The Compatibility of REACH Regulation with WTO TBT Agreement

Master of Arts in Law and Diplomacy Thesis

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To my mother

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LIST OF ABBREVIATIONS

CAP:	Conformity Assessment Procedure
CEFIC:	European Chemical Industry Council
CLP:	Classification, labelling and packaging
CMR:	Carcinogenic, Mutagenic, Reprotoxic
CSA:	Chemical Safety Assessment
CSR:	Chemicals Safety Report
DSM:	Dispute Settlement Mechanism
EC:	European Commission
ECHA:	European Chemicals Agency
ECJ:	European Court of Justice
GHS:	Global Harmonized System
GLP:	Good Laboratory Practices
HPV:	High Production Volume Chemicals
ICCA:	International Council of the Chemical Associations
ILAC:	International Laboratory Accreditation Cooperation
ISO:	International Organization for Standardization
PBT:	Persistent, bioaccumulative, toxic
REACH:	Registration, Evaluation, Authorization and Restriction of Chemicals
SIEF:	Substance Information Exchange Forums
SME:	Small and Medium Sized Enterprises
SPS:	Sanitary and Phytosanitary Measures
SVHC:	Substances of Very High Concern

TBT:	Technical Barriers to Trade
UN:	United Nations
OR:	Only Representative
OECD:	Organization for Economic Cooperation and Development
SAICM:	Strategic Approach to International Chemicals Management
vPvBs:	Very persistent, very bioaccumulative
WTO:	World Trade Organization

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WTO TBT Agreement

Abstract

This contribution analyses the comprehensive chemicals legislation implemented by the European Union (EU) since 1st June 2007, known as REACH Regulation, from the perspective of WTO Technical Barriers to Trade (TBT) Agreement. The focus of this study is to investigate certain aspects of REACH, which are likely to be subject to WTO Dispute Settlement Body (DSB). Thus, first of all, the thesis lays down the objectives and main procedures of the REACH with respect to registration, evaluation, authorisation and restriction. Second, it examines the ongoing discussions and main concerns of WTO member states regarding REACH under TBT Committee Meetings. Lastly, it asks which of these concerns might be brought to WTO DSB in the future and to what extent they might be defended under TBT Agreement. This preliminary analysis concludes that even though EU seems to be in a strong position due to its high level of aim known as human health and environment protection, the compatibility of some requirements of REACH with TBT Agreement might still be questioned seriously.

1. Introduction

EU's recent attempt to better assess and manage risks that chemicals pose to human health and environment through gathering and generating data on the properties of all chemicals produced in or imported into the EU has come into existence under REACH legislation (**R**egisration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals). REACH has been on the world scene since 1st June 2007 after years of dialogues and heated debates not only in the EU but also in the rest of the world. Thus, the creation process of REACH might have been one of the most troublesome legislation making acts for the European Commission (EC) since the new legislation has been not only the EU's most ambitious and comprehensive legislation amendment in the last two decades but it has also affected most

of the other EU and non-EU sectors using chemicals as their inputs. EU has prepared this new chemicals legislation mainly with its "precautionary principle" approach, but with incorporating "risk assessment" principle.[1]

According to the WTO data, Europe accounts for 50.2% of the world's chemical export while 42.2% of import in 2010.[2] As it is one of the largest players on the global supply and demand chain of chemicals, such a fundamental shift in the EU's chemical policy unsurprisingly reverberates in international trade. Thus, after its entry into force and application of its requirements, the debates inside the EU has calmed down while the oppositions and concerns from some of the non-EU states has been rising incrementally. Their degree of concern seems directly proportional to their degree of dependence on the EU market for their chemical exports. Therefore, REACH has become one of the "hot topics" being debated in WTO TBT Committee since 2004. In fact, during the proposal period of REACH, the EU usually welcomed some of these comments and made substantial changes to its proposal. However, after its entry into force, the EU seems to be more indifferent than before to the increasing concerns, which leads to the continuation of opposition. In reality, there exist some specific requirements of REACH that they are likely to be seriously challenged under WTO TBT Agreement.

[1] Under strict risk assessment approach, a risk must first be quantified and then controlled while strict application of the precautionary principle requires regulatory action on the basis of less certainty than that which is required for action in a strict risk-assessment approach. That is, precautionary action is proper even in the absence of an absolute, quantitative certainty of the risk.

[2] For WTO data sets, visit http://stat.wto.org/StatisticalProgram/WSDBViewData.aspx?Language=E (Last visited on 20 March 2012)

Due to the fact that the possible adverse effects of REACH have been perceived recently after its full implementation as of November 2010, there have been very few studies released so far discussing its compatibility to the WTO rules in the academic field. On the purpose of filling this gap to some extent through this thesis, first, the objectives and main procedures of the REACH are to be laid down. Second, ongoing discussions and main concerns of WTO member states regarding the REACH under TBT Committee Meetings are to be examined. Lastly, the probability of some aspects of REACH to be subject to WTO DSM is to be discussed within the framework of TBT Agreement.

