achieve a level of protection equal to that achieved by the US dolphin-safe provisions *outside* the ETP, as currently applied.”³⁵⁶ The

351. *Id.* ¶ 7.467.

352. *Id.* ¶ 7.466.

353. *Id.* ¶ 7.467.

354. The Appellate Body in *US—COOL* was unable to complete this legal analysis for purposes of determining “whether the COOL measure [was] ‘more trade restrictive than necessary to fulfill its legitimate objective.’” *US — COOL* Appellate Body Report, *supra* note 156, ¶ 479. It reached this conclusion even though “the Panel’s factual findings suggest[ed] that the COOL measure ma[de] some contribution to the objective of providing consumers with information on origin[,] that it ha[d] a considerable degree of trade-restrictiveness[,] and that the consequences that may arise from non-fulfilment of the objective would not be particularly grave.” *Id.* In addition, although Canada and Mexico had proposed four alternative measures to the U.S. COOL measure, the Appellate Body found that the Panel had failed to make factual findings with regard to such labeling schemes and had “made only limited findings with respect to the COOL measure itself, in particular with respect to its degree of contribution to the United States’ objective.” *Id.* ¶¶ 480–81.

355. *US — Tuna* Panel Report, *supra* note 154, ¶ 7.618 (emphasis added).

356. *Id.* (emphasis added). In reaching these conclusions, the *US—Tuna II (Mexico)* Panel had taken into account “available scientific and technical information, related processing technology and the end-uses of tuna products.” *Id.* ¶ 7.619. For example, it found that Mexico’s suggested alternative measure would allow for the coexistence of the U.S. and the AIDCP dolphin-safe labels in the U.S. market and would aim to convey to consumers “more detailed information about the dolphin-safe implications of the fishing methods employed to catch the tuna

Appellate Body in *US—Tuna II (Mexico)*, however, determined that the Panel's analysis "was based, at least in part, on an improper comparison."³⁵⁷ It observed that, although the Panel referred to the proposed alternative measure identified by Mexico as the coexistence of the U.S. dolphin protection and consumer information measures and those of the Agreement on International Dolphin Conservation Program ("AIDCP"), the Panel actually compared the U.S. measures to the corresponding AIDCP measures.³⁵⁸

According to the Appellate Body, a proper comparison would have revealed that "there [was] no difference between the [U.S.] measure at issue and the alternative measure identified by Mexico" with respect to "the conditions for labeling as 'dolphin-safe' tuna products containing tuna harvested *outside* the ETP."³⁵⁹ Because the AIDCP conditions for fishing applied only *inside* the ETP, and the U.S. conditions for fishing applied only *outside* the ETP, it determined that the conditions for fishing *outside* the ETP were identical whether or not the proposed alternative measure was considered.³⁶⁰ A proper comparison would have also revealed that the U.S. measure and the alternative measure imposed different requirements with respect to conditions for fishing *inside* the ETP.³⁶¹ Under the proposed alternative measure, a "dolphin-safe" label could be affixed to tuna that had been caught in the ETP by "setting on dolphins" if it satisfied AIDCP label prerequisites.³⁶² By contrast, under the challenged U.S. measure, a "dolphin-safe" label could be affixed to tuna harvested inside the ETP only "if it was caught by methods other than 'setting on dolphins.'"³⁶³

The Appellate Body found that the Panel had failed to focus on the

contained in those products." *Id.* ¶ 7.607. The Panel also found that these features would likely bring certain benefits. *Id.* ¶¶ 7.609–7.610. Based on these findings, the Panel concluded that the U.S. DPCIA measures were inconsistent with TBT Article 2.2 because, in relation to their stated objective, and compared to the proposed alternative measure, they were more trade-restrictive than necessary to fulfill their legitimate objective, taking account of the risks non-fulfillment would create. *Id.* ¶ 7.620.

357. US — Tuna Appellate Body Report, *supra* note 156, ¶ 328.

358. *See id.*

359. *Id.* ¶ 329.

360. *See id.*

361. *See id.*

362. *See id.*

363. *Id.*

conditions *inside* the ETP when analyzing the extent of the contribution made by the proposed alternative measure to U.S. objectives, and to examine whether AIDCP label-compliant tuna products could achieve U.S. objectives *within* the ETP “to an equivalent degree” as the challenged U.S. measure.³⁶⁴ Ultimately, the Appellate Body concluded that the proposed alternative measure contributed to the U.S. measure’s consumer-information and dolphin-protection objectives “to a lesser degree than the [U.S.] measure at issue, because, overall, it would allow more tuna harvested in conditions that adversely affect dolphins to be labelled ‘dolphin-safe.’”³⁶⁵ Consequently, the Appellate Body held that the Panel had erred in determining that the U.S. measure was “more trade restrictive than necessary to fulfill [its] legitimate objectives, taking account of the risks non-fulfilment would create,” and it reversed the Panel’s ruling that the U.S. measure was inconsistent with Article 2.2.³⁶⁶

4. Did the Technical Regulation’s Sponsor Fail to Take into Account Developing Country Needs When Preparing and Applying Such Measures, With a View to Ensuring That No Unnecessary Obstacles to Trade Were Created Within the Meaning of TBT Article 12.3?

TBT Article 12.3 provides:

Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.³⁶⁷

Article 12.3 comprises part of TBT Article 12 (Special and Differential Treatment of Developing Country Members) and serves to implement the general obligation of WTO Members contained within Article 12.1 “to provide differential and more favourable

364. *See id.* ¶ 330.

365. *Id.*

366. *Id.* ¶ 331.

367. TBT Agreement, *supra* note 5, art. 12.3.

treatment to developing country Members to this Agreement”³⁶⁸

a. *Developing Country “Special and Differential Needs” Three-Part Test*

The Panel in *US—Clove Cigarettes* stated:

The wording of Article 12.3 of the TBT Agreement . . . require[s] . . . that three elements must be demonstrated in order to establish a violation of the obligation set forth in [TBT Article 12.3] [The complaining WTO Member] must demonstrate that: (a) [The complaining WTO Member] is a “developing country”; (b) [The complaining WTO Member] has “special development, financial and trade needs” that are affected by [the disputed measure]; and (c) [The regulating WTO Member] failed to “take account of” [the complaining WTO Member’s] special financial, development and trade needs.³⁶⁹

Consistent with prior WTO jurisprudence, “the complainant bringing a claim under Article 12.3 . . . bears the initial burden to make a prima facie case that the [regulating WTO Member] did not ‘take account of [the complainant’s] special development, financial and trade needs’ ‘in the preparation and application of’ [the technical regulation at issue].”³⁷⁰

The first element of a TBT Article 12.3 claim can be satisfied by demonstrating that “the World Bank classifies [the complainant] as a developing country and that its status as a developing country Member of the WTO [has been] recognized.”³⁷¹ A complainant can

368. *Id.* art. 12.1.

369. *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶ 7.620; *see, e.g.*, *US — COOL Appellate Body Report*, *supra* note 156, ¶ 7.746 (noting that the United States argued that Mexico must demonstrate these factors under Article 12.3 of the TBT Agreement).

370. *US — COOL Appellate Body Report*, *supra* note 156, ¶ 7.774; *see US — Clove Cigarettes Panel Report*, *supra* note 151, ¶ 7.620.

371. *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶¶ 7.623–7.624. For example, the World Bank, which classifies economies into several groupings by reference to gross national income (“GNI”) per capita (i.e., into “low income,” “middle income” (subdivided into lower-middle and upper-middle), or “high income”), acknowledges that “[l]ow-income and middle-income economies are sometimes referred to as developing economies.” *See How We Classify Countries*, WORLD BANK, <http://data.worldbank.org/about/country-classifications> (last visited Oct. 30, 2012). The WTO, meanwhile, “recognizes as least-developed countries (LDCs) those countries which have been designated as such by the United Nations.” *Least-Developed Countries*, WTO, <http://www.wto.org/english/>

satisfy the second element by “explaining the importance” of the products affected by the technical regulation at issue to its economy in terms of GDP, trade flows, employment, and manufacturing.³⁷²

Panels have interpreted the third element of TBT Article 12.3 as imposing only *one* obligation: that Members “take into account” the special development, financial, and trade needs of developing country Members when preparing and applying technical regulations, standards, and conformity-assessment procedures.³⁷³ Prior WTO jurisprudence reflects that the phrase “take account of” “does *not* amount to a requirement for WTO Members to conform their actions to the special needs of developing countries, but merely *to give consideration to* such needs along with other factors before reaching a decision.”³⁷⁴ The phrase “take account of” does not require WTO Members to “document specifically in their legislative process and rule-making process how they actively considered the special development, financial and trade needs of developing country Members.”³⁷⁵ Nor does it specifically require WTO Members to “initiate such consultation.”³⁷⁶

In *US—COOL*, the Panel ruled that the United States did not have

[thewto_e/whatis_e/tif_e/org7_e.htm](#) (last visited Oct. 30, 2012).

372. See, e.g., *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶¶ 7.628–7.629 (noting that Indonesia satisfied the requirement of demonstrating that it “has ‘special development, financial and trade needs’ that are affected by the technical regulation at issue” by estimating the number of citizens employed in the clove cigarette industry, the portion of gross domestic product accounted for by glove cigarette production, and its long history of exporting clove cigarettes to the United States).

373. See *US — COOL Appellate Body Report*, *supra* note 156, ¶ 7.762; *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶¶ 7.615–7.617. Accordingly, the phrase “with a view to” relates to the assessment that must be undertaken to determine whether a WTO Member has met this obligation. Such an assessment requires consideration of the Member’s relevant actions or inactions with respect to the disputed measure, to confirm whether they were fulfilled or carried out with the objective of ensuring that technical regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members. See *US — COOL Appellate Body Report*, *supra* note 156, ¶ 7.746.

374. *US — COOL Panel Report*, *supra* note 151, ¶ 7.781 (emphasis added) (citing Panel Report, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, ¶¶ 7.1620–7.1621, WT/DS291/R (Sept. 29, 2006)); see *US — Clove Cigarettes Panel Report*, *supra* note 151, ¶ 7.646.

375. *US — COOL Appellate Body Report*, *supra* note 156, ¶ 7.787.

376. *Id.* ¶ 7.796.

any explicit affirmative obligation, “enforceable in WTO dispute settlement, to reach out and collect Mexico’s views during the preparation and application of the COOL Measure.”³⁷⁷ Rather, the United States was merely required to give active and meaningful consideration to “Mexico’s special development, financial and trade needs’ in the preparation and application of the COOL measure.”³⁷⁸ The *US—COOL* Panel further concluded that Mexico was unable to demonstrate that the United States had failed to satisfy this obligation.³⁷⁹ In particular, the undisputed evidence revealed that the United States had actively reached out to Mexico on the following occasions: 1) at four or more opportunities during the development of the COOL measure, where interested parties and stakeholders were invited to submit formal comments on the COOL; 2) at a USDA briefing for embassy officials on one of the interim final³⁸⁰ USDA Agricultural Marketing Service (“AMS”)³⁸¹ rules; 3) at a meeting between the AMS administrator and Mexican Embassy officials scheduled to discuss COOL rulemaking; and 4) at meetings of the United States–Mexico Consultative Committee on Agriculture chaired by USDA and USTR officials to discuss COOL rulemaking.³⁸²

In addition, the undisputed evidence also revealed that: 1) Mexico had submitted comments on key elements of the COOL measure on several occasions in the context of such consultations, and Mexico’s Secretary of Agriculture had received correspondence from the USDA Undersecretary confirming its comments had been received

377. *Id.* ¶ 7.790.

378. *Id.* (internal marks omitted).

379. *See id.* ¶ 7.791.

380. *See* OFFICE OF THE FED. REGISTER, A GUIDE TO THE RULEMAKING PROCESS 9 (last visited Oct. 30, 2012), *available at* http://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf (“Interim Final Rule: When an agency finds that it has good cause to issue a final rule without first publishing a proposed rule, it often characterizes the rule as a ‘interim final rule’ or ‘interim rule’. This type of rule becomes effective immediately upon publication. In most cases, the agency stipulates that it will alter the interim rule if warranted by public comments. If the agency decides not to make changes to the interim rule it generally will publish a brief final rule in the Federal Register confirming that decision.”).

381. *See supra* note 171 and accompanying text.

382. *See* US — COOL Appellate Body Report, *supra* note 156, ¶ 7.792.

and would be “fully considered” in the development of a final rule;³⁸³ 2) the USDA Secretary dispatched a letter to the Secretary of the Mexican Association of Secretaries of Rural Development requesting additional input or comments on the COOL rulemaking as part of the Canada–Mexico Working Group;³⁸⁴ 3) the United States modified the COOL measure by softening its record-keeping requirements and introducing commingling flexibilities, in response to concerns expressed by Mexico;³⁸⁵ and 4) the United States had extended invitations for public comments on proposed, interim, and interim final COOL rules between 2003 and 2008.³⁸⁶ Consequently, the *US—COOL* Panel ultimately held that Mexico was unable to demonstrate that the United States had failed to “take account of [Mexico’s] special development, financial and trade needs” when preparing and applying the COOL regulation, within the meaning of TBT Article 12.3.³⁸⁷

In *US—Clove Cigarettes*, the Panel held that “Indonesia [had been unable to] demonstrate[] that the United States failed to ‘take account of’ Indonesia’s special financial, trade and development needs” when preparing and applying the clove cigarette ban.³⁸⁸ The undisputed evidence revealed: 1) a 2007 correspondence from the Indonesian Trade Minister to the U.S. Trade Representative expressing concern that the proposed U.S. legislation would significantly affect Indonesian clove cigarette exports if not adequately amended, and acknowledging a U.S. Senator’s efforts to address those concerns;³⁸⁹ 2) a 2008 correspondence from the U.S. Secretary of Health and Human Services to the Ranking Member of the House Committee on Energy and Commerce recognizing the potential inconsistency of the draft legislation with U.S. trade obligations;³⁹⁰ 3) a 2008 correspondence between the Chairmen of the House Committees on Energy and Commerce and Ways and Means reflecting recognition

383. *See id.* ¶ 7.793.

384. *See id.*

385. *See id.* ¶ 7.794.

386. *See id.* ¶ 7.795.

387. *Id.* ¶ 7.799. Moreover, since Mexico had not established a violation of TBT Article 12.3, the Panel also held that Mexico had failed to demonstrate a violation of TBT Article 12.1, as well. *Id.* ¶ 7.803.

388. *US — Clove Cigarettes* Panel Report, *supra* note 151, ¶ 7.648.

389. *See id.* ¶ 7.636.

390. *See id.* ¶ 7.637.

that the proposed ban had triggered trade concerns;³⁹¹ 4) a U.S. Presidential Statement of Administrative Policy indicating that the U.S. administration had serious trade concerns about the proposed ban;³⁹² 5) two 2009 correspondences between the Chairmen of the House Committees on Ways and Means and Energy and Commerce, noting the jurisdiction of the latter committee over the subject matter of the proposed import ban;³⁹³ and 6) a 2009 correspondence from the Indonesian Ambassador to the U.S. Senate Majority Leader noting one senator's proposed language amendment considered by Indonesia as appropriate to address their trade concerns with the proposed import ban.³⁹⁴ In addition, the undisputed evidence also revealed that Indonesian officials had participated in several high-level meetings with U.S. officials.³⁹⁵

The *US—Clove Cigarettes* Panel found that these multiple “exchanges” “demonstrate[d] that Indonesia’s concerns [had been] ‘taken into account’ by the United States,” even though “the United States ultimately decided not to exclude clove cigarettes from the scope of the ban”³⁹⁶ Consequently, the Panel ultimately held that Indonesia was unable to demonstrate that the United States had failed to “take account of the special development, financial and trade needs of Indonesia, in the preparation and application of” the clove cigarette ban, within the meaning of TBT Article 12.3.³⁹⁷

IV. A FRAMEWORK FOR EVALUATING WHETHER THE EU REACH REGULATION IS A NON-TARIFF BARRIER TO TRADE

This section sets forth an analytical framework based on the prior section’s discussion of recent WTO TBT jurisprudence. It may be helpful in analyzing anecdotal evidence gathered about the design, structure, and operation of the EU REACH regulation’s

391. *See id.* ¶ 7.638.

392. *See id.* ¶ 7.639.

393. *See id.* ¶¶ 7.640–7.641.

394. *See id.* ¶ 7.642.

395. *See id.* ¶ 7.644.

396. *Id.* ¶¶ 7.645–7.646. In other words, “Indonesia ha[d] failed to demonstrate that the United States acted inconsistently with Article 12.3 of the *TBT Agreement*.” *Id.* ¶ 7.649.

397. *Id.* ¶ 7.649.

registration/data-gathering and notification provisions and their actual trade effects, for purposes of evaluating: 1) whether REACH discriminates against or provides “less favorable treatment” to “like” non-EU chemicals-based products and 2) whether REACH otherwise imposes unnecessary obstacles to trade upon non-EU chemicals-based substances, mixtures, or articles such that it restricts trade in imports more than is necessary to achieve a legitimate public objective.

This framework is subject to several caveats. First, it reflects only readily available anecdotal evidence; additional and more robust empirical and/or statistical evidence will likely be required to undertake a more thorough REACH TBT review. Second, arguably insufficient time has elapsed to permit a full analysis of and the drawing of definitive conclusions regarding the recent WTO TBT rulings, especially as they may be applied to a technical regulation as comprehensive and complex as REACH. Third, this framework will likely need updating to reflect ongoing REACH review and revision and the emergence of possible alternative regulatory models discussed in this article.

A. TBT ANNEX 1 ANALYSIS OF REACH

1. “Technical Regulation” Test

TBT Annex 1.1 defines a “technical regulation” to include a “[d]ocument which lays down product characteristics *or their related* processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.”³⁹⁸ The European Commission’s initial January 21, 2004, WTO TBT Committee REACH notification broadly states that it applies to “chemicals.”³⁹⁹ A review of Article 3 (definitions), Article 6 (substances on their own or in preparations), and Article 7 (substances in articles) identifies products subject or potentially subject to REACH registration/data-gathering and notification requirements. REACH differentiates among substances by characterizing some as SVHCs if they possess certain characteristics

398. TBT Agreement, *supra* note 5, Annex 1.1 (emphasis added); *see also* discussion *supra* Part III.B.1.

399. *See* Jan. 21, 2004, TBT Committee Notification, *supra* note 35, at 1.

of toxicity, bioaccumulation, and persistence.⁴⁰⁰ It singles out other substances containing monomers and those serving as intermediates.⁴⁰¹ It distinguishes between substances in articles depending on whether they are intended or unintended to be released.⁴⁰² Other of REACH's many provisions are quite complex and unclear regarding substance, preparation, and product coverage. REACH does not specifically refer to substances unless they are placed on the SVHC "Candidate" or "Authorization" lists.⁴⁰³

As noted above, a prominent characteristic triggering REACH registration/data-gathering and notification obligations for manufactured and imported chemical substances on their own, in preparations, and in articles is that the level (volume) at which they are manufactured and/or imported into the EU achieves an annual threshold (of one ton or more for substances and mixtures and of more than one ton for articles containing substances). Articles 6(1) and 7(1) of REACH employ yearly "volume" as a metaphor for health or environmental "hazard," and thereby imbue manufactured or imported substances, preparations, and/or substance-containing articles achieving this trading volume as sharing the same product characteristic.⁴⁰⁴

The REACH measure is a classic legal instrument known as a European Community "regulation" that serves as "the most direct form of EU law."⁴⁰⁵ Once REACH was adopted by the European

400. See *Authorisation*, *supra* note 75, at 1.

401. See REACH, *supra* note 2, art. 6(2) ("For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.").

402. See *id.* arts. 7(1)(b), 7(5)(b), Annex 1.

403. See *Candidate List of Substances of Very High Concern for Authorisation*, EUR. CHEMS. AGENCY, <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification/candidate-list-of-substances-of-very-high-concern-for-authorisation> (last visited Oct. 30, 2012) ("The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorisation procedure."); *REACH SVHC List 2012: SVHC Testing*, CHEM. INSPECTION & REGULATION SERV., http://www.cirs-reach.com/Testing/REACH_SVHC_List_SVHC_Testing.html (last visited Oct. 30, 2012) ("Some substances from the candidate list will be prioritized for authorization and be included in Annex XIV ('SVHC authorization list').").

404. See REACH, *supra* note 2, arts. 6(1), 7(1).

405. See *What Are EU Regulations?*, EUR. COMM'N, http://ec.europa.eu/eu_law/introduction/what_regulation_en.htm (last updated June

Parliament and Council in December 2006, it had binding legal force and effect from the designated “effective date(s)” throughout every Member State on par with national laws.⁴⁰⁶ In addition, REACH uses the word “shall” in laying down requirements in a number of its provisions.⁴⁰⁷

Furthermore, REACH is supported by an enforcement mechanism that foresees the possibility of imposing a fine or penalty in the event of noncompliance. For example, pursuant to Articles 125 and 126, REACH effectively delegates to EU Member State national authorities the tasks of REACH compliance enforcement, including through inspections, and of imposing REACH noncompliance penalties.⁴⁰⁸ REACH obliges the newly constituted ECHA to establish a Forum for Exchange of Information on Enforcement that serves to oversee and coordinate EU Member State policies in this regard.⁴⁰⁹ In addition, REACH imparts real decision-making authority to ECHA,⁴¹⁰ which the European Commission has classified as a “regulatory agency” able to adopt “individual decisions which are legally binding on third parties”⁴¹¹ Moreover, REACH consistently refers to its core requirement as a “mandatory” requirement.⁴¹²

25, 2012).

406. See *Regulations*, EUROPA, http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/114522_en.htm (last updated Aug. 12, 2010).

407. See, e.g., REACH, *supra* note 2, arts. 6(1), 6(3), 7(1), 7(2), 7(4), 10, 11, 12, 14, 29.

408. See *id.* arts. 125–26.

409. See *id.* arts. 76(1)(f), 77(4), 86.

410. Marco Bronckers & Yves Van Gerven, *Legal Remedies Under the EC’s New Chemicals Legislation REACH: Testing a New Model for European Governance*, 46 COMMON MKT. L. REV. 1823, 1827 (2009).

411. *Communication—European Agencies – The Way Forward*, COM (2008) final, at 7 (Mar. 11, 2008); see also Veerle Heyvaert, *The EU Chemicals Policy: Towards Inclusive Governance?* 8 (London Sch. of Econ. Law, Soc’y & Econ. Working Papers 7/2008), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1111968 (“[T]he REACH Regulation establishes the European Chemicals Agency (ECHA), which will function as both the designated supplier of scientific expertise and opinions to the Commission, and the chief administrator of the scheme.”).

412. See, e.g., REACH *supra* note 2, art. 5 (signaling through its title “No Data, No Market,” like many other articles, that “registration”/data gathering is the core obligation of REACH).

Based on REACH's apparent satisfaction of all three of the aforementioned tests or factors, REACH would arguably qualify as a "technical regulation" within the meaning of TBT Annex 1.

B. TBT ARTICLE 2.1 ANALYSIS OF REACH

1. "Like" Products Test

In light of recent WTO jurisprudence, a REACH "like" products analysis in the context of TBT Article 2.1 must first identify a sufficiently broad scope of products to be compared. This would not seem to pose any difficulty considering that REACH's registration/data-gathering and notification requirements are quite broad and apply to all chemical substances on their own, in mixtures, and in articles achieving a minimum annual European manufacturing or import volume threshold of one ton or more for substances and mixtures, and of more than one ton for articles containing substances, unless otherwise exempted.

A TBT Article 2.1 "like" products analysis of REACH would also entail an evaluation of the four criteria commonly referenced in WTO jurisprudence: physical product characteristics, product end-uses, consumer taste and habits (perceptions and behavior), and tariff classification. However, practitioners should recognize that a WTO Panel possesses and has the duty to exercise the authority and discretion to examine all "relevant" evidence.⁴¹³ Legal commentators have adopted a two-level approach to such analysis that is logically consistent with how REACH registration/data-gathering, notification, and communication obligations flow down the multiple levels and various tributaries of the global chemicals supply chain.⁴¹⁴ This approach looks beyond specific product characteristics, particular end-uses, and tariff classifications to identify two broad comparable groups of products with respect to REACH. One group includes REACH-registered and REACH non-registered articles containing chemical substances. The other group includes registered

413. See, e.g., US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 118 (noting that in *EC—Asbestos*, the Appellate Body found that the Panel must evaluate all relevant evidence when determining whether products are like).

414. See, e.g., REACH, *supra* note 2, pmb., ¶¶ 17, 25, 56, 57, 62, 70; arts. 3.17, 3.26, 3.33, 6.3, 8.3, 31–36, 38.1, 56.2 (referencing the term "supply chain"); *id.* arts. 65–66 (referencing "downstream users").

and non-registered chemical substances and/or mixtures. Each of these groups can be broken down further into subgroups of registered and non-registered articles containing SVHCs and non-SVHCs, and registered and non-registered chemical substances and/or mixtures themselves containing SVHCs and non-SVHCs.

It must be emphasized that, for purposes of analyzing the WTO-consistency of REACH's registration/data-gathering and notification requirements under the TBT Agreement, articles containing chemical substances, chemical substances, and mixtures can each be conceived of as final "products" that can be sold and used at the industrial, commercial, and retail levels. It should also be noted that REACH can potentially impose duplicative registration and notification requirements on a given "product" as it assumes slightly different forms when used or otherwise employed by different economic actors at different levels of the supply chain.⁴¹⁵ Practitioners may wish to look into this issue more closely when analyzing REACH under TBT Article 2.2.

a. SVHCs in Articles: "Like" Product Analysis

A REACH "like" product analysis should look initially to the competitive relationship between imported and domestic manufactured finished "articles" as affected by their underlying PPMs, which specify the use of particular chemical substance or mixture *inputs* that may affect a product's physical properties or performance characteristics.⁴¹⁶ REACH defines the term "article" as "an object which during production is given a special shape, surface or design which determines its *function* to a greater degree than does its chemical composition."⁴¹⁷ "This implies that the shape, surface or design must be *deliberately* determined and given during a production step," which may "include the assembly of the components (which can themselves be articles) of a complex article."⁴¹⁸

415. See STEPTOE & JOHNSON, LLP, REACH: EXCESSIVE COSTS OR CRYING WOLF? 1 (noting the United Kingdom's "One Substance – One Registration" ("OSOR") proposal indicates that duplicate registrations are a real concern).

416. See REACH, *supra* note 2, art. 7 (requiring registration and notice of substances in articles).

417. *Id.* art. 3(3) (emphasis added).

418. GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES, *supra* note

REACH requires the registration of individual substances in articles if they are manufactured within or imported into the EU in annual volumes of greater than one ton and are “intended to be released under normally or reasonably foreseeable conditions of use.”⁴¹⁹ In addition, individual substances in articles not intended for release can, nevertheless, be subject to registration if the ECHA suspects that a substance is being released from an article and that the release presents a risk to human health or the environment—as may occur with SVHCs.⁴²⁰

Legal commentators have opined that REACH Article 7’s registration/data-gathering requirement falls within the scope of TBT Annex 1.1’s explicit coverage of *product-related* PPMs⁴²¹ that can affect the performance or physical characteristics of the final product.⁴²² These commentators have relied upon prior GATT 1994 Article III:4 case law, particularly the Appellate Body ruling in *EC—Asbestos*, to support the proposition that not only can a product’s physical and performance characteristics include the product’s potential to pose human health “risks” during normal or reasonably

105, § 2.2 (emphasis added).

419. REACH, *supra* note 2, pmbl. ¶ 16, art. 7(1)(a)–(b).

420. *Id.* pmbl. ¶ 16, art. 7(5)(b)(i)–(ii); *see also* GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, § 4.1.

421. *See generally* Steve Charnovitz, *The Law of Environmental “PPMs” in the WTO: Debunking the Myth of Illegality*, 27 YALE J. INT’L L. 59, 65 (2002) (explaining that analysts often divide PPMs into two categories: product-related and non-product-related; product-related PPMs are used to safeguard the consumer who uses the product, and non-product-related PPMs are “designed to achieve a social purpose that may or may not matter to a consumer”); JOHN POLAK, TRADE AS AN ENVIRONMENTAL POLICY TOOL? GEN, ECOLABELLING AND TRADE 6, 7 (June 2003), *available at* http://www.wto.org/english/tratop_e/dda_e/symp03_gen ecolab_e.doc (discussing the debate over the use of NRP PPMs in ecolabelling criteria and whether they are covered by the TBT Agreement and explaining that developing countries generally favor the interpretation that they are not covered because they fear that TBT coverage would allow developed countries to use NPR PPMs as disguised environmental- and labor-focused trade barriers); Charles Benoit, *Picking Tariff Winners: Non-Product Related PPMs and DSB Interpretations of “Unconditionally” Within Article I:1*, 42 GEO. J. INT’L L. 583, 590 (2011).

422. *See, e.g.,* Tietje & Wolf, REACH REGISTRATION OF IMPORTED SUBSTANCES, *supra* note 93, at 48, 49 (suggesting the TBT Agreement is only applicable to registering obligations concerning substances used in the production process that are reflected in the specific characteristics of the end product); TBT Agreement, *supra* note 5, Annex.

foreseeable use, but it can also alter the competitive relationship between a product and otherwise competing products fulfilling similar end-uses to the extent such health “risks” affect manufacturer and consumer perceptions (“tastes”) and actual buying habits.⁴²³

In *EC—Asbestos*, since the putative health risks surrounding chrysotile asbestos had become a key concern among French consumers, manufacturers, and regulators, the Appellate Body ruled that this was a decisive physical characteristic of the previously imported Canadian asbestos tiles, distinguishing them from competing French PGC fibers in the marketplace.⁴²⁴ As a result, the Appellate Body found that Canadian asbestos tiles and French PGC fibers were not “like” products and, consequently, that France’s ban of Canadian chrysotile asbestos tiles was not subject to the national treatment obligation of TBT Article 2.1.⁴²⁵

These legal commentators have argued that REACH’s Article 7 registration/data-gathering requirement has similarly altered the competitive relationship “in the field of chemicals” to the extent that manufacturers of products and articles have demonstrated a decided preference in favor of REACH-registered substances due to their own competitive position having been influenced by the demands of health-sensitive consumers and users.⁴²⁶ It would certainly seem to be an express *de jure* goal of REACH to promote the registration of input chemicals by all product and article manufacturers no matter where they are located and to compel manufacturers to substitute input chemicals deemed hazardous to human health or the environment.

