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REACH and International Trade Law

Lawrence A Kogan[1]

This chapter outlines a possible analytical framework employing recent and relevant World Trade Organization (WTO) jurisprudence for evaluating whether REACH, as adopted and/or as applied, is WTO-consistent. The ensuing legal review focuses on two 'covered' agreements: the Agreement on Technical Barriers to Trade ('TBT Agreement') and General Agreement on Tariffs and Trade 1994 ('GATT 1994'). **12.1**

The first section provides an overview of these WTO regimes. The second section summarizes the discussions on REACH between the European Union and its trading partners within the TBT Committee. The third section provides an assessment of REACH under WTO law. The fourth section looks ahead at the types of evidence still needed to undertake a more comprehensive REACH TBT review. **12.2**

[1] This chapter is based on a longer analysis published as L Kogan, 'REACH Revisited: A Framework for Evaluating Whether a Non-Tariff Measure Has Matured Into An Actionable Non-Tariff Barrier to Trade' (2012) 28 *American University International LR* 2 (hereinafter referred to as Kogan, 'REACH Revisited'). An authorized SSRN website version of this article is accessible online at: <http://ssrn.com/abstract=2149756> (accessed 1 February 2013).

A. Overview of GATT and TBT Agreement[2]

12.3 Both the GATT 1994 and the TBT Agreement are multilateral treaties that form part of Annex 1A to the Marrakesh Agreement establishing the World Trade Organization. These WTO Agreements 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 procedures (such as testing or certification) for determining whether a particular product meets such regulations or standards ('conformity assessment procedures'). 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'.[3] Consequently, if REACH is determined to constitute a 'technical regulation' within the meaning of the TBT Agreement, then the latter (ie the TBT Agreement) would deal with the measure (ie REACH) in the most specific and most detailed manner'.

12.4 The TBT Agreement applies to all technical measures addressing industrial and agricultural products, except those properly characterized as sanitary and phytosanitary (SPS) measures or as specifications for government procurement, which are instead covered under separate WTO agreements. Its 'object and purpose is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members' right to regulate'.[4] The TBT Agreement aims at preventing 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'.

12.5 REACH can be described as a behind-the-border technical measure intended to address regional health and environmental concerns and impacts. It can also be appropriately classified as a type of non-tariff measure (NTM) that falls within the scope of the TBT Agreement because arguably it distorts and creates uncertainty surrounding international trade flows of chemical substance-based products. 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).

12.6 The Organization for Economic Cooperation and Development (OECD) defines the term 'non-tariff barriers' as 'barriers to trade that are not tariffs', which may, in certain circumstances, include domestic measures such as technical regulations regarding health and consumer safety (eg where they are misused). At least one OECD study which employed a cross-survey analysis to ascertain the use and incidence of NTBs in different markets[5] found that technical measures were consistently included among the highest ('top five') ranked NTBs. A related OECD study analysing the lists of WTO NTB notifications submitted by 11 OECD and 21 non-OECD countries from March 2003 to October 2004 found that

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[2] See Kogan, REACH Revisited, section 1.

[3] Panel Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products* (5 April 2001) WT/DS135/R and Add1, 8.16 (emphasis in original).

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

[5] OECD Trade Directorate, 'Looking Beyond Tariffs: The Role of Non-Tariff Barriers in World Trade' (2005) OECD Trade Policy Studies. This OECD study is actually a compilation of a number of separate studies authored by different members of the OECD Trade Directorate.

technical barriers to trade (TBTs) represented the NTB category with the highest incidence of notifications.[6]

12.7 These statistics, which are now regularly compiled by the WTO Committee on Technical Barriers to Trade ('TBT Committee'), are the product and fulfillment of one of the core obligations imposed generally on all GATT 1994/WTO Members, and, specifically, on TBT Agreement parties—that of 'transparency'. In accordance with the TBT Agreement:

> Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards' [Members *must*] 'promptly publish [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. WTO Members are also required to inform the WTO and fellow-Members of specific measures, policies or laws through regular 'notifications'.

12.8 TBT Committee statistics reflect, for the most part, a steady but growing global trend in NTB notifications of technical regulations and conformity assessment procedures, many of which reference 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 objectives for each of the years 2003 to 2011, and the protection of the environment was among the top three most frequently cited policy objectives in six of those nine years. 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': '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. Notifying WTO Members are expected to explain the objective(s) of a given measure clearly in its accompanying notification, or upon other Members' registering of specific trade concerns regarding said measure. The raising of specific trade concerns is viewed as an early barometer of the perceived 'trade-worthiness' of a given measure.[7]

12.9 TBT Committee statistics help to place TBT notifications submitted with respect to technical regulations like REACH, and WTO Members' reactions to them, into proper context. The European Union first notified the Committee about REACH on 4 January 2004. 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 environment—it was subsequently discovered that 'animal welfare' had actually played a very influential role in shaping the REACH regime.[8] The European Union thereafter submitted eight additional notifications over the ensuing seven-year period—from March 2004 to April 2010. These

[6] Of the 1,200 NTB notifications reviewed, 530 concerned TBTs comprising almost half (46 per cent) 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 per cent)'.

[7] The TBT Committee's 2011 Annual Review reflects that the number of specific trade concerns has grown steadily since 1995, and practically tripled between 2005 and 2011, with most emphasizing the need for greater clarification and transparency of regulatory measures and the avoidance of unnecessary barriers to trade. The review also reflects that 'The most commonly stated objectives of the measures discussed relate to health and safety, and the protection of the environment'. See, eg Specific Trade Concerns Raised in the TBT Committee, World Trade Organization (WTO) Committee on Technical Barriers to Trade G/TBT/GEN/74/Rev.8 (1 June 2011).

[8] DA Motaal, 'Reaching REACH: The Challenge for Chemicals Entering International Trade' (2009) 12 *Journal of International Economic Law* 643, 659

notifications reflect the several amendments, revisions, and addenda that the European Union previously issued, and has continued to issue, to the evolving REACH Regulation, as well as the introduction of various versions of new guidance documents developed to facilitate international REACH implementation following its 2007 enactment. These notifications strongly suggest that the European Union has recognized that REACH's length, complexity, and the new legal obligations it imposes present real compliance challenges for industry supply chains and have impacted international trade in chemical substance-based products. As of 10 November 2011, 34 WTO Members had expressed specific trade concerns, in particular, about REACH (ID 88), for a record 27 times since the EC's initial REACH TBT Committee notification. Indeed, a recently released (2012) WTO Secretariat report cited REACH as '*the* STC [specific trade concern] most frequently raised by the greatest number of Members (over 30)'.[9] Precisely because the EU's ongoing review of the REACH regulatory framework strongly suggests that it will continue to be revised in the future, it is very likely that more EU TBT Committee REACH notifications will be forthcoming and trigger additional specific trade concerns.

B. REACH-related Trade Concerns at the WTO: 2004 to 2011[10]

I. Main REACH features having potential impact on international trade

12.10 The primary stated objective of the REACH Regulation is to ensure *a high level of* protection of health, safety, and the environment through the creation of a single comprehensive system that covers all (existing as well as new) chemical substances, although it also has an important claimed tertiary objective of limiting the use of vertebrate animals in chemicals testing. The European Commission has described REACH as a response to the perceived inability of prior EC legislation to gather 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.

12.11 While the REACH regime is comprised of several elements, its primary (and arguably most controversial) element is its data gathering and registration requirement. It applies to each legal entity (EU manufacturer, EU importer, or EU 'only representative' appointed by a non-EU manufacturer/formulator) established within the European Community (EC) that manufactures within or imports into the European Union both existing and new substances (on their own, in preparations, or in articles) (unless otherwise exempt) in a volume of more than 1 tonne per year. Although '[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... *[v]olume is used as a proxy for exposure*. It allows a clear, enforceable priority setting for registration which also gives legal certainty'.[11]

12.12 This data gathering and registration requirement is primarily dependent on production volume, is implemented in phases (of pre-registration, late pre-registration), and can entail significant costs and fees, some of which have been reduced for small and medium-sized

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[9] WTO, *Report on G-20 Trade Measures (Mid-October 2011 to Mid-May 2012)*, 32 (emphasis added) <http://www.wto.org/english/news_e/news12_e/g20_wto_report_may12_e.doc> (accessed 31 May 2012)

[10] See Kogan, REACH Revisited, section II.A.

