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Chapter 15

The REACH Regulation and the TBT Agreement: The role of the TBT Committee in regulatory processes

Lukasz Gruszczynski

1. Introduction

The REACH Regulation[1] is one of the most complex regulatory frameworks ever designed by the European Union (hereinafter the "EU").[2] It took five years of intense legislative work to prepare its final version, while the implementation period has been projected to be phased in over eleven years owing to the serious impact on business operators and the overall complexity of the system. The REACH Regulation also replaced more than 40 different EU directives and regulations. The goals of the Regulation are indeed ambitious. It intends to comprehensively address, for the first time in history, the health and environmental risks posed by chemicals. The idea underlying REACH is that all chemical substances on the EU market – whether imported or produced locally – need to be registered, while those which are considered as potentially dangerous for human health or the environment are required to go through formal assessment and receive special authorization. Some substances are wholly restricted – their import, production and use is prohibited in the entire territory of the EU.

Not surprisingly, the Regulation has been met with strong opposition not only from European industry, but also from many of the EU's trading partners. Although countries in general have acknowledged the legitimacy of the objectives sought by the EU, they have expressed numerous concerns regarding the necessity and proportionality of the new system. Recently, the process of REACH implementation has also generated various controversies.

The World Trade Organization (hereinafter the "WTO") is one of the forums where a number of concerns have been voiced and discussed. Since REACH is a technical regulation, the Agreement on Technical Barriers to Trade (hereinafter the "TBT Agreement") has proven to be of particular importance in assessment of its compliance with international trade rules, with the Committee on Technical Barriers to Trade (hereinafter the "TBT Committee") serving as a platform for the discussion among WTO Members. This latter element is worthy of close attention. Some scholars have identified the system of WTO committees as an

[1] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, J L 396, 30.12.2006, pp. 1–849, as subsequently amended (hereinafter referred to as "REACH" or the "REACH Regulation").

[2] Until 30 November 2009 the European Union was officially known in the WTO as the European Communities. This nomenclature changed with the introduction of the Lisbon Treaty. For the sake of simplicity, this chapter uses only the term "European Union", unless it refers to official documents issued before 2009.

important element in the global governance of trade relations.[3] The case study of the REACH Regulation provides a good opportunity to test some of their hypotheses against the practice of the TBT Committee. In this context, one may ask about the exact role played by the TBT Committee in the process of shaping REACH. To what extent was it helpful in making the new EU chemical regulatory framework more acceptable for other WTO Members and, as a consequence, in reducing the potential for future trade disputes? This chapter attempt to answer these questions.

The chapter is structured as follows: the first section provides a short overview of the basic rules of the REACH Regulation, discussing all its four elements: registration; evaluation; authorization; and restrictions of chemical substances. Against this background, the second section looks at the role that has been played by the TBT Committee in the process of adoption and subsequent implementation of the REACH provisions. This section also critically assesses different functions that were performed by the Committee and identifies the limits of its involvement. The third section discusses some of the REACH-related issues that still appear to be controversial among WTO Members, while the last section draws some overall conclusions.

2. The REACH Regulation

The legislative work on the REACH Regulation was commenced in 1997 with the consultation initiative of the European Commission, aimed at assessing the system of chemical control that existed in the EU at that time.[4] The White Paper, which was published in 2001, recognized that the regime was fragmented, inconsistent and incomplete. In particular, some chemical substances were heavily regulated (i.e. those which were introduced on the market after 1981) while others were not (i.e. those which were present on the market before that date). This obviously created an obstacle for innovation, providing an incentive to companies to use older chemicals rather than to develop substances that would be subject to stricter rules. The assessment of chemical risks was slow and inefficient, with the burden of proof as to the safety of chemicals placed on national public authorities (a procedure which was not only ineffective but also costly).[5] As a result, the available data on chemicals was limited, making proper assessment of their safety very difficult. The White Paper proposed a comprehensive plan for a new regulatory regime for chemicals. The initial draft was preceded by a discussion that took place in special technical working groups comprising industry, non-governmental organizations and representatives of the EU Member States. Separate internet consultations, open to all interested parties, were also held and more than 5,000 submissions received. Although initially the Member States expressed their support for the initiative of the Commission, this changed during its later stages. Germany, the United Kingdom, and France became increasingly concerned with the economic consequences of the new regime for the European chemical industry. As a consequence, the

[3] *See particularly*, Andrew Lang & Joanne Scott, *The Hidden World of WTO Governance*, 20(3) EUROPEAN J. OF INT'L L. 575 (2009); *see also*, Richard B. Stewart & Michelle R. Badin, *The World Trade Organization: Multiple Dimensions of Global Administrative Law*, 9(3-4) INT'L J. CONSTITUTIONAL L. 556 (2011).

[4] For an interesting discussion on the evolution of the European chemical risk regime, *see*, Veerle Heyvaert, *Regulating Chemical Risk. REACH in a Global Governance Perspective*, *in* REGULATING CHEMICAL RISKS. EUROPEAN AND GLOBAL CHALLENGES 217 (Johan Eriksson, Michael Gilek & Christina Ruden eds., 2010).

[5] European, Commission, *White Paper: Strategy for a Future Chemicals Policy*, COM (2001) 88 final.

legislative proposal that materialized in October 2003 contained "substantially weaker provisions for consumer, environment, human and animal protection than the White Paper and previous drafts".[6]

During the subsequent legislative process, the proposal was amended several times. The European Parliament opted for a more stringent approach, while the Council of Ministers (the body that represents the interests of the Member States in the EU legislative process) favoured the revised initial proposal. The draft law was also strongly opposed by a number of countries, including all the major EU trading partners. As will be discussed in Section 3, their opinions were to have some influence on the final outcome of the legislative process. Both EU institutions – the European Parliament and the Council of Ministers – eventually found a common ground and a compromise version was agreed upon in December 2006. The REACH Regulation entered into force on 1 June 2007.

The REACH Regulation constitutes a very complex system. Due to space limitations, the summary presented below only outlines some basic features of the new regime. Emphasis is given to those issues which have generated significant controversies vis-à-vis EU trading partners.[7]

2.1. Burden of proof

As a preliminary remark, one has to emphasize the important change that was introduced by REACH with respect to the allocation of the "burden of proof" for assessment of the safety of chemicals. Prior to adoption of the Regulation, the burden of proof was generally on the public authorities in the country looking to regulate the use of a chemical. This meant that in a majority of cases, the public authorities of a country had to prove, usually in the form of a risk assessment, that the use of a chemical substance was unsafe in order to impose restrictions. The REACH regime shifted this burden to the chemical industry, and now it is a specific company which must demonstrate that a particular chemical can be used safely (for identified uses). This principle is manifested in all three processes envisaged by REACH (registration, evaluation, and authorization), and to a lesser extent in the restriction mechanism.

2.2. Registration

Under the REACH Regulation all companies that manufacture or import more than one tonne of a particular chemical into the EU in any given year are required to register such substance in a central database.[8] Registration, unlike previously, is required for both old (i.e. already existing on the market) and new chemicals and is done through the European Chemicals Agency (hereinafter the "ECHA"), a new agency responsible for the

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[6] Paul Kjaer, *Rationality within REACH? On Functional Differentiation as the Structural Foundation of Legitimacy in European Chemicals Regulation*, EUI WORKING PAPER LAW NO. 2007/18, at 4.

[7] For a more detailed analysis of the REACH Regulation, see: Joanne Scott, *REACH: Combining Harmonization and Dynamism in the Regulation of Chemicals*, *in* ENVIRONMENTAL PROTECTION. EUROPEAN LAW AND GOVERNANCE (Joanne Scott ed., 2009).