However, several important inquiries remain. Do the facts also suggest that it is REACH’s *de facto* goal, through imposition of Article 7’s registration/data-gathering requirement, to alter the fundamental conditions of competition between EU and non-EU article manufacturers’ articles to the detriment of non-EU-produced articles such that they are afforded less favorable treatment than

423. See Tietje & Wolf, REACH REGISTRATION OF IMPORTED SUBSTANCES, *supra* note 93, at 51–52 (explaining that the Appellate Body’s *EC—Asbestos* decision, which reversed the Panel’s finding, expressly stated that it was imperative to take aspects of health or environmental protection into account).

424. *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶¶ 122, 125.

425. See discussion *supra* Part III.B.2.

426. *Id.*

otherwise “like” EU-produced articles? Does the REACH registration/data-gathering requirement serve as a bona fide PPM that can readily identify and distinguish truly harmful articles from non-harmful articles? Or does the REACH registration requirement merely create the impression and raise expectations among consumers and industry that REACH-registered articles are safer than non-REACH-registered articles? Does a “yes” answer to any of these questions strongly suggest that REACH-registered and non-REACH-registered articles containing substances are not “like” products within the meaning of TBT Article 2.1?

It would appear that the application of REACH’s registration/data-gathering and notification requirements to articles containing substances could be more easily defended by the European Union against a claim of trade discrimination of “like” products where the substances contained in articles qualify as SVHCs.⁴²⁷ SVHCs typically include those substances fulfilling the requirements of REACH Article 57 and which may have been placed on the “candidate” list for authorization pursuant to the evaluation procedure identified in REACH Article 59.⁴²⁸ Furthermore, EU manufacturers and importers of articles incorporating SVHCs in volumes of more than one ton per year in concentrations of greater than 0.1% weight by weight are required to notify ECHA, which determines whether those articles can enter the EU market.⁴²⁹ SVHCs are defined as bearing the following characteristic properties: carcinogenic;⁴³⁰ mutagenic;⁴³¹ toxic;⁴³² persistent, bioaccumulative, and toxic (“PBT”);⁴³³ and endocrine disrupting.⁴³⁴ There is a steadily

427. See REACH, *supra* note 2, pmbl. ¶¶ 22, 29, 58, 63, 69, 70, 72, 74, 76; arts. 55, 57–59, 76(1)(e) and evolving Annex XIV (mentioning substances of very high concern, or SVHCs).

428. EUR. CHEM. AGENCY, *supra* note 47, § 4.1.

429. REACH, *supra* note 2, art. 7(2).

430. See Eur. Comm’n, *Risk Assessment Methodologies and Approaches for Genotoxic and Carcinogenic Substances*, at 37 (2009), available at http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_113.pdf.

431. *Definition of Mutagen*, NAT’L CANCER INST., <http://www.cancer.gov/dictionary?cdrid=601170> (last visited Oct. 30, 2012).

432. *Toxins*, NAT’L INST. OF HEALTH, <http://www.nlm.nih.gov/medlineplus/ency/article/002331.htm> (last updated May 29, 2011).

433. *About PTBs*, EPA, <http://www.epa.gov/pbt/pubs/aboutpbt.htm> (last updated Apr. 18, 2011).

434. *Endocrine Disruptors*, NAT’L INST. OF HEALTH SCIS.,

growing body of scientific evidence of probability of harm to human health or the environment posed by these characteristics.⁴³⁵

Because the REACH-identified intrinsic properties of SVHCs, unlike non-SVHCs, could be credibly found to pose high-level risks to human health or the environment, the EU could argue that REACH-registered articles containing SVHCs are not “like” non-REACH-registered articles containing SVHCs whose intrinsic properties would not otherwise have been identified and notified to ECHA. As the Appellate Body in *EC—Asbestos* and *US—Clove Cigarettes* found, “physical properties that make a product toxic or otherwise dangerous to health . . . could . . . influence the competitive relationship between products in the marketplace . . . [and] . . . the health risks associated with a product could influence the preference of consumers”⁴³⁶

However, would this not arguably depend on how broadly the process of “risk assessment” is defined for purposes of determining whether chemical substance inputs incorporated within a given article pose a probable rather than possible human health risk?⁴³⁷ Indeed, one of the most significant evidentiary issues the Panel in *EC—Asbestos* addressed in evaluating the “necessity” of the French asbestos ban under GATT Article XX was the disputed credibility of the risk assessment performed by the French Government upon which the chrysotile asbestos ban was based. The Canadian Government had argued that such “risk assessment” had been “cast

<http://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm> (last visited Oct. 30, 2012).

435. REACH, *supra* note 2, art. 57(a)–(f).

436. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶¶ 118–19.

437. Compare 2 THE NEW SHORTER OXFORD ENGLISH DICTIONARY ON HISTORICAL PRINCIPLES 2310 (L. Brown ed., 1993) (“The ordinary meaning of ‘potential’ relates to ‘possibility’ and is different from the ordinary meaning of ‘probability’. ‘Probability implies a higher degree or a threshold of potentiality or possibility . . . The dictionary meaning of ‘potential’ is ‘that which is possible as opposed to actual; a possibility[.]’”), with *id.* at 2362 (“In contrast, ‘probability’ refers to ‘degrees of likelihood; the appearance of truth, or likelihood of being realized’, and ‘a thing judged likely to be true, to exist, or to happen[.]’”). See EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 182 (describing the European Communities’ objections to the Canadian Government’s claim as a position that argued that it is not possible to claim “legitimate expectations” with respect to a measure taken to protect human life or health because they are excluded from the scope of Article XXIII).

[in] very real doubt . . . [by] the French and international scientific communities” because, among other reasons, it had not been “a product-by-product and use-by-use risk assessment . . . [and had] not even examine[d] . . . *exposures* to current chrysotile products.”⁴³⁸

The Appellate Body in *EC—Asbestos*, however, found that the evidence before the Panel provided the Panel with “a more than sufficient basis to conclude that chrysotile-cement products . . . pose[d] a significant risk to human life or health.”⁴³⁹ Consequently, it rejected Canada’s allegation that there was only one way to correctly perform a risk assessment. “[W]e consider that, as with the *SPS Agreement*, there is no requirement under Article XX(b) of the GATT 1994 to quantify, as such, the risk to human life or health. A risk may be evaluated either in quantitative or qualitative terms.”⁴⁴⁰ In doing so, the Appellate Body, like the Panel, essentially adopted the position advanced by the European Communities in response to Canada’s allegations.

First neither GATT nor the TBT Agreement lay down any rule whatsoever on how to perform a risk assessment. Even the SPS Agreement, which is not applicable in this case and which contains specific provisions on risk assessment, does not require the performance of a risk assessment in the way suggested by Canada. Secondly, there are in fact no internationally agreed and binding rules on how to conduct a risk assessment for dangerous substances like asbestos. In addition, neither national nor international practice (e.g. by WHO, IARC, FAO/Codex Alimentarius, etc.) support the views of Canada on the two “guiding principles” Risk assessment . . . is a very complex and interactive process and no one particular technique or methodology is always appropriate for all cases.⁴⁴¹

438. See *EC—Asbestos Panel Report*, *supra* note 8, ¶¶ 3.331–3.332 (explaining that Canada argued that the Panel erred in its finding because, among other reasons, it was based on a false premise that did not take into account the risk associated with substitute products and therefore was not a thorough or complete risk assessment).

439. *Id.* ¶ 166.

440. *Id.* ¶ 167.

441. Panel Report Addendum, *European Communities — Measures Affecting Asbestos and Asbestos — Containing Products*, Annex II, ¶¶ 272–73, WT/DS135/R/Add.1 (Sept. 18, 2000) [hereinafter *EC — Asbestos Panel Report Addendum*] (responding to “Question 7: Canada claims that France should have used two guiding principles to determine which chrysotile asbestos products should be used: (i) risk assessment product-by-product and use-by-use, and (ii)

The Appellate Body in *EC—Asbestos*, furthermore, agreed with the Panel’s rejection of Canada’s allegation that France lacked a scientifically established threshold for exposure.

The Panel found, on the basis of the scientific evidence, that “no minimum threshold of level of exposure or duration of exposure has been identified with regard to the risk of pathologies associated with chrysotile, except for asbestosis.” The pathologies which the Panel identified as being associated with chrysotile are of a very serious nature, namely lung cancer and mesothelioma, which is also a form of cancer. Therefore, we do not agree with Canada that the Panel merely relied on the French authorities’ “hypotheses” of the risk.⁴⁴²

Moreover, the Appellate Body in *EC—Asbestos* reaffirmed the Panel’s determination that France’s objective of “halt[ing] the spread of this risk which, considering the risk identified and its extent, could in principle justify strict measures.”⁴⁴³ According to the Appellate Body,

[I]t is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation. France has determined, and the Panel accepted, that the chosen level of health protection by France is a “halt” to the spread of asbestos-

demonstration of the feasibility and effectiveness of ‘controlled use’ for each product. Could the European Communities comment on these arguments?”).

442. *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶ 167; *see also EC—Asbestos Panel Report*, *supra* note 8, ¶ 8.202 (“[T]he experts confirm the position of the European Communities according to which it has not been possible to identify any threshold below which exposure to chrysotile would have no effect. The experts are also agreed that the linear relationship model, which does not identify any minimum exposure threshold, is appropriate for assessing the existence of a risk. We find therefore that no minimum threshold of level of exposure or duration of exposure or duration of exposure has been identified with regard to the risk of pathologies associated with chrysotile, except for asbestosis. Consequently, the possibility remains that low exposure over a fairly long period of time could lead to lung cancer or mesothelioma.”) (emphasis added); *id.* ¶ 8.188 (“First of all, we note that the carcinogenicity of chrysotile fibres has been acknowledged for some time by international bodies. This carcinogenicity was confirmed by the experts consulted by the Panel, with respect to both lung cancers and mesotheliomas, even though the experts appear to acknowledge that chrysotile is less likely to cause mesotheliomas than amphiboles. We also note that the experts confirmed that the types of cancer concerned had a mortality rate of close to 100 per cent. We therefore consider that we have sufficient evidence that there is in fact a serious carcinogenic risk associated with the inhalation of chrysotile fibres.”).

443. *EC — Asbestos Panel Report*, *supra* note 8, ¶ 8.204.

related health risks.⁴⁴⁴

In reaching this conclusion, the Appellate Body, like the Panel, essentially adopted the position advanced by the European Communities, namely that “existing rules permit[ted] France to apply its own, customary and normal rules on risk assessment to asbestos . . . [especially where t]he methodology applied by France [was] similar, if not identical, to the one usually applied internationally and actually used by WHO and the IARC in the case of asbestos.”⁴⁴⁵

At least one legal commentator has closely examined a number of WTO cases involving claims brought under the SPS Agreement⁴⁴⁶ where the traditional quantitative risk-assessment approach has long been vigorously challenged by an alternative holistic “qualitative” risk-assessment approach.⁴⁴⁷ This commentator’s findings strongly suggest that the WTO, in the context of the SPS Agreement, has finally shifted from the quantitative risk-assessment model

444. EC — Asbestos Appellate Body Report, *supra* note 162, ¶ 168.

445. EC — Asbestos Panel Report Addendum, *supra* note 441, Annex II, ¶ 278.

446. See Alessandra Arcuri, *Food Safety at the WTO After ‘Continued Suspension’: A Paradigm Shift? (Rotterdam Inst. of Law & Econ. (RILE) Working Paper Series No. 2010/04, 2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1633390 (examining a number of SPS cases to discern a pattern of WTO jurisprudence with respect to the interpretation of key SPS Agreement terms, including “risk assessment”); see generally Lawrence A. Kogan, *World Trade Organization Biotech Decision Clarifies Central Role of Science in Evaluating Health & Environmental Risks for Regulation Purposes*, 2 GLOBAL TRADE & CUSTOMS J. 149 (2007) [hereinafter Kogan, *WTO Clarifies Role of Science in Evaluating Health & Environmental Risks*], available at [www.itssd.org/Publications/GTCJ_04-offprints_Kogan\[2\].pdf](http://www.itssd.org/Publications/GTCJ_04-offprints_Kogan[2].pdf) (examining Panel Report, *EC — Measures Affecting the Approval & Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006)); *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, WTO, http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm (1998) (“The SPS Agreement, while permitting governments to maintain appropriate sanitary and phytosanitary protection, reduces possible arbitrariness of decisions and encourages consistent decision-making. It requires that sanitary and phytosanitary measures be applied for no other purpose than that of ensuring food safety and animal and plant health. In particular, the agreement clarifies which factors should be taken into account in the assessment of the risk involved. Measures to ensure food safety and to protect the health of animals and plants should be based as far as possible on the analysis and assessment of objective and accurate scientific data.”).*

447. Kogan, *Divergent Views Toward the Role of Science in Assessing and Managing Risk*, *supra* note 82, at 78–88.

championed by industry, economists, and legal-economic scholars⁴⁴⁸ toward a holistic qualitative risk model championed by philosophers of science, cognitive psychologists, political scientists, and lawyers⁴⁴⁹ who apparently favor incorporating the European Union's Roman civil law precautionary principle within risk assessments.⁴⁵⁰ This commentator attributes such a "paradigm shift" to the likely greater influence of the latter stakeholder group over WTO jurists and suggests that it "arguably implies that WTO Members (as long called for by the Member States and instrumentalities of the European Union) can more easily include cultural and socio-economic

448. See Arcuri, *supra* note 446, at 6 (contending that the quantitative-risk logic group is a knowledge-based group mainly fueled by economists and legal-economic scholars that focuses on a narrow idea of risk as the probability of an event occurring).

449. See *id.* at 7 ("[T]he holistic-risk logic group emphasizes that risk assessment is value-laden and that risks can be properly defined 'only within particular political and cultural contexts'. For this group, risk is a multi-faceted concept where the probability of a hazardous event occurring is not the only relevant feature; other considerations, such as the voluntary/involuntary, equitable/inequitable spread, and the novelty nature of the hazards, are important and contribute to define risk. Science is perceived as complex, entrenched with uncertainties and its results determined by the endorsement of certain value judgments; in this context some authors explicitly endorse the notion of post-normal science. Within such a framework, public participation is considered central to risk analysis, where a deliberative approach to risk governance appears to be partly the logical consequence of such a vision of risk and science.").

450. See *id.* at 5 n.10 (citing several treatises discussing various frameworks and perspectives for employing or otherwise implementing the precautionary principle in administrative and constitutional law); see also Kogan, *WTO Clarifies Role of Science in Evaluating Health & Environmental Risks*, *supra* note 446, at 151–55 (discussing Panel Report, *EC — Measures Affecting the Approval & Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006), and distinguishing between the "precautionary approach" standard found within SPS Agreement Articles 5.1 and 5.7 and the European Union's Roman civil law precautionary principle while quoting the decision in Appellate Body Report, *EC — Measures Concerning Meat & Meat Products (Hormones)*, ¶¶ 121–24, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998)); see also Lawrence A. Kogan, *What Goes Around, Comes Around: How UNCLOS Ratification Will Herald Europe's Precautionary Principle as U.S. Law*, 7 SANTA CLARA J. INT'L L. 23, 83–167 (2009) (arguing that U.S. accession to the United Nations Convention on the Law of the Sea ("UNCLOS") would require the enactment of federal implementing legislation and/or engender the issuance of presidential executive orders and memoranda that would have the effect of altering U.S. federal environmental laws and regulations by incorporating within them the European Union's Roman civil law precautionary principle).

considerations in the process of setting their food safety standards.”⁴⁵¹

Additional evidence arguably reflects that this change at the WTO tribunal level is largely indicative of the ongoing efforts of these same WTO member governments at a more fundamental level to reform the international “standards, guidelines,” and “recommendations” (principles of risk analysis)⁴⁵² developed by the several “relevant international organizations” explicitly recognized and referenced within the text of the WTO SPS Agreement.⁴⁵³ The intended purpose of these bodies is to facilitate the development and international harmonization of “science-based” SPS measures and, consequently, to ensure that national or regional SPS measures otherwise inconsistent with the provisions of the SPS Agreement and the GATT 1994 need not be scientifically “justified” (i.e., shall “be deemed to be necessary to protect human, animal or plant life or health and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994”) provided they “conform to international standards, guidelines or recommendations” such as those promulgated by said bodies.⁴⁵⁴

These findings are important because, if the more precise definition of “risk assessment” contained in SPS Agreement Annex (A)(4)⁴⁵⁵ has conclusively changed in the context of food safety for

451. Arcuri, *supra* note 446, at 22. See also Pamela A. Vesilind, *Continental Drift: Agricultural Trade and the Widening Gap Between European Union & United States Animal Welfare Laws*, 12 VT. J. ENVTL. L. 223, 250 (2011) (suggesting that the Appellate Body has shown a willingness to apply the holistic-risk logic in determining whether a rational relationship exists, as opposed to the stricter quantitative-risk logic).

452. Food and Agriculture Organization of the United Nations, *Multilateral Trade Negotiations on Agriculture – A Resource Manual*, ch. III, Module 12, § 12.1.1, art. 1.4.1.1; § 12.1.3, art. 1.4.1.3; § 12.2.3, art. 1.4.2.3; § 12.2.4, art. 1.4.2.4 (relating to Qualitative Risk Assessment), available at <http://www.fao.org/docrep/003/x7354e/x7354e12.htm>.

453. SPS Agreement, *supra* note 12, Annex A(3)(a)–(d).

454. SPS Agreement, *supra* note 12, art. 3(2).

455. See Amicus Curiae Brief Submitted to the Dispute Settlement Panel of the World Trade Organization, *EC: Measures Affecting the Approval and Marketing of Biotech Products*, at 7, WT/DS291-93 (Apr. 30, 2004) (“Only the SPS agreement, and no other WTO agreement, imposes on its Members an obligation to base regulations on scientific evidence, regardless of whether there is discrimination. This so-called ‘sound-science’ obligation means a higher justificatory burden on all WTO Members wishing to regulate GMOs and permits complaining parties to

purposes of applying the stringent standards of SPS Agreement Articles 5.1 and 5.2,⁴⁵⁶ it will also likely change for purposes of assessing health risks in the less scientifically circumscribed context of the TBT Agreement—i.e., when undertaking a “like” product analysis under TBT Article 2.1 of non-food products (e.g., cigarettes) or of the non-food aspects of food products (e.g., the environmental or country-of-origin aspects of non-product-related PPM labeling measures).⁴⁵⁷

ECHA has arguably reflected such “evolved” thinking in two recent versions of its registration guidance document. The most recent version of the document released in May 2012 enhances the prior version’s discussion of the necessary procedure for preparing a CSR as part of a registration technical dossier for substances manufactured within or imported into the EU in volumes of ten tons or more per year.⁴⁵⁸ A CSR is described as entailing the preparation of a hazard assessment, an exposure assessment, and a risk characterization.⁴⁵⁹ References to “qualitative” or “semi-quantitative” risk assessment appear in the exposure-assessment and risk-characterization stages, the stated goal of which is to establish that chemical substances pose *zero risk* to human health or the environment, consistent with REACH’s objective of ensuring a high level of protection of human health and the environment as called for by the EU precautionary principle.⁴⁶⁰

challenge such regulations on the basis of the underlying scientific evidence and reasoning. The centrality of these concepts is widely recognized.”); *see also* Arcuri, *supra* note 446, at 9 (interpreting the definition of Annex A(4) to the SPS Agreement to mean that the calculation of probability is not necessary for risk assessments concerning food-borne risks, a distinction that reflects the assessment for quarantine risk responding to quantitative risk logic while the assessment for food-borne risks responds to the holistic logic).

456. SPS Agreement, *supra* note 12, art. 5(1)–(2).

457. *See* Charnovitz, *supra* note 421, at 65 (“Non-product related PPMs are designed to achieve a social purpose that may or may not matter to a consumer.”).

458. GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.3.

459. *Id.* §§ 5.3.1.1.1, 5.3.1.2, 5.3.1.3, tbl.5, pts. (A)–(B).

460. *See id.* § 5.3.1.3 (“The risk characterization shall be carried out for each exposure scenario for both the human health and the environment and the results and discussion reported in section 10 if the CSR. As the purpose is to prove that the risks are controlled it is expected that the results of the risk characterization *should not indicate a risk.*”) (emphasis added); *see also* REACH, *supra* note 2, pmb1., ¶¶ 9, 69, art. 1(3).

This perceived paradigm shift at the WTO would arguably make it easier for the EU to distinguish REACH-registered articles deemed harmful on the basis of a flexible qualitative or semi-quantitative risk assessment that focuses on potential human health and environmental hazards without necessarily examining probable exposure scenarios from non-REACH-registered articles evaluated outside the EU pursuant to a strictly quantitative risk-assessment protocol that focuses instead on actual or probable substance exposure scenarios. This result would be obtained because the relatively lower hazard threshold for assessing product harm would enable the EU to characterize REACH-registered articles as no longer being “substitutable” by non-REACH-registered articles within the meaning of TBT Article 2.1.

Lastly, because the perceptions consumers would have of SVHCs versus non-SVHCs would likely be different once their respective physical properties, including the health risks they engender, have been identified via the REACH-registration process, the EU could more easily defend on grounds of “non-substitutability” (“non-likeness”) its distinct treatment of REACH-registered articles containing SVHCs vis-à-vis articles containing non-SVHCs, whether or not REACH registered.

b. Non-SVHC Substances on Their Own and in Preparations/Mixtures: “Like” Product Analysis

A REACH “like” product analysis could also focus on the relationship between groups of REACH-registered non-SVHCs and groups of non-REACH-registered non-SVHCs. These include non-SVHCs sold and used for any commercial, consumer, or industrial purpose including as an industrial intermediate that no longer resides in the final manufactured or processed product, given the registration requirement for monomers but not polymers.⁴⁶¹ REACH’s registration/data-gathering requirement applies to all manufactured or imported non-SVHCs not incorporated within articles, if sold or used on their own or in preparations/mixtures in annual volumes of one ton or more. The registration burden imposed on non-SVHCs increases thereafter depending on the extent to which a substance’s annual manufacturing or import

461. REACH, *supra* note 2, art. 6.

volume exceeds the minimal annual volume threshold.⁴⁶²

Unlike SVHCs, the EU institutions rely almost entirely on REACH's volume-based registration requirement to distinguish non-REACH-registered non-SVHCs from REACH-registered non-SVHCs, especially those with intrinsic characteristics that are not readily identifiable as "highly dangerous" or "hazardous" from a registration dossier.⁴⁶³ As previously noted, REACH uses volume as an "across-the-board" "proxy for exposure" and risk to both people and their environment⁴⁶⁴—i.e., as a virtual administrative presumption of harmfulness. Therefore, ECHA, EU Member State national authorities, and registrants are not required to undertake an exposure-based risk assessment or preliminary risk-screening exercise with respect to such substances until more information becomes available in REACH's subsequent evaluation and authorization stages.

In the absence of any truly harmful or "hazardous" intrinsic characteristics or evidence of risk of exposure, however, the EU

462. See Stefan Baumgarten, *ECHA Updates List of Pre-Registered Substances Under Reach*, ICIS (Mar. 27, 2009), <http://www.icis.com/Articles/2009/03/27/9204015/echa-updates-list-of-pre-registered-substances-under.html>.

463. See EVALUATION OF COMMUNICATION ON THE DIFFERENCES BETWEEN "RISK" AND "HAZARD," FED. INST. FOR RISK ASSESSMENT (E. Ulbig et al. eds., 2010), available at http://www.bfr.bund.de/cm/350/evaluation_of_communication_on_the_differences_between_risk_and_hazard.pdf ("The term 'hazard' refers to the inherent property of a substance (or a situation) to cause an adverse effect. In this context for example the International Programme on Chemical Safety (IPCS) defines a 'hazard' as the: Inherent property of an agent or situation *having the potential to cause* adverse effects when an organism, system, or (sub) population is exposed to that agent. (IPCS 2004, 12) Generally speaking 'risk' is deemed to be the possibility of the occurrence of a harmful event. . . . The IPCS definition of risk is broader and is also used in this report: *The probability of an adverse effect* in an organism, system, or (sub) population caused under specified circumstances by exposure to an agent. (IPCS 2004, 13) *This definition highlights the fact that the difference between 'hazard' and 'risk' like in exposure. A risk exists when there is exposure to a 'hazard'*, in a nutshell: risk = (hazard, exposure).") (emphasis added).

464. See ADAM D. K. ABELKOP ET AL., *Regulating Industrial Chemicals: Lessons for U.S. Lawmakers from the European Union's REACH Program*, IND. SCH. OF PUB. & ENVTL. AFFAIRS 22 (2012), available at http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf (explaining that the current timetables for registration under REACH emphasize a registrant's production volume and stating that the consideration of production volume as a valid surrogate for exposure and risk to human health and the environment is a questionable assumption to make).

would arguably find it difficult to defend any distinct treatment it might accord to non-REACH-registered non-SVHCs vis-à-vis REACH-registered non-SVHCs against a claim of trade discrimination on the grounds that they are not “like” products. Unlike with SVHCs, an importer’s violation of REACH Article 5’s “no data, no market” rule in respect to non-SVHCs may not be automatically perceived by consumers and commercial and industrial users along supply chains as reflecting that non-REACH-registered non-SVHC imports are less “safe” than domestically produced REACH-registered non-SVHCs.

In addition, unlike SVHCs, it may not also be true that an Article 5 violation would induce changes in consumer and user buying habits. Even if such changes could be induced, it is arguable that they would be government-driven, consequently rendering their credibility as bona fide expressions of market preference for registered non-SVHCs highly suspect since the choice of product “substitution” would have been removed.⁴⁶⁵ A REACH “like” product analysis of non-SVHCs, therefore, must consider whether the EU has run afoul of the *EC—Sardines* Panel’s admonition against the use of government-induced consumer distinctions capable of creating “‘self-justifying’ regulatory trade barriers.”⁴⁶⁶

2. “Treatment No Less Favorable” Test

If a REACH “like” products analysis reveals the existence of “like” EU and non-EU “chemical substance-based products”—articles, substances, or mixtures—practitioners should seek to determine whether the REACH registration/data-gathering and notification requirements accord less favorable treatment to such non-EU “like” products, within the meaning of TBT Article 2.1.

Recent jurisprudence indicates that a TBT Article 2.1 “treatment no less favorable” analysis of REACH should aim to compare “groups” of “like” products in a competitive relationship. If necessary, practitioners should consult with their non-EU clients for

465. See Tietje & Wolf, REACH REGISTRATION OF IMPORTED SUBSTANCES, *supra* note 93, at 51–53 (assessing whether the REACH registration criteria for substances in articles give rise to different competitive positions for the relevant products and asserting that it is strongly dependent on whether considerations regarding potential hazards to health and the environment affect these positions).

466. EC — Sardines Appellate Body Report, *supra* note 162, ¶ 306.

purposes of assembling further evidence establishing that a sufficiently close competitive relationship exists between identifiable groups of EU and non-EU chemical substance-based products both prior to REACH's adoption and during its pre-registration and notification-implementation phases. As the Appellate Body in *US—Clove Cigarettes* noted, evidence could arguably extend as far back in time as the legislative debates and Internet consultations that led to the adoption of the prior and current versions of REACH in order to demonstrate that REACH has long cast a “chilling effect” on non-EU chemical substance-based products in the EU market, especially those comprising or containing SVHCs.⁴⁶⁷ It must be shown not only that REACH has imposed differential treatment of “like” imported chemical substance-based products, but also that such differential treatment altered the fundamental conditions of competition in the EU market to such an extent that it disadvantaged and discriminated against “like” imported chemical substance-based products.

This type of analysis should begin with an assessment of whether REACH's text *de jure* discriminates between “like” imported and domestic chemical substance-based products, and if not, whether these REACH requirements operate in a way that *de facto* discriminates against such “like” products. Because REACH's registration/data-gathering and notification provisions do not expressly discriminate against imported chemical substance-based products, this analysis must focus on the design, architecture, revealing structure, operation, and application of such provisions. While it is not necessary to focus on REACH's actual economic effects in the EU marketplace, available econometric data may be helpful in showing how these REACH provisions operate and if they are capable of altering the fundamental conditions of competition between “like” chemical substance-based products to the economic disadvantage of non-EU chemical substance-based imports.

Prior TBT Committee meeting minutes strongly suggest that REACH's registration/data-gathering and notification provisions could, in certain situations, potentially discriminate against “like”

467. TBT Committee Minutes for the Meeting of 9 November 2007, *supra* note 83, ¶ 28 (describing questions and concerns of WTO members with regard to the REACH regulation and its implementation, including the “chilling effect” of having a substance placed on the authorization candidate list).

non-EU chemical substance-based products in EU markets. Practitioners are advised to review each of the following scenarios with their non-EU clients to assess whether any new probative evidence is available that would further substantiate these claims.

a. Potential EU Member State Discrimination Arising from Article Registration, Including Those Containing SVHCs

The minutes of TBT Committee meetings convened during 2008–2010 reveal that several WTO Members had discussed how six EU Member State national authorities had intentionally interpreted the term “article” inconsistently with ECHA guidance documents so that REACH’s registration/data-gathering and notification requirements would then apply at the sub-article level.⁴⁶⁸ It was reported that such activities had occurred with respect to two different groups of non-EU chemicals-based product imports: articles containing SVHCs and semi-finished steel products.⁴⁶⁹

In the first case, the United States and Japan had alleged that such treatment could potentially result in the segmentation of their chemical substance-based articles into distinct sub-articles, in the SVHC composition of some such sub-articles exceeding the maximum 0.1% weighted threshold, in the triggering of the REACH Article 7(2) notification requirement, in the time-consuming and costly evaluation of such chemical substance-based sub-articles pursuant to REACH Article 7(5), and, consequently, to the potential inclusion of these incorporated chemical substances (designated as “SVHCs”) on the REACH “candidate list.” They expressed concern that such designation would, in turn, result in a more in-depth and

468. See *EU REACH – Dissenting Member State Views on SVHCs in Articles*, 59 SPARKLE, Aug. 19, 2011, available at http://www.intertek.com/uploadedFiles/Intertek/Divisions/Consumer_Goods/Media/PDFs/Sparkles/2011/sparkle595.pdf (explaining the non-legally binding ECHA Guidance on Requirements for Substances and Articles and noting that several Member States have a dissenting view that regards articles within a “complex” article as a collection of several individual articles within an article); see also *France Begs to Differ on SVHC*, MOLECULE NEWSLETTER, June 2011, at 1, available at http://www.ecomundo.eu/fr/pdf/The_molecule_1.pdf (reporting that the French initiative to differ from the commonly accepted definition of an article under REACH “raised eyebrows everywhere”).

469. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 99; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 38.

costly evaluation pursuant to REACH Article 59(1) that could possibly end in the restriction or banning of such article(s) within said EU Member State markets, pursuant to the provisions of REACH Title VIII.⁴⁷⁰

Furthermore, the United States and Japan sought clarification regarding how this inconsistency in interpretation at the EU regional and Member State levels would affect the further obligation of non-EU manufacturers and importers to communicate such SVHC presence to downstream supply chain users, pursuant to REACH Article 33.⁴⁷¹ Apparently, these WTO Members expressed genuine concern that such EU Member State activities could potentially create a relatively higher cost structure for chemicals-based product imports that would place those products at a competitive disadvantage vis-à-vis the domestically manufactured “like” products of EU competitors and, consequently, alter the fundamental conditions of competition for such products within Member State national markets.⁴⁷²

These WTO Member concerns, which are arguably related to EU Member States’ delegated responsibility to evaluate SVHCs identified by ECHA, are not necessarily unfounded.⁴⁷³ According to at least one legal commentator, the ability of ECHA, a central element of REACH,⁴⁷⁴ to curtail objectionable and potentially trade-discriminatory EU Member State behavior may be hamstrung by EU

470. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 99; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 38.

471. TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 45; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶¶ 58.

472. TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶¶ 148–51.

473. EUR. CHEMS. AGENCY, GUIDANCE ON DOSSIER AND SUBSTANCE EVALUATION § 1.3.2 (2007) [hereinafter GUIDANCE ON DOSSIER AND SUBSTANCE EVALUATION], available at http://echa.europa.eu/documents/10162/13628/evaluation_en.pdf; see Bronckers & Van Gerven, *supra* note 410, at 1832 (asserting that the Member States must evaluate the substances themselves while the ECHA plays a coordinating and supervisory role).

474. See Eurostat, *supra* note 55, at 31 (explaining the essential conditions for the implementation of REACH and naming the establishment of the European Chemicals Agency as one central element).

Member State influence.⁴⁷⁵ For example, ECHA's REACH Article 51 dossier evaluation "decision-making process [has been] found to be largely dominated by the Member States," which are "able to exert considerable control over the Agency through [ECHA's] Management Board"⁴⁷⁶ In addition, this process may lead to Commission interference.⁴⁷⁷ Therefore, the commentator "concluded that the Chemicals Agency is subject to considerably tighter Member State (and Commission) control" than is generally recognized.⁴⁷⁸

Indeed, in June 2011, the French Government, supported by Austria, Belgium, Denmark, Germany, and Sweden, published legally binding guidelines directing chemical substance-based product companies to report SVHCs that exceeded the 0.1% threshold with respect to each product *component*.⁴⁷⁹ These governments embraced this position despite its inconsistency with official ECHA guidance interpreting REACH Article 7(2) to require notification only if *the entire product* exceeds the SVHC threshold.⁴⁸⁰ As reported by Bloomberg BNA, the French guidelines were "sharply at odds with official EU guidance and could [potentially] raise compliance costs and image problems for French importers and manufacturers" and, by implication, also for the importers and manufacturers from the other countries cited.⁴⁸¹

475. See Bronckers & Van Gerven, *supra* note 410, at 1827 ("[F]or many decisions ECHA remains under the direct supervision of the Member States. This is apparent from the important role played within ECHA by the so-called Member State Committee, whose members are appointed by the Member States and who are not subject to a rule that they may not accept instructions from the Member States.") (emphasis added).

476. TANJA EHNERT, UNIV. OF MAASTRICHT, THE EUROPEAN CHEMICALS AGENCY – BEYOND THE SCOPE OF THE MERONI DOCTRINE? 62 (2008), available at <http://www.stepto.com/assets/attachments/3928.pdf>.

477. *Id.*

478. *Id.*

479. See Rick Mitchell, *French Interpretation of REACH Reporting Rules Could Hurt Competitiveness, Hike Costs*, BLOOMBERG (July 13, 2011), <http://www.bna.com/french-interpretation-reach-n12884902434/> (reporting that five other member states support France's new guidelines for reporting the presence of substances of very high concern in products under REACH, which are at odds with official EU guidance).

480. See *id.* (reporting that the French system applies to each individual product component, while ECHA's system only applies "if the entire product exceeds the SVHC threshold").

481. *Id.*

Moreover, such treatment could also potentially violate international trade rules if, as was alleged, France had failed to abide by an EU directive requiring the EU Commission to be notified about technical regulations and standards when they are proposed—*before* they have been adopted.⁴⁸² The directive’s apparent objective was to prevent foreseeable trade barriers from arising from proposed EU regional technical regulations and standards, consistent with TBT Article 2.9.⁴⁸³ France explained that, since its guidelines were only “opinions” and did not rise to the level of “technical regulations,” it was not obligated to notify the Commission about their adoption.⁴⁸⁴ Practitioners should factor into their Article 2.1 analysis whether the EU Commission is capable of adequately addressing this situation without emboldening other EU Member States to proceed in “like” fashion.

In the second case, BRICS nations and developing country WTO Members relayed to the TBT Committee how several EU Member States’ had treated semi-finished steel products as alloys—substance mixtures composed of individual substances—subject to the burdensome and costly substance pre-registration requirements of REACH Article 6, rather than as finished products subject to Article 7’s relatively less burdensome and costly articles pre-registration requirements.⁴⁸⁵ These members had alleged that such EU Member State treatment could potentially place non-EU chemicals-based product imports at a competitive disadvantage.⁴⁸⁶ This decision conflicted with ECHA’s recent detailed guidance documents on

482. See, e.g., Directive 98/34/EC, of the European Parliament and of the Council of 11 June 1998 Laying Down a Procedure for the Provision of Information in the Field of Technical Standards and Regulations, *available at* <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0034:20070101:EN:PDF>.

483. See UK DEP’T FOR BUS., INNOVATION & SKILLS, GUIDANCE FOR OFFICIALS AVOIDING NEW BARRIERS TO TRADE: DIRECTIVE 98/34/EC (AS AMENDED BY DIRECTIVE 98/48/EC) 3 (2009) (U.K.), *available at* <http://www.bis.gov.uk/assets/biscore/corporate/docs/a/02-1434-avoiding-new-barriers-to-trade> (setting forth a procedure for the provision of information in the field of technical standards and regulations).

484. Mitchell, *supra* note 479.

485. See TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶ 99; see discussion *supra* Part II.C.2.

486. See discussion *supra* Part II.C.5.

substances in articles.⁴⁸⁷ It also ran counter to ECHA's written accord with the EUROFER trade association's assessment that semi-finished steel products should be treated pursuant to a special borderline case analysis tailored specifically to metals processing.⁴⁸⁸ Once again, WTO Member governments were most concerned that if such EU Member State behavior were permitted to continue, it would encourage similar actions to the detriment of imports.⁴⁸⁹

It may be possible to characterize these unilateral and ECHA-inconsistent EU Member State actions as more than ordinary regulatory distinctions imposed to pursue a legitimate public objective, i.e., as *de facto* discrimination, within the meaning of TBT Article 2.1. However, practitioners will first need to secure supporting documentation from their non-EU clients demonstrating that such actions were intentionally designed or implemented, or otherwise had the effect through their operation of indirectly altering the fundamental conditions of competition between "like" product groups of REACH-registered and REACH non-registered chemical substance-based products by administratively imposing an added cost structure upon non-EU-based product imports.

487. GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES, *supra* note 105, tbls.1–16; *id.* app. 2.1, *Aluminum Processing as an Example of Metal Processing*; see *id.* at *Note to Reader* (informing readers that the consulted national authorities did not completely support the ECHA guidelines and therefore warning companies that they may find that enforcement practices diverge with respect to some aspects of the guidelines). See generally Meike Wolf, *European Comm'n, Functioning of Directive 98/34/EC* (2008), at 4, available at http://www.sice.oas.org/TPD/CACM_EU/Negotiations/IIround_directive9834EC_e.pdf (explaining the functioning of Directive 98/34/EC by examining the objectives and scope of application of the Directive, underlying principles, related definitions, results of the procedure, and statistics).

488. See EUROFER POSITION PAPER, *supra* note 110, at 4 (recognizing the ECHA guidance's acknowledgement of the Iron and Steel industries' position on the borderline between preparations/articles for steel and steel products, which is the same as that expressed in the position paper); see also GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES, *supra* note 105, at 10 (providing indicative questions to better determine whether an object is an article in difficult cases such as semi-finished products). See generally Letter from Andreas Herdina, *supra* note 111, at 1–2 (addressing issues raised in a letter to the Chairman of the ECHA Management Board regarding the application of the rules found in the *Guidance on Requirements for Substances in Articles* to steel and steel products).

489. See, e.g., TBT Committee Minutes for the Meeting of 23 March 2004, *supra* note 83, ¶ 36.

b. *Potential EU Member State Discrimination Arising from REACH Registration-Related Compliance Inspections and Enforcement Penalties*

Under REACH, ECHA is responsible for undertaking IT-based registration “completeness checks” to ascertain that all the required elements of the registration dossier are present and that the registration fee has been paid.⁴⁹⁰ REACH also holds ECHA responsible for undertaking dossier evaluations, or “compliance checks,” to ensure dossier compliance with REACH registration requirements and examination of testing proposals to ensure against unnecessary animal tests.⁴⁹¹ However, REACH is relatively silent regarding how incomplete or inadequate registration dossiers should be addressed where registrants fail to supply the additional information that ECHA has demanded.⁴⁹² Given REACH’s delegation of responsibility for registration and evaluation of compliance enforcement to EU Member State inspections⁴⁹³ and penalties,⁴⁹⁴ ECHA’s authority in this situation is effectively limited to drawing compliance failures to Member State enforcement authorities’ attention and requesting that such failures be investigated and subject to enforcement.⁴⁹⁵

Minutes from TBT Committee meetings convened from 2008–2011 reflect WTO Member discussions about how REACH’s delegation of inspection and penalty responsibilities to EU Member State national authorities had resulted in non-uniform, nontransparent, and costly REACH-related inspection procedures;⁴⁹⁶

490. REACH, *supra* note 2, art. 20(2).

491. *Id.* arts. 40–42; GUIDANCE ON DOSSIER AND SUBSTANCE EVALUATION, *supra* note 473, §§ 1.3.1, 1.3.1.1, 1.3.1.2, 2.2.4.1.

492. REACH, *supra* note 2, arts. 40–41; *see also* *EU Member States Investigating Poor Quality Dossiers*, CHEMICAL WATCH (May 9, 2012), <http://chemicalwatch.com/11040> (citing the UK’s Department for Environment, Food and Rural Affairs (“DEFRA”) for three mechanisms to use to address incomplete or inadequate registration dossiers).

493. *See* REACH, *supra* note 2, art. 125 (stating that Member States must set up and maintain official controls and other supplementary activities designed to fit the circumstances).

494. *See id.* art. 126 (stating that Member States’ penalties for infringement of REACH provisions “must be effective, proportionate and dissuasive”).

495. *EU Member States Investigating Poor Quality Dossiers*, *supra* note 492, at 2.

496. *See* TBT Committee Minutes for the Meeting of November 2008, *supra*

extra-REACH (and perhaps, *ultra vires*⁴⁹⁷) registration/data-gathering and presentation evidentiary standards imposed during the course of investigations;⁴⁹⁸ and excessively high penalties in the event of noncompliance.⁴⁹⁹ WTO Members emphasized how such impositions could potentially result in distinct and less favorable treatment being accorded to groups of “like” non-EU chemical substance-based products to their detriment, with the consequent administrative burdens, costs, and market access delays inuring to the benefit and trade advantage of European-based competitors operating in those national markets.⁵⁰⁰ While ECHA lacks direct enforcement authority over REACH registration and evaluation-related compliance issues, it is responsible for establishing and overseeing the Forum for Exchange of Information on Enforcement (the “Forum”) for purposes of coordinating Member State enforcement activities.⁵⁰¹

note 83, ¶¶ 162–63; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶¶ 171, 176; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 57; TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 150.

497. See EUR. CHEMS. AGENCY, *Introduction to MINIMUM CRITERIA FOR REACH AND CLP INSPECTIONS*, ¶¶ v–vi (2011) [hereinafter *MINIMUM CRITERIA FOR REACH AND CLP INSPECTIONS*], available at http://www.echa.europa.eu/documents/10162/13577/mcri_minimum_criteria_reach_inspections_2011_en.pdf (stating that the document seeks to establish guidelines, not replace Member State systems of inspection); see also TBT Agreement, *supra* note 5, art. 3, annex 1.7 (providing for the handling of technical regulations at lower levels of government and also in non-government bodies).

498. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 150; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 57; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 176 (Belgium and Netherlands).

499. See, e.g., TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 176 (France, United Kingdom).

500. See TBT Committee Minutes for the Meeting of November 2008, *supra* note 83, ¶¶ 162–63.

501. REACH, *supra* note 2, art. 76(1)(f); see EUR. CHEMS. AGENCY, *RULES OF PROCEDURE FOR THE FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT* art. 1(1)–(2), Doc. MB/36/2011 final (2011) [hereinafter *RULES OF PROCEDURE FOR THE FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT*], available at http://www.echa.europa.eu/documents/10162/13577/forum_procedures_rules_en.pdf (stating that the Agency shall comprise the Forum to coordinate a network of Member States authorities responsible for enforcement of the regulation); see also REACH, *supra* note 2, art. 77(4)(b)–(f) (detailing the tasks of the Forum and specifying that it propose, coordinate, and evaluate enforcement projects and joint inspections; coordinate exchange of inspectors; identify enforcement strategies and best practices in enforcement; develop methods for local inspectors; and develop

ECHA's prescribed role is to recommend and loosely coordinate the enforcement activities, including inspections, to be undertaken directly by each Member State's national authority or inspectorate.⁵⁰² EU Member States, rather, are held individually responsible for directly enforcing registrants' REACH registration compliance obligations.⁵⁰³ To this end, Member State national authorities have adopted administrative enforcement measures, monitoring procedures, and controls⁵⁰⁴ and have enacted national legislation that impose penalties to ensure REACH registration compliance.⁵⁰⁵ A recent ECHA Forum strategy document reflects that a Member State national authority's inspection program must now "include procedures for both planned, proactive inspections, as well as reactive, *ad hoc* investigations in case of complaints," and it must provide for follow-up actions were an incident or accident "event" to occur.⁵⁰⁶ It also indicates that, since the most important aim of the enforcement process is the protection of human health and the environment, any differences or inconsistencies between the particular inspection and investigation methodologies employed by enforcing national authorities will be tolerated as long as effective REACH compliance is achieved.⁵⁰⁷

an electronic information-exchange procedure).

502. REACH, *supra* note 2, arts. 77(4)(b)–(d), 125; *see* RULES OF PROCEDURE FOR THE FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT, *supra* note 501, art. 2(1)(b)–(c) (laying out tasks the Forum should undertake in relation to Article 77(4) of REACH and Article 46(3) of CLP); *see also* *Enforcement Forum*, EUR. CHEMS. AGENCY, <http://www.echa.europa.eu/web/guest/about-us/who-we-are/enforcement-forum> (last visited Oct. 30, 2012) (displaying ECHA's role in establishing enforcement forums for Member States' national inspectorates). *See generally* *National Inspectorates*, EUR. CHEMS. AGENCY, <http://www.echa.europa.eu/web/guest/regulations/enforcement/national-inspectorates> (last visited Oct. 30, 2012) (providing links to the individual countries' national inspectorates).

503. *See Enforcement*, EUR. CHEMS. AGENCY, <http://www.echa.europa.eu/web/guest/regulations/enforcement> (last visited Oct. 30, 2012).

504. *See* REACH, *supra* note 2, art. 125.

505. *See id.* art. 126.

506. EUR. CHEMS. AGENCY, STRATEGIES FOR ENFORCEMENT OF REGULATION (EC) NO. 1907/2006 CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION & RESTRICTION OF CHEMICALS (REACH) & OF REGULATION (EC) NO. 1272/2008 ON THE CLASSIFICATION, LABELING AND PACKAGING OF SUBSTANCES AND MIXTURES (CLP) 11 (2011), *available at* http://www.echa.europa.eu/documents/10162/13577/strategies_enforcement_reach_2011_en.pdf.

507. *Id.* at 10 ("Generally, enforcement includes inspections, investigations,

WTO Member concerns about potential EU Member State trade protectionism can be traced, in part, to the lack of *EU-wide* inspection standards and effective coordination between the ECHA Forum and EU Member State national customs authorities. During late 2009 and early 2010, for example, the trade press reported how certain EU Member State enforcement strategies revealed that some national inspectors “[had] been targeting major companies,” while others, such as the UK, had endeavored to “target priority substances and companies” that were suspected of REACH registration noncompliance.⁵⁰⁸ The trade press attributed this inconsistency to the variable methods EU Member States used to integrate customs authorities into REACH enforcement programs.⁵⁰⁹ It is also commonly recognized that national customs authorities possess “extensive powers [enabling them to] order companies introducing products and containers into the EU to demonstrate [REACH] compliance” prior to securing customs approval.⁵¹⁰

However, in the absence of REACH-related compliance documentation “that can be easily shown to appease customs authorities,” it was feared that such authorities would be encouraged to act “upon the request of other authorities targeting specific products or importers, or to possibly take proactive measures *which could easily lead to arbitrary decisions to block imported products.*”⁵¹¹ Furthermore, more recent trade reporting has emphasized how EU Member State enforcement policies “differ greatly depending on their actual REACH & CLP implement[ation] progress.”⁵¹² For example, “Greek and Danish customs have severe inspections on pre-registration credentials and REACH Compliance import certificate[s],” while “the Dutch customs agency tend[s] to

formal enforcement action (such as issuing enforcement notices or instituting legal proceedings) and compliance promotion as well as communication with all the relevant stakeholders.”).

508. See *Early Lessons to Be Learned from REACH Enforcement*, CHEM. WATCH (Dec. 2009/Jan. 2010), <http://chemicalwatch.com/3042/legal-spotlight-early-lessons-to-be-learned-from-reach-enforcement>.

509. *Id.*

510. *Id.*

511. *Id.*

512. *Recent Update of REACH Enforcement Activities*, REACH24H CONSULTING GRP. (Apr. 5, 2012), <http://www.reach24h.com/en/knowledge-base/eu-reach/item/558-recent-update-of-reach-enforcement-activities.html>.

review on a regular basis Only Representative qualifications[,] and the German customs [agency] combines risk-related market surveillance with the REACH & CLP compliance inspections.”⁵¹³

A March 2010 EU Commission–funded report that evaluated whether EU Member States had fulfilled their obligation to impose effective and proportionate penalties for REACH noncompliance offences revealed similar results, concluding that “[t]he overall level of harmonisation of the sanctions for infringement of REACH across the EU Member States and the EEA countries [was] *quite low*.”⁵¹⁴ In particular, the report set forth the following specific findings:

- EU Member State enforcement regimes varied extensively between criminal, civil, and administrative law approaches, from country to country, based on national legal cultural background;⁵¹⁵
- A number of countries identified a quite extensive list of specific REACH noncompliance offenses,⁵¹⁶ whereas others employed more general terms reflecting the main obligations under REACH,⁵¹⁷ or “catch-all” provisions included through more general references to REACH violations;⁵¹⁸
- EU Member States imposed various types of civil penalties, including monetary fines, injunctions (including market withdrawal), prison sentences, and public name-and-shame methods, as well as criminal penalties, including monetary fines, imprisonment, and other orders;⁵¹⁹

513. *Id.*

514. EUR. COMM’N, *Executive Summary to REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATE* (Mar. 2010), at vi [hereinafter *REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATE*], available at <http://ec.europa.eu/environment/chemicals/reach/pdf/report%20REACH%20penalties.pdf>.

515. *Id.* at i–ii, 50.

516. Belgium (federal level), Bulgaria, Cyprus, Greece, Hungary, Italy, Lithuania, Portugal, Romania, Slovakia, Slovenia, and the United Kingdom employed this approach. *Id.* at ii.

517. Austria, Finland, France, Germany, Luxembourg, the Netherlands, Poland, and Sweden employed this approach. *Id.* at ii–iii.

518. Austria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Iceland, Ireland, Latvia, Liechtenstein, Malta, and Norway employed this approach. *Id.* at iii.

519. *Id.* at iii, 32.

- Administrative and criminal fines, as provided for in legislation, varied from country to country with most being within the range of €50,000 and €1,000,000 for first-time REACH offenses, while six EU Member States impose substantially higher maximum administrative and criminal fines,⁵²⁰ and four others choose not to provide the amounts of fines within their legislation;⁵²¹ and
- It was too early to conclude whether the enforcement measures employed had been effective, considering that REACH is still in the early stages, notwithstanding that certain comparisons have already been made.⁵²²

Although the European Commission portrayed the penalty report as “provid[ing] a useful input into better understanding the different REACH enforcement approaches and legal specificities in the Member States,” it apparently did not warmly embrace its findings.⁵²³

European Commissioner Bjorn Hansen’s May 2012 public comments strongly suggest that the EU Commission acknowledges how variations in Member State sanctions regimes can possibly result in “considerable distortions” such as forum shopping.⁵²⁴ His comments also likely reflect Commission recognition that it must do more to ensure that such enforcement discrepancies actually “avoid [creating] potential market distortions.”⁵²⁵ They may even indicate Commission concern that such distortions can potentially lead to WTO-inconsistent trade and market access barriers, especially

520. Six EU Member States impose substantially higher maximum administrative and criminal fines upon first infringement on natural as well as on legal persons: Belgium (€1.1 million administrative, €55 million criminal); Germany (€1 million criminal); Ireland (€3 million criminal); Poland (€4.7 million criminal); Portugal (€2.5 million administrative); United Kingdom (UNLIMITED criminal). *Id.* at iv, 34.

521. These countries are Denmark, Finland, Iceland, and Norway. *Id.* at iv.

522. *Id.* at 69 (stressing that the enforcement of REACH remains in the nascent stage of its development).

523. *REACH Enforcement*, EUR. COMM’N, http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm (last updated Sept. 14, 2012).

524. REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATE, *supra* note 514, at 1.

525. *EU Member States Investigating Poor Quality Dossiers*, *supra* note 492, at 2.

considering how multiple ministries within some EU Member States, such as Latvia and Poland, “control activities relating to the *trade* of chemical substances.”⁵²⁶

Arguably, the ECHA Forum’s March 2011 release of minimum EU-wide REACH inspection criteria⁵²⁷ can reasonably be interpreted as an attempted response to the penalty report’s recommendation that ECHA “ensure a minimum of consistency between the various sanction regimes in the Member States through cooperation and consultation mechanisms.”⁵²⁸ However, the ECHA Forum’s first five-year report on REACH’s operation,⁵²⁹ which revealed a rather extensive pattern of REACH noncompliance, demonstrated that greater efforts are needed.⁵³⁰

In light of the above, practitioners should confer with their clients for purposes of gathering evidence of potentially inconsistent and arbitrary EU Member State REACH compliance-related monitoring, investigatory, and enforcement activities. A viable trade discrimination claim could potentially be brought if it can be shown that divergent EU Member State competent authority determinations of REACH registration non-compliance are undertaken in an “uneven-handed manner,” resulting in imported chemical substance-based products being accorded less favorable treatment than “like” EU products, and that such less favorable treatment is sufficiently detrimental to affect the fundamental conditions of competition for such products in specific EU markets.⁵³¹

526. REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATE, *supra* note 514, at 61.

527. MINIMUM CRITERIA FOR REACH AND CLP INSPECTIONS, *supra* note 497.

528. REPORT ON PENALTIES APPLICABLE FOR INFRINGEMENT OF THE PROVISIONS OF THE REACH REGULATION IN THE MEMBER STATE, *supra* note 514, at 1.

529. *See* REACH, *supra* note 2, art. 127 (stating that these reports should include common issues agreed to by the Forum and that the reports will be made available to the Agency and the Forum).

530. *See generally* EUR. CHEMS. AGENCY, COORDINATED FORUM REACH ENFORCEMENT PROJECT ON REGISTRATION, PRE-REGISTRATION AND SAFETY DATA SHEETS—FACTS REPORT (2011), *available at* http://www.echa.europa.eu/documents/10162/13577/ref-1_prolongation_facts_report_en.pdf (detailing how non-compliance persists despite the many inspections that the report discusses).

531. *See, e.g.*, TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶¶ 162–63 (demonstrating many non-Member States’ concerns about varied treatment in enforcing REACH obligations).

c. *Potential “Only Representative” (“OR”) Discrimination*

Other REACH provisions can also serve to indirectly disadvantage “like” chemical substance-based imports in EU markets because of how they affect the cost structure of such products. For example, REACH Article 3 prohibits the submission of substance and article registrations directly by non-EU exporters—natural or legal persons—of chemical substance-based products.⁵³² Likewise, ECHA registration guidance clearly states that only EU-based manufacturers and importers—legal entities established in the EU—can register chemical substance-based products under REACH.⁵³³

The Article 3 prohibition could potentially be found *de facto* discriminatory as applied to SMEs lacking a European presence on several grounds. First, such prohibition exposes the intellectual property, including proprietary and confidential business information, of SME exporters that must be submitted as part of a registration technical dossier to the risk of appropriation by EU competitors.

Second, even if those exporters choose instead to open an EU office or to hire a REACH-recognized EU-based OR to maintain the confidentiality of their IP for registration purposes, as permitted by REACH Article 8(1), that option would necessarily entail significant added costs. Those costs would likely render the exporters’ chemical substance-based products less competitive than “like” EU-based chemical substance-based products, which can be registered directly by EU manufacturers. The cost of securing ORs can become quite expensive, especially for non-EU SME fragrance or paint manufacturers, because a “non-Community manufacturer” can appoint only one OR per exported substance, and “finished” fragrances and paints may consist of many substances, including SVHCs.⁵³⁴ As one EU Commission-sponsored study strongly

532. See REACH, *supra* note 2, art. 3(9), 3(11).

533. See GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 2.12.1; GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, §§ 1.5.2.1, 1.5.3.1, 1.5.3.3, 1.5.3.4.

534. GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, § 1.5.3.4; see 5th Meeting of the Competent Authorities for the Implementation of Regulation (EC) 1907/2006 (REACH) at 3, Eur. Comm’n Doc. CA/51/2008 (Oct. 7, 2008) (providing that, when a non-community manufacturer sends information to an importer regarding the OR, that importer becomes known as a downstream use of

suggests, the cost to a non-EU SME of retaining an OR to administrate its REACH registration obligations, while less than the cost of hiring dedicated REACH compliance personnel at between €25,000–€50,000, could potentially exceed €10,000.⁵³⁵

Third, in the absence of any EU standards for OR competency, there is little or no assurance that selected ORs could adequately protect non-EU SMEs' IP and other interests. One recently released report evaluating REACH's implementation revealed that "there is no agreed functional description of what the expected role of an OR is or should be and absence of an accreditation mechanism."⁵³⁶ Large fragrance formulators with market presence and influence, by contrast, would likely find it easier to secure the cooperation of their non-EU substance suppliers to ensure their assumption of responsibility for substance registrations via the hiring of their own ORs.⁵³⁷ Fourth, non-EU SME exporters of chemical substances and preparations had previously found it difficult to secure information from ECHA and REACH national HELP desks about EU-based

that OR); *see also* VERBAND DER CHEMISCHEN INDUSTRIE E.V., MODEL AGREEMENT FOR A CONTRACT BETWEEN AN ONLY REPRESENTATIVE AND A NON-COMMUNITY MANUFACTURER PURSUANT TO ART. 8 REACH (July 2008), *available at* http://wko.at/up/enet/chemie/VCI_Mustervertrag_Alleinvertreter_en.pdf (outlining a legal agreement between an only representative and a non-Community manufacturer that provides, among other things, for a party to reimburse the OR for any costs that arise from the OR's activities as long as they fall within the agreed budget).

535. *See* CTR. FOR STRATEGY & EVALUATION SERVS., INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH 39, 105 (2012) [hereinafter INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH], *available at* http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf; *id.* at 40, tbl. box 4.1; *see also* REACH Registration – Joint Submission, CHEM. INSPECTION & REGULATION SERV., http://www.cirs-reach.com/reach/REACH_Registration_Joint_Submission.html (last visited Oct. 30, 2012) (establishing that fees charged by the Chemical Inspection and Regulatory Service ("CIRS") consultancy to advise the whole registration process and prepare the individual part of registration dossier in IUCLID 5 can be as much as €4,000 per substance).

536. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, app. A – Case Studies, Case Study 8, at 60, *available at* http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-annex_en.pdf.

537. *See, e.g.,* James Calder, *R.E.A.C.H.—Is Now the Time to Relax?*, INSIDECOSMECEUTICALS.COM (Feb. 2, 2011), <http://www.insidecosmeceuticals.com/articles/2011/02/r-e-a-c-h-is-now-the-time-to-relax.aspx>.