2. Chemicals Trade and REACH Regulation

2.1. The Background of the REACH Regulation

The European chemicals industry is in a strong position, posting sales of €578 billion in 2010, one-fourth of world chemicals sales in value terms. [3] As the source of such a significant global chemical production with an educated and environmentally aware citizenry, the EU has been at the center of the contemporary struggle to reconcile its industrial economy with protection of human health and the environment. REACH was born with the pursuit of this reconciliation.

Despite the general knowledge about the risks associated with some industrial chemicals, relatively little is known about the hazardous properties of many widely used industrial chemicals, and how they interact with the natural environment. Therefore, REACH

[3] CEFIC (2011) Facts and Figures: European Chemical Industry in a Wordlwide Perspective Report, Brussels, p.3.http://www.cefic.org/Global/Facts-and-figures-images/Graphs%202011/FF2011-chapters PDF/Cefic_FF%20Rapport%202011.pdf (Last visited 20 March 2012)

is designed to generate data on the hazardous properties of industrial chemicals to close this knowledge gap, and the means by which people and the environment are exposed to them. Armed with this information, the EU considers that it will be possible to better assess and manage the risks that chemicals pose to people and the environment.

In addition to the general lack of knowledge about the properties and the uses of existing chemicals, former EU legislation had some serious deficiencies. As Orellana (2006) exemplifies that the task of providing credible information about chemical safety was falling on regulator authorities instead of the producers or importers of chemicals. Additionally, the risk assessment process was slow and costly, and that was allowing continued production, marketing, and use of potentially dangerous chemicals. Further, the EC was responsible for carrying out risk assessments and adequate cost/benefit analysis prior to any regulatory proposal relating to marketing and use of dangerous substances. Finally, the EU's former legal framework on chemicals was a patchwork of Directives and Regulations that had been characterized as a barrier to innovation by discouraging research and favoring existing substances over new, safer chemicals. [4] Thus, as Ackerman *et.al.* (2006) truly states "REACH is intended to revamp chemicals regulation in the EU, replacing a complicated set of more than 40 interlocking regulations with a single piece of legislation. REACH closes loopholes that have existed in European chemicals regulation for years and lays out a series of

[4] Marcos A Orellana (2006) "Europe's Reach: A New Chapter in International Chemicals Law." *Sustainable Development Law & Policy*, p.22.

requirements for collecting, systematizing and using information about the health and environmental and health effects of industrial chemicals." [5]

In fact, the REACH proposal is the result of a review of the existing EU laws and procedures governing chemicals, which was initiated in 1998. A milestone in the review process included the Commission's 2001 White Paper on a Strategy for a future Chemicals Policy. The White Paper identified several objectives necessary to achieve sustainable development in the chemicals industry within the EU, which are reflected in REACH, including: the protection of human health and the environment in conformity with EU international obligations under the WTO.[6] White Paper upon which REACH was built, brought about a contentious, complex political debate with unprecedented participation by NGOs, business and other stakeholders.

While making its environmental or human health protective legislations, EU usually prefers using "precautionary principle" approach, which is generally accepted as the guiding principle. The principle is defined in the Communication on the Precautionary Principle (2000) as it "…applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be

[5] F.Ackerman, E. Stanton&R. Massey (2006), "European Chemical Policy and the United States: The Impacts of REACH", *Global Development and Environment Institute, Tufts University, GDAE Working Paper* No. 06-06, p.2.

[6] White Paper on a Strategy for a future Chemicals Policy, (Brussels, 27.02.2001) COM (2001) 88 final) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:en:PDF (Last visited 22 December 2011)

inconsistent with the high level of protection chosen by the EU". The Communication also states that the "principle is to be considered "within a structured approach to the analysis of risk," and not, for example, as an alternative to risk assessment." [7] The principle might be applied in a wide spectrum ranging from absolute bans on any potentially harmful activity, without consideration of associated costs to a more tempered approach taking into account of risks with costs but is nonetheless willing to impose restrictions without certainty of the potential for harm. As Harrell (2006) confirms the EU has employed the latter approach in REACH Regulation.[8]

Thus, it is reasonable to state that the REACH is an example of an application of the precautionary principle that incorporates risk assessment. Motaal (2009) explains that the EC argues that the implementation of the precautionary principle incorporating risk assessment to the REACH procedures are as follows: "If there is uncertainty over scientific evidences at the safety assessment stage (e.g. conflicting data exist), REACH requires that the safety assessment should normally be based on the evidence that gives rise to the highest concern. In terms of risk-management measures, while a company is awaiting further test data on a particular hazard, REACH requires that it should take the risk-management measures appropriate for the potential risks and that it describe these measures in its safety assessment. Furthermore, at authorization stage, REACH requires industry to seek authorization for uses of substances of very high concern (SVHC), regardless of the measures taken to control risks.