[8] According to the estimations of the Commission there are approximately 30,000 substances which meet this criterion. The tonnage of a chemical substance is calculated by a manufacturer/importer on the basis of anticipated level of production/import in a particular year.

implementation and management of the EU regulatory framework for chemicals. In principle, this element of REACH is hazard-based, as chemical substances must be registered irrespective of whether they pose any risk.[9] If the registration is not rejected within a deadline specified in the Regulation (i.e. three weeks), a company may begin or continue to manufacture or import the substance. At the same time, the REACH Regulation exempts certain chemicals from the registration requirement. The first group includes substances that are already regulated under other pieces of EU legislation (e.g. medicinal products, radioactive substances, wastes, or food additives). The second group covers substances which present such low risks as not to require registration (e.g. water, or various fatty acids)[10] or for which registration would be inappropriate or unnecessary (e.g. for substances occurring in nature or substances which result from a chemical reaction that occurs incidentally).[11] This is a reflection of a risk-based approach. Polymers are exempted from the registration requirement,[12] but monomers are covered. The significance of this distinction will be discussed in Section 4 below.

Registration requires submission of a technical dossier, which needs to include specific information relating to the properties, uses, and classification of a substance as well as guidance on its safe use. The amount of required information is proportional to the volume of the substance subject to registration. In particular, a separate chemical safety report has to be completed for all substances that exceed a ten tonne threshold for an individual registrant.[13] A report consists of hazard identification and assessment (to human health or the environment), and if a substance is identified as: (i) dangerous, according to predefined criteria; (ii) persistent, bio-accumulative and toxic (PBT): or (iii) very persistent and very bio-accumulative (vPvB),[14] an assessment of actual risk(s) must be included. This requires identification and description of exposure scenarios for specific uses of substances. Such scenarios describe how a particular substance is manufactured and subsequently used, as well as how the manufacturer or importer controls, or makes recommendations to control, the exposure of humans and the environment.[15] The exposure scenarios also include proposed risk management measures, which must provide sufficient guarantees that the identified risks from the uses of the substance are adequately controlled. Together, the above requirements mean that, under the registration process, it is primarily the obligation of the chemical industry to gather the necessary information on substances, their uses, and available risk management tools.[16]

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[9] *Cf.* the discussion in Section 4 explaining the difference between hazard- and risk-based approaches.

[10] REACH Regulation, Article 2.7(a) and Annex IV.

[11] *Id.* Article 2.7(b) and Annex V.

[12] *Id.* Article 2.9.

[13] *Id*. Article 14.

[14] PBT is a denotation for chemicals that are toxic, persist in the environment, and bioaccumulate in food chains, posing a high risk to the environment and human health. vPvB is a subcategory that covers substances which are toxic and very persistent and bioacumulative.

[15] REACH Regulation, Article 3.37.

[16] REACH also envisages a joint submission of registration data. In such a case, it is a lead registrant or consortium, which is responsible for most of data collection and preparation of a chemical dossier. Co-registrants, after preparing their individual parts of the registration dossier and paying a fee to lead registrant/consortium can simply refer to a joint registration.

There are specific provisions for the registration of substances used in manufactured articles. While manufactured articles as such are not subject to the REACH Regulation, certain substances incorporated into manufactured articles have to be registered. This obligation is activated whenever the substance in question is intended to be released from the article during normal or foreseeable conditions of use (e.g. ink in a pen), and its quantity exceeds one tonne a year (per producer or importer).[17] For substances that are not intended to be released, but may be released incidentally during the use of the article, a simple notification is required. On the basis of such a notification, the ECHA may request a registration (i.e. if it believes that the substance which can be released poses a risk to human health or the environment).

Due to the revolutionary character of the new system, the REACH Regulation was designed to be phased in over time. The deadlines for registration depend on two variables: the volume of the substance on the market, and the risk in question. The shortest deadlines apply to those substances that are the most prevalent (above 1,000 tonnes of production and/or import), or toxic. For other substances, the deadline for registration is either six years or 11 years (e.g. for low volume chemicals) from the date of entry into force of the REACH Regulation.[18]

2.3. Evaluation

The evaluation performed under the REACH Regulation refers to two distinctive processes – dossier evaluation and substance evaluation. As far as the first category is concerned, the ECHA is expected to examine testing proposals in submitted dossiers as to their quality and necessity (tests are performed in order to supply certain information on substance(s) which are required by the Regulation). The ECHA is also obliged to undertake random compliance checks with respect to submitted registrations (five per cent of the dossiers in each tonnage band). The aim of this examination is to verify the completeness of information in a dossier and the quality of hazard (and risk) assessment submitted by a registrant.[19]

The second category concerns substance evaluation. In this context, the ECHA performs a coordinating function, while competent national authorities from Member States are responsible for the examination of particular substances. The ECHA, in cooperation with the Member States, also sets criteria for prioritising the evaluation of particular substances. A competent national authority may of course request a registrant to supply additional information concerning a substance and its properties.[20] As a consequence of the evaluation process, the relevant authorities (the ECHA or Member State authorities) may conclude that an action needs to be taken under either the authorisation or restriction procedure.

2.4. Authorisation

[17] REACH Regulation. Article 7.

[18] *Cf.*, Section 4 of this Chapter.

[19] REACH Regulation, Articles 40-43.

[20] *Id.* Articles 44-47.

Unlike the registration step, authorisation is principally a risk-based process. Its aim is to ensure that risks from specific substances are adequately controlled and that such substances are progressively substituted with less risky alternatives. More specifically, authorisation is required for those substances that are included in a special list of substances prepared by the ECHA (i.e. substances of very high concern).[21] This category covers, among the other things, substances that are carcinogens or mutagens, toxic to the reproductive system, as well as PBT and vPvB substances. The authorisation process is independent from both registration and evaluation and applies without tonnage limits. This means that a substance may be subject to authorisation even if it does not need to be registered and evaluated (e.g. because of tonnage limitations). Authorisation is granted by the Commission[22] on the basis of the evaluation made by special technical committees, and applies only to a particular applicant and for specific uses of a particular chemical substance.

In order to obtain authorization, an applicant (i.e. manufacturer, importer and/or downstream user) must show that the risks to human health or the environment from the use of a substance are adequately controlled. If the risk cannot be controlled or if the procedure concerns certain specific substances (e.g. those with PBT and vPvB properties) authorization may only be granted if two conditions are met: (i) socio-economic benefits arising from the use of the substance outweigh the risk to human health or the environment, and (ii) there are no suitable alternative substances or technologies. Again, the burden of proof is on the applicant. The authorization is subject to time-limited reviews and may be amended or withdrawn.[23]

2.5. Restrictions

Any substance, either on its own, in a preparation, or in a manufactured article, may be subject to restrictions on a European-wide level, meaning that it cannot be placed on the market unless it complies with certain restrictions. The potential restrictions may consist of placing conditions for the manufacture and use(s) of a substance, or even consist in the absolute prohibition of a substance.[24] The initial list of restrictions on specific substances is included in Annex XVII of the REACH Regulation and is subject to an on-going review process (including the listing and delisting of particular restrictions).[25] A new restriction is imposed on the basis of a technical dossier prepared by the ECHA, either on its own initiative or upon a request from the Commission or one of the Member States. The aim of this dossier is to demonstrate the existence of a risk to human health or the environment that needs to be addressed at the European level, and to identify the most appropriate set of risk reduction measures.

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[21] This list is revised every two years, and after each review a particular substance can be added or removed from the list (e.g. as a consequence of new scientific information).

[22] REACH Regulation, Article 60.

[23] *Id.* Articles 60.8 and 61.

[24] *Id.* Article 67.