ORs, which further burdened such companies and added to their EU market cost structure.⁵³⁸

Practitioners are advised to consult with their non-EU manufacturing clients to secure documentary evidence of the costs they incurred to retain ORs in order to register the substances they export to the EU region. In some respects, a non-EU substance manufacturer's choice between registering its substances via a newly hired OR or a potentially disloyal EU-based importer is tantamount to having no choice at all. Indeed, in operation, this aspect of REACH is arguably akin to a "local agent" requirement, the effect of which may be trade-restrictive, but not necessarily trade-discriminatory.⁵³⁹

The evidence, therefore, must show how the economic IP risks of working with an EU "importer" and the costs of working with one or more ORs, together with the costs and burdens of registration itself, can indirectly serve to drive non-EU SME chemical substance-based products manufacturers out of the EU market, or to drive EU and non-EU product/article manufacturers from their current non-EU sources of chemical inputs to more economically efficient and reliably REACH-compliant EU chemicals manufacturers and formulators. In addition, the evidence must also show that these REACH provisions can, consequently, operate to alter the fundamental conditions of competition in the EU chemicals market to the detriment of non-EU SME manufacturers.⁵⁴⁰

538. See discussion *supra* Part IV.B.2.c.

539. See, e.g., *EU Statement: 1st Trade Policy Review of the Kingdom of Saudi Arabia* (Jan. 25–27, 2012), http://eeas.europa.eu/delegations/wto/documents/press_corner/eu_statement_saudia_arabia_tpr.pdf (last visited Oct. 30, 2012) (outlining an EU complaint about the restrictive nature of either a "legal obligation or practical necessity to use local agents"); see also, e.g., Saifur Rahman, *WTO Urges UAE to Liberalise Trade Regime*, GULFNEWS.COM (Apr. 2, 2012), <http://gulfnews.com/business/economy/wto-urges-uae-to-liberalise-trade-regime-1.1002822>; Report by the Secretariat, Trade Policy Review Body, World Trade Organization, *Trade Policy Review Qatar*, at § II 'TRADE AND INVESTMENT REGIMES,' WT/TPR/S/144 (Jan. 24, 2005) ¶ 33 (detailing requests by WTO members to the government of UAE to do away with requirements for the hiring of local agents while increasing "the transparency, accountability, and effectiveness of government administration").

540. Furthermore, depending on the robustness and sufficiency of the evidence, it may also be possible to show that these REACH provisions operated in an indirect manner that was tantamount to imposing a "local content requirement,"

d. *Potential SIEF Discrimination*

The minutes of TBT Committee meetings convened during 2004 and 2008–2011 reflect WTO Member discussions about how the lack of EU institutional oversight regarding matters of SIEF governance and data sharing, and LoA negotiation protocols and procedures, had placed non-EU stakeholders, especially SMEs, at a potential competitive disadvantage vis-à-vis their EU-based competitors.⁵⁴¹ They alleged that EU-based SIEF lead registrants and consortium organizers had assumed effective control over the determination and allocation of testing costs and the costs of letters of access for data sharing charged to non-EU SIEF participants to secure referral rights to robust study summaries required to satisfy their REACH registration obligations.⁵⁴²

REACH mandates the formation of SIEFs to facilitate data sharing and the submission of joint pre-registrations among manufacturers and importers of the *same* phase-in or non-phase-in *substance*.⁵⁴³ SIEFs must also be accessible to downstream data holders, users, and other stakeholders.⁵⁴⁴ Although SIEFs are based in the EU, they are not legal entities⁵⁴⁵ and, therefore, are ineligible to submit

contrary to GATT 1994 Article III:4 and paragraph 1(a) of the Illustrative List Annex to the WTO Agreement on Trade-Related Investment Measures (“TRIMS Agreement”). “[L]ocal content requirements are not allowed as these will afford foreign products less favourable treatment than those produced domestically. In analysing the Illustrative List it becomes clear that it not only clarifies GATT Article III:4 but that it also sets out a non-exhaustive list of what measures are per se inconsistent with GATT Article III:4.” Paul Kruger, *The Impact of WTO Law on Foreign Investment: The Walmart/Massmart Merger* 7–8 (Tralac Trade Ctr. Working Paper No. S12WP03, Feb. 2012), (emphasis added) available at <http://www.tralac.org/files/2012/02/S12WP032012-Kruger-Impact-WTO-law-foreign-investment-WalmartMassmart-merger-FIN.pdf>.

541. See discussion *supra* Part II.C.6.

542. See discussion *supra* Part II.C.7; see also GUIDANCE ON DATA SHARING VERSION 2.0, *supra* note 56, §§ 1.3, 3.3.1, 3.3.5.3, 3.4.2.2 (noting costs of testing and letters of access are supposed to be negotiated fairly, transparently, and without discrimination).

543. See GUIDANCE ON DATA SHARING VERSION 2.0, *supra* note 56, § 3.2.2.

544. See REACH, *supra* note 2, art. 29(1).

545. Uwe Wolfmeier, CEFIC, *What to Bear in Mind When Becoming a Lead Registrant* (2009), available at http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=5245; see *Programme: REACH Lead Registrants Workshop*, EUR. CHEMS. AGENCY (Sept. 11, 2009), available at http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=4604 (noting the legal challenges associated with SIEF formation).

registrations under REACH.⁵⁴⁶ The primary aim of a SIEF, which serves to regroup “all pre-registrants of the same substance,”⁵⁴⁷ is to prevent duplicative studies, especially those that require vertebrate animal testing.⁵⁴⁸ Because SIEFs were creatures of the pre-registration period and had no prescribed legal form, SIEF pre-registrants were free to organize themselves as was necessary to carry out their SIEF objectives of data sharing, classification, and labeling and their joint submission of data obligations for both phase-in and non-phase-in substances.⁵⁴⁹ For example, SIEF pre-registrants could have either established one or more formal contractually or rules-based “consortiums” or simply acted as independent parties in loose, informal cooperation with one another. They could have then agreed upon a set of formal SIEF operating rules and procedures to govern the SIEF’s activities during the 2008–2018 pre-registration period for phase-in substances.⁵⁵⁰ “The designation of the lead registrant as well as the SIEF management is under the responsibility of the SIEF participants.”⁵⁵¹

REACH SIEF participants consist of “potential registrants” and “data holders.” “Data holders can . . . only provide data to active members (potential registrants) of the SIEF and request cost sharing for the data supplied[;] . . . [they do not] have an active role in deciding on the studies to be included in joint submissions nor on the classification and labelling proposals.”⁵⁵² Data holders can include only “[m]anufacturers and importers of phase-in substances in quantities of less than 1 tonne per year who have not pre-registered[,] [d]ownstream users who may be in possession of data . . . [and]

546. “Only a natural or legal person *established in the EU* can be a registrant.” GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 2.1.2.1 (emphasis added).

547. GUIDANCE ON DATA SHARING VERSION 2.0, *supra* note 56, § 8.2.

548. REACH, *supra* note 2, art. 29(2)(a).

549. See GUIDANCE ON DATA SHARING VERSION 2.0, *supra* note 56, §§ 1.2.6, 3.2.6.2, 8 (listing numerous examples of points that SIEF participants may want to include in an agreement laying out the functioning of the SIEF).

550. See *id.* §§ 1.2.6, 8, 8.2 (allowing that the SIEF participants can seek the services of third parties, such as a trade or sector association, a consultant or law firm, or other such service providers when detailing the terms of their cooperation).

551. *Id.* § 3.2. The joint submission will be made by a lead registrant elected by the other potential registrants of the same substance. See REACH, *supra* note 2, art. 11(1)–(2).

552. GUIDANCE ON DATA SHARING VERSION 2.0, *supra* note 56, § 3.2.3.2.

[o]ther third parties holding information on phase-in substances.”⁵⁵³ Potential registrants can include EU manufacturers and importers of phase-in substances or articles containing phase-in substances and the EU “only representatives” of non-EU manufacturers of phase-in substances; they can also include such parties where they have filed on a “late pre-registration” basis.⁵⁵⁴

At least one European legal commentator has concluded that non-EU manufacturers are “weakly placed in relation to SIEFs as they themselves cannot be directly present but only through their importers or only representatives.”⁵⁵⁵ This same commentator also noted how non-EU manufacturers may also be potentially exploited and placed at a competitive disadvantage by participating in REACH-focused voluntary consortia putatively governed by binding contractual agreements.⁵⁵⁶ At least one Chinese regulatory consulting firm providing REACH registration advisory and OR services to Chinese and U.S. exporters of chemical substance-based products to the EU has had a similar experience. It found that non-EU companies “do not have any power to negotiate the price of letter[s] of access,” which “makes them very vulnerable as they need to pay whatever price [is] charged by [the] lead registrant or consortium.”⁵⁵⁷

Indeed, non-EU manufacturers have incurred SIEF and consortia LoA costs for data sharing approaching €1 million or more and have encountered significant SIEF and consortium management fees. For example, Synthetic Amorphous Silica (“SAS”) consortium charges €1 million administrative fees to SIEF members representing a cumulative fee charged to each SIEF participant for the period spanning from 2010 to 2018.⁵⁵⁸ This fee does not even include data

553. *Id.*

554. *Id.* § 3.2.3.1.

555. Nicolas Gardères, *REACH and the Risks of Anticompetitive Agreements*, CHEM. TODAY (July/Aug. 2009), at 22, available at http://chemistry-today.teknoscienze.com/pdf/garderes_reach09.pdf.

556. *See id.* at 22–23 (suggesting that the non-EU manufacturers should at least be able to participate as associate members and should also attend and take part in consortium meetings).

557. *CIRS Receives Interviews from the European Commission DG Enterprise & Industry About the Impact of REACH on the Competitiveness of the General Chemical Industry and Non-EU Firms*, CHEM. INSPECTION & REG. SERV. (July 4, 2011), http://www.cirs-reach.com/news/CIRS_Receives_Interview_From_European_Commission_DG_Enterprise_and_Industry.html.

558. *See* SAS Consortium, *Criteria Applied by the SAS for REACH Consortium*:

fees, or dossier and CSR fees.⁵⁵⁹ While the available REACH Article 30(3) data-sharing dispute procedure offers non-EU SIEF participants possible redress where the owner of a vertebrate animal study⁵⁶⁰ “refuses to provide the proof of the costs of that study or the study itself,” such procedure can require the retention of counsel and, consequently, the incurrence of significant additional costs and time.⁵⁶¹

Practitioners are advised to consult with their non-EU manufacturer clients, especially SMEs, to ascertain whether their experiences with REACH-related SIEFs and consortia have been sufficiently one-sided and disproportionate as to indicate the indirect imposition of a relatively higher product cost and compliance structure not borne by their EU competitors.⁵⁶² Because SIEF governance policies and procedures and consortia contractual terms may appear neutral *per se* and even escape EU Commission antitrust scrutiny,⁵⁶³ the evidence must demonstrate that they can potentially

Calculating the Cost of a Letter of Access (LoA): Short Form of the Cost Calculation for Internet Publication (Sept. 9, 2012), at 2, available at <http://www.reach-sas.org/documents/Cost%20Calculation%20SASFORREACH%20Consortium.pdf> (detailing the inclusions in the cost such as dossier updates, the service of a legal advisor, communication within the SIEF, and other maintenance and management costs).

559. *Id.*; see CHEM. INSPECTION & REGULATION SERV., 2010 REACH REGISTRATION REPORT (2010), available at http://www.cirs-reach.com/REACH/2010_REACH_Registration_Statistics_and_Report_CIRS.pdf (giving numbers for the potential costs of data and dossier preparation at €4 million while confirming that administrative fees do not usually include these numbers).

560. Such studies are to be shared pursuant to Article 30(1) during the preparation of a joint registration dossier or following its submission. See REACH, *supra* note 2, art. 30(1).

561. See GUIDANCE ON DATA SHARING VERSION 2.0, *supra* note 56, § 3.4.2.1.

562. See EUR. ASSOC. OF CRAFT, SMALL & MEDIUM-SIZED ENTERS., POSITION PAPER: PROBLEMS FOR SMES ARISING FROM THE IMPLEMENTATION OF REACH AFTER TWO YEARS OF ITS ENTRY INTO FORCE (2009), available at http://www.ueapme.com/IMG/pdf/0910_pp_REACH_problems.pdf (supporting the position that the share of costs in a SIEF or consortia should be fair and not discriminate against non-EU manufacturers).

563. See REACH, *supra* note 2, pmb1., ¶ 48; see also *REACH Consortia Without Breaching Competition Law*, CHEM. WATCH (Feb. 2009), available at <http://chemicalwatch.com/1793/legal-spotlight-reach-consortia-without-breaching-competition-law> (noting that membership issues are not merely an antitrust issue and that different rules can apply to different members as long as they are essentially proportionate and acceptable from an antitrust standpoint); Craig

operate in an uneven-handed and *de facto* discriminatory manner that results in an overall higher cost structure for, and consequential distinct treatment of, non-EU manufactured chemical substances in the EU marketplace. Furthermore, the evidence adduced must show that such distinct treatment has altered the fundamental conditions of competition in the EU marketplace for “like” groups of EU- and non-EU manufactured chemical substances to the detriment of the non-EU client’s products in that market.

C. TBT ARTICLE 2.2 ANALYSIS OF REACH

1. *Technical Regulation’s “Trade-Restrictiveness”*

Recent WTO jurisprudence indicates that a TBT Article 2.2 “unnecessary obstacles to trade” or “no more trade-restrictive than necessary” analysis of REACH must first focus on whether its disputed registration/data-gathering and notification provisions are “trade-restrictive.” This article’s prior discussion of these REACH provisions clearly reflects that they have affected the competitive opportunities available to non-EU-imported chemical substance-based products within EU markets.⁵⁶⁴ Consequently, REACH’s registration/data-gathering and notification provisions may be considered to be trade-restrictive within the meaning of TBT Article 2.2 without regard to either their specific level of “trade-restrictiveness” or their actual trade effects.

2. *Technical Regulation’s “Objective”*

Once this initial determination has been made, a TBT Article 2.2 analysis must next identify REACH’s policy objective(s), recognizing the European Union’s right, as a WTO Member, to establish that objective(s) for itself. Typically, a regulation’s

Simpson, STEPTOE & JOHNSON LLP, SIEFS AND CONSORTIA: COOPERATION UNDER REACH 16–17 (2007), available at http://www.stepto.com/assets/htmldocuments/REACH_presentation_November_2007.pdf (detailing the measures that all consortium members will take to avoid violating EC antitrust laws); Craig Simpson, STEPTOE & JOHNSON LLP, SIEFS AND DATA SHARING: PRACTICAL ISSUES 12–18 (2007), available at http://www.stepto.com/assets/htmldocuments/Simpson_-_SIEFs_and_data_sharing.pdf (explaining why consortium members should be wary of violating EC antitrust laws and again laying out how to avoid doing so).

⁵⁶⁴ See discussion *supra* Part IV.B.

objective precedes the establishment of the regulation to be adopted or maintained. The evidence reveals that the EU white paper on a regional chemicals strategy setting forth the framework that led to the adoption of REACH expressly lists “[p]rotection of human health and the environment” as the primary objective of such strategy.⁵⁶⁵ In addition, the TBT notifications the EU submitted to the WTO TBT Committee concerning REACH in advance of and subsequent to its adoption, and which enjoy a rebuttable presumption of truthfulness and good faith, state that the objective of the REACH regulation is the protection of human health and the environment.⁵⁶⁶ An examination of the text of numerous REACH provisions furthermore reveals that the principal objective is *to ensure a high level of protection* of human health and the environment.⁵⁶⁷ The EU Commission has also suggested that REACH is intended to reduce vertebrate animal testing.⁵⁶⁸ This is more properly characterized as a tertiary, incidental objective.⁵⁶⁹

Finally, a review of REACH’s design, architecture, and structure indicates that it was designed and structured with the purpose of achieving its principal objective of *ensuring a high level of protection* of human health and the environment. Arguably, the provisions of REACH evidence this objective by:

- Requiring that all existing substances are tested within a prescribed period of time and thereafter properly assessed for their impact on human health and the environment;⁵⁷⁰

565. See *Commission White Paper on the Strategy for a Future Chemicals Policy*, §§ 2.2, 2.3, COM (2001) 88 final (Feb. 27, 2001).

566. Jan. 21, 2004, TBT Committee Notification, *supra* note 35, at 2.

567. See, e.g., REACH, *supra* note 2, pmbl. ¶¶ 1, 3, 7, 69, 71, 76, 80, 86, 112, 131; arts. 1(1), 31(4), 37(3), 58(2), 87(4), 123, 138(2)(b), 138(9), Annex II.

568. See *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, at 7 (calling for a balance between protection of human health and the protection of laboratory animals); see, e.g., REACH, *supra* note 2, pmbl. ¶¶ 37, 40, 47, 64; arts. 13, 25(1), 117(3), 138(9).

569. See *EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*, UK DEP’T FOR ENV’T, FOOD & RURAL AFFAIRS, <http://www.defra.gov.uk/environment/quality/chemicals/reach/> (last visited Oct. 30, 2012) (describing the limits on animal testing as companion requirements when putting together testing proposals to get information on substance registrations that had been missing).

570. See *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, at 7–8 (requiring tests within five years, followed by

- Reversing the burden of proof and imposing on industry the responsibility of ensuring that the chemicals they place on the market are safe for their intended uses and of providing knowledge about chemicals by a) generating and assessing data, b) assessing the risks of the use of the substances, and c) providing adequate information about the risks to downstream users;⁵⁷¹
- Holding “producers of preparations and other downstream users” responsible for “assess[ing] the safety of their products for the part of the life cycle to which they contribute, including disposal and waste management”;⁵⁷²
- Subjecting SVHCs to an authorization procedure pursuant to which use-specific permission will be required “before they can be employed in particular uses,” provided evidence demonstrates that such a use presents only a negligible risk or if such risk is deemed acceptable based on various socio-economic factors;⁵⁷³ and
- Requiring the substitution of SVHCs where suitable alternatives can be reasonably found.⁵⁷⁴

3. “Legitimacy” of Technical Regulation’s Objective

Bearing in mind the right of every WTO Member to regulate in order to pursue certain legitimate objectives, a TBT Article 2.2 analysis must next evaluate whether the objective identified is “legitimate.” An objective’s legitimacy can generally be found in the “genuine nature” of the objective and its justification, as reflected in relevant supporting public policies or other social norms. One relevant mutually supporting European regional public policy and

assessments of the impact the substance will have on human health).

571. REACH, *supra* note 2, tit. II: arts. 5–7, 10, 12–14, 17–18 and tit. IV: arts. 31–34.

572. *Id.* tit. III: arts. 25–30; see *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, § 2.2 (explaining the expansion of responsibility to other entities within the manufacturing chain).

573. REACH, *supra* note 2, tit. VII: arts. 55–60; *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, § 2.3.

574. REACH, *supra* note 2, tit. VII: arts. 60–63; see *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, § 2.3 (highlighting the importance of this objective in making sure that a substance is safe for its designed use).

emerging social norm that REACH is intended to help achieve *by ensuring a high level of protection* of human health and the environment with respect to chemicals is the concept of “sustainable development.”⁵⁷⁵ Sustainable development also serves as the policy basis for a number of U.N.-based multilateral environmental treaties pertaining to chemicals, to which the EU is a named and active party.⁵⁷⁶ In addition, the legitimacy of REACH’s primary objective is included in the open list of “legitimate objectives” found within the text of TBT Article 2.2 itself: “Such legitimate objectives are, *inter alia* . . . protection of human health or safety; . . . or the environment”⁵⁷⁷

Consequently, it would appear, based on recent WTO jurisprudence, that REACH’s primary objective of *ensuring a high level of protection* of human health and the environment is a “legitimate” objective within the meaning of TBT Article 2.2. Moreover, REACH’s incidental objective of reducing animal testing can also be found within the non-exclusive list of “legitimate” objectives set forth in the text of TBT Article 2.2: “protection of . . . animal or plant life or health” As noted by the Panel in *US—Tuna II (Mexico)*,

[A] measure that aims at the protection of animal life or health need not . . . be directed exclusively to endangered or depleted species or

575. See *Sustainable Development*, EUR. COMM’N, <http://ec.europa.eu/environment/eussd/> (last updated Feb. 23, 2012) (calling for the EU and each of its Member States to link their sustainable development strategies more closely); EUR. COMM’N, ENVIRONMENT FACT SHEET: SUSTAINABLE DEVELOPMENT (2006), available at http://ec.europa.eu/environment/pubs/pdf/factsheets/sust_dev.pdf (defining sustainable development as “development that meets the needs of the present without compromising the ability of future generations to meet their own needs”); see also *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, § 2.2 (pointing to the overarching goal of sustainable development).

576. See REACH, *supra* note 2, pmbl. ¶ 4 (mentioning the implementation plan adopted by the Johannesburg World Summit); see also Press Release, Office of Legal Affairs, Sustainable Development Treaty-Signing Event Concludes at UN Headquarters: Representatives of 48 States Affirm Support for Sustainable Development-Related and Other Multilateral Legal Instruments, U.N. Press Release L/T/4370 (Sept. 9, 2002), available at <http://www.unis.unvienna.org/unis/pressrels/2002/lt4370.html> (showcasing UN member states’ recent support for sustainable development treaties, including at the World Summit on Sustainable Development).

577. TBT Agreement, *supra* note 5, art. 2.2.

populations, to be legitimate. Article 2.2 refers to “animal life or health” in general terms, and does not require that such protection be tied to a broader conservation objective.⁵⁷⁸

4. *Technical Regulation’s “Fulfillment” of Its Legitimate Objective*

Once REACH’s actual objective has been identified and its legitimacy verified, the next step in a TBT Article 2.2 analysis of REACH is to determine whether REACH “fulfills” this objective. The Appellate Body in *Brazil—Retreaded Tyres*, *US—Tuna II (Mexico)*, and *US—COOL* have construed the term “fulfill,” in the context of GATT 1994 Article XX and TBT Article 2.2, as requiring that a measure make a “contribution” capable of achieving the objective pursued.⁵⁷⁹ This determination is focused primarily on the degree to which the technical regulation contributes to the achievement of the legitimate objective as discerned from the measure’s design, structure, and operation, as well as from evidence relating to its application.⁵⁸⁰ A measure will be deemed to make a contribution to an underlying objective if it can be demonstrated that there is “a genuine relationship of ends and means between the objective pursued and the measure at issue,” informed by an examination of the regulation *per se* and how it operates in practice.⁵⁸¹

The Appellate Body’s analysis in *Brazil—Retreaded Tyres* is relevant to determining the degree to which the REACH regulation’s

578. See US — Tuna Panel Report, *supra* note 154, ¶ 7.437.

579. See Appellate Body Report, *Brazil — Measures Affecting Imports of Retreaded Tyres*, ¶ 149, WT/DS332AB/R (Dec. 3, 2007) [hereinafter *Brazil — Retreaded Tyres Appellate Body Report*] (stressing that the Panel’s analysis had to consider both the immediate effects of an Import Ban as well as the possibility that the Ban will actually lead to a reduction in “the exposure to the targeted risks”); US — Tuna Appellate Body Report, *supra* note 156, ¶¶ 315–17 (stating that fulfillment of an objective by a technical regulation depends on how much that regulation helps to actually achieve that objective, and an adjudication panel should consider the regulation’s overall contribution); US — COOL Appellate Body Report, *supra* note 156, ¶¶ 461–66 (speaking approvingly of the *US—Tuna II* Adjudication Panel’s determination of the contribution made by a technical regulation and then applying that same method in its own determination in the present case).

580. See US — COOL Appellate Body Report, *supra* note 156, ¶ 461 (citing US — Tuna Appellate Body Report, *supra* note 156, ¶¶ 315–17).

581. *Brazil — Retreaded Tyres Appellate Body Report*, *supra* note 579, ¶ 145; US — COOL Panel Report, *supra* note 151, ¶ 7.693.

complex and burdensome registration/data-gathering and notification provisions, which reflect the EU's "chosen high level of protection,"⁵⁸² have contributed to the achievement of REACH's legitimate objective to protect human health and the environment.⁵⁸³ In *Brazil—Retreaded Tyres*, the Appellate Body distinguished between the objective of Brazil's retreaded tire ban—"the *reduction of the 'exposure to the risks to human, animal or plant life or health arising from the accumulation of waste tyres'*"—and Brazil's "chosen level of protection" for achieving that objective—"the *reduction of the risks of waste tyre accumulation to the maximum extent possible.*"⁵⁸⁴ It acknowledged that Brazil, as a WTO Member, was entitled to adopt and implement measures that sought a *high level of protection* of health and the environment via *risk elimination or reduction* in an effort to achieve the tire ban's legitimate objective of health and environmental *risk exposure reduction*.⁵⁸⁵ Ultimately, the Appellate Body concluded that Brazil's comprehensive regulatory schema was capable of materially contributing to the achievement of the objective of reducing the potential exposure to risks arising from the accumulation of waste tires.⁵⁸⁶

Although the Appellate Body in *Brazil—Retreaded Tyres* assessed the Brazilian measure's contribution as "a function of the nature of the risk, the objective pursued, and the level of protection sought," its analysis arguably did not adequately address the distinction between a "risk" and a "hazard."⁵⁸⁷ "A risk exists when there is *exposure* to a

582. In other words, the EU's chosen high level of protection was the *elimination or reduction* of health and environmental *hazards* posed by chemical substance-based products. See GUIDANCE ON REGISTRATION Sept. 2011 Draft, *supra* note 48, § 5.3.1.3. "The risk characterisation shall be carried out for each exposure scenario for both the human health and the environment and the results and discussion reported in section 10 of the CSR. *As the purpose is to prove that the risks are controlled it is expected that the results of the risk characterisation SHOULD NOT INDICATE A RISK*" (emphasis added). *Id.*

583. REACH, *supra* note 2, art. 1(1).

584. Brazil — Retreaded Tyres Appellate Body Report, *supra* note 579, ¶ 144 (emphasis added).

585. See *id.* ¶ 144.

586. See *id.* ¶¶ 154–55 (stressing that the Import Ban under consideration should be analyzed as part of the comprehensive strategy that Brazil designed and implemented with the goal of eliminating the negative impacts of waste tires).

587. *Id.* ¶ 145.

‘hazard’”⁵⁸⁸ The Brazilian tire ban endeavored to reduce potential health and environmental risk exposures engendered by the accumulating, burning, and landfilling of retreaded tires. However, it did *not* do so by *managing* those particular exposure risks. Rather, it sought to eliminate *ab initio* the underlying hazards posed by retreaded tires based on their intrinsic characteristics that could potentially but not necessarily give rise to such exposure risks.

The Appellate Body apparently agreed with the Panel’s decision “to conduct a *qualitative analysis* of the . . . Import Ban[‘s] . . . contribution to the achievement of its objective,” since the Appellate Body had not previously required “that such a contribution be *quantified*”⁵⁸⁹ Similarly, in *EC—Asbestos*, the Appellate Body permitted France to apply its own, customary and normal rules of *qualitative rather than quantitative risk assessments* to determine whether imported chrysotile asbestos tiles had posed a risk to human health.⁵⁹⁰ These determinations would appear to confirm in the TBT context what some legal commentators have already observed in the SPS context, namely the WTO’s gradual shift from the traditional

588. See EVALUATION OF COMMUNICATION ON THE DIFFERENCES BETWEEN “RISK” AND “HAZARD,” *supra* note 463, at 7–8 (“The term ‘hazard’ refers to the inherent property of a substance (or a situation) to cause an adverse effect. In this context for example the International Programme on Chemical Safety (IPCS) defines a ‘hazard’ as the: Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub) population is exposed to that agent. (IPCS2004, 12) . . . The IPCS definition of risk is broader and is also used in this report. . . The probability of an adverse effect in an organism, system, or (sub) population caused under specified circumstances by exposure to an agent. (IPCS 2004, 13) This definition highlights the fact that the difference between ‘hazard’ and ‘risk’ lies in exposure. A risk exists when there is exposure to a ‘hazard’, in a nutshell: risk= (hazard, exposure).”); see also INT’L PROGRAMME ON CHEM. SAFETY, WORLD HEALTH ORG., IPCS RISK ASSESSMENT TERMINOLOGY 1, 27–28 (2004), available at <http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf> (explaining that the terms “risk” and “hazard” are both significant in describing risk assessors, but each term when combined with other important expressions represents a distinct concept).

589. See *Brazil — Retreaded Tyres Appellate Body Report*, *supra* note 579, ¶¶ 146–47 (“In our view, the Panel’s choice of a qualitative analysis was within the bounds of the latitude it enjoys in choosing a methodology for the analysis of the contribution.”).

590. See *EC — Asbestos Appellate Body Report*, *supra* note 162, ¶¶ 27, 167–68 (noting a risk may be evaluated either in quantitative or qualitative terms, and that the Panel accepted France’s determination to protect against health risks by restricting use of chrysotile asbestos).

quantitative risk-assessment model toward a more holistic semi-quantitative/qualitative risk model.⁵⁹¹

REACH practitioners should consider whether the regulation's objective of protecting human health and the environment from potential exposure to risks posed by chemical substance-based products can be achieved via REACH's onerous registration/data-gathering and notification requirements, which are primarily aimed at identifying and reducing the underlying hazards associated with such substances. When determining the degree to which these provisions contribute to the achievement of REACH's principal legitimate objective, practitioners should direct their attention to the following factors:

- The basis for requiring and the nature—amount, type, quality (quantitative vs. qualitative)—of the data to be submitted as part of a chemical substance registration;
- The capacity of—the financial and human capital resources available to—the relevant EU institutions to efficiently gather and process said information; and
- The likelihood that such information can be meaningfully disseminated and communicated as intended—to transmit hazard information through chemical substance-based product supply chains and to the public via the Internet.

a. Basis for Registration Data

The EU Commission's chemicals strategy white paper reveals that the central motivation behind REACH's registration/data-gathering requirement is the EU Commission's prior lack of knowledge about the properties and the uses of the thousands of substances manufactured within and imported into the EU.⁵⁹² This information was said to reside primarily with industry and was generally difficult

591. See discussion *supra* Part III.B.1.a (defining the three-part test for a technical regulation that is subject to the TBT Agreement as including an identifiable group of products, characteristics related to the products, and mandatory compliance with the product characteristics).