[11] European Commission, 'The REACH Baseline Study: A Tool to Monitor the New EU Policy on Chemicals—REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)' (2009), Eurostat Methodologies and Working papers, 26, 32 (emphasis added); European Commission, *Questions and Answers on REACH*, Environment Directorate (2007) Q&A 2.5.1, 15.

enterprises (SMEs). It obliges all such entities: (i) to gather information in the form of a technical dossier describing the intrinsic characteristics of (hazards presented by) each such substance 'through literature search, data sharing and testing if necessary', but to avoid vertebrate animal testing where deemed appropriate; (ii) to use that information in generating exposure information (for quantities of substances between 1 and 10 tonnes per year), in preparing a chemical safety report (CSR) assessing the risks from identified uses (if more than 10 tonnes per year) and for putting in place and recommending risk management measures that would ensure the safe use of each substance; (iii) to submit such information to a newly created centralized regulatory agency known as the European Chemicals Agency (ECHA), with multiple organs and functions, including EU Member State coordination tasks, for review and for inclusion within a newly created 'central chemicals database' to be administered by this agency; and (iv) to share the gathered information with the rest of the manufacturing supply chain through voluntary consortia and mandatory substance information exchange forums (SIEFs) for purposes of: (a) harmonized classification and labeling; and (b) the submission of joint supply chain registrations that permit new supply chain registrants to refer to previously prepared studies and serve to minimize the likelihood of duplicative vertebrate animal testing. Various levels of dossier information are required depending on the manufactured or imported volume of each such substance (ie tonnage band) and on whether the substance is characterized on the basis of hazard (not risk) as persistent, bio-accumulative, and toxic.

12.13 Substances, including substances of very high concern (SVHCs), 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 and is more extensive than a dossier evaluation (ie it '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'), is intended to clarify the presence and degree of risk posed. The ECHA has stated that 'The selection and eventual prioritization of substances for evaluation is made according to risk-based criteria'. Substances to be evaluated are listed in a Community Rolling Action Plan (CoRAP), the first iteration of which was adopted by EU Member State representatives on 9 February 2012. It currently includes 90 substances, 43 of which are SVHCs.

12.14 Once SVHCs have been notified to the ECHA, they undergo a two-step regulatory process (including the substance evaluation process), after which they may be placed on an 'authorization list' and are subject to authorization. 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. The authorization process is 'risk-based' and is intended to ensure that risks from SVHCs are adequately controlled/restricted and/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. Authorizations can '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 outweigh ... the risks'. The risks of alternative substances ('substitutes') are also taken into account.

12.15 In essence, the REACH registration/data gathering requirement, consistent with the precautionary principle, reflects a regulatory paradigm shift that arguably (and incompletely) reverses the burden of proof (both the burden of production *and* the burden of persuasion) from the 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. The complete and satisfactory fulfillment of this requirement is a condition precedent to the marketing of a given manufactured or imported substance,

substance-mixture, or substance-containing article, which is otherwise known as the principle of 'no data, no market'.

II. REACH review and consultation at the WTO[12]

12.16 The REACH Regulation had already triggered international trade concerns among WTO Member governments and non-EU industries by the time the European Commission first formally notified the WTO TBT Committee of REACH's proposed adoption in January 2004. WTO Members have since continued to register their concerns at a record number of TBT Committee meetings, and as recently as November 2011.

12.17 REACH, thus far, has not been challenged at the WTO. This can perhaps be explained by reference to the following factors: (1) the EC's submission to the TBT Committee of an 'early notification' under TBT Agreement, Article 2.9.1 acquainting Members with the proposed REACH regulation; (2) the EU's almost simultaneous hosting of a public internet-based consultation that received up to 6,500 comments in response to the REACH proposal; (3) the EU's granting of a 60-day extension to the REACH comment period; (4) the EU's willingness to respond in writing and in person to WTO Members' numerous concerns at several TBT Committee meetings and to engage in private bilateral consultations with some WTO Members; (5) considerable WTO Member government and non-EU industry lobbying; (6) 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; (7) the passage of time deemed necessary for the purpose of accurately assessing whether the adopted REACH registration/data gathering obligation has been applied in a WTO-consistent manner; (8) a dedicated cadre of academic, civil society, and industry advocates/lobbyists who have laboured to defuse accusations of REACH WTO non-compliance; and (9) the EU's likely comprehensive review of the Panel and Appellate Body decisions in the WTO *Shrimp-Turtle* case.[13] They, in part, highlight 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 which 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.

12.18 With respect to this last point, if challenged, the European Union 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)', that it had 'implemented a large number of the SAICM objectives (Strategic Approach to International Chemicals Management)', and that 'the REACH proposal [did] not negatively affect the OECD Screening Information Data Set (SIDS) programme and the USA's HPV programme'. In other words, it can be expected that the European Union will assert that it had previously 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', consistent

[12] See Kogan, REACH Revisited, section II.B.

[13] WTO, *United States-Import of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, WT/DS58/AB/R (1998).

with how the Appellate Body in *Shrimp-Turtle* had envisioned WTO Members should fulfill their obligations under the chapeau of GATT (1994), Article XX.

12.19 Following REACH's adoption, the European Union endeavoured to address a few specific issues that caused trade concerns. First, the Commission partly fixed a problem arising under REACH for imported cosmetics. The REACH regime inadvertently excluded from pre-registration imported ingredients for cosmetic products that were lawfully on the market before 1 June 2008.[14] Second, in its practice, the ECHA permits an only representative (OR) to submit an application for authorization,[15] although the REACH Regulation does not provide for this arrangement.

III. Specific REACH-related trade concerns raised by TBT Committee Members[16]

12.20 As noted in para 12.9, at least 34 non-European WTO Members expressed specific trade concerns about the REACH Regulation following its notification to the TBT Committee, most of which pertain to REACH's registration/data gathering and notification obligations. These concerns (ie objections) are described here.

1. *REACH is complex, burdensome, costly and hazard (not risk)-based.* These objections highlighted REACH's complex and detailed data gathering and registration provision, and the placement of SVHCs on the Candidate List without evidence that the substances pose a risk in particular concentrations or for particular end-uses and channels of exposure, and without information on the risks to consumers of using an alternative substance.
2. *EU Member States engage in inconsistent treatment of substances (SVHCs) in articles.* Some WTO Members voiced concern about the legal uncertainties created by six EU Member States' refusal to interpret/implement REACH, Article 7(2) consistent with ECHA's (and the EU Commission's) interpretation of that provision as set forth within ECHA's May 2008 guidance document. Article 7(2) requires EU manufacturers and importers of articles to notify ECHA if articles containing more than 0.1 per cent (by weight) of an SVHC placed on the Candidate List are to be imported. Other WTO Members emphasized how certain EU Member States classified steel slabs as component-based 'mixtures' rather than as finished 'articles', contrary to a EUROFER trade association analysis with which ECHA had agreed.
3. *REACH's monomer registration requirement is costly and burdensome, and threatens intellectual property.* WTO Members questioned why REACH subjects reacted monomers in polymers to registration even though polymers themselves are exempt from registration. They emphasized that such requirement would adversely impact non-EU polymer manufacturer profitability, intellectual property rights, and market access, and complained that such requirement would likely compel non-EU manufacturers unable to register their monomers themselves to withdraw from the EU market, and encourage non-EU distributors to switch to EC polymer suppliers that had directly registered the monomers in those polymers. Consequently, EC-based

[14] Commission, 'Communication on the enquiry and registration under Regulation (EC) No 1907/2006 (REACH) of substances that were lawfully on the market before 1 June 2008 but which do not have phase-in status' 2008/C 317/02.

[15] ECHA, 'REACH Factsheet: Applications for authorization under REACH' (2012).

[16] See Kogan, REACH Revisited, and section II.C.

monomer producers and polymer manufacturers would effectively bear a lesser cost and burden and a lower risk of IP theft than non-EC manufacturers, and thereby derive a competitive economic advantage, which strongly suggested the presence of a disguised discriminatory trade barrier. While questions concerning the scientific necessity for the monomer registration requirement were subsequently resolved in July 2009, when the European Court of Justice upheld said requirement as legally valid in an unsuccessful challenge brought by several European companies,[17] the trade issues surrounding it remain unresolved.