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[7] European Commission Communication on the Precautionary Principle (2000) http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf (Last visited on 5 May 2012)

[8] Sarah, Harrell (2006), "Beyond REACH? An Analysis of the European Union's Chemicals Regulation Program Under World Trade Organization Agreements" *Wisconsin International Law Journal,* p. at p. 482.

The precautionary principle can also be applied in cases where it would take too long to establish the data necessary for a scientific evaluation or where data does not allow the risk to be determined with sufficient certainty."[9]

2.2. The Objectives of the REACH Regulation

The objectives of REACH are to demonstrate the linkages between the economic, public health, and environmental dimensions of chemicals management under the broader umbrella framework of sustainable development. With this approach, REACH is redefining the different roles of the various social actors involved in chemicals production and trade by stringent requirements regarding information on chemicals, summarized by the "*no data, no market*" quote. REACH's requirements also show a preference for safer substitutes (without having to fully prove dangers) as a means to gradually secure health as well as stimulate innovation. The political objectives of REACH are elaborated in the Commission White Paper as follows:

a*) Protection of Human Health and Promotion of a Non-toxic Environment:* This objective requires a process for ensuring the safety of chemicals. This process would distinguish substances according to proven or suspected hazardous properties, uses, exposure, and volumes of production or trade, in order to prioritize actions. Industry, including companies along the manufacturing chain, would be responsible for generating and assessing data and the risks of the use of the substances. Ultimately, this process would fill the large

[9] Doaa Abdel Motaal (2009), Reaching REACH: The Challenge for Chemicals Entering International Trade, *Journal of International Economic Law 12(3),* p.646.

data gap concerning chemical hazards and uses, thereby enabling a sound chemicals policy for the protection of human health and the environment.

b) Maintenance and Enhancement of the Competitiveness of the EU Chemical Industry: Given the economic importance of the chemical industry in the EU, including with respect to jobs, the White Paper encouraged innovation and in particular the development of safer chemicals through REACH. As a result, REACH may drive adoption of safer substitutes or the generation of inherently greener solutions.

c) Prevention of Fragmentation of the Internal Market: In this light, the White Paper views health and environment protection as fully compatible with the proper functioning of the internal market in the chemicals sector, as in any other industrial sector within the Union. The White Paper also proposes that to meet its objectives, the new chemicals policy be based on full harmonization.

d) *Increased Transparency:* Transparency in the White Paper is addressed from two approaches. The first approach is the "public right to know;" that is, the public's right to access information about the chemicals to which they are exposed. The second approach is to enhance institutional and administrative transparency; a single system applying to all chemicals will improve the transparency of the regulation.

e) Integration with International Aspects: This objective encompasses several dimensions, including recognizing test results carried out using globally harmonized system (GHS) in order to reduce costs and animal testing; preventing distortions to the global market by covering importers; and supporting multilateral environmental initiatives relating to

chemical safety. In this latter aspect, the White Paper supports efforts by the Stockholm Persistent Organic Pollutants Convention, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. This objective also addresses the need to strengthen developing countries' capabilities and capacities for managing chemicals. Many countries outside Europe will feel the ripple effects of REACH through global supply chains and evolving international standards.

f) Promotion of Non-animal Testing: This objective seeks to reduce animal testing to an absolute minimum by maximizing the use of existing non-animal test methods. Also, this objective calls for the development of new non-animal test methods.

g) Conformity with EU International Obligations under the WTO: This objective calls for preventing discrimination against imported products; ensuring that its measures are based on sound scientific evaluation of the potential threats to human health and the environment; and ensuring that its technical regulations do not create unnecessary obstacles to international trade. [10]

2.3. Cost and Benefit Analysis of REACH

According to White Paper (2000), it is estimated that base-set testing for a chemical will cost about €85,000 per substance. The cost of long-term testing is more uncertain as there is less experience. EU industry will not be the only sector to pay for these costs, everyone who imports substances into the EC would make a fair contribution to these costs ensuring a

[10] White Paper on a Strategy for a future Chemicals Policy, (Brussels, 27.02.2001) COM (2001) 88 final) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:en:PDF (Last visited 22 December 2011) p.7-10.

global approach. It is estimated that the testing of approximately 30,000 existing chemicals, which are subject to registration procedure, would result in total costs of about €2.1 billion until 2012.