[25] *E.g.*, benzene is not permitted in toys or parts of toys if its concentration in the free state exceeds 5 mg/kg of the weight of the toy or part of toy (*Id.* Annex XVII).

The restriction and authorisation procedures are mutually exclusive. Consequently, a substance that is restricted at the European level cannot be authorised for use in violation of said restriction.

2.6. Downstream users

The REACH Regulation distinguishes downstream users of chemical substances as a separate category of entities. A downstream user is defined as any natural or legal person established within the EU that is not qualified as a manufacturer or importer, but which uses a substance, either on its own or in a preparation, in the course of its industrial or professional activities. "Use" is understood broadly and includes processing, storage, mixing, or production of articles. However, a distributor or a consumer falls outside this definition.[26] A downstream user is not required to apply for registration but it may assist the producer or importer in supplying necessary information (e.g. relating to practicalities in safe handling of chemical substances) .[27] On the other hand, a downstream user can apply for authorization.

Downstream users may use a substance for an authorised use provided they obtain the substance from an entity for whom an authorisation has been granted and that they keep within the conditions of that authorisation. They are primarily responsible for the safe management of chemical substances and form an important element in the transfer of information concerning substances along the supply chain (in the form of the so-called Safety data sheets).

3. Shaping the REACH Regulation: the TBT Committee and the dynamics of the regulatory process

The TBT Agreement, apart from its substantive obligations, also imposes on WTO Members certain transparency and notification requirements. These requirements are activated whenever a WTO Member intends to introduce a new technical regulation and there is no relevant international standard, or when such a regulation deviates from a standard.[28] In particular, the regulating Member is obliged to supply other Members, via the WTO Secretariat, with basic information concerning the proposed regulation (e.g. product coverage, objectives, and its basic provisions).[29] This needs to be done at an early stage of the regulatory process, when amendments to the proposed regulation are still possible. Other WTO Members have the right to make comments within a reasonable period of time. If a commenting Member so requests, these comments must be discussed and taken into account by the regulating Member, along with the result of the consultations, when adopting a final

[26] *Id.* Article 3.17.

[27] *Id.* Article 37.1

[28] TBT Agreement, Article 2.9 (a proposed technical regulation also needs to have a significant effect on the trade of other WTO Members. For the criteria used to determine "significant effect", *see*, TBT Committee, *Decisions and recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995*, G/TBT/1/Rev.10, 9 June 2011, at 19.

[29] In order to accelerate the process of notifications, Members are expected to transmit them to the WTO Secretariat electronically via the Central Registry of Notifications. *Cf. also* chapter in this book by Petros C. Mavroidis & Erik N. Wijkström (*Taking Care of Business. The Rules and Tools of the WTO TBT Committee*), section III.A (discussing technical details of the notification process).

version of a particular TBT measure.[30] On the other hand, it should be noted that the TBT Agreement does not require disclosure of the replies to other WTO Members, and the consultations in principle are a purely bilateral process. However, the 2004 recommendations of the TBT Committee encourage Members to voluntarily respond to comments in writing and to share their responses with the TBT Committee.[31]

The TBT Committee provides a platform for multilateral discussion among countries on their technical regulations and standards.[32] In particular, a WTO Member may raise, at a meeting of the Committee, a specific trade concern relating to a technical measure of another country. This mechanism requires a responding Member to provide necessary explanations in front of all Members. In practice, a WTO Member raising a concern is expected to inform the WTO Secretariat and the Member(s) involved in advance (no less than 14 days before the meeting) of its intention to raise a particular concern and provide some details on its content.[33] This allows a responding Member to prepare for the meeting and address the concern in a more precise way.[34]

The WTO committees, including the TBT Committee, are seen by some scholars as a vital, yet unappreciated, component of the governance of international trade relations. Lang and Scott describe them as "multilateral for[a] in which Members are called upon to explain and justify their (proposed) regulations."[35] They identify two particular functions that are performed by various WTO committees: facilitation of information exchange between WTO Members, and engagement in the process of elaboration of norms.[36] The first function, which seems to be more relevant when it comes to REACH, is normally carried out through the mechanism of trade concerns.

The mechanism for raising and discussing specific trade concerns can serve different functions. Lang and Scott list three of them. In particular, raising a particular concern at a meeting may promote closer cooperation between the WTO Members concerned (e.g. by establishing a joint working group, conducting inspection visits, recognizing foreign testing laboratories, etc.). At the same time, "resolution may flow not so much from the adjustment in concrete regulatory expectations (...), but from a shift in perception as to the regulatory capacities of other states, and from an increase in levels of mutual trust."[37] Second, such discussions may improve the awareness of a Member contemplating a measure of potential negative implications for other countries (which in turn can result in amendments to the

[30] TBT Agreement, Articles 2.9.2 and 2.9.4.

[31] TBT Committee, *Third Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade*, G/TBT/13, 11 November 2003, para. 26.

[32] Article 13.1 of the TBT Agreement provides, in relevant part, that the Committee shall meet "for the purpose of affording Members the opportunity of consulting on any matters relating to the operation of this Agreement or the furtherance of its objective."

[33] TBT Committee (Decisions), *supra* note 28, at 44.

[34] *Cf.* Mavroidis & Wijkström, *supra* note 29, section III.B.

[35] Lang & Scott, *supra* note 3, p. 592. *Contra*, Richard H. Steinberg, *The Hidden World of WTO Governance: A Reply to Andrew Lang and Joanne Scott*, 20(4) EUROPEAN J. OF INT'L L. 1063 (2010).

[36] Lang & Scott, *supra* note 3, at 578. Mavroidis and Wijkström identify two main functions of the TBT Committee: the multilateral review of measures and the discussion of thematic issues. They also recognize the norm elaboration aspect of its activities (*cf.* Mavroidis & Wijkström, *supra* note 29, section II.B).

[37] Lang & Scott, *supra* note 3. p. 592.

initial proposal). Third, concerns may sensitize a Member as to the need to provide technical assistance to other Member(s) in order to facilitate compliance with a contemplated measure (e.g. in the form of training or financial assistance).[38] One may add to this list one additional element. The discussion in the Committee may be helpful in removing uncertainties relating to the proposed measure or the process of its implementation (e.g. as to the meaning of specific terms that may be ambiguous for other Members, or practicalities in the operation of a measure). By providing additional clarifications on a proposed regulation, a Member may also demonstrate that its proposed measure is in compliance with its WTO obligations, or at least articulate its understanding as to what is required under specific WTO provisions. In this context, one may argue that the technical nature of the discussion provides the opportunity for countries to depoliticize (at least in some cases) such controversies and facilitates compromise, especially when compared to the conventional political processes at the international level.[39] Its multilateral character also changes the traditional allocation of power among states, making the voices of smaller and less developed countries more audible. These observations seem to find some support in the opinions expressed by WTO Members themselves. In the context of the TBT Agreement, it has been noted that Members recognize the value of the discussions on specific trade concerns and see them as an important mechanism for resolution of trade-related controversies. In a number of cases the discussion "has effectively facilitated the resolution of – or diffused at an early stage – issues arising between Members relating to specific trade concerns."[40]

In the context of this chapter, the question naturally arises: how have these mechanisms worked in practice in the case of the REACH Regulation? The answer is not an easy one and requires a careful analysis of the whole process that took place in the TBT Committee.

An initial notification of its intent to develop and implement a new regime for the regulation of chemical substances was made by the European Commission as early as May 2003, just before the internet consultations were held. This was followed by a formal notification in January 2004, a few months after the Commission finalized the first draft of the REACH Regulation.[41] At a later stage, the EU also made a number of additional notifications relating to changes that were introduced during the legislative process (including a notification of the final version), as well as various measures that were introduced as part of the implementation process.[42] In principle, other Members recognized the entire legislative procedure as relatively transparent.