592. See *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, at 6 (reporting that although existing substances account for 99% of total volume of all substances on the market, there is deficient information known about these substances under the current system).

to obtain, save for a slow and resource-intensive government-initiated risk-assessment process.⁵⁹³ REACH's registration/data-gathering requirement is intended to generate the necessary information concerning manufactured or imported substances that would enable manufacturers and importers to assess the risks related to such substances and to develop and recommend appropriate risk-management measures.⁵⁹⁴

b. Quantity, Quality, and Types of Required Pre-Registration Data

REACH requires manufacturers and importers "to collect *all available existing information* on the properties of the substance for registration purposes, regardless of the tonnage manufactured or imported."⁵⁹⁵ Such information includes "test data (in vivo and in vitro)[,] non-test data from alternative methods[,], and information on manufacture, uses, risk management measures and resulting exposures."⁵⁹⁶ The standard information requirements with respect to a given substance differ depending on annual volumes. For a substance with an annual volume of one ton or more, information regarding its physicochemical, toxicological, and ecotoxicological properties must be provided.⁵⁹⁷ For a substance with an annual volume of ten tons or more, the same information plus additional

593. See TBT Committee Minutes for the Meeting of 4 November 2004, *supra* note 46, ¶ 24 (describing that REACH was implemented to resolve the difficulty of risk identification and the absence of an effective instrument to address problematic substances under the EU Chemicals Management system); see also *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, at 6 (explaining the ineffectiveness of having authorities conduct risk assessment when enterprises are the entities responsible for production, importation, and use of substances).

594. See GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 1.2; GUIDANCE ON REGISTRATION VERSION 1.6, *supra* note 47, § 1.2 (noting that the registration system requires manufacturers and importers to gather information and submit a dossier on the substances they work with so they can use this data themselves for risk management).

595. REACH, *supra* note 2, Annex VI, Step 1; GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 3.1.1; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 3.1.1.

596. REACH, *supra* note 2, Annex VI, Step 1; GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 3.1.1; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 3.1.1.

597. REACH, *supra* note 2, Annex VII, col. 1.

toxicological and ecotoxicological information must be provided.⁵⁹⁸ For a substance with an annual volume of 100 tons or more, the same information, plus additional information on the physicochemical properties of the substance and toxicological and ecotoxicological information, must be provided.⁵⁹⁹ For a substance with an annual volume of 1,000 tons or more, the same information, plus additional toxicological and ecotoxicological information, must be provided.⁶⁰⁰ *All relevant and available information* must be documented in both a technical dossier and, for substances manufactured or imported in quantities of ten tons or more per year per registrant, in a CSR.⁶⁰¹

The technical dossier must include:

- General information for the identification of the registrant and the substance to be registered;⁶⁰²
- Substance classification and labeling information;⁶⁰³

598. *Id.* Annex VIII, col. 1 (noting there are “specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way”); GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, tbl.2; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, tbl.2.

599. REACH, *supra* note 2, Annex IX, col. 1; GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, tbl.2; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, tbl.2.

600. REACH, *supra* note 2, Annex X, col. 1; GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, tbl.2; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, tbl.2.

601. GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, tbl.2; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.1 (“The information needs to be reported in [International Uniform Chemical Information Database (“IUCLID”)] format, and submitted to ECHA via REACH-IT . . .”).

602. *See* REACH, *supra* note 2, Annex VI (including contact information of the registrant and location of the registrant’s production); *see also* GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 5.2.1; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.2.1 (stressing the identification step as crucial for REACH because it enables the substance to be recorded accurately).

603. *See generally* Commission Regulation 453/2010, pmb. ¶ 4, art. 1(1)–1(2), 2010 J.O. (L 133) [hereinafter Commission Regulation 453/2010] (“Directives 67/548/EEC and 1999/45/EC will be replaced over a transitional period . . . from 1 December 2010 and 1 June 2015, although [during that time] classification of substances according to both Directive 67/548/EEC and [CLP] Regulation (EC) No 1272/2008 is required.”); GUIDANCE ON REGISTRATION May 2012 Draft, *supra* note 48, § 5.2.2; GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.2.2 (requiring that classification and labeling be submitted according to the criteria in Directive 67/548/EEC until December 2010

- Manufacture and use(s) information;⁶⁰⁴
- *All relevant available information* on substance physicochemical, toxicological, and ecotoxicological intrinsic properties in the form of study summaries or robust study summaries, with robust study summaries being provided when a chemical safety report is required, i.e., for substances above ten tons per year;⁶⁰⁵ and
- Guidance on safe use.⁶⁰⁶

The CSR must include:

- A chemical safety assessment of the substance's physicochemical, human health, and environmental dangers and an assessment of whether the substance is PBT “or very persistent and very bioaccumulative” (“vPvB”);⁶⁰⁷
- A qualitative or quantitative exposure assessment if the hazard assessment leads to a hazard classification or categorization;⁶⁰⁸ and
- A risk characterization that “prove[s] that the risks are

when the CLP Regulation criteria should take effect).

604. See REACH, *supra* note 2, Annex VI, § 3 (explaining required information like tonnage manufactured, used, or imported, and a brief description of the process employed in the manufacture and production of articles); see also GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.2.3 (underlining that the registrant can decide how detailed his submission of manufacture and use information is, but there are certain items that need to be included).

605. See GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.2.4 (issuing robust study summaries “facilitate[s] the evaluation work to be done by ECHA and eventually Member States in the frame of substance evaluation and may potentially avoid the need for them to request further information”).

606. See REACH, *supra* note 2, Annex VI, § 5 (including first-aid measures, firefighting measures, accidental release measures, handling and storage, and transport information); see also GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 5.2.5 (noting that information must be consistent with a safety data sheet where it is needed).

607. See GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, §§ 5.3.1–5.3.1.1.4 (clarifying that the hazard assessment will be conducted on all the information contained in the technical dossier and describing the vPvB assessment process).

608. See *id.* § 5.3.1.2 (demonstrating that the exposure assessment consists of (1) the generation of exposure scenarios, which evaluates how the substance is used throughout its life cycle and how its exposure is controlled vis-à-vis humans and the environment, and (2) the exposure estimation).

controlled . . . [and that] should not indicate a risk.”⁶⁰⁹

Given the massive amount of information required as part of the pre-registration process, REACH has been referred to “as a central information system” that “entails an all-encompassing approach.”⁶¹⁰ It is arguable that since the REACH registration/data-gathering requirement pulls in too much information, much of which is irrelevant to addressing health and environmental risks, it actually serves to undermine the regulation’s ability to convey useful information that contributes to the fulfillment of its underlying objective. For example, one recently released report found that REACH’s

contribution . . . in the development of new knowledge has been rather limited . . . [because] the huge amount of information generated to date by REACH [was not] of use in developing new substances or new uses for existing substances One explanation often provided by industry representatives and experts is that, so far, REACH registration has mainly covered substances for which most of the relevant information was already available⁶¹¹

c. *ECHA’s and EU Member States’ Capacity to Process/Use Pre-Registration-Related Data*

Ever since REACH was first proposed as a chemicals strategy in 2001, the European Commission and Parliament have estimated that REACH’s registration requirements would affect approximately only 30,000 substances.⁶¹² Notwithstanding these estimates, on December

609. See *id.* § 5.3.1.3 (stating that the risk characterization will be conducted with regard to both human health and the environment).

610. See Eurostat, *supra* note 55, at 29 (instructing that, while it is fair to presume multiple legislative efforts improve the environment and human health, REACH should be understood as more comprehensive).

611. See INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at VI, 90–91 (reporting that the majority of firms surveyed believed the information acquired from REACH has not had any contribution in knowledge development).

612. See *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, at 15–16, 28, 31 (explaining the REACH system will be composed of the registration of 30,000 substances and estimating a cost of €2.1 billion for the testing of 30,000 substances over eleven years); see also UK Parliamentary Office of Sci. & Tech., *EU Chemicals Policy*, POSTNOTE, Sept. 2004, at 2, available at www.parliament.uk/briefing-papers/POST-PN-229.pdf (noting that the European Commission deems that 30,000 substances are used in

19, 2008, ECHA reported that approximately 170,000 substances had actually been pre-registered between June 1 and December 1, 2008.⁶¹³ It also reported that the screening of the approximately 2.75 million pre-registrations for the 150,000 substances, “around 15 times more than originally estimated,” would take longer than expected.⁶¹⁴ Thereafter, on March 29, 2009, ECHA published an updated list of pre-registered substances under REACH, which reflected a slightly lower number—approximately 143,000 pre-registered substances.⁶¹⁵

Moreover, it is generally accepted that “[t]he technical heart of ECHA is [REACH-IT], the information technology system with which the agency receives and saves registrations, requests, reports,

higher volumes that require registration); Press Release, Parliament Adopts REACH – New EU Chemicals Legislation and New Chemicals Agency (Dec. 13, 2006) at 3, available at <http://www.europarl.europa.eu/sides/getDoc.do?language=en&type=IMPRESS&reference=20061213IPR01493> (providing that registration of a substance is determined by the risk the substance poses and the quantity produced of the substance); Press Release, Europa, REACH: Industry Urged to Pre-Register All Chemicals by 1 December 2008 (Apr. 11, 2008), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/564> (“Registration is expected to impact some 30,000 chemicals between 1 June 2008 and 30 May 2018.”); cf. Eurostat, *supra* note 55, at 11 (demonstrating that 237 substances had been chosen for pre-REACH snapshot from the 30,000 substances covered by REACH).

613. See PRICEWATERHOUSECOOPERS, FINAL REPORT ON THE REVIEW OF THE EUROPEAN CHEMICALS AGENCY 17, § 2.1.2 (2012) [hereinafter PWC Report], available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach-review2012/echa-final-report_en.pdf (claiming the increased number of pre-registrations demanded more from systems like REACH-IT).

614. See Sean Milmo, *Chemical Data Forums Latest Stumbling Block for Reach*, CHEM. WORLD (May 11, 2009), <http://www.rsc.org/chemistryworld/News/2009/May/11050901.asp> (explaining that after having difficulty with pre-registration, the REACH process continues to pose challenges with the next stage of forming substance information forums (SIEFS)); see also Chris Jones, *ECHA Delays Publication of Final Reach Pre-registration List*, ICIS (Dec. 19, 2008), <http://www.icis.com/Articles/2008/12/19/9180868/echa-delays-publication-of-final-reach-pre-registration-list.html> (declaring that the fully screened list of substances would be published past its deadline).

615. See Stefan Baumgarten, *ECHA Updates List of Pre-Registered Substances Under REACH*, ICIS (Mar. 27, 2009), <http://www.icis.com/Articles/2009/03/27/9204015/echa-updates-list-of-pre-registered-substances-under.html> (reporting that ECHA stated the list contains some substances that did not require registration and some improvements of the previous list, including CAS numbers that only had been identified by chemical name in the prior list).

and payments”⁶¹⁶ However, due in part to what ECHA Executive Director Geert Dancet described as computer and finance-related start-up difficulties and the unanticipated flood of pre-registrations ECHA received during late 2008,⁶¹⁷ the REACH-IT system was severely compromised and required extensive revamping.⁶¹⁸ One university report observed that, unless ECHA’s size and capacity are increased, “a majority of the data submitted under the REACH registration process may never be evaluated.”⁶¹⁹ Another EU Commission–funded report evaluating ECHA’s performance since start-up confirmed that the REACH-IT system failure had an adverse impact on ECHA’s subsequent ability to prepare dossier evaluation decisions.⁶²⁰

In addition, a third recently released study evaluating the impact of REACH implementation obligations on EU markets and European chemicals industry competitiveness cited the lack of adequate EU Member State resources as posing another impediment to effective use of the information generated as the result of the REACH pre-registration process.⁶²¹

[EU] Member State Authorities consider the knowledge created through

616. Brigitte Osterath, *Let Registration Commence*, CHEM. WORLD, May 2008, at 71, available at http://www.rsc.org/images/ECHA_tcm18-119381.pdf (explaining that companies use REACH-IT to send complete registration dossiers to the agency).

617. See Anne Eckstein, *Chemicals: Geert Dancet: Budget Problems Looming for ECHA (European Chemicals Agency)* (July 16, 2008), available at <http://www.highbeam.com/doc/1G1-181376416.html> (discussing ECHA budget problems caused by many companies rushing to receive authorization under the previous rules so they could avoid paying a fee).

618. See Milmo, *supra* note 614 (highlighting that REACH software systems are continuously being enhanced to facilitate the substance information exchange forms (SIEFS)).

619. ABELKOP ET AL., *supra* note 464, at 24 (“[T]he REACH registration process may ultimately be seen more as a system of data collection and warehousing than a procedure for protecting the public and the environment from exposures to hazardous substances.”).

620. See PWC ECHA Report, *supra* note 613, at 16, 56 (noting REACH IT absorbed more resources than anticipated, and there were delays in the development of ECHA’s internal systems).

621. See INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 92 (indicating survey responses showed most industry associations were pessimistic about the capacity to employ the knowledge acquired).

REACH “fundamental” and “absolutely necessary for authorities” in their own policy making The key issue for most of them *is the actual capacity to utilize this knowledge*. Not all Member States are equally equipped and resource limitations are often stated as an important constraint in this direction.⁶²²

These observations strongly suggest that the relevant EU regional and national institutions have experienced rather serious capacity limitations that have challenged their ability to efficiently process and use the very large volume of complex hazard-based information they continue to receive from registrants in satisfaction of REACH’s registration/data-gathering requirement.

d. ECHA’s Capacity to Clearly Disseminate REACH Registration Data to Stakeholders

REACH anticipates that the hazard information generated as the result of the registration/data-gathering process will be used for various purposes by EU and EU Member State institutions. For example, information contained in registration dossiers⁶²³ and a classification and labeling inventory⁶²⁴ are included by ECHA in REACH-IT.⁶²⁵ Said database shall be notified to EU Member State national authorities⁶²⁶ and made freely accessible to the EU public⁶²⁷ to permit them to make informed decisions about their use of chemicals, subject to REACH confidentiality provisions protecting registrants’ proprietary, sensitive, and confidential business information submitted as part of a REACH registration.⁶²⁸ In

622. *Id.*

623. REACH, *supra* note 2, art. 10(a)–(b) (including contact information of the manufacturer or importer, details about the substance, and a chemical safety report when required).

624. *Id.* art. 114(1) (asserting the inventory will include the information described in Article 113(1) as well as information submitted as part of registration).

625. *Id.* art. 77(2)(e) (explaining the database will be available over the Internet free of charge).

626. *Id.* art. 20(4) (claiming all Member States where the manufacture takes place or the importer is established shall be notified no later than 30 days after the submission date).

627. *Id.* art. 119.

628. *See id.* pmb. ¶ 117 (allowing the public to review descriptions of hazardous properties, labeling requirements, and laws on uses of substances and risk management); *see also id.* arts. 10(a)(xi), 105, 109, 118, 120 (requiring

addition, REACH also anticipates that such information will be included in the development of a voluntary EU regional eco-labeling scheme or an EU quality mark.⁶²⁹

One EU Commission-funded report found that the exposure-related information contained in the REACH pre-registration dossiers and CSRs submitted through REACH-IT was quite complex, and that the ECHA database dissemination website was “poorly laid out and structured” and not very user-friendly.⁶³⁰ It determined that these deficiencies could potentially prevent ECHA from effectively communicating and disseminating meaningful and new substance exposure-related information to: a) EU Member State national authorities for purposes of ensuring REACH registration compliance and enforcement via the REACH Information Portal for Enforcement;⁶³¹ b) industry for purposes of developing more ecological and less harmful chemical “substitutes”;⁶³² and c)

registrants to give an explanation of why such information would be harmful for commercial interests if he or she wants to refrain from disclosure on the Internet, except the registrant need not disclose information covered by the duty of professional secrecy); Bronckers & Van Gerven, *supra* note 410, at 1839–43 (discussing the conflict within REACH between these confidentiality provisions and Preamble paragraph 117, which obliges ECHA and EU Member States to provide access to such information consistent with the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters otherwise known as the “Aarhus Convention”). See generally *The Aarhus Convention*, EUR. COMM’N, <http://ec.europa.eu/environment/aarhus/> (last updated Sept. 14, 2012) (noting the Aarhus Convention gives rights to the public with regard to the environment like the right to receive information held by public authorities).

629. REACH, *supra* note 2, pmbl. ¶ 14.

630. See PWC Report, *supra* note 613, at 25, 30, 35, 42 (claiming information was difficult to locate on the website and that the site lacked clarity in the routing and search capabilities); see generally INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 17 (explaining that, as part of its objective to share chemical information among interested parties, REACH-IT has “a dissemination-focused website addressed to the general public where non-confidential data on chemicals and information on the status of those chemicals are provided.”).

631. See generally Press Release, Eur. Chems. Agency, ECHA Releases a Web Portal for REACH and CLP Inspectors (June 28, 2011), available at http://echa.europa.eu/web/guest/view-article/-/journal_content/7b1e2ff9-38a0-4cac-b93e-ae9e18347552 (noting that inspectors can use the REACH Information Portal for Enforcement (RIPE) website to see who submitted a dossier and when, among other information about the relevant substance).

632. See INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL

consumers of typical household or recreational products for purposes of ensuring their safer use.⁶³³ Furthermore, the report found that ECHA's poor dissemination of information to these stakeholders "deprived . . . stakeholders . . . of the information they need for their learning processes and to contribute to the learning processes of ECHA as well as the Member States and other private actors"⁶³⁴ Consequently, the report's authors concluded that,

[i]n the area of dissemination . . . [ECHA] did not achieve its own goals, or those set or implied by the REACH . . . regulation Dissemination is of particular importance, as it is a key area in which ECHA can contribute to achieving the goals of REACH.⁶³⁵

Moreover, REACH provides for the establishment of a classification and labeling inventory system that identifies the intrinsic hazardous properties of and provides safe-use information for substances and substance mixtures designated as "dangerous"—information that requires notification and submission to ECHA.⁶³⁶ REACH anticipates that the presentation and public reporting of such information will take into account existing and emerging international standards in the regulation of chemicals, such as the United Nations Globally Harmonized System ("GHS") of classification and labeling of chemicals, which aims "to provide a harmonised basis for globally uniform physical, environmental and health and safety information on hazardous chemical substances and mixtures."⁶³⁷ During 2008, the EU enacted a separate classification,

MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 26 (expressing that matters concerning confidentiality may also affect the "innovative capacity of the industry").

633. See PWC Report, *supra* note 613, at 25, 32, 41, 42 ("The dissemination of non-confidential (pre)registration data through ECHA's dissemination website has been criticized as insufficient by representatives of various stakeholder groups."); see also INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at VI, 26, 37 (declaring that REACH has not made a significant contribution to increasing consumer confidence in chemical products).

634. See PWC Report, *supra* note 613, at 32 (explaining that, while there is no deadline for publication of information, the fact that it has already taken over a year is detrimental to stakeholders).

635. *Id.* at 5.

636. REACH, *supra* note 2, arts. 112–16.

637. See UK DEP'T FOR ENV'T, FOOD & RURAL AFFAIRS, SCOPING STUDY FOR THE EVALUATION OF EU REACH AND CLP REGULATIONS § 2.2.3 (2009),

labeling, and packaging (“CLP”) regulation⁶³⁸ with terms and definitions consistent with those of REACH⁶³⁹ to implement the general principles of the GHS.⁶⁴⁰ REACH and CLP were deemed similar to the extent they both were hazard-based and focused on gathering hazard data with the objective of *ensuring a high level of protection* of health and the environment.⁶⁴¹ The subsequent 2010 amendment of REACH Annex II has since resulted in the actual convergence of REACH and CLP to the extent updated REACH Annex II guidelines for compiling “safety data sheets” “take into account the rules for safety data sheets of the [GHS]” over the course of a five-year phase-in period.⁶⁴²

Pursuant to this amendment, suppliers already required to prepare and submit a safety data sheet (“SDS”) to their downstream users must now provide their downstream users and distributors with an SDS on substances and substance mixtures where “[a] substance [or mixture] meets the criteria for classification as hazardous according to CLP”⁶⁴³ Practitioners will notice that the CLP regulation, by

available at <http://archive.defra.gov.uk/environment/quality/chemicals/reach/documents/eu-reach-clp-regs-report.pdf> (explaining how REACH complements GHS goals by using the same chemical classifications to protect humans and the environment against hazardous effects of chemicals and to facilitate trade).

638. *See generally* Commission Regulation 1272/2008, 2008 O.J. (L 353) 1 [hereinafter CLP Regulation] (“repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006”).

639. *Id.* pmbl. ¶ 12.

640. *See* European Commission Directorates General Enterprise and Industry and Environment, *An Introduction to the CLP Regulation for Professional Suppliers/Users*, at 1, *available at*, http://ec.europa.eu/enterprise/sectors/chemicals/files/ghs/clp_introduction_en.pdf (describing that users will see new pictograms on chemical labels as suppliers switch to the GHS system to achieve the goal of a single worldwide operation to identify hazards).

641. *Compare* REACH, *supra* note 2, pmbl. ¶ 1 (differing slightly in that it calls for the promotion of alternative hazard assessment methods), *with* CLP Regulation, *supra* note 638, pmbl. ¶¶ 1, 3 (differing only in that it calls for a mixture of protection of human health with attempts to achieve sustainable development).

642. *See* REACH, *supra* note 2, arts. 1(1)–(2), 2(1)–(7) (defining the aim, scope, and application of REACH); *see also* EUR. CHEMS. AGENCY, GUIDANCE ON THE COMPILATION OF SAFETY DATA SHEETS § 1.1 (2011), *available at* http://www.schc.org/pdf/ECHA_fourth_draft_sds_Guidance_july_2011.pdf (providing that additional GHS elements beyond the safety data sheet were also implemented into EU legislation introduced by CLP via REACH Annex II); Commission Regulation 453/2010, *supra* note 603, at 133/4 (listing requirements for the compilation of safety data sheets).

643. *See* ECHA Compilation Guidance, *supra* note 642, § 1.1 (explaining

comparison, communicates hazard information in simpler, more comprehensible and symbolic terms than does REACH, primarily through use of point-of-purchase labels, containing hazard statements, hazard pictograms, and precautionary statements that are directed at both downstream members of the substance supply chain *and* at end-consumers.⁶⁴⁴ Thus, practitioners should question the extent to which REACH's registration/data-gathering and notification requirements contribute to the regulation's objective of ensuring a high level of protection of human health and the environment without the classification, labeling, and packaging procedures required by the CLP regulation.

ECHA and the EU Commission may be inclined to argue that ECHA's capacity is not a problem since it is the responsibility of suppliers under REACH and the subsequently enacted CLP regulation to produce and convey substance information contained in dossiers and CSRs in a clear and comprehensible manner that ECHA can then disseminate.⁶⁴⁵ However, such claims do not necessarily relieve ECHA and the EU Commission of the burden of ensuring for WTO purposes that REACH's registration/data-gathering requirement achieves the regulation's objective without imposing unnecessary obstacles to international trade.

e. ECHA's Perfunctory and Infrequent Evaluation of Harmful Substances

Of arguably greater significance are ECHA's perfunctory, automated registration "completeness checks"⁶⁴⁶ and the infrequent

application of such a provision will apply to a mixture by June 2015); *see also* GUIDANCE ON REGISTRATION March 2012 Draft, *supra* note 48, § 6.1.1 (concluding that the supplier must also provide an SDS to downstream users and distributors if substance is persistent, bioaccumulative, and toxic in accordance with Annex XIII of REACH or if it is among the candidate list substances).

644. *See* CLP Regulation, *supra* note 638, arts. 19, 21, 26–28 (taking measures to reduce the number of hazard pictograms and precautionary statements on substances to avoid duplication and redundancy).

645. *See id.* (demonstrating how the CLP regulation arguably communicates hazard information in a more comprehensible manner using point-of-purchase labels, containing hazard statements, hazard pictograms, and precautionary statements).

646. *See* REACH, *supra* note 2, art. 20(2) ("The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted."); *see also* GUIDANCE ON DOSSIER AND SUBSTANCE EVALUATION,

substantive registration dossier evaluations entailing both registration “compliance checks”⁶⁴⁷ and registration testing proposal examinations of phase-in substances subject to the first registration deadline,⁶⁴⁸ particularly those involving vertebrate animals.⁶⁴⁹ These practices strongly suggest that relatively few potentially harmful substances can or will be prioritized and adequately examined during the course of any given fiscal year. They also raise serious questions about the extent to which REACH could contribute to the fulfillment of its objective of ensuring a high level of health and environmental protection, and also about whether the benefits of REACH outweigh its costs.

For example, REACH Article 41(5) and accompanying ECHA guidance documents indicate that ECHA need only evaluate little more than 5% of the dossier registrations received for each tonnage band for compliance, regardless of the year of manufacture or import.⁶⁵⁰ Dossier registrations numbered approximately 25,300 by

supra note 473 (confirming no quality or adequacy assessment is done during the completeness check). *See generally* JAVIER SANCHEZ, EUR. CHEMS. AGENCY, OVERVIEW OF THE TECHNICAL COMPLETENESS CHECK PROCESS (2010), *available at* http://apps.echa.europa.eu/legacy/doc/webinars/overview_of_the_technical_completeness_check_process_javier_sanchez_echa.pdf (detailing both the information requirements that need to be submitted and the entire technical completeness check process).

647. *See* REACH, *supra* note 2, art. 41 (declaring that, to ensure that registration dossiers are in compliance, a small amount of the total received will be examined for compliance checking).

648. *See id.* arts. 40, 43 (giving different time schedules for draft decisions for non-phase-in substances and for phase-in substances).

649. *See id.* art. 40 (informing that the information on test proposals involving vertebrate animals will be published on the Agency website).

650. REACH, *supra* note 2, art. 41(5); *see* GEORGE CATLIDGE, EUR. CHEMS. AGENCY, FEEDBACK FROM EVALUATION 8 (2012), *available at* http://echa.europa.eu/documents/10162/1674131/05_feedback_from_evaluation_catlidge_en.pdf (claiming the ECHA has discretion in choosing which dossiers to check); *see also* EUR. CHEMS. AGENCY, EVALUATION UNDER REACH: PROGRESS REPORT 2011 12 (2012) § 1.2 [hereinafter EVALUATION UNDER REACH: PROGRESS REPORT 2011], *available at* http://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf (explaining the compliance check is one of three processes of evaluation with the other two being testing proposal examination and substance evaluation); EUR. CHEMS. AGENCY, EVALUATION UNDER REACH: PROGRESS REPORT 2010 6 (2010) [hereinafter EVALUATION UNDER REACH: PROGRESS REPORT 2010], *available at* http://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_report_2010_en.pdf (noting that the number of registration submitted per year varies and the 5% target does not always

year-end 2011,⁶⁵¹ and approximately 28,000 as of June 1, 2012, covering “more than 5,500 different substances” in all.⁶⁵² At most, only 1,400 of these 28,000 dossiers will be subject to an ECHA REACH compliance check for purposes of prioritizing substances for evaluation by EU Member States and identifying SVHCs.⁶⁵³ The balance of 95%, or 26,600 dossiers, was *not* subject to any ECHA compliance check at all.⁶⁵⁴

Indeed, ECHA initiated only 16 dossier compliance checks in 2009, 135 dossier compliance checks in 2010, and 158 dossier compliance checks in 2011, for a total from 2009 to 2011 of 309, or 1.22%, compliance checks initiated with respect to 25,300 submitted dossier registrations during the same period.⁶⁵⁵ This means that unless a Member State Competent Authority itself commences a substance dossier evaluation based on information obtained from non-ECHA sources, such as supply chain members, the substance(s) registered within these dossiers may not be evaluated for some time, if ever.⁶⁵⁶ Furthermore, of the 25,000 dossiers thus far registered,

have to be met every year); GUIDANCE ON DOSSIER AND SUBSTANCE EVALUATION, *supra* note 473, at 42 (explaining that prioritization criteria for the compliance check will be further developed).

651. See EVALUATION UNDER REACH: PROGRESS REPORT 2011, *supra* note 650, at 14 (citing more than 3,700 new registrations in 2011). See generally EVALUATION UNDER REACH: PROGRESS REPORT 2010, *supra* note 650, at 10 (noting approximately 21,600 registrations submitted by year-end 2010).

652. See Press Release, Fed. Env'tl. Agency & Fed'n of German Consumer Orgs., Scope of Information About Chemicals Improved: Five Years after REACH – Positive Balance Despite Obvious Deficits (May 31, 2012) [hereinafter *Scope of Information about Chemicals Improved: Five Years After REACH*], available at http://www.umweltbundesamt.de/uba-info-presse-e/2012/pe12020_scope_of_information_about_chemicals_improved.htm (citing the number of dossiers as evidence that REACH may be going in the right direction).

653. See generally GUIDANCE ON DOSSIER AND SUBSTANCE EVALUATION, *supra* note 473, at 14–15, 39 (providing the actors and their responsibilities in the evaluation process and the scope and purposes of the compliance check).

654. See ABELKOP ET AL., *supra* note 464, at 34–35 (noting the ECHA will complete its compliance checks for dossiers submitted in 2010 by the year 2013).

655. Compare EVALUATION UNDER REACH: PROGRESS REPORT 2010, *supra* note 650, at 10–11 (containing an additional overview of compliance checks undertaken by the agency since the beginning of the evaluation process), with EVALUATION UNDER REACH: PROGRESS REPORT 2011, *supra* note 650, at 20 (explaining that ECHA opened more dossiers for compliance checks than was anticipated).

656. See EVALUATION UNDER REACH: PROGRESS REPORT 2011, *supra* note

only 1,116 carcinogenic, mutagenic, or toxic for reproduction (“CMR”)⁶⁵⁷ substances have been identified as being included within the CLP inventory to-date, and 40% of those have been found not to be registered, let alone prioritized, under REACH.⁶⁵⁸ In addition, only eighty-four registered substances have thus far been identified as SVHCs that may include CMRs and/or endocrine disruptors.⁶⁵⁹

EU officials may be inclined to argue that REACH, by design, imposes upon chemical substance-based product manufacturers and importers the legal responsibility “to assess the risks and hazards of

650, at 13, 16 (claiming dossier evaluation includes compliance checks and testing proposal examinations).

657. See REACH, *supra* note 2, art. 40(1) (“Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitizing and/or carcinogenic, mutagenic or toxic for reproduction [CMR] properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.”).