4. *The delayed and confusing EU REACH implementation process belies lack of EU institutional capacity to meet regulatory burdens.* WTO Members complained that the EU institutions vastly underestimated the volume of data that would be submitted and the number of technical assistance requests made incident to the complex REACH registration process. 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.
5. *Non-EU manufacturers are placed at an economic disadvantage if they must choose between an importer and OR registration to protect their intellectual property.* WTO Members alleged that REACH indirectly imposed additional registration costs and burdens on non-EU manufacturers required to employ the services of either an EU-based importer (ie a customer) or an OR if they desired to protect their proprietary information from EU competitors, including customers. This requirement effectively places SMEs and non-EU chemical substance-based product manufacturers at a competitive economic disadvantage in EU markets because they, unlike multinationals, are less likely to have a European presence or to know where to find a competent and reliable OR.
6. *REACH's mandatory data sharing and SIEF membership places non-EU manufacturers at a competitive economic disadvantage.* REACH's mandatory information/data sharing and SIEF participation requirements, and REACH's EU-based legal entity precondition to SIEF formation and registration, would practically render non-EU chemical substance-based product manufacturers susceptible to exploitation and/or discrimination by EU-based companies charged with operating the very SIEFs and 'voluntary' consortia non-EU-based companies must join to fulfill their REACH SIEF information sharing obligation.
7. *REACH's extra-territorial vertebrate animal testing prohibition imposes unnecessary burdens and costs on non-EU manufacturers.* WTO Members emphasized that REACH's extra-territorial prohibition against vertebrate animal testing of chemical substances, plus its cost-intensive joint registration and SIEF information-sharing obligations, impose unnecessary burdens and significant costs upon otherwise competitive non-EU chemical substance-based product manufacturers, especially SMEs. They also expressed scepticism about whether the European Union would actually permit

[17] The ECJ's ruling was based on a finding that the current costs and burdens imposed by REACH, Art 6(3) registration requirement were outweighed by the associated future benefits of fulfilling the legitimate public policy objective of protecting human health and the environment by means of gathering further knowledge about polymers and monomer residues and the health and environmental risks they present: Comment of the Representative of the European Communities, G/TBT/M/52. See also Case C-558/07 *The Queen, on the application of SPCM SA, CH Erbslöh KG, Lake Chemicals and Minerals Ltd, Hercules Inc v Secretary of State for the Environment, Food and Rural Affairs* (2009) C 205, P. 0006–0006.

REACH registrations to include data generated from outside the European Union by non-EC laboratories fulfilling ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories.

8. *REACH's delegation of direct enforcement and penalty responsibilities to EU Member States yields inconsistent treatment of non-EU manufacturers.* WTO Members warned that REACH's delegation of direct enforcement responsibilities to EU Member States loosely cooperating under ECHA auspices (the Forum for Exchange of Information on Enforcement) may result in non-uniform EU Member State inspections, registration data generation and presentation standards, and penalty impositions that provide EU-based companies operating in those Member States with a competitive trade advantage. They also highlighted that the United Kingdom, Poland, and other EU Member States had enacted different inspection procedures to confirm company compliance with REACH pre-registration requirements, and reported that during one large-scale inspection inspectors had demanded more information than REACH legally requires. Inconsistent and excessive pre-registration evidentiary requirements were potentially problematic because they would affect only imports and, thereby, restrict legitimate international trade. The EU representative responded that Commission monitoring of Member State REACH penalty enactment procedures had resulted in all but two Member States adopting the relevant sanctions, and that Commission infringement proceedings had been commenced against two Member States that had not notified their enforcement measures, with Belgium becoming the first of these defendants to receive an adverse European Court of Justice ruling. [18]
9. *REACH does not satisfy EU's WTO obligation to accord special and differential treatment to developing countries.* Developing country WTO Members complained that the European Union had failed to provide adequate/sufficient technical assistance with respect to REACH, despite their multiple requests. The EU's provision of mostly web-based technical assistance and stakeholder forum guidance to all WTO Members to facilitate REACH implementation did not satisfy the EU's WTO obligation to accord special and differential treatment specifically to developing countries and their industries.

C. Assessment of REACH under TBT Agreement[19]

12.21 These specific comments on REACH signal that the EU's trading partners are concerned about REACH's potential effects on trade. The mere presence of effects on international trade, of course, is not a sufficient basis for holding that REACH, in whole or in part, violates the EU's obligations under WTO law. To assess whether REACH is WTO-consistent, as adopted and as applied, this chapter sets forth a brief summary of an analytical framework to evaluate REACH in light of WTO Members' specific trade concerns and recent and relevant WTO jurisprudence.

[18] On 5 May 2011, the Court of Justice ruled that it had 'failed to fulfil its obligations under Article 126 of [REACH]... by failing to adopt all the laws, regulations and administrative provisions necessary to implement the penalties applicable to infringements of [REACH]... within the prescribed period'. As a result, the Court ordered Belgium to pay all of the costs of the proceeding. See Case C-265/10 *Commission v Kingdom of Belgium* 186/13; See also Actio Blog, *REACH Penalties: Belgium Found Guilty* (9 May 2011) <http://www.actio.net/default/index.cfm/actio-blog/reach-penalties-belgium-found-guilty/> (accessed 18 March 2013).

[19] See Kogan, REACH Revisited, section IV and generally.

12.22 This legal evaluation of REACH analyses three recent WTO 'cases of first impression' (*US—Clove Cigarettes*,[20] *US—Tuna II (Mexico)*,[21] and *US—COOL*[22]) interpreting the TBT Agreement's non-discrimination, unnecessary obstacles to trade, and special and differential developing country treatment provisions, and analogous GATT 1994 case law concerning disputed health and environment-related technical regulations (NTMs) alleged to constitute illegal NTBs. All three Panel decisions were subsequently appealed and resulted in final 'clarifying' Appellate Body rulings.[23]

12.23 REACH's primary stated objective is to ensure a high level of protection of health, safety, and the environment through the creation of a single comprehensive system that covers all (existing as well as new) chemical substances. REACH's other recognized objectives are to enhance competitiveness and innovation and to limit the vertebrate animal testing of chemicals. The European Commission has described REACH as essential to enabling the relevant EU government institutions to properly identify, evaluate, and manage the known and unknown risks arising from chemicals in industrial and commercial use. Arguably, the REACH regime's most controversial elements from a trade perspective are its registration/data gathering and notification requirements.

12.24 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. Although REACH does not refer to specific substances unless they are placed on the SVHC 'candidate' and/or 'authorization' lists or they are subject to restrictions, REACH probably qualifies as a 'technical regulation' within the meaning of TBT Agreement, Annex 1, and thereby falls within the coverage of the TBT Agreement. This result arguably obtains because: (1) REACH is a classic EU Regulation that serves as the most direct form of EU law and has had binding legal force and effect; (2) REACH is supported by a cooperative 'enforcement' mechanism entailing, inter alia, coordination of Member State national inspection and enforcement policies by ECHA's Enforcement Forum, and inspections and penalties for non-compliance to be directly administered by EU Member State competent authorities, that foresees the possibility of imposing a fine/penalty in the event of non-compliance; and (3) REACH consistently refers to its core registration/data gathering requirement as a 'mandatory' requirement and precondition to securing access to EU markets.[24]

I. Non-discrimination

a. Like products analysis[25]

12.25 TBT Agreement, Article 2.1 provides that 'Members shall ensure that in respect of technical regulations, 'like' products imported from the territory of any Member shall be accorded

[20] See Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US-Clove Cigarettes')* (2 September 2011) WT/DS406/R.

[21] See Panel Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products ('Mexico-Tuna II')* (15 September 2011) WT/DS381/R.

[22] See Panel Report, *United States—Certain Country of Origin Labelling ('COOL') Requirements* ([18 November 2011) WT/DS384R, WT/DS386R.

[23] See Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US-Clove Cigarettes AB')* (4 April 2012) WT/DS406/AB/R; Appellate Body Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products ('Mexico Tuna II AB')* (16 May 2012) WT/DS381/AB/R; Appellate Body Report, *United States—Certain Country of Origin Labelling ('COOL') Requirements* (29 June 2012) WT/DS384/AB/R, WT/DS386/AB/R. See also Kogan, REACH Revisited, section III.A.

[24] Kogan, REACH Revisited, sections III.B.1 and IV.A.1.

[25] Kogan, REACH Revisited, sections III.B.2.b and IV.B.1 ('like' products test).

treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country'.[26] The key term in this provision is 'like' products. The 'likeness' of imported and domestic products should generally be determined on a case-by-case basis pursuant to four general criteria:[27]

> (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.[28]

12.26 A 'like' product analysis of REACH, which focuses either on finished articles containing chemical substances, chemical substances, or mixtures, reveals the growing importance of product-related process and production methods (PPMs) as a factor in evaluating putative claims of trade discrimination.[29] In other words, within some segments of the global economy, how products are made is becoming almost as important as how products perform.[30]

12.27 It would appear that the European Union may more easily defend against a claim of trade discrimination arising from the distinct application of REACH's registration/data gathering and notification requirements to groups of SVHC-containing foreign manufactured articles, mixtures, and chemical substances ('SVHC products') vis-à-vis groups of non-SVHC-containing articles, mixtures, and non-SVHCs themselves ('non-SVHC products'). Groups of imported SVHC products may arguably be distinguished from groups of domestic non-SVHC products in the industrial, wholesale, and retail market places to the extent of any likely distinct health risks associated with each group of products. Indeed, it may be possible, based on a comparison of product characteristics and consumer tastes and habits, which include actual and perceived product-related health risks, to show that they would not be deemed 'like products'.[31] Consequently, one could possibly conclude that REACH-registered SVHC-containing domestic articles or mixtures are not 'like' imported non-REACH-registered SVHC-containing articles or mixtures or non-SVHCs of which ECHA or EU Member State competent authorities remain unaware.