From the beginning, the new European regulatory regime for chemicals was a standing item on the agenda of every meeting of the TBT Committee. The proposal was met with

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[38] *Id.* pp. 593-594.

[39] *Cf.* Mavroidis & Wijkström, *supra* note 29, section II.B (noting that a work of the TBT Committee is "done in a step-by-step fashion, quietly, far from the spotlight by experts who – at least to some extent – have been untroubled by the larger political drama of missed deadlines and ministerial meetings").

[40] TBT Committee, *Fifth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade under Article 15.4*, G/TBT/26, 13 November 2009, para. 65.

[41] TBT Committee, *Notification: Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - COM(2003) 644 final*. G/TBT/N/EEC/52, 21 January 2004.

[42] For example, in 2007 the EU officially issued official notification on its website where the draft technical guidance documents developed as a part of the REACH implementation were posted (*see*, TBT Committee, *Notification (Addendum) of the European Communities*, G/TBT/N/EEC/52/Add.4, 13 June 2007).

intense opposition from a number of WTO Members. Although countries recognized and supported the objectives of the new EU chemical policy (i.e. protection of human health and the environment), they were concerned with the complexity of the system and the high costs of compliance for their industries (especially for small and medium-sized enterprises, hereinafter "SMEs"). Later, a range of issues arising out of the practical operation of REACH also became an important point of the debate. In legal terms, it was argued that different aspects of REACH could be regarded as discriminatory, inasmuch as they accorded to imported products less favourable treatment than that accorded to like products of national origin (in violation of Article 2.1 of the TBT Agreement), and were more trade restrictive than necessary to fulfil a legitimate objective (in violation of Article 2.2). These problems are reviewed in more detail in Section 4 of this chapter.

It is very difficult, if not impossible, to precisely assess the significance of the TBT Committee in the process of adopting the REACH Regulation. First, as correctly noted by Lang and Scott, one should keep in mind that "the activities of the committee take shape in a system which is not 'merely' cooperative, but characterized also by the presence of binding … norms, susceptible to enforcement by the WTO 'courts'."[43] In other words, any discussion takes place in the shadow of the binding WTO rules and the potential application of the compulsory dispute settlement mechanism. It is clear that the REACH Regulation was influenced by the existing WTO obligations, in particular those included in the TBT Agreement (e.g. Articles 2.1 and 2.2). One of the objectives explicitly stated by the Commission in its White Paper was to ensure the conformity of the proposed reform with EU's international obligations under WTO law.[44] The same refrain was repeated in the Explanatory Memorandum attached to the proposal for the REACH Regulation. Both the Council and the European Parliament also made their internal assessments on WTO conformity of the subsequent amendments to REACH.[45] It is, however, less clear what impact could be attributed to the processes which have taken place within the TBT Committee.

Secondly, it would be incorrect to see the Committee as the only platform for the discussion between WTO Members. In fact, detailed consultations between the EU and interested countries were run almost exclusively on bilateral basis, either in *ad hoc* form (e.g. with the US and Japan) or through different structured cooperation mechanisms. For example, Chile discussed various aspects of the REACH system within the EU – Chile Association Agreement,[46] while the US, at a later stage, used the US – EU Chemicals Dialogue that was established within the framework of the Transatlantic Economic Council.[47] A number of WTO Members participated in the internet consultations organized by the Commission[48] or directly contacted the Commission or the ECHA. The REACH proposal

[43] Lang & Scott, *supra* note 3, at 595.

[44] European Commission, *supra* note 5, pp. 7 and 10.

[45] *See e.g.*, Council of the European Union, *Statement of the Council's reasons (re: Common Position)*, 27 June 2006, 7524/8/06 REV 8 ADD 1, at 4.

[46] TBT Committee, *Minutes of the Meeting held of 23 March 2004*, G/TBT/M/32, 19 April 2004, para. 39.

[47] Office of the United States Trade Representative, *2011 Report on Technical Barriers to Trade*, p. 73, (April 20, 2012) http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20-%20Adobe%20Acrobat%20Pro.pdf (last visited 25 August 2012).

[48] TBT Committee, *Minutes of the Meeting held on 2 July 2003*, G/TBT/M/30, 19 August 2003, para. 53.

was also discussed in various other international fora,[49] such as the Organization for Economic Cooperation and Development (OECD) or the International Organization for Standardization (ISO).

Thirdly, the impact of WTO Members on the final form of the REACH Regulation, whether acting within the TBT Committee or in the context of bilateral relations, is also difficult to assess. There were a number of similar or identical concerns expressed by both WTO Members and various internal EU actors (i.e. non-governmental organizations, industry, EU institutions and Member States). In fact, the influence of the latter was quite significant. As mentioned above, the adoption of the initial draft was preceded by intense discussions with representatives of EU industry, while the internet consultations mainly involved local stakeholders. EU Members States played an equally important role through the Council of the European Union (e.g. the REACH proposal was moved from the Environmental Council to the newly created Competitiveness Council, which was more concerned with the economic implications of the new law for European industry).[50] As a consequence, the proposed draft was less stringent than initially planned. The impact of the Council was also visible during the later stage of the legislative process. While the European Parliament was generally in favour of mechanisms that would provide a high level of health and environmental protection, the Council tended to take a more balanced approach that considered the economic consequences of the new regulatory framework for Member States' industries. As a consequence, it is difficult to distinguish between those parts of REACH that were amended as a result of purely internal processes and those which could be attributed to external influences. Depending on the specific issues involved, these two dimensions could play either a mutually supportive or neutralizing role.

Having made the above reservations, it seems nonetheless clear that the activities of the TBT Committee were of some importance. Even though ultimately the international consultations were run on a bilateral basis, the Committee arguably played a useful role as an initial intermediary. To some extent, the discussion that took place within the Committee improved the awareness of the EU as to the negative implications of REACH for other WTO Members, and served as a catalyst for the subsequent bilateral consultations. Indeed, some of the issues which were later discussed bilaterally were raised for the first time at meetings of the TBT Committee. A process of learning took place not only between the EU and its trading partners, but also among the WTO Members as such. Delegations were confronted with various concerns raised by other Members. This allowed them to recognize particular issues as relevant for them and in some cases resulted in numerous Members adopting a joint stance. In a purely bilateral setting this arguably would not have been possible (or at least it would have been more difficult). The EU Commission actually made this process even easier by sharing with all WTO Members, via the internet, the replies provided to specific comments (thus following one of the recommendations of the Committee). The multilateralised discussion, with a number of countries opposing particular provisions, also brought additional pressure to bear on the EU. This process worked to the advantage of those smaller economies whose voices would have less influence in bilateral negotiations (e.g. Egypt or Thailand).

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[49] *E.g.*, TBT Committee (Minutes, G/TBT/M/32), *supra* note 46, para. 29.

[50] Kjaer, *supra* note 6, at 4. Although the Council is a single body, it meets in different configurations, depending on the subject matter under discussion. Each configuration is attended by different ministers from the Member States responsible for a particular area.

In some cases, the improved awareness of the EU (understood in terms of recognition of a particular problem and/or its gravity, as measured by the number of opposing Members) was translated into changes in the REACH Regulation, particularly in the case of technical and less fundamental issues. In other cases, the increased awareness may have facilitated compromises at the bilateral level. EU representatives openly admitted that "the comments received from several countries had resulted in changes to the REACH system which made it less costly, less bureaucratic, and more workable, while reinforcing the health and environmental protection objectives."[51] This was also acknowledged several times by Members that had raised specific concerns.[52] Two examples follow as illustrations.