658. See EUR. CHEMS. AGENCY, CMR SUBSTANCES FROM ANNEX VI OF THE CLP REGULATION REGISTERED UNDER REACH AND NOTIFIED UNDER CLPA – FIRST SCREENING 5, 12 (2012), available at http://echa.europa.eu/documents/10162/13562/cmr_report_en.pdf (noting that UVCB substances used in the petroleum industry make up some of the 40% of substances for which no match could be found); see also Press Release, Eur. Chems. Agency, ECHA Publishes the First Report on CMR Substances Registered or Notified After the 2010 Registration Deadline (June 4, 2012), available at http://echa.europa.eu/en/web/guest/view-article/-/journal_content/84609700-3f19-4bcb-83c8-cd0c48ec2df2 (reasoning that some of the substances with no match could have been substituted for less hazardous substances, and some are so rare that they will not likely be found on the market).

659. See Emma Chynoweth, *EU Commission Drives Towards Candidate List Goal*, CHEM. WATCH (Aug. 17, 2012), <http://chemicalwatch.com/12091/eu-commission-drives-towards-candidate-list-goal> (“In a surprise move aimed at hitting its target of 136 substances on the REACH candidate list by the end of 2012, the European Commission has requested ECHA prepare 38 dossiers nominating substances of very high concern [SVHCs]. The Annex XV SVHC proposal dossiers, which are all for substances classified as carcinogenic, mutagenic and reprotoxic [CMR], are expected to be completed in time for the next candidate list consultation beginning on 3 September. If the proposals are not challenged the substances could be added to the candidate list by the end of 2012 and – in combination with dossiers for 15 substances from member states [CW 15 August 2012] – fulfil the European Commission’s target. At present there are just 84 substances on the list.”); see also Scope of Information About Chemicals Improved: Five Years After REACH, *supra* note 652, at 1 (noting fourteen chemicals may no longer be in use without approval by 2014 and 2015); REACH SVHC List 2012: SVHC Testing, *supra* note 403 (explaining the SVHC candidate list will expand as member states provide more suggestions for inclusion).

substances,”⁶⁶⁰ to manage “the risks of substances,”⁶⁶¹ and ultimately “to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected” by manufactured or imported substances.⁶⁶² However, such putative delegations of responsibility by government to the private sector do not necessarily relieve the European Commission, ECHA, or EU Member State governments of legal liability in the event EU Member State citizens are injured by a dangerous chemical substance-based product that was not sufficiently evaluated and prioritized by such authorities.⁶⁶³ Similarly, such delegations of responsibility do not relieve the EU of its sole burden under international trade law to ensure that REACH’s registration/data-gathering and notification requirements contribute as much as possible to the fulfillment of the regulation’s stated objective without creating unnecessary obstacles to international trade.

f. REACH Pre-Registration Process Design Flaws Impaired Phase-in Substance Identification

Several commentators have noted that although “[o]ne of ECHA’s goals for the pre-registration process was to determine which phase-in substances were actually still on the market . . . ECHA failed to accomplish this objective . . . [d]ue to the high volume of pre-registration applications.”⁶⁶⁴ In their view, several REACH

660. See REACH, *supra* note 2, pmbl. ¶ 25 (providing that those handling the chemicals should also take risk-management measures).

661. See *id.* pmbl. ¶ 18 (“Information on this regulation should be easily accessible, in particular for SMEs.”).

662. See *id.* pmbl. ¶ 16 (stating that REACH provides specific duties and obligations for manufacturers and importers in this regard).

663. See Consolidated Version of the Treaty on the Functioning of the European Union art. 340, ¶ 2, 2010 O.J. (C 83) 53 (stating that the Union will address any damage caused by its institutions or servants in the execution of their duties); see also Case C-352/98P, *Laboratoires Pharmaceutiques Bergaderm SA v Comm’n*, 2000 E.C.R. I-5291 (declaring that the Court of Justice stated there is EU liability where “the rule infringed confers rights on individuals, the breach is sufficiently serious and there is a direct causal link between the breach and the damage.”). See generally Tamara Čapeta, ACTION IN DAMAGES AGAINST EU INSTITUTIONS (Univ. Maribor, Lecture Notes, Dec. 2008), available at www.pf.uni-mb.si/datoteke/knez/t_capeta_-_damages.doc (explaining contractual and non-contractual liability for EU institutions as provided for under Article 288 TEC).

664. ABELKOP ET AL., *supra* note 464, at 21; see EUR. COMM’N; REACH IN BRIEF: WHY DO WE NEED REACH? HOW DOES REACH WORK? WHAT ARE THE

registration process design flaws triggered this occurrence:

- REACH required each “legal entity not pre-registering a substance manufactured or imported at more than 1 tonne per year to halt manufacture/import of that substance immediately after the pre-registration deadline”;⁶⁶⁵
- ECHA had made various changes or clarifications to the pre-registration process prior to the pre-registration deadline, which likely raised uncertainties among prospective registrants;⁶⁶⁶
- “[N]either REACH nor ECHA established any barrier or disincentive [to manufacturers, producers and importers] to pre-register,” thereby encouraging the prudent “pre-registering [of] more rather than fewer substances” to avert “the risk of a potential supply disruption”;⁶⁶⁷
- Pre-registration uncertainties encouraged pre-registration by “downstream users who . . . [either] misinterpreted ECHA’s guidance . . . or . . . feared [being held] liable as potential importers if their suppliers . . . forgot to pre-register”;⁶⁶⁸ and
- Several opportunistic “firms pre-registered chemical substances that they did not even produce or import in an attempt to earn profit from involvement in substance registration by acting as an importer for companies who missed the pre-registration deadline.”⁶⁶⁹

According to these commentators, had REACH and ECHA imposed a more “modest fee for registration,” poorly considered submissions could have been discouraged.⁶⁷⁰ In addition, had REACH and ECHA imposed “a more modest financial penalty for a

BENEFITS AND COSTS? WHAT WAS THE DECISION-MAKING PROCESS? HOW WILL REACH BE IMPLEMENTED? 3–4 (Oct. 2007), available at http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf (noting the problems of the former chemical legislation, including the system’s hampering of research and innovation within the EU chemicals industry).

665. ABELKOP ET AL., *supra* note 464, at 21.

666. *Id.*

667. *Id.*

668. *Id.*

669. *Id.* at 22.

670. *See id.* (claiming such a reform could lead to a more manageable number of submissions to review).

first-time failure to pre-register (rather than an immediate halt of production),” it might have prevented companies from thinking that their failure to pre-register would result in a forced government cessation of their production and the consequent loss of their products’ market share.⁶⁷¹ Practitioners should consider the extent to which these alleged pre-registration process design flaws undermined the ability of REACH’s registration/data-gathering requirement to contribute to the regulation’s principal objective of ensuring *a high level of protection* of human health and the environment.

5. *Whether the Technical Regulation Is “More Trade Restrictive Than Necessary” to Fulfill the Objective Concerned, Taking into Account the Risks Nonfulfillment Would Create*

As the *US—Tuna II (Mexico)* Panel explained:

[T]o determine whether a measure is more trade restrictive than necessary within the meaning of Article 2.2 . . . [practitioners] must assess the manner in which and the extent to which the measures at issue fulfill their objectives, taking into account [the WTO Member’s] chosen level of protection, and compare this with a potential[ly] less trade restrictive alternative measure, in order to determine whether such alternative measure would similarly fulfill the objectives pursued by the technical regulation at the Member’s chosen level of protection.⁶⁷²

The prior section’s findings strongly suggest that the REACH registration/data-gathering and notification provisions are capable of at least partially contributing to the achievement of REACH’s legitimate objective of ensuring a high level of protection of human health and the environment. Therefore, the next step in this TBT Article 2.2 analysis should entail an examination of whether REACH is “more trade restrictive than necessary” to fulfill that objective.

A “more trade restrictive than necessary” inquiry, within the meaning of TBT Article 2.2, should focus on REACH’s “trade restrictiveness” rather than on its necessity, and it should seek to ascertain whether REACH’s level of trade restrictiveness is required to fulfill its legitimate objective(s) “at its chosen level of

671. *See id.* (explaining the need to prevent panic among companies due to fear of cessation of production).

672. US — Tuna Panel Report, *supra* note 154, ¶ 7.465.

protection.”⁶⁷³ First, REACH’s trade restrictiveness must be compared to a reasonably available alternative to determine whether such alternative is potentially less trade restrictive than REACH and is also capable of achieving REACH’s objective at the same level of protection.⁶⁷⁴ Second, the “risks of nonfulfillment” of REACH’s legitimate objective at the EU’s desired level of protection must be considered.⁶⁷⁵ In other words, practitioners should seek to ascertain the likelihood and gravity of the potential risks, and any associated adverse consequences that would arise if the identified and reasonably available, less trade-restrictive alternative were unable to fulfill the EU’s legitimate objective. In assessing such risks, practitioners should secure and make reference to available scientific and technical information and related processing technology, intended product end-uses, and other relevant probative evidence.⁶⁷⁶

a. Demonstrating How REACH Is More Trade Restrictive Than Necessary

As previously discussed, REACH may appropriately be classified as a type of non-tariff measure that arguably distorts and creates uncertainty surrounding international trade flows of chemical substance-based products. However, many WTO Members have also alleged that REACH’s costly and burdensome hazard-based registration/data-gathering and notification requirements constitute a non-tariff trade barrier because they have served to restrict international trade in chemicals by imposing on global industry a significantly altered cost structure in order to achieve REACH’s primary objective of ensuring *a high level of protection* of human health and the environment.⁶⁷⁷

One recently released report evaluating REACH implementation in relation to its impact on EU markets and European chemicals

673. *Id.* ¶ 7.460; *see also* discussion *supra* Part III.B.3.d (examining the analysis of trade restrictiveness employed by the WTO in previous disputes).

674. *Id.* ¶ 7.465; *see also* discussion *supra* Part III.B.3.d.i (identifying several factors previously used by the WTO in determining trade restrictiveness).

675. *See* discussion *supra* Part III.B.3.d.ii (explaining the analysis of non-fulfillment risk in the WTO U.S.-Mexico tuna dispute).

676. US — Tuna Panel Report, *supra* note 154, ¶¶ 7.466–7.467.

677. *See* discussion *supra* Part IV.B (analyzing REACH under TBT Article 2.1 to show that it accords less favorable treatment to “like” chemicals and products containing such chemicals that originate outside the EU).

industry competitiveness sets forth a number of findings that appear to strongly corroborate this allegation.⁶⁷⁸ Perhaps the report's most prominent revelation is that EU as well as non-EU chemical manufacturers and importers incurred approximately €2.1 billion in costs for the first REACH registration period, "close to double . . . the initial estimations made by the [European] Commission in 2003."⁶⁷⁹ The report indicates that this aggregate figure was composed of various direct and indirect REACH compliance-related expenses that were incurred to:

- Secure human resources to carry out the various REACH compliance-specific activities;
- Pre-register and register manufactured and imported substances;
- Apply for authorizations for manufacturing, importing, and downstream use of substances;
- Engage in information-exchange activities along the supply chain;
- Notify governmental authorities about articles containing SVHCs and to submit chemical safety reports; and
- Change production, substitute substances, manage risks, and undertake other necessary investments.⁶⁸⁰

The following subsections will briefly discuss items 1, 2, 4, and 5 above and their likely trade impacts.

i. Human Resource–Related Costs

The report clearly indicates that, in most of the cases surveyed, large chemical manufacturers, importers, and downstream users established a REACH unit occupied by between one and five full-time equivalent ("FTE") staff to satisfy their REACH compliance obligations; in some cases, they hired up to 100 FTE staff.⁶⁸¹ Such

678. See INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 105 (identifying data collection and ECHA registration as the key drivers of REACH compliance costs).

679. *Id.* at iii–iv, 105.

680. *Id.* at 38.

681. *Id.* at 39 (finding that "according to the survey responses, in most cases — around 55% — REACH units typically occupy between one and five staff (Full

companies also appointed a minimum of one REACH officer to each separate production unit.⁶⁸² Small firms, meanwhile, dedicated “at least one member of staff with technical background working on REACH on a full or part-time basis.”⁶⁸³ “Based on an average [EU-27]⁶⁸⁴ cost of €50,000/FTE for the EU chemicals industry, annual human resource costs for the typical large firms are in the range of €100,000–€250,000 per annum, and €25,000–50,000 for smaller size firms.”⁶⁸⁵

ii. ECHA Registration Costs

The report also clearly indicates that registration costs, which include data collection, ECHA registration, and supply-chain communication and exchange-of-information costs, were quite substantial.⁶⁸⁶ It found that ECHA fees represented “close to 36% of the median value of the total registration costs for large firms and 38% for medium size. In comparison they represent[ed] around 22% of the costs for small firms and around 9% of the average registration costs for very small (micro) firms.”⁶⁸⁷ In addition, it found that ECHA fees and registration costs “more generally . . . represent[ed] a greater share of the turnover [or sales revenue] of smaller size firms by a factor of 4 to 5.”⁶⁸⁸ For each REACH Article 6, 7, and 11 individually registered substance, substance mixture, or substance-in-an-article, ECHA fees can range from €1,600 to €31,000, whereas for each REACH Article 7 and 11 jointly registered substance-in-an-

Time Equivalent). The survey responses suggest that . . . manufacturers of chemicals tend to have more sizable REACH units than downstream users and distributors”).

682. *Id.*

683. *Id.* at 105.

684. See *Glossary: EU Enlargements*, EUR. COMM’N, http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Glossary:EU-27 (last visited Oct. 31, 2012) (using EU-27 to refer to the number of countries in the EU upon the accession of Bulgaria and Romania in 2007).

685. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 39.

686. See *id.* at 41 (stating that 70% of respondents to a business survey estimated their total cost of REACH registration compliance at between €25,000 and €250,000 for one substance).

687. *Id.* at 101.

688. *Id.* at 101–02 (showing that, for each €1 million in sales revenue, micro, small, medium, and large firms incurred ECHA fees of €1550, €1240, €434, and €310, respectively).

article, ECHA fees can range from €1,200 to €23,250, depending on the annual tonnage range.⁶⁸⁹ SMEs are afforded reduced rates for such filings.⁶⁹⁰

Further ECHA registration fees are charged for “updates of tonnage bands,” which can range from €2,700 to €29,500 for individual registrations, and from €2,025 to €22,050 for joint submissions, with reduced rates for SMEs, depending on the tonnage band in question.⁶⁹¹ An additional ECHA fee of €1,500 for individual registrations will be charged for changes in identity of the registrant involving a change in legal personality and for each item change in the access granted to information in the submission, with reduced rates applicable to SMEs.⁶⁹² Additional, not insignificant registration-related ECHA fees are imposed for requests for access to a study summary to be referenced in an individual registration, which can range from €1,500 to €4,500 depending on the type of information sought and whether the request is made by an SME.⁶⁹³

iii. Data Gathering, Supply-Chain Communication and Exchange, and IT-Related Costs

Furthermore, the report revealed rather considerable supply-chain information and exchange-related costs for “the handling of [SDSs]” and “the extensive and continuous information exchange along the supply chain—inside and outside Europe.”⁶⁹⁴ For example, it noted that small manufacturers or formulators with no more than five employees “might have to deal with 50-100 substances *each with an SDS of some 100 pages*,” whereas slightly larger firms “with 50-100 employees might have 5-10,000 substances to handle,” each with a comparable SDS of approximately 100 pages.⁶⁹⁵

The report also observed that many companies utilize external

689. Commission Regulation 340/2008, art. 3, Annex I, tbl.1, 2008 O.J. (L 107) 6 (EC) [hereinafter FCP Regulation].

690. *Id.* tbl.2.

691. *Id.* art. 5, Annex III, tpls.1–2.

692. *Id.* tpls.3–4.

693. *Id.* art. 6, Annex IV, tpls.1–2.

694. See INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at iv, 105 (stating that the cost of IT systems implemented for the management of SDSs can rise to more than €1 million for large firms with complex systems).

695. *Id.* at 97 (emphasis added).

consultants to assist them in the development and translation of SDSs and extended Safety Data Sheets (“eSDSs”), which can cost approximately “€200 for each SDS and €500 for each [eSDS],” without translation costs; translation costs can then add between €100 and €300 per language.⁶⁹⁶ Given the amount of information and the volume of pages involved, companies often purchase IT applications or systems to facilitate their development and handling of SDS and electronic eSDSs and associated supplier and customer communications.⁶⁹⁷ Although the report does not provide direct information concerning such costs, its individual discussions with industry members yielded estimated IT application costs of €30,000 for medium-sized companies and upwards of €100,000 for large firms.⁶⁹⁸ The report also referred to an Accenture analysis of the cost of IT systems that “support a greater range of REACH activities”⁶⁹⁹ According to the Accenture report, REACH IT investments to maintain compliance can cost upwards of €1,000,000 to €3,000,000 for a small to medium-sized company, and between €5,000,000 and €15,000,000 for a medium- to large-sized company.⁷⁰⁰

Moreover, the REACH report identified other supply-chain communication and exchange-of-information costs, including hidden transportation costs and SIEF LoA costs.⁷⁰¹

LoAs are most often used by importers and non-EU-based firms through their only representatives and represent, together with ECHA fees, the most important driver of registration costs. They are also the most typical approach adopted by SMEs that are not willing or do not have the resources to be involved in creation and sharing of data within the context of SIEFs.⁷⁰²

696. *Id.* at 45.

697. *Id.*

698. *Id.* at 46.

699. *Id.*

700. ACCENTURE, MASTERING THE CHALLENGE OF REACH FOR HIGH PERFORMANCE: THE CLOCK IS TICKING 4 (2009), available at http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture_Chemicals_POV_REACH.pdf.

701. See INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 77–78 (reporting that 80% of survey respondents stated that SIEFs had caused them to incur significant information-exchange costs).

702. *Id.* at 78.

It found that LoAs can exceed €100,000 in some cases, as may be readily confirmed by the €200,000 price charged for a LoA issued by the SAS Consortium.⁷⁰³

Apparently, the high cost of LoAs is driven, in part, by REACH's strict limitation on the use of vertebrate animals for purposes of conducting chemical health and environmental testing⁷⁰⁴ proposed as part of the technical dossier submitted at the time of substance registration.⁷⁰⁵ On the one hand, these limitations oblige companies to reduce their overall use of vertebrate animal tests to establish chemical safety by becoming participants in SIEFs whose members must negotiate how to share such existing testing data.⁷⁰⁶ As discussed previously, however, SIEF participation, with its attendant LoA expense, is likely to increase registration costs given REACH's obligation to utilize and rely on relatively unproven non-animal testing methods to perform reproductive toxicity testing.⁷⁰⁷ According to one recent study, REACH is likely to have severely underestimated the number of animal tests required and associated

703. *Id.* at 95; *see* discussion, *supra* Part IV(B)(2)(d) (discussing the weak bargaining position of non-EU firms when negotiating LoA costs).

704. *See, e.g.*, REACH, *supra* note 2, pmb. ¶¶ 37, 40, 47, 64, arts. 13(1)–(2), 25(1), 117(3), 138(9); *Commission White Paper on the Strategy for a Future Chemicals Policy*, *supra* note 565, at 7 (affirming that a reduction in vertebrate animal testing is one of the political goals of REACH).

705. REACH, *supra* note 2, art. 10(a)(ix).

706. *See id.* art. 29 (mandating that SIEF members share testing data between themselves); *see also* EUR. CHEMS. AGENCY, PRACTICAL GUIDE 10: HOW TO AVOID UNNECESSARY TESTING ON ANIMALS 5 (2010), http://echa.europa.eu/documents/10162/13655/pg_avoid_animal_testing_en.pdf (providing guidance to practitioners on how to effectuate useful transfers of data in a SIEF to avoid unnecessary animal testing).

707. *See, e.g.*, Press Release, Comm'n Joint Research Ctr., EURL ECVAM Issues Recommendation on Three Alternative-to-Animal Testing Methods for Carcinogenicity (Mar. 14, 2011), *available at* http://ec.europa.eu/dgs/jrc/index.cfm?id=1410&obj_id=14660&dt_code=NWS&lang=en (discussing three in vitro test methods that can help decide whether animal testing for carcinogenicity is necessary to satisfy EU legislation). *See generally* Press Release, Comm'n Joint Research Ctr., EURL ECVAM Recommendation on Three Cell Transformation Assays Using Syrian Hamster Embryo Cells (SHE) and the BALB/c 3T3 Mouse Fibroblast Cell Line for In Vitro Carcinogenicity Testing (Mar. 14, 2012), *available at* http://ihcp.jrc.ec.europa.eu/our_activities/alt-animal-testing/eurl-ecvam-recommendations/EURL-ECVAM%20-Recommendation.pdf (exploring the three Cell Transformation Assays [CTAs] that can curtail the use of animal testing, including discussions of the methods, overall performance, possible regulatory uses, and limitations of the tests).

costs for exacting studies in the area of reproductive toxicity testing, “suggest[ing] a demand of 54 million vertebrate animals and testing costs of 9.5 billion euro. This clearly challenges the feasibility of the [REACH] program without a major investment into high-throughput methodologies.”⁷⁰⁸ Should this study’s calculations be proven correct, it would arguably further demonstrate that the high cost structure that REACH’s registration/data-gathering requirement has imposed on chemical substance-based imports is more trade restrictive than necessary to achieve the regulation’s primary objective of ensuring a high level of protection of human health and the environment, and also its tertiary objective of reducing vertebrate animal testing.⁷⁰⁹

iv. Notification, Hidden and External Consultant Costs

One previously mentioned report indicated that there are notification-related costs with respect to articles “using SVHCs . . . when the use of the substance is not already described in the registration.”⁷¹⁰ This same report also noted that “the cost for a notification is usually in the range of €800-1000.”⁷¹¹

Many companies are increasingly outsourcing REACH registration tasks to outside consultants.⁷¹² “In addition to in-house staff, or often instead of them, firms sometimes employ external consultants for the provision of legal and technical support. A large

708. COSTANZA ROVIDA & THOMAS HARTUNG, RE-EVALUATION OF ANIMAL NUMBERS AND COSTS FOR IN VIVO TESTS TO ACCOMPLISH REACH LEGISLATION REQUIREMENTS FOR CHEMICALS – A REPORT BY THE TRANSATLANTIC THINK TANK FOR TOXICOLOGY, 26 ALTEX 187, 187, 205 (2009), available at http://www.altex.ch/resources/rovida_hartung_altex_3_09.PDF.

709. See *id.* at 194–97, 205–06 (detailing the report’s calculations, including the determination that implementing REACH as it is would require tests on nearly 141 million vertebrate animals).

710. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 49, 105 (emphasizing that the figures are based on limited experience and still require confirmation).

711. *Id.* at 49.

712. See CHEM. WATCH, SERVICE PROVIDERS GUIDE 2011: A GUIDE TO CHEMICALS MANAGEMENT AND CONTROL SERVICES 24 (2011), available at <http://chemicalwatch.com/downloads/ServiceProvidersGuide2011.pdf> (establishing that 77% of firms surveyed expected to increase their reliance on outside consultants in the next five years).

number of small firms outsource most, if not all, of the registration and other REACH related activities,” and for many such “firms the small number of FTEs dedicated to REACH is replaced by fees to consultants.”⁷¹³ The report, furthermore, noted that with respect to registration activities, approximately half of those surveyed who had made use of external consultants “suggested that their fees did not exceed 10% of the[ir] total registration costs, while 32% suggested that this was in the range of 10-25%.”⁷¹⁴

The report then provided the following example: “A small size producer of paints and varnishes has a technical person dedicated full time along with support for communication along the supply chain. The total annual cost is estimated at around €50,000. On top of that they spent around €13,000 for consulting support.”⁷¹⁵ Lastly, the report provides a total estimate of the costs incurred incident to the first REACH registration period, indicating that “for the majority of firms that submitted a registration in the first registration period, the total registration costs were within the range of €100,000 to €1,000,000[, while] [f]or the fewer large firms with more than 100 registrations, total registration costs ha[d] sometimes exceeded the total of €10 million.”⁷¹⁶

v. *Trade Impacts of REACH Registration Costs*

The REACH implementation report reflects that these substantially higher than anticipated registration-related costs have already begun to negatively affect international trade flows in chemicals.⁷¹⁷ For example, the report found that because of such expenditures a number of large and SME chemicals companies have

713. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 40.

714. *Id.*

715. *Id.* at tbl. box 4.1; *see also REACH Registration - Joint Submission, supra* note 535 (stating that fees charged by the Chemical Inspection and Regulatory Service (CIRS) consultancy “to advise the whole registration process and prepare the individual part of registration dossier in iuclid 5” can be as much as €4,000 per substance).

716. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 45.

717. *See id.* at v (noting that 35% of those surveyed said they had had at least one substance withdrawn from at least one their suppliers, with registration costs being cited as the primary cause).

decided to reduce substance production volumes to a lower and less expensive tonnage band and, thereby, effectively shrink their EU market share.⁷¹⁸ Furthermore, high registration costs and the inclusion of substances on the SVHC candidate list, which can potentially trigger additional ECHA authorization request-related fees and make the overall trading of such substances unprofitable,⁷¹⁹ have seemed to persuade non-EU SME chemical companies to withdraw substances from the EU market⁷²⁰ or to abandon or forsake entering the EU market altogether.⁷²¹

For example, “the additional costs for exporting to the EU as a result of registration obligations and supply-chain communication—calculated to be between €60,000–€72,000 for Indian companies—is leading a number of them to withdraw from the EU market.”⁷²² High registration costs have also been observed to motivate EU downstream users to shift their procurement of substances to EU sources.⁷²³ The report strongly suggests that these responses to REACH and the cost of REACH compliance could very well lead to fewer available substances, somewhat higher prices, and a potentially more concentrated and less competitive EU chemicals market.⁷²⁴ “[This] analysis suggests that there is still scope for the reduction of

718. *Id.* at v, 65.

719. *See* FCP Regulation, *supra* note 689, Annex VI, tbls.2–3 (demonstrating that such fees for a small or medium-sized enterprise begin at €25,000 and €40,000, respectively, and can increase by €8,000 and €10,000, respectively, for each substance and use for which an authorization is requested).

720. *See* INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 57–60, 66 (declaring that survey results revealed that 37% of firms surveyed experienced the withdrawal of a substance, either as a user or producer, because of REACH).

721. *Id.* at 97, 106.

722. *Id.* at 66; *see also* A. Nair, *REACH Threatens Exports*, SOC'Y OF CHEM. INDUS. (Mar. 21, 2011), <http://www.soci.org/Chemistry-and-Industry/CnI-Data/2011/6/REACH-threatens-exports.aspx> (stating that REACH has raised exportation costs by between €69,000 and €82,800 per chemical for Indian producers).

723. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 66, 106.

724. *Id.* at 57, 59, 64, 66, 97, 99, 105–08, case study #8, app. A at 62; *see* FCP Regulation, *supra* note 689, Annex VI, tbls.2–3 (showing that the base application fees for medium and small enterprises are €40,000 and €25,000, respectively); *see also* Nair, *supra* note 722 (opining that REACH compliance has been difficult for small and medium-sized Indian chemicals producers, many of whom have decided to curtail exports).

costs without a detrimental effect on other objectives of the Regulation.”⁷²⁵

Based on the above findings, it is arguable that REACH’s registration/data-gathering and notification requirements are more trade restrictive than necessary to achieve REACH’s legitimate objective, especially considering the *limited indirect qualitative* benefits that these requirements have generated to date.⁷²⁶ As the findings of another recently released study have revealed, REACH’s registration/data-gathering, notification, and information-sharing requirements have merely contributed to a general increase in awareness of hazardous chemicals and their raw materials, as reflected in the ongoing changes that are being made to substance classifications⁷²⁷ and by the gradual withdrawal of certain SVHCs from the marketplace.⁷²⁸ Although the study concludes that

725. INTERIM EVALUATION: FUNCTIONING OF THE EUROPEAN CHEMICAL MARKET AFTER THE INTRODUCTION OF REACH, *supra* note 535, at 11.

726. See Risk & Policy Analysts Limited, *Assessment of Health and Environmental Benefits of REACH, Final Report, Executive Summary*, EUR. COMM’N (Apr. 2012), http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/benefits-final-report-summary_en.pdf [hereinafter *Assessment of Benefits, Executive Summary*] (“A key conclusion from this work is that, at this current stage in the implementation of REACH, *it is not possible to quantify benefits* and the assessment will have to rely on the use of a series of qualitative information together with a limited set of quantitative indicators The drivers of benefits within REACH . . . are the set of legal provisions which are expected to trigger direct or indirect human health and/or environmental benefits.”) (emphasis added); *id.* at 1–2; see also Risk & Policy Analysts Limited, *Assessment of Health and Environmental Benefits of REACH, Final Report, Part B – Assessment of Benefits*, EUR. COMM’N (Apr. 2012), http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study11b.pdf [hereinafter *Assessment of Benefits, Final Report*].

727. “The realisation of benefits expected from the registration driver through these four pathways *is limited to date* but expected to have a greater impact in the future. . . . [I]t is clear that the information being generated by REACH is resulting in changes in classification, with the majority of these being more restrictive classifications. This is particularly noticeable for endpoints such as acute toxicity, sensitisation, reproductive toxicity and aquatic toxicity (acute and chronic).” *Assessment of Benefits, Final Report, supra* note 726, at 149 (emphasis added). “It can also be concluded that the need to communicate on SVHCs has delivered benefits, in that it has made companies more aware of raw materials in their products. In the longer term, this will lead to much greater awareness throughout the supply chain of chemicals management issues and the replacement of SVHCs in articles” *Id.* at 154.

728. “With regard to substance withdrawal, there is evidence that substances

industry's evolving behavior suggests the potential for improved health and environmental protection over time,⁷²⁹ the study nevertheless fails to compare these new benefits with the benefits previously secured through the use of to-be-substituted chemicals, or with the risks of using potential new substitutes that can ultimately undermine such protection.⁷³⁰

have been 'dropped' from the market or otherwise not registered due to their properties (in particular CMRs) and the potential costs of supporting them through authorisation as well as registration. It is also clear though that substance withdrawal may be taking place as part of the rationalisation of product portfolios." *Assessment of Benefits, Final Report, supra* note 726, at 150. "Candidate listing is leading to early action towards substitution by formulators and demands for substitution within their supply chains by article producers. Thus SVHCs are gradually being withdrawn from use, particularly from supply chains that produce end-consumer goods." *Id.* at 154.