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[26] In Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US–Clove Cigarettes AB')*, para 112, the Appellate Body found that the likeness of imported and domestic products, within the context of TBT Agreement, 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..

[27] See EC–Asbestos Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products* (5 April 2011) WT/DSI35/AB/R, paras 102–103 (recognizing, however, that Panels possess and should exercise the authority and discretion to examine all 'relevant' evidence).

[28] Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US-Clove Cigarettes')*, paras 7.121–7.123 (citing EC–Asbestos Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, paras 101–103). See also Report of the Working Party, *Border Tax Adjustments*, L/3464 (2 December 1970), GATT BISD 18S/97; Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US–Clove Cigarettes AB')*, para 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: para 159 (citing Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US-Clove Cigarettes')*, para 7.239).

[29] 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. See REACH, Art 7 (requiring registration and notice of substances in articles); Kogan, REACH Revisited, 183–184.

[30] For example, the Appellate Body in *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US–Clove Cigarettes AB')*concluded (para 119) that '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, Art III:4 and TBT Agreement, Art 2.1]... to the extent they have an impact on the competitive relationship between and among the products concerned' (emphasis added) (citing EC–Asbestos Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, paras 113–14 and 122).

[31] Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes ('US–Clove Cigarettes AB')*, 118–119.

12.28 Any such finding would depend, however, on whether ECHA and/or EU Member State competent authorities, when classifying the substances incorporated within such products and later reviewing technical and substance dossiers, employ(s) a semi-quantitative or qualitative rather than a quantitative risk assessment approach.[32] Semi-quantitative or qualitative analyses tend to focus mostly on the health *hazards* (based on intrinsic substance characteristics) posed by SVHC or non-SVHC products, which entails a lower threshold of potential harm, as compared to a strictly quantitative risk assessment approach. A quantitative approach instead focuses on the health *risks* engendered by such products, which necessarily takes into account exposure, dosage, and actual use. If hazard assessment eventually replaces risk assessment as the new threshold for regulating both SVHCs and non-SVHCs under REACH, as may be indicated by the subtle shift that has been discerned at the WTO,[33] the European Union would ultimately have a more difficult task differentiating SVHC from non-SVHC products for purposes of rendering a 'like product' determination. Furthermore, if a semi-quantitative and/or qualitative risk approach predominates in assessing the relative health hazards rather than health risks posed by groups of EU-manufactured and imported *non*-SVHC products, it would be even more difficult for the European Union to distinguish between these groups when undertaking a 'like product' analysis, especially considering that annual manufacturing or importation volumes are presumptively treated for purposes of REACH's registration/data gathering requirement as a *proxy* for likelihood of exposure.[34]

12.29 Unlike in the situation involving SVHCs, it would appear that a TBT Agreement, Article 2.1 discrimination claim made against the European Union would have a greater chance of succeeding if it focused on groups of imported substances that are not SVHCs, not incorporated within articles, and not shown to pose empirical health or environmental risks. These substances must be registered if they are merely sold or used on their own or in mixtures in annual volumes of 1 tonne or more, as REACH employs exposure as an across-the-board proxy for harmfulness. Granted, ECHA, EU national authorities, and registrants must undertake an exposure-based risk assessment or preliminary risk screening of substances at REACH's subsequent evaluation and authorization stages. However, until then the physical characteristics, end-uses, and tariff classifications of such imported and domestic substances are neither easily distinguishable by regulators, nor likely adversely to influence consumer and business user buying preferences, tastes, and habits. Thus, due to their perceived 'likeness' at the earlier registration stage, the relatively greater burden and expense REACH effectively imposes on such imported substances would be more difficult to justify.[35]

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[32] See discussion in Kogan, REACH Revisited, sections IV.B.1.a (on TBT Agreement, Art. 2.1), and IV.C.4 (on TBT Agreement, Art. 2.2). One recently released report corroborates this finding: 'In most of the CSRs analysed, *no quantitative risk assessments have been made* for the impact areas consumers and humans via the environment': European Commission, *The REACH Baseline Study 5 Year Update*, Eurostat Methodologies and Working papers accessible, 10, 30, and 36 (Table 3.10) <http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-12-019/EN/KS-RA-12-019-EN.PDF> (accessed 18 March 2013).

[33] See ECHA, 'Guidance on Registration' (version 2.0, May 2012), s 5.3.1.2. See also A Arcuri, 'Food Safety at the WTO After "Continued Suspension": A Paradigm Shift?', in Antonis Antoniadis, Robert Schütze, and Eleanor Spaventa (eds), *The European Union and Global Emergencies: A Law and Policy Analysis* (Oxford: Hart Publishing, 2010).

[34] European Commission, 'The REACH Baseline Study' (2009), 26; European Commission, 'Questions and Answers on REACH' (2007), 15.

[35] Kogan, REACH Revisited, 194–196. Unlike with SVHCs, an importer's violation of REACH Art 5's 'no data, no market' rule in respect of 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 in the case of SVHC imports, it may not also be true that an Art 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

b. Less favorable treatment analysis[36]

A TBT Agreement, Article 2.1 analysis of the facts supporting WTO Member grievances concerning the design and implementation of REACH's registration/data gathering and notification requirements reveals various scenarios that could potentially lead to a finding of de facto REACH trade discrimination against non-EU manufacturers. Given the relative limitations REACH places on ECHA's authority,[37] several such scenarios have involved divergent and/or inconsistent applications of REACH regulatory and/or enforcement provisions by and among EU Member States. Indeed, available evidence shows that EU Member State implementation of REACH's registration/data gathering and notification requirements arguably imposes a higher cost structure upon, and thus impairs the competitiveness of, 'like' chemical substance-based product imports in EU markets. It does so by subjecting groups of imported non-REACH-registered SVHC-containing articles and non-REACH-registered non-SVHCs to treatment 'less favorable than' that accorded to 'like' groups of REACH-registered domestic articles and substances.[38] 12.30

A claim of less favourable treatment of 'like' imported products could arise with respect to imported SVHC-containing articles if, as reported, the EU Member State national authorities in France, Austria, Belgium, Denmark, and/or Germany, contrary to ECHA guidance,[39] determine that an imported article contains more than 0.1 per cent (by weight) of a Candidate List SVHC on the basis of each article 'component' rather than each 'finished article'.[40] This concern arose as the result of divergent EU Member State assessment and enforcement of importers' registration/data gathering and notification obligations under REACH, Articles 7(2) and 33. A claim of discrimination may potentially succeed if it can be shown that such imported products would be subject to more extensive and costly restrictions relative to 'like' EU products that could render them less competitive in EU markets. 12.31

II. Unnecessary obstacles to trade; more trade restrictive than necessary

TBT Agreement, Article 2.2 provides that '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 fulfill a legitimate objective taking account of the risks non-fulfillment would create'. The TBT Agreement recognizes as legitimate objectives 'the protection of human health or safety, animal or plant life or health, or the environment'. In assessing the risks of non-fulfillment of these objectives, relevant considerations are, among others, 'available scientific and technical information, related processing technology, or intended end-uses of products'. 12.32

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bona fide expressions of market preference for registered non-SVHCs highly suspect since the choice of product 'substitution' would have been removed: Kogan, REACH Revisited, 196.

[36] See Kogan, REACH Revisited, sections III.B.2.c and IV.B.2 (less favorable treatment test).

[37] M Bronckers and Y Van Gerven, 'Legal Remedies Under the EC's New Chemicals Legislation REACH: Testing a New Model of European Governance' (2012) 46 CMLR 1823, 1827–1828.

[38] Kogan, REACH Revisited, 196–217.