Delegates of Australia were particularly concerned with registration requirements for minerals, ores, concentrates, and metals. They considered that since these elements posed minimal risks to public health and the environment, requiring their registration and/or authorization was more trade restrictive than necessary to achieve a legitimate objective and therefore constituted a violation of Article 2.2. Australia proposed that the EU exclude them altogether from the scope of the Regulation.[53] The relevant change was introduced by the Council and subsequently approved by the European Parliament.[54] Although ultimately the REACH Regulation does not exclude minerals, ores, concentrates, and metals from its scope, such substances are exempted from the registration obligation if they are not chemicals, not modified, and not dangerous.[55] This development was welcomed not only by Australia but also Chile, which shared the same concern. A similar situation occurred with respect to cellulose pulp, one of the concerns of Canada. The EU ultimately excluded this substance from the registration requirement altogether.[56]

A number of WTO Members, including ASEAN countries, also criticized the substitution principle with respect to substances of very high concern.[57] The European Parliament had introduced an amendment which required automatic refusal in the authorization process for substances of very high concern where a safer alternative was available. The Council again modified that provision so as to allow authorization for such substances when the risks related to the use of the substance are adequately controlled. This modification was partially included in the final version of the REACH Regulation,[58] and the substitution principle was maintained only for some substances, and not as a general rule.[59] In addition, under the current text the Commission is obliged to consider the health and

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[51] TBT Committee, *Minutes of the Meeting held of 7 November 2003*, G/TBT/M/31, 9 December 2003, para. 33.

[52] *Id.* para. 25.

[53] TBT Committee, *Minutes of the Meeting of 16-17 June 2005*, G/TBT/M/36, 4 August 2005, para. 12.

[54] TBT Committee, *Minutes of the Meeting of 7-9 June 2006*, G/TBT/M/39**,** 31 July 2006, para. 52.

[55] REACH Regulation, Annex V. Note that the opposition of the European metal industry sector was also an important factor in shaping the final formulation of the relevant provision. This exemplifies one of the methodological problems mentioned above.

[56] TBT Committee, *Minutes of the Meeting of 15 and 17 March 2006*, G/TBT/M/38, 23 May 2006, para. 75; *see also*, Annex IV of the REACH Regulation.

[57] TBT Committee, *Minutes of the Meeting of 9 November 2006*, G/TBT/M/40, 26 January 2007, para. 43.

[58] REACH Regulation, Article 60.2.

[59] *Id.* Article 60.3. An applicant also needs to show that the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance.

environmental risks that might arise from the use of a substitute, which softens even further the substitution principle and responds to some extent to the concerns of other WTO Members.[60]

At the same time, it must be admitted that some of the issues raised at the meetings of the TBT Committee remained unaddressed and did not lead to any amendments of the REACH Regulation. This was particularly true with respect to those concerns that related to the basic principles of the Regulation. For example, the EU effectively refused, entirely or partially, to make changes concerning allocation of the burden of proof (e.g. a concern of China), the scope of the registration requirement, which was seen by some Members as more than necessary to protect human health and environment[61] (e.g. a concern of Japan, US, China, Chile and Singapore), registration of substances in manufactured articles, which was seen by a number of countries as unnecessary (e.g. a concern of Japan and Thailand), or regarding special or differential treatment for developing countries (e.g. a concern of some ASEAN countries, the Dominican Republic, and China). The changes introduced with respect to the above-mentioned issues were minimal and did not affect the essence of the new regulatory framework. A number of other more technical and specific matters were also left as originally proposed. This clearly shows that there are limits to the process that takes place in the TBT Committee. I will come back to the problem of compatibility of specific requirements in REACH with the TBT Agreement in Section 4 of this chapter.

When it comes to the sensitizing function of the TBT Committee, one may also be left with a mixed impression. The discussion in the Committee undoubtedly alerted the EU as to the need for technical assistance to developing countries (because the complexity of the system would make compliance therewith difficult for such countries). One would expect that since this concern was so widely shared, it would generate a large number of initiatives facilitating the adjustment process for industries from less developed economies. In fact, Article 77 of the REACH Regulation expressly recognizes technical assistance for developing countries as one of the ECHA's tasks. The initial statements made by the EU were promising indeed. EU representatives stated repeatedly at the meetings of the TBT Committee that special technical assistance and scientific support, as well as training and information seminars, would be provided to interested parties.[62] However, in reality this has not worked out so well. Although the Commission has provided some additional funding (e.g. under the Strategic Approach to International Chemicals Management), published a number of guidance materials, provided some training, and established REACH help desks in EU Member States, the common perception among interested WTO Members is that these actions have been insufficient and have not met the needs of developing countries. The funds made available by the EU have been limited, the staff of the ECHA responsible for the provision of training services have been frequently unavailable (because of over-demand for their services), and some guidance materials have proven to be too difficult for users in developing states to use. As stated by Argentina during one of the TBT meetings, particularly

[60] TBT Committee (Minutes, G/TBT/M/39), *supra* note 54, para. 46.

[61] *E.g.*, by making the registration a more risk-based process, under which only substances suspected of posing a risk to health and environmental would be registered (or at least prioritizing substances for registration). The EU answered that one of the aims of the Regulation was to collect information on all chemicals and that this would be not possible if registration requirements are excessively limited. See also the discussion in Section 4 below.

[62] *E.g.*, TBT Committee (Minutes, G/TBT/M/38), *supra* note 56, para. 73.

problematic was "the limited capacity of the European Communities and the … ECHA to provide adequate technical assistance to users." The Argentinean representative also explained that "the complexity of REACH, coupled with the lack of appropriate technical assistance, was contributing to increased confusion and concerns among companies that were trying to comply with REACH."[63] In a similar vein, the representative of Chile, during another meeting of the Committee, noted that "technical assistance for non-EU countries regarding (…) REACH was almost non-existent."[64]

The role of the TBT Committee as a promoter of closer cooperation between Members was not a particular success either. The EU rejected all calls for the possibility of registration of chemical substances through certified agents located abroad. However, even less revolutionary proposals did not find a sympathetic ear in the EU. For example, Cuba argued for broader recognition of foreign laboratories for the purpose of toxicological and eco-toxicological testing. According to Cuba this could have been done on the basis of individual recognition arrangements with interested WTO Members. The EU refused and instead proposed a uniform benchmark for all laboratories (i.e. OECD Guidelines on Good Laboratory Practices).[65]

The TBT Committee was probably more successful in acting as an intermediary in the process of clarifying different aspects of REACH. This should not come as a surprise as in practice this is one of the main tasks of the Committee. As noted in the most recent review report on the Committee's activities, "the most frequently invoked reason for raising a concern in the TBT Committee is the need for more information or clarification about the measure at issue."[66] The REACH Regulation was no exception. WTO Members, besides raising standard concerns as to the compatibility of the Regulations with TBT rules, repeatedly asked for clarifications and explanations, both of a general and specific nature. In response to those questions, the representatives of the EU made two detailed presentations, one relating to the initial proposal and the other to the final version of the Regulation.[67] More technical and specific questions were answered either during the meetings themselves, or in written form, which was communicated directly to the Member raising the concern.[68] As mentioned before, these answers were subsequently published on the Commission webpage on TBT notifications. It seems that in a majority of cases the Members present were satisfied with the answers, sometimes even openly acknowledging that the EU properly clarified a specific issue.[69] If there was some remaining discontent, this related more to the substance of

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[63] TBT Committee, *Minutes of the Meeting of 1-2 July 2008*, G/TBT/M/45, 9 September 2008, para. 32.