While the direct costs (testing) of chemicals are already high at an estimated value of €2.1 billion, the indirect costs of REACH could be substantially high. According to DiGangi (2004) indirect costs of REACH are estimated by the EC at $15 billion to $30 billion. As seen, "other or indirect cost" of REACH estimates ranges up to almost ten times the amount of the Commission estimate for direct costs. Besides costs, although total health benefits are difficult to calculate, EC estimates range from the $20 billion to $50 billion for occupational health benefits alone. The World Wildlife Fund estimates total health benefits at $180 billion.[11]

2.4. The scope and requirements of REACH

REACH title is not intended to denote a series of steps through which all chemicals must pass. Rather, the vast majority of chemicals are only required to be 'registered' under REACH, with the process going no further. It is the potentially new chemicals on which little information is available, or existing sources information are inappropriate, that must go through an evaluation. Authorization, which is an independent process, is only required for a pre-determined set of sub-stances that are already known to be highly toxic. Therefore,

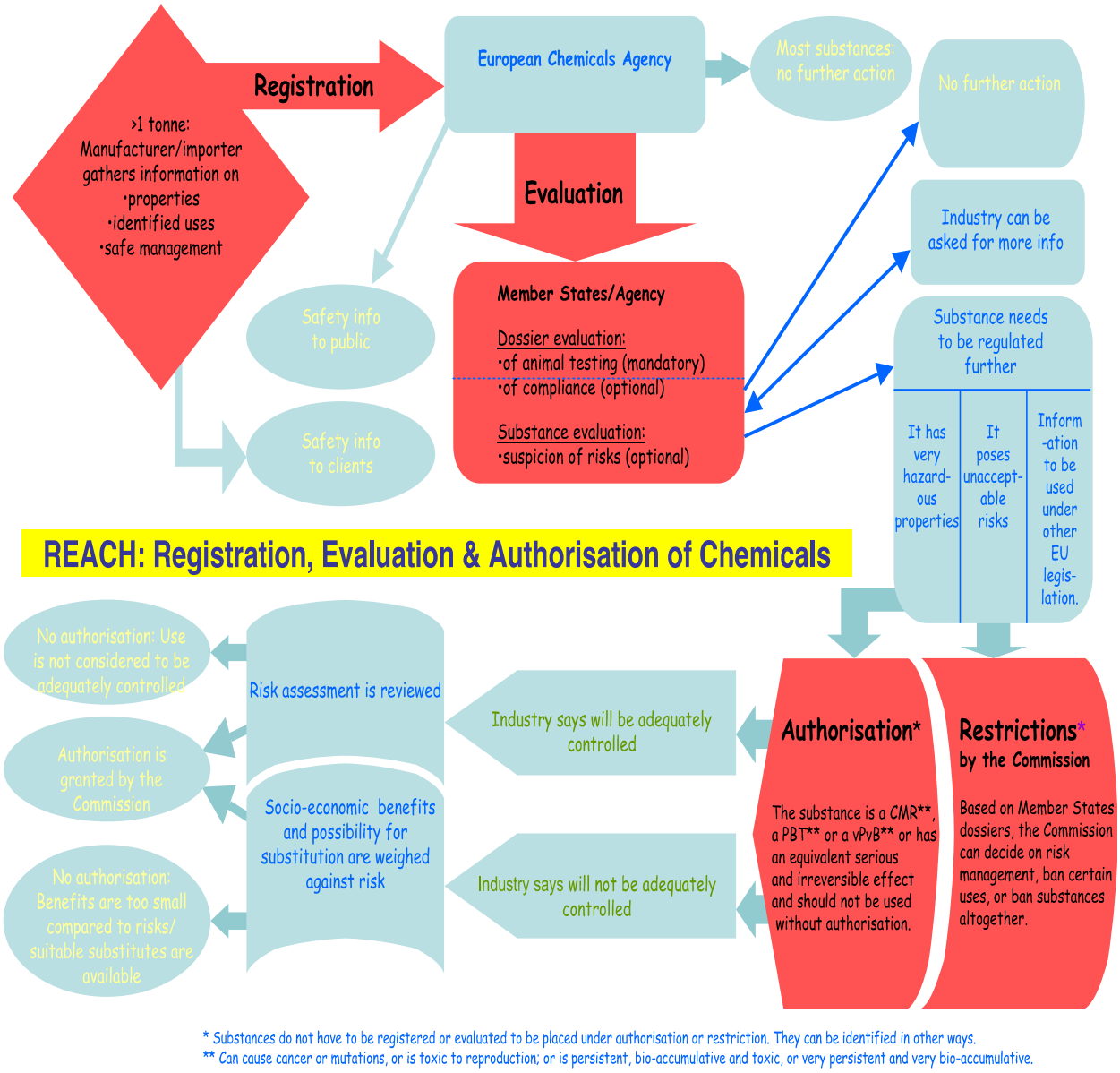
[11] Joseph DiGangi, (2004) "REACH and the Long Arm of the Chemical Industry", *Multinational Monitor*, September, Vol 25 No. 9, p.20.

substances that are harmless must be registered, substances that may be harmful must be evaluated and substances that are known to be harmful must be authorized.