[39] ECHA, 'Guidance on Requirements for Substances in Articles' (version 1, May 2008). See also ECHA, 'Note to the Reader—Guidance on Requirements for Substances in Articles' (version 2, 1 April 2011); European Commission, 'Summary Record 6th Meeting of Competent Authorities for REACH and CLP' (24 February 2011) CA/02/2011 section 9.1; European Commission, '7th Meeting of Competent Authorities for REACH and CLP (CARACAL), Update of Commission Opinion—Substances in Articles' (4 February 2011) CA/26/2011.

[40] See R Mitchell, 'French Interpretation of REACH Reporting Rules Could Hurt Competitiveness, Hike Costs' (13 July 2011) Bloomberg BNA.

a. Are REACH's objectives legitimate?[41]

12.33 An analysis of REACH reveals that REACH's primary objective of ensuring a high level of protection of human health and the environment consistent with sustainable development likely qualifies as a legitimate objective and that the REACH registration/data gathering and notification requirements' default reliance upon a volume (hazard)-based exposure proxy can be respected as reflecting the EU's chosen level of protection. However, such an analysis also strongly suggests that REACH's registration/data gathering requirement may be flawed as designed and as implemented, and these observations raise serious questions about the extent to which REACH can contribute to the fulfillment of that objective.

b. To what extent is REACH capable of fulfilling its legitimate objectives?[42]

12.34 Of great significance are the perfunctory (automated) registration 'completeness checks'[43] and the infrequent substantive registration dossier evaluations entailing both registration 'compliance checks'[44] and registration testing proposal examinations (particularly those involving vertebrate animals)[45] of phase-in substances subject to the first (1 December 2010) registration deadline.[46] These practices strongly suggest that relatively few potentially harmful substances can (and 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 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 five per cent of the dossier registrations received[47] for each tonnage band for compliance, regardless of the year of manufacture or import.[48] Dossier registrations numbered approximately 25,300 by year-end 2011[49](approximately 21,600 of which were submitted by year-end 2010[50]), and approximately 28,000 as of 1 June 2012 (relating to the final 1 June 2013 phase-in registration period), covering 'more than 5,500 different substances' in all.[51] At most, only 1,400 of these 28,000 dossiers will be subject to an

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[41] Kogan, REACH Revisited, sections III.B.3.b and IV.C.2–3.

[42] Kogan REACH Revisited, sections III.B.3.C and IV.C.4.

[43] REACH, Art 20(2); ECHA, 'Guidance on Dossier and Substance Evaluation' (version 1, June 2007), 17, 39, and 49; see also J Sanchez, 'Overview of the Technical Completeness Check Process' (25 February 2010) <http://apps.echa.europa.eu/legacy/doc/webinars/overview_of_the_technical_completeness_check_process_javier_sanchez_echa.pdf> (accessed 6 August 2012).

[44] REACH, Art 41.

[45] REACH, Art 40; ECHA, 'Guidance on Registration' (version 2.0, May 2012), s 7.3(a).

[46] Registration deadlines and phase-in substances are discussed in Chapter 4.A.

[47] REACH, Art 41(5).

[48] G Cartlidge, 'Feedback from Evaluation' (23 May 2012), 8 <http://echa.europa.eu/documents/10162/1674131/05_feedback_from_evaluation_cartlidge_en.pdf> (accessed 6 August 2012); ECHA, 'Evaluation under REACH Progress Report 2011' (27 February 2012), 12; Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH' (30 March 2012), 13: 'The REACH Regulation requires that the Agency carries out compliance checks on at least 5% of the total number of registration dossiers received for each tonnage band. *Since the number of registration dossiers submitted each year may vary significantly, the 5% target is not meant to be reached every year but rather over a period of several years*. The Agency will establish a timeframe for the 5% target in its Multi-Annual Work Programme and monitor its progress' (emphasis added). ECHA, 'Evaluation under REACH Progress Report 2010' (28 February 2011), 1.3.1; see also ECHA, 'Guidance on Dossier and Substance Evaluation', 39.

[49] See ECHA, 'Evaluation under REACH Progress Report 2011', 14.

[50] See ECHA, 'Evaluation under REACH Progress Report 2011', 10.

[51] Federal Environment Agency and Federation of German Consumer Organisations, 'Scope of Information About Chemicals Improved: Five Years After REACH—Positive Balance Despite Obvious Deficits' (31 May 2012) Joint Press Release No 20/2012 <http://www.umweltbundesamt.de/uba-info-presse-e/2012/pe12-020_scope_of_information_about_chemicals_improved.htm> (accessed 6 August 2012).

ECHA REACH compliance check for purposes of prioritizing substances for evaluation by EU Member States and identifying SVHCs,[52] with the balance (95 per cent or 26,600 dossiers) *not* being subject to any ECHA compliance check at all.[53] Indeed, ECHA initiated only 16 dossier compliance checks in 2009, 135 dossier compliance checks in 2010, and 158 dossier compliance checks in 2011,[54] for a running total during 2009–2011 of 309 compliance checks initiated with respect to 25,300 submitted dossier registrations during the same period (or 1.22 per cent). This means that unless a Member State competent authority itself initiates a substance dossier evaluation based on information obtained from non-ECHA sources (eg supply chain members),[55] the substance(s) registered within these dossiers may not be evaluated for some time, if ever. Furthermore, of the 25,000 dossiers registered thus far, only 1,116 CMR substances have been identified as being included within the Classification and Labelling (C&L) Inventory to-date,[56] and 40 per cent of those have been found not to be registered, let alone prioritized, under REACH. In addition, only 73 registered substances have thus far been identified as SVHCs,[57] which may include CMRs and/or endocrine disruptors. EU officials may be inclined to claim that REACH, by design, imposes upon chemical substance-based product manufacturers and importers the legal responsibility 'to assess the risks and hazards of substances',[58] to manage 'the risks of substances',[59] and, ultimately, 'to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected' by manufactured or imported substances.[60] However, as previously noted, such putative delegations of responsibility by government to the private sector do not necessarily relieve the European Commission (an EU institution), ECHA (an instrumentality of the EU Commission), or EU Member States' governments of legal liability in the event that EU Member State citizens are injured by a dangerous chemical substance-based product that was not sufficiently evaluated and prioritized by such authorities.[61] Similarly, such delegations of responsibility do not relieve the European Union 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 its stated objective without imposing undue restrictions on international trade.

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[52] ECHA, 'Guidance on Dossier and Substance Evaluation',14–15 and 39.

[53] '[T]he REACH registration process may ultimately be seen as more a system of data collection and warehousing than a procedure for protecting the public and the environment from exposures to hazardous substances… [A] majority of the data submitted under the REACH registration process may never be evaluated': ADK Abelkop, Á Botos, LR Wise, and J D Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program' (January 2012) School of Public and Environmental Affairs, Indiana University, 24 <http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf> (accessed 6 August 2012).

[54] See ECHA, 'Evaluation under REACH Progress Report 2010' (28 February 2011), section 2.1.2, 10; ECHA, 'Evaluation under REACH Progress Report 2011' (27 February 2012), 20

[55] ECHA, 'Evaluation under REACH Progress Report 2011', 13–16.

[56] ECHA, 'CMR Substances from Annex VI of the CLP Regulation Registered under REACH and/or Notified under CLP, First Screening—Report 2012' (May 2012), 5, section 4.1, and 12; ECHA, 'ECHA Publishes the First Report on the CMR Substances Registered or Notified After the 2010 Registration Deadline' (4 June 2012) ECHA Press Release ECHA/PR/12/13.

[57] Federal Environment Agency and the Federation of German Consumer Organisations, 'Scope of Information About Chemicals Improved: Five Years After REACH—Positive Balance Despite Obvious Deficits'; Chemical Inspection and Regulation Service, 'REACH SVHC List 2012—SVHC Testing' <http://www.cirs-reach.com/testing/REACH_SVHC_List_SVHC_Testing.html> (accessed 6 August 2012).

[58] See REACH, recital 25. [59] See REACH, recital 18. [60] See REACH, recital 16.