[64] TBT Committee, *Minutes of the Meeting of 23-24 June 2010*, G/TBT/M/51, 1 October 2010, para. 55. *See also*, the statement of El Salvador made during the same meeting (para. 57) and the discussion at the subsequent meeting (TBT Committee, *Minutes of the Meeting of 3-4 November 2010*, G/TBT/M/52, 10 March 2011, paras. 96-97).

[65] TBT Committee, *Minutes of the Meeting of 20 March 2008*, G/TBT/M/44, 10 June 2008, para. 133.

[66] TBT Committee (Fifth Triennial Review), *supra* note 40, para. 66; *see also* Mavroidis & Wijkström, *supra* note 28, section III.2.

[67] TBT Committee, *Minutes of the Meeting of 4 November 2004*, G/TBT/M/34, 5 January 2005, paras. 14-32; TBT Committee, *Minutes of the Meeting of 21 March 2007*, G/TBT/M/41, 12 June 2007, paras. 23-42.

[68] *E.g.*, TBT Committee (Minutes, G/TBT/M/36), *supra* note 49, para. 16.

[69] *E.g.*, TBT Committee (Minutes, G/TBT/M/41), *supra* note 63, para. 43. It also should be noted that even WTO Members that do not have representatives at the TBT Committee meetings are able to benefit from

a particular rule rather than the quality of clarifications provided by the EU. At the same time, there were also cases where the same question was repeated several times at subsequent meetings of the Committee, suggesting that the Members concerned were not satisfied with the explanations received.[70] There were also occasional instances when EU representatives limited their replies to a simple reference to relevant documents or information available on the Commission or ECHA webpage or some specific technical documents, without really answering the question. Arguably, some clarifications also helped to show the actual compliance of REACH with the TBT rules (at least one may assume so, if a specific issue was not raised at subsequent meetings of the Committee). This impact was, however, rather limited in those situations where the EU and its trading partners fundamentally disagreed as to compatibility of specific rules or mechanisms in the REACH Regulation with the TBT provisions.

4. Current state of affairs

The implementation of the REACH is an on-going process. Although, the Regulation came into force in June 2007, the registration process only started a year later. For non-phase-in substances[71] immediate registration was required (if their amount was more 1 tonne per year), while phase-in substances could be registered over a period of 11 years from the entry into force of the REACH Regulation. The evaluation and authorization process also began in 2008. The first registration deadline for phase-in substances was set for 2010 (in principle if ≥ 1,000 tonnes per year, while for carcinogens, mutagens or reprotoxins if ≥ one tonne per year). In 2011, the requirement for notification of substances in articles began. However it was limited only to substances of very high concern (if ≥ one tonne per year and more than 0.1% of an article). The second deadline is envisaged for 2013 (if ≥ 100 tonnes per year), while the third one will come in 2018 (≥ one tonne per year). As part of the implementation process, a number of technical guidelines of a non-binding nature were also adopted, explaining specific aspects of REACH, such as the content of applications, rules of gathering scientific evidence and sharing them between different market operators, etc.[72] The Regulation, as such, has been amended nineteen times since its adoption and a major revision is expected to take place in 2012/2013.[73]

The general concern with the REACH regime, shared by many WTO Members, is that it is overly complex, burdensome and costly, especially for SMEs and companies from

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information provided. The minutes of the meetings are published on the WTO webpage. Moreover, in a case of REACH answers to specific questions were also available on a webpage of the EU Commission.

[70] *E.g.*, TBT Committee (Minutes, G/TBT/M/52), *supra* note 60, paras. 84-85 and 90; *Minutes of the Meeting of 24-25 March 2011*, G/TBT/M/53, 26 May 2011, para. 142.

[71] These are substances that do not meet the definition of phase-in substances (*see*, Article 3.20 of the REACH Regulation).

[72] There is some disagreement between the EU and other WTO Members whether guidelines fall under the TBT Agreement and whether they should be notified as other technical regulations. The official position of the EU is that these documents are not of mandatory character and do not contain specifications for products. As a consequence, they do not need to be notified under the TBT Agreement (TBT Committee (Minutes, G/TBT/M/44), *supra* note 64, para. 146). Since no WTO Member has recently raised this issue again, one may assume that the position of the EU was implicitly accepted.

[73] TBT Committee, *Minutes of the Meeting of 10-11 November 2011*, G/TBT/M/55, 9 February 2012, para. 59.

developing parts of the world. As a consequence, it may easily disrupt the international market in chemical products and limit the size of exports from other countries to the EU. This concern, however, cannot be easily translated into a claim of violation under the TBT Agreement (or any other WTO agreement).[74] WTO Members, in principle, retain a wide margin of autonomy when adopting technical regulations such as REACH. They may set whatever level of protection they deem appropriate, even if this has a serious impact on international trade or generates additional costs for traders.[75] What is disciplined under the TBT Agreement is discrimination between domestic and like imported products and the necessity of particular measures (in the sense that they need to constitute the least trade restrictive alternative to achieve the regulatory goals of a particular WTO Member).[76] Awareness of this situation has obviously led WTO Members to articulate their claims in terms of discrimination and/or weak proportionality.

Due to space limitations and the complexity of the REACH system, it is not possible to analyze here all aspects relating to compatibility of the Regulation with the TBT Agreement. The section which follows only highlights those aspects that have generated particularly intense discussion in the Committee and still remain unresolved.[77] In other words, it is aimed at supplying a picture of the typical problems posed by the REACH Regulation. This includes the general question as to whether a hazard-based approach is a legitimate method for regulating chemicals, and two more specific issues, relating to registration requirements for monomers in polymers, and the institution of an "Only Representative".

As highlighted several times above, the REACH Regulation is partially founded on a hazard-based approach, and partially on a risk-based paradigm.[78] The former focuses on possible effects of substances, regardless of their low or high (or even non-existent) likelihood. The latter takes into account both the hazard and the likelihood of the effect occurring. In other words, hazard can be understood as the potential to cause harm (e.g. carcinogenicity) which is inherent in a particular substance, while risk is the likelihood of that harm actually occurring. Whether hazard will transform into risk depends on many factors, such as the degree of exposure (i.e. a low exposure to a hazard may result in low or zero risk, and no exposure results in no risk), the effects of such exposure and its likelihood (e.g. an extremely low likelihood may cause the risk to be regarded as negligible).

The hazard-based approach is reflected in different parts of the REACH Regulation (e.g.

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[74] Other WTO agreements that are potentially relevant include the General Agreement on Tariffs and Trade 1994 and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Some disclosure obligations may violate Article 39 of TRIPS, which requires the protection of undisclosed information of commercial value and data submitted to governments in approval procedures). Due to the scope of this chapter this aspect, however, will be not addressed here.

[75] Panel Report, *United States – Measures Affecting the Production and Sale of Clove Cigarettes,* WT/DS406/R (not yet adopted), para. 7.370 ("no country should be prevented from taking measures 'necessary … for the protection of human … life or health … at the levels it considers appropriate'"); the Appellate Body in its report did not change this finding.

[76] Of course there is more than that in the TBT Agreement. However, these two obligations appear to be the most crucial when it comes to assessment of the REACH Regulation's compliance with the TBT Agreement.

[77] For a summary of different TBT concerns relating to REACH, *see* Doaa A. Motaal, *Reaching Reach: The Challenge for Chemicals Entering International Trade*, 12(3) J. OF INT'L ECONOMIC L. 643 (2009).