Regarding the scope of REACH, it is important to note that the legislation covers not only chemical substances and preparation but also 'articles' containing dangerous chemicals from which there may be 'intentionally release of the chemical'. However, articles are not directly subject to registration, only the "dangerous chemicals" in articles produced or imported over 1 ton/year are subject to registration and only if that dangerous chemical releases from the article intentionally to fulfill the article's main function during normal and reasonably foreseeable conditions of use. For instance, ink releasing intentionally from a pen is subject to registration since it is intentionally released from a pen to be able to implement its main function. On the other hand, the pen, itself is not subject to registration. Besides articles, there are also some exemptions under REACH i.e. food additives, pesticides and pharmaceuticals, radioactive substances, wastes, non-isolated intermediates and substances that Members States deem necessary for their defense interests.

The procedures of REACH are illustrated in Diagram 1 as follows:

Diagram 1: REACH Procedures Flowchart



Source: European Commission DG Enterprise REACH Website

2.4.1 Pre-Registration

REACH envisaged a pre-registration procedure, which enabled chemical importers and producers in the EU to waive their registration requirements for a certain period of time (until 2011, 2013 or 2018) depending on the tonnage (volume) and toxicity of their chemicals. The Pre-registration period lasted only for 6 months and has closed in December 2008 since ECHA only requested simple and basic information about the chemicals such as company's name, estimated production or import volume, estimated registration date. As of January 2009, ECHA already started to publish on its website the list of the pre-registered substances.

2.4.2 Registration

As it might be noticed in Diagram 1, registration is at the core of the REACH system. Unless otherwise exempted, failure to register means that the substance will not be allowed in the EU market. Therefore, all manufacturers or importers of chemicals are required to register their chemicals brought into the EU at a volume of 1 tonne or more per year. As the European Commission (EC) states, it is expected that registration for around 30,000 substances submitted by companies in a central database and around 80% of all registered substances would require no further action.[12]

A new regulatory authority named European Chemicals Agency (ECHA) was created to which all these registration applications have to be made. [13] As Orellana (2006) states

[12] *See* News Release, European Commission, Chemicals: Commission Presents Proposal to Modernise EU Legislation (Oct. 29, 2003), http://www.eurunion.org/news/press/2003/2003067A.htm

[13] ECHA is also expected to provide Member State authorities with technical and scientific support, as well as to coordinate the evaluation of substances by national environmental authorities. A key aspect of the new ECHA

ECHA is expected to build on the Commission's experience with other agencies in other fields, in particular those working on medicinal products and food safety.[14] ECHA has no enforcement powers and relies on Commission to enforce REACH.

The objective of the registration phase is to have the manufacturers and importers gather information on the properties of their substances, indicate how they intend to manage them safely and turn all of this comprehensive information over to the ECHA for the creation of a central chemicals database system. The burden of proof to show that substance is safe shifts from the regulator to the manufacturer or importer who are required to carry out all health and environmental safety tests on their products. In registering a chemical, the manufacturer or importer is responsible for specifying safe conditions of use and appropriate risk management techniques for each known use of the chemical.

If there is enough information about the substance, other joint registrants might be able to refer or use each other's registration data through participating SIEFs (Substance Information Exchange Forums). REACH encourages but not obliges registrants to share all test data from tests on vertebrate animals to keep animal-testing to a minimum levels. Although, REACH enables SIEF formation for cost-sharing, the importance of respecting property rights to data and fair allocation of the cost of producing the required information, there exists no obligatory provisions in REACH laying down the exact rules of data-sharing

concerns its role with respect to information on chemicals since it manages the registration process. ECHA will also undertake compliance checks and evaluation of testing proposals of the dossiers. The agency maintains a comprehensive central database on all registered chemicals. Crucially, ECHA also provides access to non-confidential information about chemicals to the general public/

[14] Marcos A Orellana (2006) "Europe's Reach: A New Chapter in International Chemicals Law." *Sustainable Development Law & Policy*, Spring 2006, p.26.