[61] TFEU, Art 340(2); see also Case C-352/98P *Laboratoires Pharmaceutiques Bergaderm SA and Goupil v Commission* [2000] ECR I-5291, cited in S Hargreaves, *EU Law Concentrate* (Oxford: Oxford University Press, 2nd edn, 2011), 80–85; T Ćapeta, 'Action in Damages Against EU Institutions, Materials prepared for the Lecture at the University of Maribor' (December 2008) <http://www.pf.uni-mb.si/datoteke/knez/t._capeta_-_damages.doc> (accessed 6 August 2012).

c. Is REACH more trade restrictive than necessary?[62]

12.35 A recent EU Commission-funded report indicates that EU and non-EU industries' REACH registration-related costs were more than twice the amount previously estimated by the EU Commission. The approximate €2.1 billion of costs consisted of several classes of expenditures, including human resource, ECHA registration, data gathering, supply-chain communication, notification, and external consultant costs,[63] in part due to excessive vertebrate animal testing[64] that resulted in significantly higher than estimated animal testing costs.[65] Such analysis also reflects that these substantially higher-than-anticipated registration costs have already begun to negatively impact international trade flows in chemicals. For example, the report found that such expenditures encouraged many large and SME chemicals companies to reduce substance production volumes to a lower and less expensive tonnage band, and thereby to effectively shrink their EU market share.[66] These high costs also apparently persuaded some non-EU SME chemical companies to withdraw substances from the EU market[67] or to abandon or forsake entering the EU market altogether.[68] Furthermore, some EU downstream users have been motivated to shift their procurement of substances to EU sources 'to avoid registration costs'.[69] 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.[70] It is therefore arguable that REACH's registration/data gathering and notification requirements are more trade restrictive than necessary to achieve REACH's

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[62] See Kogan, REACH Revisited, sections III.B.3.d and IV.C.5.a.

[63] See Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH' (2012), iii-iv, 39–40, 45–46, 49, 78, 97, 101, 102, table box 4.1, table 4.16 and 105; see also Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ('Fees Regulation'), Arts 3, 5–6, Annex I, tables 1–2, Annex III, tables 1–4, Annex IV, tables 1–2; Accenture, 'Mastering the Challenge of REACH for High Performance: The Clock is Ticking' (2009) Chemicals Executive Series, 4 <http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture_Chemicals_POV_REACH.pdf> (accessed 6 August 2012); Chemical Watch, *Service Providers Guide 2011—A Guide to Chemicals Management and Control Services* (2011), 24; L Halpin, 'REACH Registration—Joint Submission', Chemical Inspection and Regulation Service <http://www.cirs-reach.com/reach/REACH_Registration_Joint_Submission.html> (accessed 6 August 2012).

[64] See Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH', 11 and 44.

[65] See, eg REACH, recitals 37, 40, 47, 64, Arts 10(a)(ix), 13(1)–(2), 25(1), 29, 117(3), 138(9); European Commission White Paper, *Strategy for a Future Chemicals Policy* COM (2001) 88 final, 7; ECHA, 'Practical Guide 10: How to Avoid Unnecessary Testing on Animals' (6 February 2010); see also C Rovida and T 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' (2009) 3 ALTEX 26, 187, 205 <http://www.altex.ch/resources/rovida_hartung_altex_3_09.PDF> (accessed 6 August 2012).

[66] See Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH', 65.

[67] The withdrawal of substances is driven primarily by their registration costs and the introduction of substances on the SVHC Candidate List, which can make the overall trading of such substances unprofitable; Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH', v, 57–58, 59–60, and 66.

[68] Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH', 97, 106.

[69] Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH', 66, 105.

[70] Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European Chemical Market After the introduction of REACH', 57, 59, 64, 66, 97, 99, 105–108, and Case Study #8 of Appendix A. See also Fees Regulation, Annex VI, tables 2–3; A Nair, 'REACH Threatens Exports' (23 March 2011), C&I Magazine Issue 6, The Society of Chemical Industry (SCI).

legitimate objective(s), considering the benefits that REACH, thus far, has been recognized to provide.[71]

d. Are there less trade-restrictive alternatives available?[72]

12.36 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 while ensuring a commensurate high level of protection of human health and the environment. 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'.[73] In response, the study's authors have suggested that the alternative chemicals management regulatory strategies in Canada and Japan, each of which feature 'an iterative screening approach' that permits regulators to 'set aside a vast array of substances/uses at the beginning if they are unlikely to cause unacceptable risk', may qualify as less burdensome alternatives to REACH. These experts have reasoned that, because an iterative screening approach focuses on a substance's potential for 'risk' rather than 'hazard,' it would likely significantly reduce the costs and administrative burdens associated with substance registration while ensuring the same high level of protection of human health and the environment sought by REACH.

(i) Canada's risk prioritization-based Chemicals Management Plan[74]

12.37 According to these commentators, the substance registration/data gathering requirement of Canada's Chemicals Management Plan (CMP) may serve as one such potential 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 1 January 1984 and 31 December 1986 to a scientific risk assessment. The CMP is notable primarily because risk prioritization is undertaken 'before industry and government are compelled to produce and review dossiers'.[75]

12.38 The CMP is implemented primarily through the Canadian Environmental Protection Act 1999 ('CEPA 1999'). 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"'. The Canadian Government has employed CEPA 1999 to ensure that 'all 'new' chemical substances manufactured within or imported into Canada since 1994 above certain thresholds 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. If a substance is found to have the potential to pose risks to human health or the environment,

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[71] Practitioners would be prudent to consider the results from a soon-to-be released study that assesses and explains the benefits to human health and the environment that are expected to be realized from the implementation of REACH. See Risk & Policy Analysts Ltd, 'Assessment of Health and Environmental Benefits of REACH' (2012), Abstract.

[72] See Kogan, REACH Revisited, sections III.B.3.d.i and IV.C.5.b.

[73] See ADK Abelkop, Á Botos, LR Wise, and JD Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program' (January 2012), School of Public and Environmental Affairs, Indiana University, 24 <http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf> (accessed 6 August 2012).

[74] See Kogan, REACH Revisited, section IV.C.5.b.i.

[75] Abelkop, Botos, Wise, and J D Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program', 22, citing Government of Canada, 'Chemical Substances: The Rapid Screening Approach' (17 June 2011) <http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/rapid-eng.php> (accessed 6 August 2012).

CEPA 1999 permits control measures to be imposed before such substance is granted access to the Canadian market place. A substance may be prohibited if it is determined that the risks are significant or cannot be adequately managed. 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. Section 73(1) of CEPA 1999 required the Canadian government to examine 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' by 2006.

12.39 The CMP employs the CEPA 1999 categorization process, pursuant to which governmental scientists prioritize for examination only those substances that are: (1) inherently toxic (harmful, by their very nature, to humans or to the environment); (2) persistent (take a very long time to break down); (3) bioaccumulative (collect in living organisms and end up in the food chain); and (4) substances to which people might have the greatest potential for exposure. 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 instead to focus resources on those substances that have a 'higher probability of causing harm'. This 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, and the use of complex hazard and other tools to identify, based on conservative assumptions, true priorities for testing and assessment in the absence of data. By the time the Canadian government's categorization process was completed in 2006, it had identified approximately 4,300 substances requiring further attention: 'The CMP was developed (and its objective is) to address these chemicals by 2020'.

12.40 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: (1) 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 agents in jet fuels and chemical/industrial processes; (2) 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; (3) the restriction of new uses of 150 priority chemicals identified pursuant to the categorization process but not currently used in Canada until data are provided to support a risk assessment demonstrating that the substance would not pose an unacceptable health or environmental risk; (4) the identification of the health and environmental effects of 2,600 medium-priority substances through successive rounds of assessment; and (5) the rapid screening of low-concern substances.

12.41 The government of Canada has described the rapid screening approach as consisting of a series of steps that seek to ascertain a substance's potential to cause ecological harm. Step 1 entails the identification of substances categorized as high priority for purposes of further evaluation and assessment (eg substances identified as persistent, bioaccumulative, and inherently toxic (PBiTs)). Step 2 involves the application of different exposure scenarios to identify potential concerns near the point of a substance's discharge into the environment. 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 such organisms. 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. The aim is to identify whether or not 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 their hazardous properties and/or high commercial trading volume. The information contained within such lists and sources is then vetted to ascertain its relevance to the particular inquiry.

12.42 During 2007, the Canadian government applied the rapid screening approach to '1066 substances that [were identified as] persistent and inherently toxic to non-human organisms (PiT(eco)) or 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'. PBiTs that were 'persistent and bioaccumulative and inherently toxic to non-human organisms [were] excluded from consideration under this assessment, due to particular concerns identified for substances having this combination of properties'. The Canadian rapid screening approach exercise yielded 312 substances requiring further assessment and 754 substances deemed unlikely to cause ecological harm, and, therefore, as not meeting the criterion of CEPA 1999, section 64(a). The results broke down as follows: four organic substances were found to bear chemical structures similar to PBiTs that were deemed as priority substances necessitating further assessment; exposure scenarios for 836 of the 1,062 substances did not indicate a potential for ecological harm; 226 of the remaining 1,062 substances were found to require further assessment; application of various information source filters to the remaining 836 substances revealed 29 such substances appearing on international lists of high production volume chemicals and requiring further assessment, and 498 substances not requiring further assessment; of the remaining 309 substances manually evaluated, 53 were found to require further assessment. In other words, approximately 70 per cent 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 REACH.