[78] For an interesting discussion on differences between hazard-based and risk-based approaches and their application in the European context, *see* Kristina Nordlander, Carl-Michael Simon & Hazel Pearson, *Hazard v. Risk in EU Chemicals Regulation*, 1(3) EUROPEAN J. OF RISK REGULATION 239 (2010).

the process of identifying and selecting substances of very high concern), but it is probably most visible in the registration process. It will be recalled that under the Regulation all chemical substances above certain tonnage thresholds, unless specifically exempted, are subject to registration. This means that a particular chemical needs to be registered even if the likelihood of any negative consequences is very low (or even non-existent because, for example, humans are not exposed at sufficient levels). Although the exemptions provided in Annex IV and V of the REACH Regulation introduce some elements of risk rationality, the general rule remains the same – registration is primarily concerned with hazards, not risks. Along the same lines, some information requirements, which are partially based on the volume of production/importation of a particular substance rather than on the risk related to such a substance, also reflect a hazard-based approach.

The TBT Agreement does not explicitly prescribe a risk-based approach nor prohibit hazard-based regulations. Nevertheless, some WTO Members believe that the broad formulation of the registration requirement may violate Article 2.2 by imposing obligations which are unnecessarily restrictive.[79] For example, China has argued that substances whose characteristics and performance are well known due to their long-term use should be exempted from the Regulation,[80] as they are unlikely to pose any significant risk to health or the environment. This concern was shared by Japan, which maintained that registration has to be based on a positive list of those substances or products which could be regarded as risky. The US was of a similar opinion.[81] The above criticism has some merits. Since the Regulation in effect provides that some substances which may not pose any risk need to be registered, their registration could be deemed unnecessary. At the end of the day, if there is no risk of harm why impose on importers of a specific substance additional regulatory burdens that will create obstacles to international trade? This narrative also seems to correspond closely with the approach taken under the parallel treaty – the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) – where mere identification of a hazard is regarded as insufficient to justify a measure. Instead, WTO Members are expected to assess specific SPS risks, which includes a determination of likelihood.[82] Hazard identification as such is recognized as just the first step in such an assessment that is followed by hazard characterization, exposure assessment, and risk characterization. It should also be noted that the precautionary principle that underpins hazard-based mechanism[83] has been explicitly rejected in the context of SPS case law as not being a valid ground for justifying trade restrictive measures.[84] There is nothing in the text of

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[79] *E.g.*, TBT Committee, *Minutes of the Meeting of 1 July 2004,* G/TBT/M/33, 31 August 2004, para. 46. The relevant part of Article 2.2 provides that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create."

[80] TBT Committee (Minutes, G/TBT/M/33), *supra* note 74, para. 46.

[81] Respectively, TBT Committee (Minutes, G/TBT/M/32), *supra* note 46, para. 31; (Minutes, G/TBT/M/31), *supra* note 47, para. 25.

[82] *Cf.* SPS Agreement, Articles 2.2 and 5.1-5.3. While there is no TBT case law that would address this issue, a panel may, however look for interpretative inspiration to the SPS Agreement and its case law. This is conventionally done by the WTO dispute settlement bodies, especially when interpreting similar expressions located in different agreements.

[83] *See e.g.*, REACH Regulation, Recitals no. 9, 69 and Article 1.3.

[84] Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135, para. 124; Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R,

the TBT Agreement that would suggest any other outcome.

On the other hand, if one sees the registration as only one element of a larger system that aims at protecting human health and the environment, its necessity may be easier to establish. Although some specific substances may not pose any risk, the broad scope of the registration requirement could be justified by the need to have an effective general rule that would facilitate the achievement of the REACH objectives. One of the mechanisms which contributes to the achievement of the high level of human and environmental protection sought by the EU is the generation of technical and scientific data in the process of registration.[85] Since information on the majority of chemicals is incomplete, it is necessary first to collect data that would allow subsequent identification and evaluation of risks (and activation of the corresponding authorization and restriction processes) without predetermining whether particular substance may pose any risk. In other words, it will not be possible to effectively regulate risks prior to the comprehensive collection of information on the hazardous properties of various chemical substances. It should be also stressed that SPS case law is not easily transplantable to the TBT Agreement. The SPS Agreement introduces a more stringent regime that requires risk assessment for any trade restrictive measures, while its TBT counterpart uses somewhat softer language (e.g. by stating that WTO Members are only required to *take account* of the risks of non-fulfilment of a legitimate objective if a measure is not adopted). Consequently, the approach of panels and the Appellate Body to national risk measures in the context of the SPS Agreement is not determinative for the purpose of the TBT Agreement. Even if it bears some relevance, one also needs to note that although the Appellate Body rejected the precautionary principle as a basis for defending an SPS measure, it also recognized that governments may "act from perspective of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned."[86] This gives an additional margin of discretion to Members when choosing and enforcing health–related measures. Of course, one may disagree on the inclusion/exclusion of certain specific substances in the lists provided by Annexes IV and V, but the hazard-based approach as such (at least as far as the REACH regime is concerned) seems defensible under the TBT Agreement.

A more specific trade concern,[87] with relatively high potential for causing a dispute in the future, relates to the registration rules for polymers. Polymers are chemical substances composed of repeating structural units (e.g. monomers). Synthetic polymers are used for the production of many materials of everyday life such as polyethylene, polypropylene or polyethylene terephthalate (commonly abbreviated as PET). According to REACH, polymers

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WT/DS292/R, WT/DS293/R, Add.1 to Add.9, and Corr.1, adopted 21 November 2006, DSR 2006:III-VIII, 847, para. 7.89.

[85] *E.g.*, REACH Regulation. Recital no. 14, which confirms that "this Regulation will generate information on substances and their uses"; *see also* recitals nos. 17 and 19.

[86] Appellate Body Report, *EC Measures Concerning Meat and Meat Products*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135, para. 124.

[87] This issue was also discussed at the European level by the European Court of Justice in its judgment of 7 July 2009, *The Queen, on the application of S.P.C.M. SA, C.H. Erbslöh KG, Lake Chemicals and Minerals Ltd and Hercules Inc. v Secretary of State for the Environment, Food and Rural Affairs*, ECR 2009, I-05783. The Court ultimately found the relevant provision of the REACH to be compatible with EU law, in particular with the general principles of proportionality and equal treatment. However, due to differences between the EU and WTO (both in terms of the substantive obligations and institutional settings), the relevance of this judgment is limited.

are exempted from registration as they are generally regarded as not posing any significant risk.[88] On the other hand, the monomers used in the polymers must be registered. Consequently, a manufacturer or importer of a polymer must register monomer substances, unless an actor further up the supply chain has already done so. There are two formal conditions that need to be met in order to activate a registration obligation: (a) the polymer consists of at least 2% (by weight) of such monomer substance(s), and (b) the total quantity of such monomer substance(s) makes up one tonne or more per year.[89] Monomers as such (i.e. not as a part of polymer) are also required to be registered in accordance with the normal registration obligation laid down in Article 6 of REACH.

The above requirements have been criticized on different grounds. For example, it has been argued by number of WTO Members that this mechanism provides an incentive to rely on local suppliers of polymers as the relevant monomers would be already registered (e.g. by the producers of monomer substances), while in the case of imported polymers their registration would still be required. This may amount to a prohibited discrimination under Article 2.1 of the TBT Agreement (domestic polymer products v. imported ones).[90] The more important question, however, relates to the necessity of such a registration and potential infringement of the provisions of Article 2.2. Some WTO Members (e.g. China, India, Japan and the US) believe that REACH may be excessive because it requires registration of substance(s) which, if reacted, are not present anymore as individual substances in the final product (i.e. polymer). Since they are not present in polymers, they cannot pose any risk as such.[91] If there is any risk it should be attributed to polymers and not to monomers. It is also added that monomers are normally very stable within polymers. Consequently, information concerning the risks of monomers does not explain the risks posed by polymers.[92] The answers provided by the EU at the TBT meeting did not really clarify why the registration of monomers used for the production of polymers is required. The EU only explained that such registration furthered knowledge on polymers and monomers and "addressed certain health and environmental risks such as monomer residues."[93] In addition, the ECHA Guidance recognized that the registration of polymers might be not feasible because of the extensive number of different polymer substances on the market, while monomer registration is easier.[94] In the case of a dispute, a WTO panel will need to answer two questions: (i) to what extent do these requirements contribute to the objectives of health and environmental protection? and (ii) could the same level of protection be achieved by an alternative measure that is less trade restrictive?[95] The crucial role in answering these two questions will be

[88] ECHA, *Guidance for monomers and polymers*, April 2012, Version 2.0 (Guidance for the implementation of REACH), at 8.