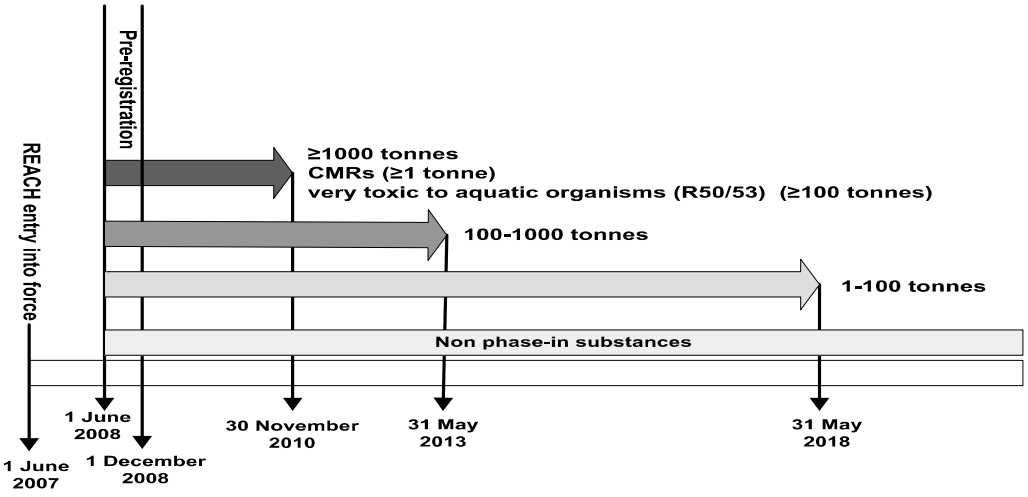
in SIEFs. Considering that the setting of these rules has been left to the registrants and massive number of SIEFs, which has reached to 150.000, cooperation during registration is quite complex and burdensome. As CEFIC (2009) stated that the complexity could, lead to a situation where companies in particular SMEs, and/or representatives of non-EU manufacturers are *de facto* kept out of the process, leaving them little time to complete their registration work that they have to perform together.[15] If the necessary information is not available, then further epidemiological studies or testing are required which is a costly option depending on the tonnage and toxicity of the chemical substance.

The registration processes has been designed in a way to be phased-in gradually through prioritizing chemicals by their production volume or toxicity. For instance, very harmful substances such as specific categories of CMRs classified under CLP Regulation[16] meeting the minimum 1 tonne/year volume requirement need to be registered first while less harmful chemicals might be registered over longer timeframes according to their tonnage. The indicative timeline for the registration of chemicals is illustrated in Diagrem 2 as follows:

[15] CEFIC Legal Guidance for REACH Compliance in particular versus WTO rules, 20 May 2009, p.1. http://www.cefic.org/Documents/Other/Cefic%20Legal%20Guidance-for-REACH-Compliance-WTOrules.pdf (Last visited on 21 December 2011)

[16] CLP Regulation (EC) No 1272/2008, OJ L 353 entered into force on 20 January 2009 as the Regulation on classification, labelling and packaging of substances and mixtures so as to align existing EU legislation to the United Nations Globally Harmonised System (GHS). CLP Regulation is the parallel legislation to REACH Regulation http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/. (Last visited on 21 December 2011)

Diagram 2: REACH Timeline



Source: European Commission DG Environment REACH website

After the submission of registration dossiers detailing the substance's properties, intended uses, likely exposure scenarios, potential risks to health and the environment, and how those risks are to be managed to the ECHA, the Agency conducts completeness check (technical and procedural) and no detailed analysis is made unless the dossier is selected for evaluation.

The registration process for non-EU countries is quite different than the one for EU member states. According to the REACH, chemicals imported from non-EU producers can only be registered either by the EU importer or the Only Representative (OR) office that an exporter may designate and the OR is required to be a "natural or legal person established in the EU". An OR must be a technically qualified individual or entity with a developed understanding of REACH. The OR has an obligation to keep available and up-to-date

information on the quantities of the chemicals imported and the customers that the chemicals are sold to. In case an exporting country chooses to designate an OR; rather the importer, the OR, would carry out the registration procedures. Registration via EU importer or OR requirement for non-EU countries is one of the most criticized parts of the system by non-EU countries.

2.4.3. Evaluation

Evaluation is the process, which is triggered for the chemicals if they are found to require further animal testing or if there is reason to believe that a substance may present a high risk to human health or the environment. It is carried out by EU Member State authorities and co-ordinated by ECHA. According to White Paper (2000) evaluation of the registered information for all substances exceeding a production volume of 100 tonne per year is around 5,000 substances corresponding to 15 % of all chemicals.[17]

The evaluation process consists of an examination of the data contained in the registration dossiers provided by industry. In *dossier evaluation*, the accuracy of the registration dossier and testing proposals are checked. Here, the EU member state authorities evaluate the animal testing proposals to prevent repetition of existing tests and poor quality tests. In *chemical substance evaluation* suspicions of risks to human health or the environment are focal areas that might require for further information from the industry or expedited action such as authorization or restriction.

[17] White Paper on a Strategy for a future Chemicals Policy, (Brussels, 27.02.2001) COM (2001) 88 final) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:en:PDF (Last visited 22 December 2011) p. 16.