12.43 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 assessments, and proposed risk management activities'. 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.

12.44 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 (WSSD) for Sound Management of Chemicals. Upon the renewal of the CMP in 2011, the Canadian government also undertook a strategic environmental assessment (SEA) to ensure the taking into account of environmental considerations during the decision-making process. 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'. The Canadian government has concluded that the the SEA satisfies Canada's international commitments under the WSSD because the SEA process aims to develop measures that promote positive environmental impacts.

12.45 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. REACH, by comparison, implements a hazard-based version of the precautionary principle through its Preamble, paragraphs 9 and 69 and Article 1(3), which is informed by quasi-quantitative or qualitative risk assessments. As one recently released report observed,[76] 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', it fails to discuss how serious the risk or its consequences must be in order to trigger the application of the precautionary principle. While ECJ case law is helpful, it does not appear determinative. According to the report, such case law holds, for example, that it is not sufficient to make a generalized presumption about a putative risk[77] or to make reference to a purely hypothetical risk in the absence of scientific (data) support.[78] The report concludes that, in the absence of further 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'.

12.46 This absence of a risk threshold for action within the European Union would seem to explain the difference between the Canadian CMP prioritized screening approach informed by a quantitative risk assessment-focused precautionary principle and the REACH hazard-based pre-registration/data gathering approach informed by a hazard assessment/qualitative risk-focused precautionary principle. Under REACH, the 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 (ie at a pre-risk assessment stage), premised only on a 'volume-based exposure proxy' (annual substance manufacturing and import volumes) and, perhaps, also on some qualitative risk data informed by socio-economic analysis ('general scientific acceptance'). By comparison, under the CMP, the precautionary principle 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 (exposure) to human health or the environment under particular exposure scenarios.

12.47 Thus, prior to drawing any conclusions, practitioners should secure evidence showing whether this difference will undermine the Canadian CMP's ability to serve as a reasonably available, less trade-restrictive alternative to REACH's complex and burdensome registration/data gathering requirement that can also ensure a high level of protection of human health and the environment.

(ii) Japan's risk prioritization-based chemical substance control law[79]

12.48 During 1973, Japan enacted the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc (Act No 117 of 16 October 1973) referred to as the Chemical Substance Control Law ('Kashinho'). Although Kashinho's introduction of a notification and prior-assessment system to cover 'new' substances being placed on the market preceded the enactment of the US Toxic Substance Control Act of 1976 ('TSCA') by several years, it 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

[76] Milieu Ltd and The TMC Asser Institute and Pace, 'Considerations on the Application of the Precautionary Principle in the Chemicals Sector' (August 2011).

[77] Case C-333/08 *Commission v France* [2010] ECR I-757.

[78] Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305.

[79] See Kogan, REACH Revisited, section IV.C.5.c.ii.

or imported substances. As of 2007, only 1,500 such substances had been subject to a risk assessment.

12.49 Kashinho was amended during May 2009 (revised by Act No 39 of 20 May 2009) to initiate the review of measures concerned with the assessment of chemical hazards and to update them consistent with international health and environmental law and policy trends. A primary objective of the 2009 amendment is to ensure consistency with the Global Harmonized System of Classification and Labeling of Chemicals (GHS) established by the WSSD and the SAICM.

12.50 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 goes beyond consideration of chemical substances' intrinsic hazardous properties to employ risk assessments, risk control measures, and risk communication for purposes of ascertaining and reflecting the nature and amount of health and environmental emissions exposures for all chemical substances, consistent with a risk-based precautionary approach. Japan's Ministry of Economy, 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. 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 upon the Japanese reform. 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—ie by requiring such data as part of a priority substance assessment only *after* the Japanese government has already conducted a chemical substance screening assessment.

12.51 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. Amended Kashinho, Article 2(5) provides that such information will be used by the Japanese government to create a list of 'priority substances'. 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). Kashinho, Article 2(5) 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'. Kashinho, Article 9(1) obliges persons manufacturing or importing an existing chemical substance requiring 'priority assessment' (ie a 'Class I Specified Chemical Substance') in excess of specified volumes (eg 1 tonne or more/year) to notify and submit to METI annually information about estimated substance quantities, usage, and other matters as may be required.

12.52 According to at least one commentator, the changes to Kashinho, Articles 2 and 8 reflect the influence of the EU REACH Regulation on Japan's chemicals management system. Kashinho was originally applied to substances having 'persistent' properties. Before the amendment, substances having persistent, bioaccumulative, and toxic (PBT) properties 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 covered under Kashinho which, like REACH, now includes endocrine disruptors.

12.53 Once a substance is designated as a 'priority chemical' and undergoes a 'priority assessment', Amended Kashinho, Article 10(1) and (2) 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. Depending on the results, such priority substances may be 'subject to further risk assessment by the government'. At least one commentator has noted that Amended Kashinho imposes a significantly lower informational and testing burden on manufacturers and importers than does REACH, because under Kashinho, unlike under REACH, risk assessment is performed by the government and companies are *not* required to identify substance uses incorporated within their own products, as well as in their respective supply chains. In other words, Japanese industry bears less of a responsibility than does European industry under REACH to generate information with respect to chemical substances. REACH obliges European industry to provide better information, including risk assessment, as a precondition to entering the market as reflected by the 'no data, no market' rule of REACH, Article 5. Amended Kashinho, by contrast, sets forth a prioritization approach pursuant to which government remains responsible for demanding additional data from industry concerning prioritized substances.

12.54 Furthermore, Amended Kashinho has many similarities to, but does not replicate, the Canadian CMP. Discussions held during the Kashinho amendment process reveal how Japanese legislators had referenced the Canadian chemical substances prioritization system, particularly its process of risk assessment and information gathering and the party it held responsible for performing the risk assessment (ie government). Japanese legislators had also favourably 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 restrictive control). Overall, it would appear that Japanese chemical policy favoured the Canadian system over REACH as its model.

12.55 Thus, in the context of this TBT Agreement, 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. Like 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 in eliminating a substantial number of substances from further government consideration where the most rapid of first-level screens had found that they posed no risk to human health and the environment, thereby saving scarce government financial and human capital resources. Nevertheless, none of the three chemicals-management regulatory regimes (REACH, CMP, and Amended Kashinho) has been in operation for more than a few years, and, therefore, they continue to evolve. Consequently, it is probably too soon to draw any definitive conclusions regarding their relative effectiveness such that the CMP or Amended Kashinho can be justified as a

less trade-restrictive alternative to REACH that can, partially or completely, fulfill REACH's legitimate objective to the same extent as REACH.

III. Developing countries' needs[80]

12.56 TBT Agreement, Article 12.3 provides that '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'. Article 12.3 comprises part of 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 treatment to developing country Members to this Agreement'.

12.57 In the process of adopting and implementing REACH, the European Union endeavoured to respond to developing countries' needs and to fulfill its obligations towards them under the TBT Agreement (including also the Article 11.3 obligation 'to render technical assistance to other WTO Members') through several means. They included the following:

- *Establishing ECHA help desks*: The European Union 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. Apparently, the EU has since established ECHA help desks in all 27 EU Member States, Iceland, Lichtenstein, and Norway, and contact points within EU embassies, consulates, and/or missions capable of directing REACH-related queries from outside Europe.
- *Providing REACH regulatory guidance*: The European Union indicated that ECHA would provide internet-based guidance materials consisting of: (a) general/summarized REACH process information internet pages; (b) an internet-based 'Guidance Navigator' flow chart directing web visitors to relevant detailed guidance; and (c) detailed guidance on roles, obligations, and actions to be taken with respect to REACH.
- *Providing international funds for technical assistance and capacity building*: The European Union stated that it would make funds available within international 'assistance programs' falling under the auspices of the SAICM process, and engage United Nations agencies such as United Nations Industrial Development Organization (UNIDO) for the purpose of facilitating REACH compliance. The European Union indicated that it was also possible to incorporate technical assistance in ongoing EU trade-related (bilateral or regional) assistance programs.
- *Rendering bilateral technical assistance*: The European Union 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. The European Union 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. Alternatively, the European Union indicated that its representatives would meet directly with concerned delegations in Brussels.

[80] Kogan, REACH Revisited, sections III.B.4 and IV.D.

- *Convening REACH training-based webinars:* ECHA had organized a series of webinar-based 'training sessions' and 'stakeholder days' to provide stakeholders with critical information about various REACH matters, including: (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. The European Union also emphasized that developing country delegations and industries were invited to, and should participate in, such sessions, and that session recordings would be available afterwards for viewing on the ECHA website.