[89] REACH Regulation, Article 6.3.

[90] *See, e.g.*, TBT Committee (Minutes, G/TBT/M/44), *supra* note 64, para. 119.

[91] An ethylene monomer may serve as a good example, as that monomer is a hazardous gas used for the production of polyethylene (polymer), which is not hazardous.

[92] TBT Committee (Minutes, G/TBT/M/52), *supra* note 60, para. 88.

[93] *Id.* para. 104.

[94] ECHA (Guidance), *supra* note 82, at 8.

[95] Panel Report, *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/R, adopted 13 June 2012, as modified by Appellate Body Report WT/DS381/AB/R, para. 7.589.

played by scientific evidence relating to the existence or nonexistence of risks posed by reacted monomers and monomer residues in polymers. If a complainant can establish that the scientific data does not support the premise on which the registration mechanism is based, the measure will be regarded as incompatible with Article 2.2. However, when assessing alternative measures, the issue of their feasibility will be also important. A measure which, owing to practical difficulties in its implementation, does not make an equivalent contribution to achievement of the level of protection sought by the EU will not be regarded as reasonably available.[96] The ECHA Guidance seems to suggest that this might be the case.

Another concern that is shared by a number of WTO Members relates to the institution of an "Only Representative" (OR). Under the REACH regime it is primarily the obligation of importers and local manufacturers to fulfil the obligations of the Regulation, including the registration requirements. Manufacturers located outside the EU (and without an EU presence) do not have direct access to the registration process and they need to rely either on importers of their products, or use the institution of an OR. An OR is defined as a legal entity established in the EU, nominated by natural or legal persons that manufacture substances, formulate preparations, or produce articles outside the EU.[97] The main task of an OR is to "represent" foreign manufacturers by taking responsibility for the registration process and the transfer of necessary data along the supply chain within the EU (i.e. to downstream users). There are number of potential problems with this mechanism. First, the lack of direct access for foreign manufacturers to the registration process[98] may be regarded as a form of discrimination that amounts to a violation of the national treatment principle of Article 2.1. This unequal treatment is repeated in the so-called Substance Information Exchange Forums (SIEFs),[99] which are accessible to foreign manufacturers only through their ORs.[100] The institution of an OR as such is also problematic, as an OR is eligible to act for foreign producers solely in the registration process. As a result, only an importer can apply for authorization. This also means that each importer needs to submit a separate application, which results in multiple authorization requests (otherwise they could be combined by one OR representing different manufacturers into one application).[101] Another issue is the narrow formulation of entities that can appoint an OR. Under REACH this category is limited to manufacturers and does not encompass foreign distributors, who must always rely on EU importers. Once again this may be regarded as discriminatory. Overall, these requirements seem to be quite burdensome for foreign entities (i.e. manufacturers, distributors) and it may be difficult for the EU to show their compliance with the TBT Agreement.[102]

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[96] *E.g.*, Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001, DSR 2001:VII, 3243, para. 308.

[97] REACH Regulation, Article 8.1.

[98] *E.g.*, TBT Committee, *Minutes of the Meeting of 18-19 March 2009*, G/TBT/M/47, 5 June 2009, para. 174.

[99] The mechanism for exchange of information on chemical substances between interested parties; in theory this mechanism should help to avoid unnecessary duplication of research activities.

[100] TBT Committee, *Minutes of the Meeting of 5-6 November 2009*, G/TBT/M/49, 22 December 2009, para. 59.

[101] TBT Committee (Minutes, G/TBT/M/55), para. 61. This aspect of the REACH Regulation is still the subject of discussion in the EU Commission and may be changed in the future (*cf. Id.* para. 69).

[102] Note, however, that no precise data are available which would quantify additional costs for foreign producers and distributors.

Other important issues relating to compatibility of REACH with TBT provisions were also raised and discussed at various meetings of the Committee, but are omitted here due to space limitations. A few of them should be noted briefly, however: the alleged *de facto* discrimination of SMEs from developing countries in the registration process; the alleged *de facto* discrimination of foreign companies within the framework of SIEFs; differences in the implementation of REACH across EU Member States; and the necessity of certain rules pertaining to the registration of substances in articles.

5. Conclusions

As indicated above, there are certain grounds for disappointment with the role that has been played by the TBT Committee in the process of adoption and subsequent implementation of the REACH system. This observation suggests that the role of the WTO committees, and in particular the TBT variation, may be not as significant as Lang and Scott have suggested. It is true that the Committee has served as an important platform for clarifying and explaining REACH to other WTO Members[103] and that to some extent it improved the awareness of the EU as to the externalities of the Regulation, which in some cases resulted in amendments to the Regulation and its implementing measures. Nevertheless these changes, if they can be ascribed to the TBT process at all, were limited primarily to secondary and technical issues and did not affect the basic principles of REACH (e.g. allocation of burden of proof, or general registration requirements applicable to all chemical substances). This suggests that when it comes to fundamental differences between WTO Members as to the choice of regulatory mechanisms, the discussion at the Committee may be of limited importance, with internal regulatory processes playing the most prominent role. The same is true when there is fundamental disagreement as to a specific factual issue (i.e. the hazardous and risky nature of monomers in polymers). One may also argue that the size of regulating (and opposing) Member matters. Smaller and less powerful countries seeking to put the regulation is place are probably more easily pressured in the TBT Committee by larger WTO Members. Since the EU is one of the biggest Members it can be more resistant to external pressure and preserve a larger room of regulatory autonomy.

An important factor in determining the success of the consultations (both in the Committee as well as at the bilateral level) would seem to be also the costs of the required changes (e.g. modifying rules on the burden of proof for certain chemical substances will impose additional costs on public authorities). One may assume that the higher the costs of requested modifications, the lower are the chances for compromise. The sensitizing function, as far as the need for technical assistance is concerned, also remained rather limited in the case of the discussions concerning the REACH Regulation. In the opinion of many WTO Members, the official statements of the EU have not really corresponded with its actual practice. Once again one of the reasons that could explain this disconnect might be the financial costs that would be incurred by the EU in order to pursue a more aggressive program of technical assistance. It should also be noted that the discussions in the TBT Committee did not lead to any breakthrough in levels of technical cooperation between the EU and its trading partners. The level of trust proved to be too low to outsource some of the mechanisms of REACH to the EU's trading partners.

[103] This also goes in line with the general observations of Mavroidis and Wijkström on the activities of the TBT Committee (*cf.*, Mavroidis & Wijkström, *supra* note 28, section VI).

Since many issues arising under the REACH Regulation still remain unresolved, one may expect that the discussions in the TBT Committee will continue in the future. If they remain as effective as the previous ones, there is a good chance that some aspects of the new EU chemical regime will eventually be tested in the WTO dispute settlement system. This will also raise doubts with regard the overall effectiveness of the system provided by the TBT Committee as a dispute prevention mechanism (at least for politically difficult cases).