729. "[T]o ensure that REACH does result in the desired shift in mind-set and deliver its intended human health and environmental benefits, ECHA and the European Commission should continue and build upon the level of their activities aimed at building trust and cooperation. . . . It was envisioned from the beginning that REACH would be a 'learning system'. It is therefore important to provide sufficient time for that learning to take place and to collect sufficient information about the system [I]t is clear that for REACH to deliver its intended human health and environmental benefits, priority has to be given to supporting the less experienced registrants and smaller companies who will have less capacity to respond to its requirements." *Assessment of Benefits, Executive Summary, supra* note 726, at 4. "[I]t is too soon to have a complete picture of the extent of the impacts: databases are still being set up and all the relevant stakeholders (from the chemical companies to the Agency and the Commission) are in the 'learning by doing' process, familiarising themselves with the duties imposed by this ambitious Regulation. Nevertheless, the assessment carried out for this study provides an indication of areas where improvements should be made if the expected benefits of REACH are to materialise. It also verifies the general hypothesis that REACH will deliver human health and environmental benefits. Although the extent to which it has done so to date is limited, this is much as expected for the first round of phase-in substances to be registered. As problems in implementation are ironed out and more and better information is generated for those substances where the lowest levels were available prior to REACH, benefits can be expected to improve and for many of these to have a last impact in relation to human health and the environment." *Assessment of Benefits, Final Report, supra* note 726, at 147–48.

730. "It is less clear that where substances have been withdrawn, they have been replaced by a less hazardous alternative as consultees report that, in some cases, manufacturers are offering alternative substances of a similar hazard profile." *Assessment of Benefits, Executive Summary, supra* note 726, at 6; *Assessment of Benefits, Final Report, supra* note 726, at 150. "There are concerns, though, that substitutes are not necessarily always better from a human health or environmental perspective. There is also concern that candidate listing leads to pressure for substitution even in those applications which have been assessed as

b. Comparing REACH to a Reasonably Available Less Restrictive Alternative

REACH's registration/data-gathering requirement should also be evaluated in light of other reasonably available regulatory models that could potentially prove less trade restrictive than REACH.⁷³¹ One recent study prepared by several risk analysis experts concludes that "a majority of the data submitted under the REACH registration process may never be evaluated."⁷³² With this in mind, they have recommended Canada's and Japan's chemicals management regulatory strategies as possible alternatives to REACH. Each of these regulatory frameworks features "an iterative screening approach" that permits regulators to "set aside a vast array of substances/uses at the beginning on the grounds that they are unlikely to cause unacceptable risk" ⁷³³ Because these screening approaches also focus on a substance's potential for "risk" rather than "hazard," they may significantly reduce the costs and burdens associated with substance registration while ensuring the same high level of protection of human health and the environment. This section examines whether Canada's and Japan's chemicals management regulatory strategies qualify as reasonably available less trade-restrictive alternatives to REACH that are also capable of achieving REACH's principal objective.

i. Canada's Risk Prioritization-Based Chemicals Management Plan

According to these commentators, the substance registration/data-

being safe and for which there may be no feasible or suitable alternatives. In other words, all applications are blacklisted even if they do not pose a real risk. Although this is one of the stated aims of the authorisation provisions, it has potential implications for both costs and human health and the environment if it results in shifts to alternatives (substances, techniques or materials) which present their own risks. It is therefore important that consideration is given to the risks from substitution with alternative chemicals or processes vis-à-vis the risks from continued use of the candidate list substance and whether there would be a net reduction in risks with substitution." *Assessment of Benefits, Final Report, supra* note 726, at 104 (emphasis added).

731. See discussion *supra* Part III.B.3.d (discussing prior WTO jurisprudence on the issue of less-restrictive alternatives to non-tariff barriers to trade).

732. ABELKOP ET AL., *supra* note 464, at 24.

733. *Id.* at 24–25.

gathering requirement of Canada's Chemical Management Plan ("CMP") may serve as a potentially less trade-restrictive alternative to REACH's registration/data-gathering provision. The CMP, adopted in December 2006, subjects all "legacy chemicals" manufactured within or imported into Canada between January 1, 1984, and December 31, 1986, to a scientific risk assessment.⁷³⁴ The CMP is notable primarily because it "has a prioritization process that takes place *before* industry and government are compelled to produce and review dossiers."⁷³⁵

The Canadian Environmental Protection Act, 1999 ("CEPA 1999") "is the primary statute the Government [uses] to implement the [CMP]. The information developed through CEPA's categorization process provided the basis for establishing the priorities for action under the Plan."⁷³⁶ CEPA 1999 is considered "one of Canada's most important laws respecting pollution prevention and the protection of the environment and human health in order to contribute to sustainable development... [by] support[ing] a 'precautionary approach.'"⁷³⁷

The Canadian Government has employed CEPA to ensure that all "new [chemical] substances manufactured [within] or imported into Canada above certain thresholds since 1994 undergo government-led human health and environmental assessments" to determine whether they are toxic or capable of becoming toxic to the environment or human health.⁷³⁸ If a substance potentially poses risks to human

734. See Press Release, Prime Minister of Can., Canada's New Government Improves Protection Against Hazardous Chemicals (Dec. 8, 2006), available at <http://www.pm.gc.ca/eng/media.asp?category=1&id=1450> (last visited Sept. 14, 2012). See generally Chemicals Management Plan, Chemical Substances Website (last visited Nov. 12, 2012), <http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>.

735. ABELKOP ET AL., *supra* note 464, at 22 (citing *The Rapid Screening Approach*, GOV'T OF CAN., <http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/rapid-eng.php> (last visited Oct. 30, 2012)) (emphasis added).

736. *CEPA Review: The Interim Government Response*, ENV'T CAN., at 4, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=586965A3-1&offset=2&toc=show> (last visited Oct. 30, 2012).

737. *Canada Nat'l Reporting to CSD-18/19 – Thematic Profile on Chemicals*, COMM'N ON SUSTAINABLE DEV., U.N. DESA, at 1 (May 2011), http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/canada/Chemicals.pdf [hereinafter *Canada Nat'l Rep.*].

738. *Id.* at 2.

health or the environment, CEPA 1999 permits control measures to be imposed before such substance is granted access to the Canadian marketplace.⁷³⁹ If the risks are deemed significant or become too difficult to adequately manage, Canada may prohibit the substance.⁷⁴⁰ The cornerstone of CEPA 1999 is Canada's Domestic Substance List ("DSL"), which establishes a foundation for distinguishing between new substances and those contained within an "existing substances" inventory.⁷⁴¹ Section 73(1) of CEPA 1999 required the Canadian Government to examine, by 2006, all existing substances contained on the DSL, approximately 23,000 substances, "to determine if they were potentially harmful to human health or the environment" and to identify and categorize those that "warranted further attention. . . ."⁷⁴²

The CMP employs the CEPA 1999 categorization process pursuant to which governmental scientists prioritize for examination only those substances that:

- are inherently toxic (harmful, by its very nature, to humans or to the environment);
- are persistent (take a very long time to break down);
- are bioaccumulative (collect in living organisms and end up in the food chain); and
- have the greatest potential for human exposure.⁷⁴³

From this process, the CMP developed a new Rapid Screening Approach that has enabled the Canadian Government to rapidly identify substances that have a low likelihood of toxicity as defined in CEPA 1999 Section 64(a) and to instead focus resources on those substances that have a "higher probability of causing harm."⁷⁴⁴ This

739. *Id.*

740. *Id.*

741. *Id.*

742. *Id.* at 2–3; Canadian Environmental Protection Act (CEPA), S.C. 1999, c. 33, art. 73(1).

743. *Canada Nat'l Rep.*, *supra* note 737, at 3.

744. *Technical Approach for "Rapid Screening" of Substances of Lower Ecological Concern*, ENV'T CAN., at 3 (Mar. 30, 2007), http://www.ec.gc.ca/lcpe-cepa/AF2B4B54-A419-1BAE-DD4E-23AC1DB194C0/at-ta_epr-rs_eng.pdf [hereinafter *Technical Approach*]; *see also* CEPA, *supra* note 742, art. 64(a) (defining a substance as toxic if it "is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity").

process entails the application of a series of qualitative and quantitative steps to evaluate a substance's likelihood to cause harm to human health or the environment under conservative—worst-case—exposure scenarios. It also employs complex hazard and other tools to identify, based on conservative assumptions, true priorities for items to test and assess in the absence of data.⁷⁴⁵ By the time the Canadian Government's categorization process was completed in 2006, it had identified approximately 4,300 substances requiring further attention.⁷⁴⁶

The CMP was developed (and its objective is) to address these chemicals by 2020.⁷⁴⁷ To achieve this objective, the CMP calls for a number of actions to be taken pursuant to the authorities vested under CEPA 1999. These include:

- the immediate regulation of five groups of chemicals deemed to pose a risk to the environment or human health, including draft regulations on flame retardants and substances used in the manufacturing of some non-stick coatings and stain repellents, and amendments to the Prohibition of Certain Toxic Substances Regulations covering impurities or resulting from waste incineration and anti-icing agent in jet fuels and chemical/industrial processes;⁷⁴⁸
- the implementation of a new “Challenge Approach,” which challenges stakeholders to provide use and risk management information about 200 high-priority chemical substances identified pursuant to the CEPA 1999 categorization process as being the highest priority for further action on these chemical substances;⁷⁴⁹
- the restriction of new uses of 150 priority chemicals identified pursuant to the categorization process but not currently used in Canada until data is provided to “support a

745. *Canada Nat'l Rep.*, *supra* note 737, at 3.

746. *Id.*; see also *Canadian Environmental Protection Act, 1999 Annual Report for April 2009 to March 2010*, ENV'T CAN., at iv (2010), available at http://www.ec.gc.ca/lcpe-cepa/477203E8-2DA5-422B-84FB-FC3597E7EBD3/ar09_10-eng.pdf (relating the results of many quality-monitoring initiatives and other aspects of the CEPA program).

747. *CEPA Review: The Interim Government Response*, *supra* note 736, at 2.

748. *Id.*

749. *Id.* at 2–3.

risk assessment demonstrating that the substance would not pose an unacceptable health or environmental risk”;⁷⁵⁰

- the identification of “the health and environmental effects of 2,600 medium-priority substances through successive rounds of assessment”;⁷⁵¹ and
- the “Rapid Screening of low-concern substances.”⁷⁵²

The Government of Canada has described the Rapid Screening Approach as a series of steps that seek to ascertain a substance’s potential to cause ecological harm.⁷⁵³ Step 1 entails the identification of substances categorized as high priority for purposes of further evaluation and assessment.⁷⁵⁴ Step 2 involves the application of different exposure scenarios to identify potential concerns near the point of a substance’s discharge into the environment.⁷⁵⁵ Further substance assessment is required if these “scenarios indicate a potential harmful effect to aquatic or terrestrial organisms,” whereas a substance proceeds to Step 3 if these “scenarios indicate a low likelihood of harm to these organisms.”⁷⁵⁶ Step 3 employs a series of information source “filters” to determine whether a given substance requires further assessment or can be designated as being unlikely to cause harm.⁷⁵⁷ The aim is to identify whether the substance appears on or within one or more domestic or international hazard or exposure lists or information sources that designate such substance as being of greater concern due to its hazardous properties and/or high commercial trading volume.⁷⁵⁸ The information contained within such lists and sources is then vetted to ascertain its relevance to the particular inquiry.⁷⁵⁹

During 2007, the Government of Canada applied the Rapid Screening Approach to “1066 substances that [were identified as] persistent and inherently toxic to non-human organisms (PiT(eco)) or

750. *Id.* at 3.

751. *Id.*

752. *Id.*

753. *Technical Approach*, *supra* note 744, at 3.

754. *Id.*

755. *Id.* at 4.

756. *Id.*

757. *Id.* at 5.

758. *Id.*

759. *Id.*

bioaccumulative and inherently toxic to non-human organisms (BiT(eco)), and that [were] believed to be in commerce in Canada at a maximum of 1000 kg [low quantities] per year across the country.”⁷⁶⁰ Substances that were “persistent and bioaccumulative and inherently toxic to non-human organisms” (“PBiTs”) were “excluded from consideration under this assessment, due to particular concerns identified for substances having this combination of properties.”⁷⁶¹

The Canadian Rapid Screening Approach exercise yielded 312 substances requiring further assessment and 754 substances for which further assessment was unnecessary because they were deemed unlikely to cause ecological harm.⁷⁶² In other words, approximately 70% of all the substances rapidly screened were found unlikely to cause ecological harm and were consequently not subject to costly and burdensome mandatory registration. Such a result would not be possible under the EU REACH.

Moreover, Canada’s CMP provides for the communication and exchange of risk-based information about chemical substances with industry and the public for the purpose of informing their chemicals-assessment and risk-management activities via the Canadian Government’s Chemical Substances, CEPA Environmental Registry, and Chemicals Management Plan websites. These websites provide “up-to-date information on the progress being made [and] links to key initiatives in related program areas... searchable or downloadable lists of existing chemical substances, results of rapid screening and prioritization exercises, detailed substance

760. ENV’T CAN., RAPID SCREENING OF SUBSTANCES OF LOWER ECOLOGICAL CONCERN: RESULTS OF THE ECOLOGICAL SCREENING ASSESSMENT 2 (2007) [hereinafter RAPID SCREENING OF SUBSTANCES OF LOWER ECOLOGICAL CONCERN], available at http://www.ec.gc.ca/lcpe-cepa/5189C3B6-B777-1FD4-CD3B-B04A1F4FA0CC/epr-rs_eng.pdf.

761. *See id.* at 4.

762. *See id.* at 8–9, fig.2 (finding that 4 organic substances bore chemical structures similar to PBiTs that were deemed priority substances necessitating further assessment, that 836 substances did not indicate a potential for ecological harm, and that 226 substances required further assessment. After application of various information source filters to the 836 substances, it was revealed that 29 of the substances appeared on international lists of high-production-volume chemicals requiring further assessment, 417 of the substances were unlikely to meet the criterion of paragraph 64(a) of CEPA 1999, and of the remaining 390 substances manually evaluated, 53 were found to require further assessment).

assessments, and proposed risk management activities.”⁷⁶³ These media also facilitate public input taken into account for risk-management decisions following the release of the government’s conclusions of a draft screening assessment report.⁷⁶⁴

Canada’s CMP is also consistent with several international environmental initiatives, including the Strategic Approach to International Chemicals Management (“SAICM”), and is designed to meet the 2020 goals established by the World Summit on Sustainable Development for Sound Management of Chemicals.⁷⁶⁵ Upon the renewal of the CMP in 2011, the Canadian Government also undertook a Strategic Environmental Assessment (“SEA”) to ensure it took into account environmental considerations during the decision-making process.⁷⁶⁶ The SEA evaluates the positive and negative “environmental effects . . . of a proposed policy, plan, or program and its alternatives . . . [and] informs strategic decision-making through analysis of environmental risks and opportunities.”⁷⁶⁷ The Canadian Government has concluded that the SEA satisfies the commitments Canada undertook at “the World Summit for Sustainable Development” because the SEA process aims at developing measures that promote positive environmental impacts.⁷⁶⁸

Lastly, CEPA 1999, which serves as the legal basis for Canada’s risk-based CMP, arguably implements, through Preamble paragraph 6 and Articles 2(1), 6(1.1), and 76.1, a risk-based version of the precautionary principle—i.e., a precautionary approach.⁷⁶⁹ The EU REACH, by comparison, implements a hazard-based version of the precautionary principle through its Preamble paragraphs 9 and 69

763. *Canada Nat’l Rep.*, *supra* note 737, at 6.

764. *See id.* at 7 (stressing the role the public plays in informing the decisions of the Canadian Government as it develops risk-management methods).

765. *See* Christine Norman, GOV’T OF CAN., *Canada’s Experience from Assessment of Highest Priorities Under Its Chemicals Management*, at 1, 3 (May 2011), available at http://www.isesweb.org/Meetings/Docs/session-a2_cnorman.pdf.

766. *See Strategic Environmental Assessment of the Chemicals Management Plan*, GOV’T OF CAN., <http://www.chemicalsubstanceschimiques.gc.ca/plan/sea-ees-eng.php> (last visited Oct. 30, 2012).

767. *Id.*

768. *See id.*

769. *See* CEPA, *supra* note 742, arts. 2(1), 6(1.1), 76.1; *see also* *Canada Nat’l Rep.*, *supra* note 737, at 1.

and Article 1.3, which is informed by quasi-quantitative or qualitative risk assessments. As one recently released report observed, although the EU Commission's communication on the precautionary principle provides that "[t]he precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data," such communication fails to discuss how serious the risk or its consequences must be to trigger the application of the precautionary principle.⁷⁷⁰

While ECJ case law is helpful, it does not appear determinative. According to the report, such case law holds, for example, that "[i]t is not sufficient to make a generalized presumption about a putative risk"⁷⁷¹ or to make reference to a purely hypothetical risk in the absence of scientific support.⁷⁷² It is generally recognized that REACH identifies a hazard—"negative effect"—in part through a regulatory risk assessment.⁷⁷³ The report concludes that, in the absence of such direction, "it cannot be deduced that the [precautionary principle] only applies where a potentially serious risk is identified," and consequently "the burden of proof necessary to justify such application may be lower."⁷⁷⁴

This absence of a risk threshold for action would seem to explain much of the difference between the Canadian CMP prioritized screening approach informed by a quantitative risk assessment-focused precautionary approach and the REACH hazard-based pre-registration/data-gathering approach informed by a qualitative hazard-focused precautionary principle.⁷⁷⁵ Under REACH, the

770. See MILIEU LTD., T.M.C. ASSER INST. & AND PACE, EUR. COMM'N, CONSIDERATIONS ON THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN THE CHEMICALS SECTOR 36 (Aug. 2011), available at <http://ec.europa.eu/environment/chemicals/reach/pdf/Final%20report%20PP.pdf>.

771. See *id.*

772. See *id.*

773. See *id.* (suggesting that hazard can also be identified through epidemiological studies that search for causes within particular populations or through monitoring/biomonitoring of a certain chemical where it is known that such chemical's presence may have an adverse effect).

774. *Id.* at 37.

775. See *id.* at 38 ("The scientific evaluation is assumed to be a risk assessment since the Communication refers to the four components of risk assessment: hazard identification, hazard characterisation, appraisal of exposure and risk

precautionary principle appears already to have been applied in requiring the pre-registration of tens of thousands of substances for which risk assessments have not yet been performed at a pre-risk assessment stage, premised only on the annual substance manufacturing and import volumes and, perhaps, also on some qualitative risk data informed by socioeconomic analysis.⁷⁷⁶ By comparison, under the CMP, a precautionary approach would appear to be applied at the risk management stage once a risk assessment has been performed on a medium- or high-priority substance and has revealed a high likelihood of harm to human health or the environment under particular exposure scenarios.

*ii. Japan's Risk Prioritization-Based
Chemical Substance Control Law*

In 1973, Japan enacted the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. referred to as the Chemical Substance Control Law (“Kashinho”).⁷⁷⁷ The Kashinho introduced a notification and prior-assessment system to cover “new” substances being placed on the market several years prior to the enactment of the U.S. Toxic Substance Control Act of 1976.⁷⁷⁸ However, the

characterization. If the evaluation and/or risk assessment can show that there is sufficient data and evidence, the risk management decisions can be based on the prevention principle, rather than on the [precautionary principle].”).

776. See Ortwin Renn & Andreas Klinke, *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Strategies*, 22 RISK ANALYSIS 1071, 1074 (2002), available at <http://josiah.berkeley.edu/2007Fall/NE275/CourseReader/6.pdf>; EUR. COMM’N, FINAL REPORT ON SETTING THE SCIENTIFIC FRAME FOR THE INCLUSION OF NEW QUALITY OF LIFE CONCERNS IN THE RISK ASSESSMENT PROCESS 9–11 (adopted Apr. 10–11, 2003), available at http://ec.europa.eu/food/fs/sc/ssc/out362_en.pdf; W. MARZOCCHI ET AL., EUR. COMM’N, PRINCIPLES OF MULTI-RISK ASSESSMENT: INTERACTION AMONGST NATURAL AND MAN-INDUCED RISKS 7–11 (2009), available at http://ec.europa.eu/research/environment/pdf/multi-risk_assessment.pdf.

777. See Kagakubusshitsu no Shinsa oyobi Seizoto no Kisei nikansuru Horitsu, [Kashinho] [Chemical Substances Control Law] Law No. 117 of 1973, art. 1 (amended by Law No. 39 of 2009) (Japan), translated in Japanese Law Translation Database Sys., <http://www.japaneselawtranslation.go.jp/law/detail/?ft=5&re=02&dn=1&gn=99&sy=1973&ht=A&no=117&x=65&y=6&la=01&ky=&page=1> (laying out the purpose of the act as an attempt to create a system to prevent chemical pollution from impairing human health or destroying the environment).

778. Yoshiko Naiki, *Assessing Policy Reach: Japan's Chemical Policy Reform in Response to the EU's REACH Regulation*, 22 J. ENVTL. L. 171, 184 (2010); see also Kashinho, *supra* note 777, arts. 3–4 (providing the procedures that must be

Kashinho actually applied to both “new” and “old” industrial chemical substances by virtue of an “old” substance list that had, at such time, identified approximately 20,000 regularly manufactured or imported substances.⁷⁷⁹ By 2007, only 1,500 of those substances had been subject to a risk assessment.⁷⁸⁰

The Kashinho was amended during May 2009⁷⁸¹ to initiate the review of measures concerned with the assessment of hazards posed by chemicals and to update them consistent with international health and environmental law and policy trends.⁷⁸² A primary objective of the 2009 amendment was to “ensure consistency with the [GHS] established by the 2002 World Summit for Sustainable Development [(“WSSD”)] and the 2006 [SAICM].”⁷⁸³

The Kashinho amendment was phased in over a two-year period and effectively facilitated Japan’s shift from a hazard-based to a risk-based chemical substance management framework. It looks beyond the intrinsic hazardous properties of chemical substances to employ risk assessments, risk control measures, and risk communication for

followed to notify government agencies of a desire to manufacture a particular substance and the procedure by which the government will evaluate the substance to determine its impact on human health and the environment).

779. See Naiki, *supra* note 778, at 185–87 (explaining that Japanese law suffered from the same deficiencies as EU law prior to REACH, that is, a lack of data on the safety of “old” chemicals already being sold on the market).

780. *Id.* at 185.

781. See *id.* (describing the process the government ministries went through to create the report that formed the foundation of the new law).

782. See Kashinho, *supra* note 777, art. 4(6) (calling for international trends to be respected when dealing with establishing items to be tested); see also JAPAN MINISTRY OF ECON., TRADE & INDUS., NOTIFICATION OF THE MANUFACTURING AMOUNT, ETC. OF GENERAL CHEMICAL SUBSTANCES AND PRIORITY ASSESSMENT CHEMICAL SUBSTANCES – PRELIMINARY PREPARATION MATERIALS 2 (2010), [hereinafter METI PRIORITY SUBSTANCES], available at http://www.meti.go.jp/policy/chemical_management/english/files/CSCL-setsumeih22-12-jizen-12eng.pdf (explaining that Japan amended the Chemical Substance Control Law, in part, to establish regulations that reflected international trends).

783. Sunanda Banerjee, *Reach-like Regulations Enacted Globally: A Regulatory World Tour*, ICIS CHEM. BUS., May 31, 2010, at 28, available at <http://www.icis.com/Articles/2010/05/31/9362538/reach-like-regulations-enacted-globally.html>; Abstract of the Joint Committee Report, New System of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (the Chemical Substances Control Law) to be Established by 2020, at 1, 6–7 (Dec. 22, 2008), available at http://www.meti.go.jp/policy/chemical_management/english/files/joint_committee_report.pdf.

purposes of ascertaining and reflecting the nature and amount of health and environmental exposure for all chemical substances, consistent with a risk-based precautionary approach.⁷⁸⁴

Japan's Ministry of Economic Trade and Industry ("METI") has indicated that this shift was precipitated by Europe's enactment of REACH, which effectively triggered a systematic strengthening by national governments of chemical substance management regimes to address environmental concerns.⁷⁸⁵ However, according to at least one commentator, because Japan was hesitant to move toward a European "REACH-type policy," REACH had only a limited influence on the Japanese reform.⁷⁸⁶ Consequently, although the amended Kashinho, like REACH, expedites risk assessment for a good number of "existing" substances already on the market, it goes about ensuring the supply of information relating to such assessment in a different manner—by requiring such data as part of a priority substance assessment only *after* the Japanese Government has already conducted a chemical substance screening assessment.⁷⁸⁷

Amended Kashinho Article 8 added a new requirement obliging manufacturers and importers of "general chemical substances" to notify and submit data annually to METI regarding estimated substance quantities and uses, regardless of hazard.⁷⁸⁸ Amended Kashinho Article 2(5) provides that such information will be used by the Japanese Government to create a list of "priority substances."⁷⁸⁹

784. METI PRIORITY SUBSTANCES, *supra* note 782, at 2.

785. *See id.* (reflecting on the increased public awareness of safety and security issues and the strengthening of chemical management methods based on the Environmental Summit in 2002); *see also* Japan Ministry of Econ., Trade & Indus., Chemical Substances Control Law (CSCL) 8–10 (Mar. 2010) [hereinafter CSCL Presentation], *available at* http://www.meti.go.jp/policy/chemical_management/english/files/CSCL_English.pdf (suggesting that one reason that the amendment needed to bring Japan up to international standards in chemical substance management was the passing of REACH in 2007).

786. *See* Naiki, *supra* note 778, at 171, 187–93 (pointing to four factors as possible explanations for Japan's hesitation to adopt the European system: "(1) incompatibility with the Japanese domestic structures; (2) Japanese industry's lack of support for the European model; (3) the possible effects of information disclosure in Europe; and (4) difficulties in mobilizing non-state actors").

787. *See id.* at 185–86.

788. Kashinho, *supra* note 777, art. 8.

789. *Id.* art. 2(5); *see* Naiki, *supra* note 778, at 186 (using the term "priority chemicals").

Priority substances are essentially “substances requiring prior assessment” because it is not clear whether they qualify under the criteria for “Class II Specified Chemical Substances” set forth in Amended Kashinho Article 2(3).⁷⁹⁰ Kashinho defines “priority substances” as substances that, due to their known highly residual properties, are thought “likely to damage human health or to damage the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution”⁷⁹¹ Kashinho also obliges manufacturers or importers of an existing chemical substance “requiring priority assessment”—a “Class I Specified Chemical Substance”⁷⁹²—in excess of specified volumes to notify and submit information to METI each year regarding estimated substance quantities, usage, and other matters as may be required.⁷⁹³

According to at least one commentator, certain changes to Kashinho reflect the influence of the EU REACH on Japan’s chemicals management system.⁷⁹⁴

Kashinho was originally applied to substances having ‘persistent’ properties. Before the amendment, substances having PBT (persistent, bioaccumulative and toxic) were subject to the restrictive control (known as Class I Specified Chemical Substances), and substances having persistent, toxic but without bioaccumulative properties were subject to the less restrictive process (known as Class II Specified Chemical Substances). Under the amended Kashinho, these two classifications still remain, but the latter category of Class II now covers substances that do not have ‘persistent’ properties. This suggests that the amendment expanded the scope of high-risk chemicals under Kashinho and endocrine disruptors are now covered, which is similar to REACH.⁷⁹⁵

Once a substance is designated as a “priority chemical” and

790. Kashinho, *supra* note 777, art. 2(3)(i)–(ii) (covering “class II specified chemical substances”); *cf. id.* art. 2(2)(i)(1)–(2), 2(2)(ii) (covering “class I specified chemical substances”).

791. *Id.* art. 2(5); Naiki, *supra* note 778, at 186.

792. *See* CSCL Presentation, *supra* note 785, at 22–23 (stating that the Stockholm Convention in 2009 designated twelve substances as Class I Specified Chemical Substances, including Perfluorooctane sulfonate, or PFO).

793. *Kashinho*, *supra* note 777, art. 9(1).

794. *See* Naiki, *supra* note 778, at 182, 185 (identifying the similarities as the expedited risk assessment for old substances already on the market, an element of “prioritization,” and the scope of high-risk chemicals).

795. *Id.* at 186–87.

undergoes a “priority assessment,” Amended Kashinho may require manufacturers and importers of that substance to conduct a hazard and an exposure assessment, the results of which must then be submitted to the Japanese Government.⁷⁹⁶ Depending on the results, such priority substances may be “subject to further risk assessment by the government.”⁷⁹⁷

At least one commentator has noted that the Amended Kashinho imposes a significantly lower informational and testing burden on manufacturers and importers than does the EU REACH because under the Kashinho, unlike under REACH, risk assessment is performed by the government and companies are *not* required to identify uses of a substance incorporated within “their own product[s] [*as well as*] in their respective supply chains.”⁷⁹⁸ This lower burden is attributable in part to the relatively lower responsibility imposed on Japanese industry to generate information with respect to chemical substances. REACH obliges European industry to provide better information, including risk assessments, as a precondition to entering the market, per the “no data, no market” rule of REACH Article 5. The Amended Kashinho, by contrast, sets forth a prioritization approach pursuant to which government remains responsible for demanding additional data from industry concerning prioritized substances.⁷⁹⁹

Furthermore, the Amended Kashinho has many similarities to, but did not replicate, the Canadian CMP.⁸⁰⁰ Discussions, held during the Kashinho amendment process, revealed how Japanese legislators referenced the Canadian chemical substances prioritization system, particularly its process of risk assessment and information gathering and that the government would be responsible for performing risk assessments.⁸⁰¹ Japanese legislators had also favorably compared the Canadian chemical substances prioritization system to Japan’s then-existing stepped prioritization approach of screening old substances, classifying them as “monitored chemical substances,” and then subjecting them to further risk assessment and, possibly, to

796. Naiki, *supra* note 778, at 186.

797. *Id.*

798. *Id.*

799. *Id.* at 187.