12.58 It would appear that the European Union has gone a long way towards 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 noted in para 12.57. However, the EU representative also made it very clear at one TBT Committee meeting that there would be no derogations afforded to WTO developing country members with respect to REACH's registration requirement. Since 'the primary objective of REACH 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'.

12.59 The directness of the EU representative's statement is indisputable. However, it remains uncertain, at this juncture, whether such statement reveals that the European Union had more broadly failed to 'take account of' developing country WTO Members' development, financial, and trade needs when proposing, adopting, and/or implementing REACH, within the meaning of TBT Agreement, Articles 12.3 and 12.1. It would be difficult, but not impossible, for developing country WTO Members to demonstrate that the European Union had failed adequately to consider their special development, financial, and trade needs prior to proposing, adopting, and/or implementing REACH's registration/data gathering and notification provisions. TBT Agreement, Article 12.3 does not require the European Union to document within its executive or legislative promulgations and proceedings that it has expressly taken into account such needs. Yet, the European Union may be required to do more than allocate European assistance funds to international technical assistance and capacity building initiatives and programs operating under UN agency auspices, and to engage in general outreach to all WTO Members, including developing countries, to facilitate foreign industry REACH registration/data gathering and notification compliance. The securing of evidence confirming the preparation or convening of bilateral meetings, briefings, initiatives, and correspondence between the European Union and specific developing country governments would help to confirm whether it had considered the particular interests of developing country WTO Members.

D. Recap and Looking Forward[81]

12.60 The analysis presented in this chapter 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 emerging WTO TBT jurisprudence. Therefore, it should be reviewed with the full understanding that additional and more robust empirical and/or statistical evidence may be required to undertake a comprehensive REACH TBT review. While all three of the recent WTO TBT

[81] Kogan, REACH Revisited, section V.A–B.

Panel decisions have resulted in final 'clarifying' Appellate Body rulings, not enough time has arguably 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 and/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 European 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.

12.61 Moreover, the ongoing evaluation of REACH should take into account the European Commission's efforts to promote 'more global attention to chemical *hazards* in line with REACH, particularly, by 'including chemicals regulation in the Rio talks on sustainability' (ie at the June 2012 UN Commission on Sustainable Development's 'Rio + 20' Conference). 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 REACH, or a more ambitious 'global institutional framework for sustainable development which... include[s] a strengthened environmental dimension' (ie an international environmental organization to rival the WTO), as has been suggested, is uncertain. Any such proposal, however, would likely engender some international resistance.

12.62 At the same time, any evaluation of REACH should consider the WTO Secretariat's recent report prepared in advance of the 'Rio + 20' Conference. It recognizes that 'Many 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 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'. 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 [PPMs]* ...to improve energy efficiency or emissions performance, minimize waste, improve forestry management, or enhance the protection of soil, wildlife and natural habitats'.[82] 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 unnecessary obstacles to international trade. To this end, the WTO Secretariat report, most importantly, reaffirms the Appellate Body's recent clarification in *Clove Cigarettes* of the TBT Agreement's primary directive which serves as the underlying premise of this chapter.[83]

12.63 Last, but not least, any ongoing evaluation of REACH must factor in longstanding EU-US governmental and industry efforts to reduce NTBs via enhanced regulatory cooperation and mutual standards recognition,[84] and, perhaps, even to achieve what often has been billed

[82] Emphasis added.

[83] 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': Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, para 9.

[84] Michael T McCarthy, 'International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1, Administrative Conference of the United States (19 October 2011)' <http://www.acus.gov/sites/default/files/COR-IRC-report-10-19-11.pdf> (accessed 18 March 2013), 11: 'Improving international regulatory cooperation

as 'the impossible dream'[85]—a formal transatlantic regional trade agreement.[86] While such efforts have focused on increasing cross-border market access by reducing 'unnecessary' cross-border regulatory uncertainty and related transaction costs,[87] they have also, arguably, been undertaken to dissuade emerging third-country regulatory opportunism elsewhere (eg in Asia and Latin America).[88]

has been a focus of the Executive Office of the President across Administrations, with substantial participation from several components—the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB), the Office of the U.S. Trade Representative (USTR), the National Security Council, and the National Economic Council. Much of the work in this field has been establishment of high-level regulatory cooperation partnerships with the European Union and, more recently, Canada and Mexico'. See also 'Inside U.S. Trade, Companies, Trade Groups Float Ideas for U.S.-EU Regulatory Cooperation', WORLD TRADE ONLINE, 9 November 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' (28 September 2012), <https://www.federalregister.gov/articles/2012/09/28/2012-23613/promoting-us-ecregulatory-compatibility> (accessed 18 March 2013) (including a request for public comments and a link to the public comments received); International Affairs, 'EU-USA–Regulatory Cooperation, Commission DG Enterprise and Industry' <http://ec.europa.eu/enterprise/policies/international/cooperatinggovernments/usa/regulatory-cooperation/index_en.htm> (last updated accessed 11 September 2012); John Morrall III, 'Determining Compatible Regulatory Regimes Between the U.S. and the EU, US Chamber of Commerce' (2012) <http://transatlantic.sais-jhu.edu/partnerships/Cornerstone%20Project/cornerstone_project_morrall.pdf.> (accessed 18 March 2013).

[85] See, eg Reinhard Quick, 'Transatlantic Regulatory Cooperation on Chemicals—An Idealist's Dream?', in Simon J Evenett and Robert M Stern (eds), *Systemic Implications of Transatlantic Regulatory Cooperation and Competition* (London: World Scientific Publishing Company, 2011), 241–285; *The Economist*, 'Transatlantic trading: Why America and Europe need a free-trade deal—and why they might fail to get one' (2 February 2013) <http://www.economist.com/news/europe/21571195-why-america-and-europe-need-free-trade-dealand-why-they-might-fail-get-one-transatlantic> (accessed 18 March 2013). 'The Impossible Dream' is the main song from the 1965 musical *Man of La Mancha*, composed by Mitch Leigh, with lyrics by Joe Darion. 'The song is sung all the way through once in the musical by Don Quixote as he stands vigil over his armor, in response to Aldonza (Dulcinea)'s question about what he means by "following the quest". It is reprised partially three more times—the last by prisoners in a dungeon as Miguel de Cervantes and his manservant mount the drawbridge-like prison staircase to face trial by the Spanish Inquisition': 'The Impossible Dream (The Quest)', Wikipedia <http://en.wikipedia.org/wiki/The_Impossible_Dream_(The_Quest)> (accessed 18 March 2013).

[86] See also Olga Khazan, 'Transatlantic trade: How chlorine-washed chicken prevents greater US-E. trading', *Washington Post* <http://www.washingtonpost.com/blogs/worldviews/wp/2013/02/13/the-transatlantic-trading-partnership-how-chlorine-washed-chicken-prevents-u-s-e-u-trade/> (accessed 13 February 2013); Gregor Peter Schmitz, 'State of the Union: Obama Backs Trans-Atlantic Trade Deal with EU', *Spiegel Online* <http://www.spiegel.de/international/world/us-president-obama-backs-trans-atlantic-free-trade-agreement-with-eu-a-883104.html> (accessed 13 February 2013); Ian Traynor, 'US and EU governments aiming to agree transatlantic free trade pact', *Guardian* <http://www.guardian.co.uk/business/2013/feb/13/us-and-eu-transatlantic-trade-liberalisation> (accessed 13 February 2013); Rebecca Christie, 'EU to Present Draft Terms for U.S. Trade Deal in March', *Bloomberg* <http://www.bloomberg.com/news/2013-02-13/eu-to-present-draft-terms-for-u-s-trade-deal-in-march.html> (accessed 13 February 2013); Joshua Chaffin, 'EU sets ambitious US trade pact deadline', *Financial Times* <http://www.ft.com/intl/cms/s/0/23f35c94-75da-11e2-b702-00144feabdc0.html#axzz2KpI9MChP> (accessed 13 February 2013).

[87] See Presidential Executive Order 13609, 'Promoting International Regulatory Cooperation', 77 FR 26413 (1 May 2012): 'The regulatory approaches taken by foreign governments may differ from those taken by U.S. regulatory agencies to address similar issues. In some cases, the differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts might not be necessary and might impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements'.

[88] See Lawrence A Kogan, 'Is REACH a Trade Barrier? Imported Chemicals Suffer from Higher Cost Structure, Chemical Watch Business Briefing', *Chemical Watch Business Briefing—Expert Focus*, (14 December 2012).