2.4.4. Authorization and Restriction

Authorization is only required for the use and marketing of SVHC such as CMRs; PBTs or vPvB; and the chemicals having equivalent effects on humans or the environment. The SVHC is listed by the Commission and the Member States under REACH Annex XIV which is a "living" list since it is open to updates periodically. The decision to include chemicals of SVHC to Annex XIV specifies a date after which those chemicals cannot be sold in the EU market, unless they have been authorised or exempted from authorisation in accordance with REACH. According to the White Paper (2000) of the estimated 30,000 produced chemical substances above one tonne per year, an estimated 1,400 chemicals (5% of the registered substances) may require authorization.[18]

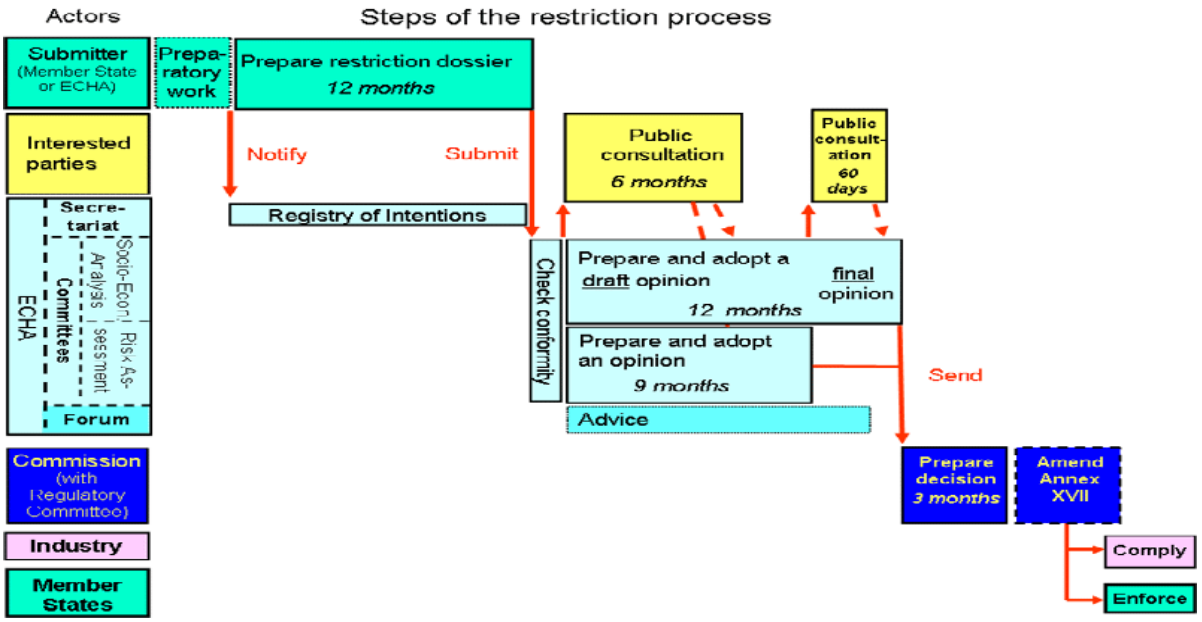
The authorization process consists of two steps. The *first step* focuses on identifying the substances to be included in the authorization system; the uses of substances that will be exempted because of sufficient controls; and the deadlines that have to be met. SVHC are initially selected by ECHA in a hazard-based screen and are then prioritized. The *second step* requires industry to apply for an authorization for each use of their SVHC that they wish to defend which is completely based on risk assessment, demonstrating that either the risk of each use of the substance is adequately controlled, or that the socio-economic benefits of the substance outweigh its risks, taking into account of its alternative substitutes. If such a demonstration fails, the use of these substances will not be authorized. There also exists an

[18] White Paper on a Strategy for a future Chemicals Policy, (Brussels, 27.02.2001) COM (2001) 88 final) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:en:PDF (Last visited 22 December 2011) at p.16. This 1400 substances of SVHC estimate is based on: 850 substances currently classified as CMR substances (categories 1 and 2), substances with POPs characteristics and 500 additional CMR substances (categories 1 and 2) which may be identified through future testing.

option of review period for the authorization, which allows the regulator to re-visit decisions, to examine if conditions have changed, for example (if the use is not adequately controlled), or whether an alternative is now available.

Finally, as a safety net in case a substance is not "adequately controlled" through these measures, REACH also allows for *restriction* of substances (such as sale bans or conditions may be placed on the manufacture, sale or use) that pose unacceptable risks to health or the environment. The steps for restriction procedure under REACH is illustrated in the Diagram 3 as follows:

Diagram 3: REACH Restriction Process



Source: European Chemicals Agency (ECHA) Website

Chemicals do not have to be registered in order to be restricted. The restrictions process can deal with chemicals that are exempt from registration, and can also lead to action being taken on an existing chemical that has not yet had to be registered. The main element of the

restrictions process is the preparation by the ECHA or Member States of a dossier demonstrating that risk to human health or the environment is not "adequately controlled".