800. *Id.* at 188.

801. *Id.* at 189–90.

restrictive control.⁸⁰² Overall, it would appear that “Japanese chemical policy favoured the Canadian system over REACH as its model.”⁸⁰³

Thus, in the context of this TBT Article 2.2 analysis, the key issue is whether the registration/data-gathering and notification provisions of the Canadian and Japanese regulatory chemicals management regimes, employing iterative screening methods, represent reasonably available alternatives that could achieve the same level of protection—a high level of protection of human health and the environment—as REACH’s more costly and burdensome hazard-based registration/data-gathering and notification provisions.

c. Taking into Account the Risk(s) That a Reasonably Available Less Trade-Restrictive Alternative Will Not Fulfill the Legitimate Objective

In this final step of a TBT Article 2.2 analysis, practitioners should seek to ascertain the likelihood and gravity of the potential risks and any associated adverse consequences that would arise if an identified reasonably available less trade-restrictive alternative was unable to fulfill REACH’s legitimate objectives—the “risk of nonfulfillment.” When assessing such risks, it is important to secure and/or make reference to available scientific and technical information and related processing technology, intended product end-uses, and other relevant probative evidence.⁸⁰⁴

In assessing the risk of nonfulfillment, however, proper attention should first be directed toward whether and how the data gathered from the REACH registration process will be utilized in furtherance of protecting human health and the environment. Several risk analysis experts have observed that the testing and hazard data that has been gathered from REACH registrations does not appear to be prioritized pursuant to any “systematic risk-ranking process” that could meaningfully contribute to ECHA’s decision concerning whether to restrict the use of a given substance.⁸⁰⁵ In addition, as

802. *Id.* at 190.

803. *Id.* at 193.

804. See discussion *supra* Part III.B.3.d.ii.

805. See ABELKOP ET AL., *supra* note 464, at 48 (“[T]here does not appear to be a systematic risk-ranking process in the EU that informs which uses of chemicals become targets of restrictions.”).

noted previously, the perfunctory, automated registration “completeness checks” and the infrequent substantive dossier evaluations of phase-in substances strongly suggest that relatively few potentially harmful substances will be prioritized and adequately examined under REACH during the course of any given fiscal year.⁸⁰⁶ Also, the uncertainty surrounding the degree to which REACH’s registration/data-gathering requirement contributes to the achievement of the regulation’s objective raises serious questions about whether the consequences from the Canadian and Japanese alternative measures’ nonfulfillment of REACH’s principal objective would be particularly grave.⁸⁰⁷ It is against this backdrop that the risk-based priority assessment mechanisms of the Canadian and Japanese chemicals management regimes should be reviewed and compared with REACH’s registration/data-gathering requirement for purposes of determining whether they are capable of equally contributing to the achievement of REACH’s principal objective.

Like the hazard-based EU REACH, the Canadian and Japanese systems rely on dated national chemicals inventories to assess the harm posed by high-priority substances. In addition, like the EU REACH, both of these systems are consistent with international environmental and chemicals initiatives such as GHS⁸⁰⁸ and the 2006 SAICM.⁸⁰⁹ Furthermore, like the EU, Canada and Japan contribute to Organization for Economic Cooperation and Development chemicals testing and management initiatives and to the chemicals-related public health and environmental initiatives of the World Health Organization and United Nations Environment Program.⁸¹⁰

806. See discussion *supra* Part IV.C.4.e.

807. See US — COOL Appellate Body Report, *supra* note 156, ¶¶ 478–79 (discussing how the consequences that may arise from nonfulfillment of the COOL labeling measure’s objective would not be particularly grave, given consumers’ reluctance to pay extra to receive meat origin information).

808. See *About the GHS*, U.N. ECON. COMM’N FOR EUR., http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html (last visited Oct. 30, 2012) (describing the role that GHS plays in the classification of chemicals); see also Rep. of the World Summit on Sustainable Dev., ¶¶ 19–20, Aug. 26–Sept. 4, 2002, U.N. Doc. A/CONF.199/20 (2002) (calling for the renewal of the commitment “to sound management of chemicals” and encouraging nations to adopt the GHS).

809. STRATEGIC APPROACH TO INT’L CHEMS. MGMT., <http://www.saicm.org/index.php?ql=h&content=home> (last visited Oct. 30, 2012).

810. *Canada Nat’l Rep.*, *supra* note 737, at 11–13; *Japan Nat’l Rep. to CSD-*

Moreover, like the EU REACH, the Canadian CMP and Japanese Amended Kashinho are consistent with Canada's and Japan's commitments as Parties to several international environmental conventions pertaining to toxic chemicals, including the Basel,⁸¹¹ Rotterdam,⁸¹² and Stockholm⁸¹³ Conventions.

Unlike the hazard-based REACH registration/data-gathering provision, however, the multiple-level screening mechanisms of Canada's CMP and Japan's Amended Kashinho focus mostly on the exposure risks posed by substances rather than on merely a substance's hazardous intrinsic properties.⁸¹⁴ These screening mechanisms are iterative in nature and flexible, and thus capable of adapting to new exposure-related information as it is acquired.⁸¹⁵ They have thus far been successful in channeling potentially problematic substances to further levels of risk assessment and in eliminating a substantial number of substances from further government consideration where the most rapid of first-level screens had found they posed no risk to human health and the environment,

18/19, COMM'N ON SUSTAINABLE DEV., U.N. DESA, at 7–8, 12–13 [hereinafter *Japan Nat'l Rep.*], available at http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/japan/Chemicals.pdf.

811. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Mar. 22, 1989, 1673 U.N.T.S. 125, art. 10.

812. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 10, 1998, 2244 U.N.T.S. 337.

813. Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 2256 U.N.T.S. 119, arts. 1, 3; *see also Canada Nat'l Rep.*, *supra* note 737, at 12–13 (confirming Canada's participation in all three international initiatives); *Japan Nat'l Rep.*, *supra* note 810, at 3 (discussing Japan's promotion of aligning its "evaluation and regulation systems with international standards").

814. *See* RAPID SCREENING OF SUBSTANCES OF LOWER ECOLOGICAL CONCERN, *supra* note 760, at 10–11 (detailing the myriad information types that will trigger the need for a substance to be evaluated further in the Canadian system); *see also* LSR Assocs., *Japanese Chemical Substance Control Law (Kashinho), Criteria for "Flexible Assessment,"* NEWS WATCH (Nov. 2011), http://www.lsr-associates.com/pages/news%20watch/nov2011/japanese_chemical_substance_control_law.html (showing that exposure assessments play a role in each level of risk assessment in Japan).

815. RAPID SCREENING OF SUBSTANCES OF LOWER ECOLOGICAL CONCERN, *supra* note 760, at 10; *see also* Banerjee, *supra* note 783, at 28–29 (discussing how the approach of Japan's government is to "gradually evaluate[] the risk and request[] appropriate management by manufacturers and importers according to the risk in CSCL" while Canada's CMP process "leads to categorization and prioritized assessment of existing substances that need further evaluation").

thereby saving scarce government financial and human capital resources.

Based on these observations, one can make the following findings. None of the three chemicals management regulatory regimes (REACH, CMP, and Amended Kashinho) have been in operation for more than a few years, and all continue to evolve. Consequently, it is likely too soon to draw any definitive conclusions regarding their relative effectiveness such that the CMP or the Amended Kashinho can be justified as a less trade-restrictive alternative to REACH that can contribute to the fulfillment of REACH's legitimate objective of ensuring a high level of protection of human health and the environment to the same extent as REACH, within the meaning of TBT Article 2.2.

D. TBT ARTICLES 12.3 AND 12.1 ANALYSIS OF REACH

As previously discussed, the Panels in *US—Clove Cigarettes* and *US—COOL* were in general agreement about the analysis that must be performed to determine whether a WTO Member's regulatory actions have violated the obligation owed to developing countries under TBT Articles 12.3 and 12.1.⁸¹⁶ A complaining WTO Member must demonstrate that it qualifies as a “developing country”; that the disputed measure affects its special development, financial, and trade needs; and that the regulating WTO Member failed to take account of—i.e., give consideration to—such needs in the preparation and application of the disputed measure.⁸¹⁷

1. Analyzing Whether the EU Considered Developing Country “Special Development, Financial, and Trade Needs” in Proposing, Adopting, and Implementing REACH

a. Developing Country Trade Concerns Summarized

As previously discussed, fourteen developing country WTO Members raised trade concerns about the EU REACH regulation during several TBT Committee meetings convened March 2007 to March 2011.⁸¹⁸ They related to the EU's alleged failure to provide

816. See discussion *supra* Part III.B.4.

817. See discussion *supra* Part III.B.4.a.

818. See discussion *supra* Part II.C.9.

adequate and sufficient compliance-oriented technical assistance with respect to the REACH regulation and its accompanying guidance documents, despite multiple WTO Member requests having been made.⁸¹⁹ Many of these members claimed that the term “technical assistance” should be construed in light of the “special and differential” circumstances of developing countries.⁸²⁰ To remedy these perceived failings, the Argentine, Chilean, Chinese, and Chinese Taipei representatives offered the EU representative the following proposals: 1) The EU should establish REACH Help Desks within non-EU WTO Members to provide guidance on classification of chemical substance-based products just as it had done for EU Member States, consistent with the EU’s WTO national treatment obligation; and 2) The EU should dispatch technical experts to developing countries to provide local industry with direct training on REACH, which, in their view, would be more effective, prompt, and precise than the assistance provided online.⁸²¹

b. European Union Response to Developing Country Trade Concerns

The EU arguably endeavored to respond to these criticisms and proposals at nine separate TBT Committee meetings during which it proceeded to outline the actions that it was then undertaking and was prepared to undertake to address developing country grievances.⁸²²

819. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 142; TBT Committee Minutes for the Meeting of 3–4 November 2010, *supra* note 83, ¶¶ 96–98; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 57; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶¶ 40, 46–49; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶¶ 45, 56, 64; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 132; TBT Committee Minutes for the Meeting of 9 November 2007, *supra* note 83, ¶ 27.

820. See TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 57; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 46; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 64.

821. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 41; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 198; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 165; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 40; TBT Committee Minutes for the Meeting of 9 November 2007, *supra* note 83, ¶¶ 33–34.

822. See TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra*

The EU representative(s) conveyed that the EU intended to fulfill its TBT Agreement Article 11.3 obligations to render technical assistance to other WTO Members with respect to REACH through several means.⁸²³ The following subsections examine those means.

i. Establishing ECHA Help Desks

The EU stated that ECHA would establish a Help Desk within each EU Member State to serve as an access point for EU and non-EU manufacturers.⁸²⁴ Apparently, the EU has since established ECHA Help Desks in all twenty-seven EU Member States, Iceland, Lichtenstein, and Norway, as well as contact points within the EU Embassy, Consulate, and Missions capable of directing REACH-related queries from outside Europe.⁸²⁵

ii. Providing REACH Regulatory Guidance

The EU indicated that ECHA would provide Internet-based guidance materials consisting of: a) general, summarized REACH process information web pages; b) an Internet-based “Guidance Navigator” flowchart directing web visitors to relevant detailed

note 83, ¶ 164; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 60; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 53; TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 76; TBT Committee Minutes for the Meeting of 25–26 June 2009, *supra* note 83, ¶ 108; TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 203; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 198; TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 65; TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 149; TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 42.

823. TBT Agreement, *supra* note 5, art. 11.3; *see* TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 42 (“[E]xtensive guidance material, technical assistance and capacity building was planned.”).

824. *See* TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 42; *see also* *ECHA Helpdesk*, EUR. CHEMS. AGENCY, <http://www.echa.europa.eu/web/guest/support/helpdesks/echa-helpdesk> (last visited Oct. 30, 2012) (“The ECHA Helpdesk provides administrative advice to those who have obligations under the REACH . . . Regulations.”).

825. *ECHA Helpdesk Contact Form*, EUR. CHEMS. AGENCY, http://apps.echa.europa.eu/forms/cms_helpdesk_form.aspx (last visited Oct. 30, 2012); *HelpNet*, EUR. CHEMS. AGENCY, <http://echa.europa.eu/web/guest/about-us/partners-and-networks/helpnet> (last visited Oct. 30, 2012); *List of National Helpdesks*, EUR. CHEMS. AGENCY, <http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks> (last visited Oct. 30, 2012).

guidance; and c) detailed guidance on roles, obligations, and actions to be taken with respect to REACH.⁸²⁶

iii. Providing International Funds for Technical Assistance and Capacity Building

The EU stated that it would make funds available within international “assistance programs” falling under the auspices of the United Nations SAICM process and engage United Nations agencies such as United Nations Industrial Development Organization for purposes of facilitating REACH compliance.⁸²⁷ The EU indicated that it was also possible to incorporate technical assistance in ongoing EU trade-related—bilateral or regional—assistance programs.⁸²⁸

iv. Rendering Bilateral Technical Assistance

The EU invited any WTO Members, including developing countries, interested in receiving technical assistance regarding REACH to direct their requests to European Commission delegations located in their respective territories.⁸²⁹ The EU assured non-EU WTO representatives that their requests would be evaluated to see whether they could be met under existing EU assistance programs or would require further resources.⁸³⁰ Alternatively, the EU indicated

826. TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 203; TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 42; *see Guidance on REACH*, EUR. CHEMS. AGENCY, <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach> (last visited Oct. 25, 2012) (displaying internet-based “guidance navigator”).

827. TBT Committee Minutes for the Meeting of 21 March 2007, *supra* note 83, ¶ 57.

828. TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 203; TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 198; *see* TBT Committee Minutes for the Meeting of 1–2 July 2008, *supra* note 83, ¶ 65 (“For specific technical assistance to third countries, the EC representative recalled the intervention of the representative of UNIDO.”).

829. TBT Committee Minutes for the Meeting of 18–19 March 2009, *supra* note 83, ¶ 203 (“She invited WTO Members having specific needs for technical assistance programmes, to direct their requests to the respective delegations of the European Commission in their country.”).

830. *See* TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 60 (“[R]eadily available tools were a form of technical assistance, meant to assist both EU and non-EU manufacturers.”); TBT Committee Minutes for the Meeting of 5–6 November 2009, *supra* note 83, ¶ 76 (“[The EC representative]

that its representatives would meet directly with concerned delegations in Brussels.⁸³¹

v. *Convening REACH Training-Based Webinars*

The EU ECHA organized a series of webinar-based “training sessions” and “stakeholder days” to provide stakeholders with critical information about various REACH issues. These issues included: 1) how to prepare a registration dossier for submission to ECHA, 2) the 2010 and 2011 registration deadlines, 3) how to ensure that SIEFs operate more efficiently, and 4) the ECHA registration and dossier evaluation process.⁸³² The EU also emphasized that developing country delegations and industries were invited to and should participate in such sessions, and that recordings of the sessions would be available afterwards for viewing on the ECHA website.⁸³³

c. *Adequacy of the European Union Response*

It would appear that the EU has gone a long way toward responding to the trade concerns of all WTO Members, including developing countries, which were provided some special indirect financial and technical assistance through international programs and perhaps some bilateral financial and technical assistance, as well. However, the EU representative also made it very clear at one TBT Committee meeting that there would be no derogations afforded WTO developing country members with respect to REACH’s registration requirement. Because “the primary objective of REACH

invited Members who considered that appropriate assistance had not been provided to clarify whether specific requests had not been adequately followed up.”); TBT Committee Minutes for the Meeting of 20 March 2008, *supra* note 83, ¶ 149 (“[R]equests would be examined also in light of whether they could be met by existing technical assistance programmes or whether further assistance would be needed.”).

831. TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 164.

832. TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 60; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 53.

833. TBT Committee Minutes for the Meeting of 24–25 March 2011, *supra* note 83, ¶ 164; TBT Committee Minutes for the Meeting of 23–24 June 2010, *supra* note 83, ¶ 60; TBT Committee Minutes for the Meeting of 24–25 March 2010, *supra* note 83, ¶ 53.

was the protection of human health and environment . . . no exceptions for developing countries could therefore be provided . . . [in the context] of special and differential treatment and technical assistance . . . for requirements such as the pre-registration/registration obligation.”⁸³⁴

While the directness of the EU representative’s statement is indisputable, it remains uncertain, at this juncture, whether such statement symbolizes that the EU had more broadly failed to “take account of” developing country WTO Members’ development, financial, and trade needs when proposing, adopting, and implementing REACH, within the meaning of TBT Articles 12.3 and 12.1. The EU may be required to do more than allocate European assistance funds to international technical-assistance and capacity-building initiatives and programs operating under the auspices of various UN agencies, and to undertake ongoing outreach to and liaison with all WTO Members, including developing countries, for purposes of facilitating foreign industry REACH registration/data-gathering and notification compliance.

Practitioners are therefore advised to confer with their non-EU clients resident or having operations in WTO Member developing countries to ascertain the extent of any liaison between their governments and the EU’s REACH-related institutions. In this regard, it would be helpful to secure evidence confirming any access to EU federal government officials; any REACH-related developing country government comments submitted prior or subsequent to REACH’s adoption; any EU governmental responses thereto; any bilateral or regional exchanges of executive, regulatory, or legislative branch REACH-related correspondences; and any bilaterally or regionally convened REACH-related meetings, briefings, and/or initiatives.

V. CONCLUSION

A. SUMMARY OF REACH TBT FINDINGS

This article has outlined a possible analytical framework employing recent and relevant WTO jurisprudence for evaluating

834. TBT Committee Minutes for the Meeting of 5–6 November 2008, *supra* note 83, ¶ 198.

whether technical regulations in REACH, as adopted or as applied, are WTO-consistent. This legal review focused on the WTO TBT Agreement and analogous case law under the GATT 1994, concerning disputed health- and environment-related technical regulations alleged to constitute illegal nontariff barriers to trade. At least thirty-four WTO Members, including developing countries, have expressed specific trade concerns about the EU REACH regulation, most of which pertain to the REACH's registration/data-gathering and notification obligations, and arguably its registration/data-gathering requirement.

Three WTO Panels and the Appellate Body have reaffirmed that the TBT Agreement recognizes the sovereign right of WTO Members to regulate for the protection of human health and the environment at their chosen level of protection, provided that right is not exercised to employ such regulations in a discriminatory manner or as unnecessary obstacles to trade. The EU REACH regulation would arguably qualify as a "technical regulation" within the meaning of TBT Annex 1 and, thereby, fall within the coverage of the TBT Agreement.

A TBT Article 2.1 "like product" analysis of REACH reveals the growing importance of product-related PPMs, which focus on how products are made in addition to how they perform, as a factor in evaluating putative claims of trade discrimination. On the one hand, it would appear that the EU could potentially defend the application of REACH's registration/data-gathering requirement against a claim of trade discrimination where the substances contained in articles qualify as SVHCs because their intrinsic properties could credibly be found to pose high-level health risks. These risks indicate distinct physical properties and are capable of triggering distinct consumer preferences and buying habits; therefore, the EU could argue that REACH-registered articles containing SVHCs are not "like" non-REACH-registered articles containing SVHCs, the intrinsic properties of which would not otherwise have been identified and notified to ECHA and the public. However, this finding may depend on whether the ECHA or EU Member State competent authorities, when classifying such substances and later reviewing technical and substance dossiers, employ a semi-quantitative or qualitative rather than a purely quantitative risk-assessment approach.

On the other hand, it would appear that the EU would find it difficult to defend the distinct treatment it might accord to non-REACH-registered non-SVHCs against a claim of trade discrimination vis-à-vis REACH-registered non-SVHCs on the sole grounds that their manufacturing and/or import volumes had exceeded an arbitrarily determined annual threshold, without more. In the absence of any known or reasonably suspected or actual harmful intrinsic characteristics, and in the absence of any preliminary risk-based screening exercise, REACH's volume-based exposure and risk proxy would not likely be sufficient to substantiate that groups of REACH-registered non-SVHCs and groups of non-REACH-registered non-SVHCs are not "like" products.

EU Member States have been observed to implement REACH's registration/data-gathering and information-sharing provisions in a manner that raises the cost structures of imported chemical substance-based SVHC and non-SVHC products. However, it is too early to draw any definitive conclusions concerning whether these provisions, as enacted or applied, accord "less favorable" treatment to, and thus discriminate against, "like" groups of imports. Additional and updated information is required to determine whether the conditions and expectations for competition between groups of non-SVHC imports and "like" domestic non-SVHCs have been fundamentally altered to the detriment of the former. Similarly, additional and updated information is needed to identify more clearly the particular markets or market segments in which such groups of "like" chemical substance-based products compete.

A TBT Article 2.2 analysis of REACH, meanwhile, reveals that REACH's primary objective of ensuring a high level of protection of human health and the environment likely qualifies as a legitimate objective and that the REACH registration/data-gathering requirement's default reliance upon a volume-based exposure and risk proxy may reasonably reflect its chosen level of protection. Such analysis also indicates, however, that REACH's registration/data-gathering requirement may suffer both from design flaws and implementation irregularities. A number of reports indicate that the operation, implementation, and effects of said provisions have undermined REACH's ability to contribute to its objective and have imposed on third-country products more trade-restrictive treatment than is necessary for REACH to achieve said objective. Still other

reports indicate that REACH's hazard-based registration/data-gathering, notification, and information-sharing requirements have imposed on global industry a significantly altered cost structure that is more trade restrictive than necessary to achieve REACH's objective.

Moreover, in evaluating whether there are less trade-restrictive regulatory alternatives available that are capable of achieving REACH's objective taking into account the risks non-fulfillment would create, it is advisable to consider the iterative risk-based priority assessment systems utilized by the Governments of Canada and Japan. Like the EU REACH, the Canadian and Japanese systems rely on dated national chemicals inventories to assess the harm posed by high-priority substances and reflect government efforts to implement a number of international chemicals-related initiatives and treaty obligations. Unlike the hazard-based REACH registration/data-gathering provision, however, the multiple-level screening mechanisms of Canada's CMP and Japan's Amended Kashinho focus mostly on the exposure risks posed by substances rather than on merely a substance's hazardous intrinsic properties. These screening mechanisms have, thus far, been successful in channeling potentially problematic substances to further levels of risk assessment and have also eliminated a substantial number of substances from further government consideration where the most rapid of first-level screens found they posed no risk to human health and the environment. Nevertheless, because neither REACH, CMP, nor Amended Kashinho have been in operation for more than a few years, and all three continue to evolve, it is likely too soon to draw any definitive conclusions regarding their relative effectiveness. More information is required to substantiate whether Canada's CMP or Japan's Amended Kashinho can be justified as a less trade-restrictive alternative to REACH.

Lastly, a TBT Article 12.3/12.1 analysis of REACH reveals that it would be quite difficult, but not impossible, for developing country WTO Members to demonstrate that the EU had failed to adequately consider their special development, financial, and trade needs prior to proposing, adopting, or implementing REACH's registration/data-gathering, notification, and information-sharing provisions. The securing of evidence of the existence or non-existence of bilateral meetings, briefings, initiatives, and correspondences would go a long

way toward confirming whether or not the EU particularly considered developing country WTO Member interests.

B. LOOKING FORWARD

The framework proposed in this article has been largely shaped by the limited anecdotal evidence that has been available to date and by the current state of REACH's evolution and WTO law. While all three of the recent WTO TBT Panel decisions in *US—Clove Cigarettes*, *US—Tuna II (Mexico)*, and *US—COOL* have resulted in final “clarifying” Appellate Body rulings,⁸³⁵ arguably not enough time has elapsed to draw definitive conclusions from them, especially as they may be interpreted to apply to a technical regulation as comprehensive and complex as REACH. Consequently, this framework may need to be updated or enhanced to reflect future ongoing analyses of REACH, these WTO decisions, and the possible alternative regulatory models discussed in this article. Indeed, given the EU Commission's five-year REACH review, it is likely that additional relevant reports evaluating REACH's cost-effectiveness and its potential to enhance human health and environmental protection will be forthcoming. Such findings, once released, should be incorporated into the analysis underlying this framework before any final determinations are made regarding REACH's WTO consistency.

Moreover, the ongoing evaluation of REACH should take into account the European Commission Directorate General's efforts to promote “more global attention to chemical *hazards* in line with the EU's REACH regulation,” particularly by “including chemicals regulation in the Rio talks on sustainability.”⁸³⁶ It is, however, uncertain whether these efforts could eventually mature into a formal initiative such as a proposal for the development of a binding global chemicals management framework treaty modeled after the EU REACH or in a more ambitious “global institutional framework for sustainable development which . . . include[s] a strengthened

835. See generally *US — Clove Cigarettes Appellate Body Report*, *supra* note 15; *US — Tuna Appellate Body Report*, *supra* note 156; *US — COOL Appellate Body Report*, *supra* note 156.

836. *EU Environment Chief Vows 'Concrete Results' at Rio+20*, EURACTIV.COM (Feb. 8, 2012), <http://www.euractiv.com/sustainability/eu-environment-chief-vows-concrete-results-rio20-news-510639> (emphasis added).

environmental dimension” such as an international environmental organization to rival the WTO, as has been suggested, considering how such proposals are likely to engender international resistance.⁸³⁷

At the same time, such evaluation should consider a recent WTO Secretariat report prepared in advance of the Rio + 20 Conference that advises governments that the transition to a green economy in pursuit of sustainable development goals, if carefully and conscientiously designed and implemented, need not give rise to disguised nontariff barriers to trade.⁸³⁸ The report explicitly acknowledges that “[m]any countries are concerned that the transition to a green economy may lead to an increase in the use of measures that could adversely affect trade,” and it admonishes WTO Members to pay heed to “Principle 12 of the Rio Declaration [which] expresses the international community’s resolve that trade measures with an environmental purpose should not be disguised restrictions on international trade”⁸³⁹

Some of the myriad measures that could potentially trigger trade concerns include environmental requirements established by the “setting [of] technical specifications . . . for products and production methods . . . to improve energy efficiency or emissions performance, minimize waste, improve forestry management, or enhance the protection of soil, wildlife and natural habitats.”⁸⁴⁰ With respect to these measures, the report emphasizes the TBT Agreement’s critical role in balancing the right of governments to regulate to pursue legitimate public policy goals such as the protection of human health and the environment, with the obligation of governments to ensure that such measures are non-discriminatory and do not create

837. *EU Leaders Eye Stronger UN Role to Police the Environment*, EURACTIV.COM (Apr. 2, 2012), <http://www.euractiv.com/sustainability/eu-leaders-eye-stronger-un-role-police-environment-news-511197>; see *EU Environment Chief Vows ‘Concrete Results’ at Rio+20*, *supra* note 836 (suggesting that other world actors have paid attention to the commitment to chemical regulation displayed by the EU in REACH and may want to address a new world program at Rio).

838. See *Harnessing Trade for Sustainable Development and a Green Economy*, WTO, 9, 16 (2011), http://www.wto.org/english/res_e/publications_e/brochure_rio_20_e.pdf; *EU Leaders Eye Stronger UN Role to Police the Environment*, *supra* note 837 (stressing that the rules and transparency mechanisms built into the multilateral trading system can diffuse the concern about hidden nontariff barriers to trade).

839. *Id.*

840. *Id.* at 9–10 (emphasis added).

unnecessary obstacles to international trade.⁸⁴¹ In this regard, the Secretariat's report, most importantly, reaffirms the Appellate Body's recent interpretation of the TBT Agreement in *US—Clove Cigarettes* that serves as the underlying premise of this article: “[WTO] Members’ right to regulate should not be constrained if the measures taken are necessary to fulfill certain legitimate policy objectives, *and* provided that they are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade”⁸⁴²

Lastly, any ongoing evaluation of REACH should remain cognizant of longstanding EU-U.S. governmental and industry efforts to reduce NTBs via enhanced regulatory cooperation and mutual standards recognition,⁸⁴³ the primary objectives of which are to increase market access and reduce regulatory uncertainty and related cross-border transaction costs within the greater North Atlantic region, and to dissuade emerging third-country regulatory opportunism elsewhere (e.g., in Asia and Latin America).⁸⁴⁴

841. *Id.* at 10; US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 95.

842. US — Clove Cigarettes Appellate Body Report, *supra* note 15, ¶ 95 (emphasis added).

843. *See, e.g.*, Inside U.S. Trade, *Companies, Trade Groups Float Ideas for U.S.-EU Regulatory Cooperation*, WORLD TRADE ONLINE, Nov. 9, 2012, <http://insidetrade.com/Inside-Trade-General/Public-Content-World-Trade-Online/companies-trade-groups-float-ideas-for-us-eu-regulatory-cooperation/menu-id-896.html?S=LI>; Office of the United States Trade Representative, *Promoting U.S. EC Regulatory Compatibility*, 77 Fed. Reg. 59702 (Sept. 28, 2012), available at <https://www.federalregister.gov/articles/2012/09/28/2012-23613/promoting-us-ec-regulatory-compatibility> (including a request for public comments and a link to the public comments received); *International Affairs: EU-USA — Regulatory Cooperation*, EUROPEAN COMMISSION DIRECTORATE FOR ENTERPRISE AND INDUSTRY, http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/regulatory-cooperation/index_en.htm (last updated Sept. 11, 2012); John Morrall III, *Determining Compatible Regulatory Regimes Between the U.S. and the EU*, U.S. CHAMBER OF COMMERCE (2012), available at http://transatlantic.sais-jhu.edu/partnerships/Cornerstone%20Project/cornerstone_project_morrall.pdf; *cf.* Reinhard Quick, *Transatlantic Regulatory Cooperation on Chemicals—An Idealist’s Dream?*, in SYSTEMIC IMPLICATIONS OF TRANSATLANTIC REGULATORY COOPERATION AND COMPETITION 241–85 (Simon J. Evenett & Robert M. Stern eds., 2011).

844. *See* Lawrence A. Kogan, *Is REACH a Trade Barrier? Imported Chemicals Suffer from Higher Cost Structure*, CHEM. WATCH BUSINESS BRIEFING – EXPERT FOCUS (Dec. 14, 2012), available at http://www.koganlawgroup.com/uploads/CW53_December12_Kogan.pdf.