3. Main Concerns on REACH discussed under WTO TBT Committee

REACH has been on WTO TBT Committee Agenda since 2003. Almost all of the non-EU WTO member states have been underlining that they have understood the pursuit of the EU for establishing such a high level of standards for human health and environment by REACH in their territory. However, that does not prevent them to raise their concerns insistently regarding the implementation of this highly complicated and horizontal technical regulation in the TBT Committee. Among them, the most outstanding concerns are:

a) Potential of national treatment principle infringement due to some of its discriminatory implementations,

b) More trade restrictiveness than necessary,

c) Adverse affects on SMEs,

d) Data-sharing problems in SIEFs,

e) Absence of Special and Differential Treatment for developing countries,

f) Frequently revised, complicated structured legislation with its broad scope,

g) Inflexibility and incompatibility with relavant international standards,

h) Lack of its uniform implementation throughout the EU

i) Subsitition mechanism related with authorization list

The EU has been defending the legitimacy of REACH in every TBT Committee Meetings regarding the rise of these issues. However it seems that the EU has not been successful yet to smooth down the concerns of other states.

Regarding the transparency of REACH Legislation process, the EC has done necessary notifications about the most major changes in REACH to WTO members. Pursuant to TBT Article 2.9.1[19], EC communicated an early notice on the REACH system, so as to provide WTO members with the opportunity to become acquainted with the new system. According to the EC, the comments received from several countries 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.

As a general response to the comments and concerns, which are to be detailed in the following sub-sections, the EC made general presentations in response to comments submitted by Members under G/TBT/N/EEC/52 and its addendums.[20] In these presentations, the EC reiterates that the key objective for REACH is to improve the level of health and environmental protection within the EU associated with exposure from the use of chemicals. Thus, the information about the risks arising from the use of chemicals to manage them is

[19] TBT Agreement Article 2.9: 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, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

- 2.9.1: publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation.

[20]TBT notification G/TBT/N/EEC/52, 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, see http://www.wto.org/english/news_e/news08_e/tbt_20march08_e.htm (last visited on 18 March 2012)

indispensable to reach this objective and REACH would address this relative lack of information regarding chemicals in the EU market.

However, the concerns regarding REACH have still been one of the "hot topics" in TBT Committee Meetings. In this section, first non-legal concerns expressed under TBT Committee are to be laid down and then TBT related legal concerns are to be discussed through analyzing their compatibility with related TBT provisions.

3.1. Non-Legal Concerns Regarding REACH under TBT Committee

3.1.1. Concerns regarding adverse affects on SMEs

The impact of REACH on SMEs has been an issue of particular concern to non-EU countries and also closely linked to the extra costs of non-EU SMEs as discussed above. In TBT Committee Meetings, it is seen that many countries, in particular developing countries, have questioned how SMEs could comply with such a complex regulation and have insisted on technical assistance in its implementation and stated clearly otherwise net effect of REACH would be to drive SMEs out of the EC chemicals market.

Among those developing countries advocating the rights of SMEs, Argentina stands at the forefront in criticizing the EU. Argentina maintained the view that the situation was even more difficult for SMEs, which generally produced a large variety of chemical products at low volumes in Argentina. According to Argentina, and most of the developing countries, the cost would be outside the possibilities of SMEs because REACH required individual registrations per product and on a case-by-case basis. This potential results in very low profit margins and difficulties in accessing new technologies. Furthermore, it was difficult to

estimate the actual value that had to be added to the product to absorb the additional costs and this introduced more uncertainity, which affected competitiveness. [21]

In TBT Committees, ideas from Argentina and other developing countries have also been supported by some developed countries such as the US and Australia. With respect to the burden on SMEs, the US has stressed many times that REACH placed a significant communication burden on global supply chains. Faced with the task of obtaining all of the necessary data to comply with REACH, many manufacturers were requesting each of their upstream substance suppliers to provide them with information required to register the manufacturers' products, or the substances they contained. As a result, substance manufacturers were facing enormous data requests, including business-sensitive information. Many SMEs, who were engaged in selling their products domestically, neither have the resources nor the ability to discern the data necessary to ensure complete and accurate registration under REACH. [22]

Furthermore, another concern regarding SMEs is the problems related with their representation via OR. According to the US, unlike large multinationals, SMEs would be less likely to have a European presence and, therefore, would effectively have little choice but to appoint an OR to register their products. US Chemical Industry reported that registration and testing fees could easily exceed US $50,000 per substance; if a particular company used 50 substances in its preparations and articles, the cost could be prohibitive. In conclusion, the

[21] Minutes of the Committee on Technical Barriers to Trade Meeting, 9 November 2007, G/TBT/M/43, published on 21 January 2008, p.7.

[22] Minutes of the Committee on Technical Barriers to Trade Meeting, 9 November 2007, G/TBT/M/43, published on 21 January 2008, at p.20.

representative of the US stressed that many SMEs could not afford to re-tool, or set up separate, production lines for substances, preparations, and articles bound for the EC market.[23] Australia also shares the concerns of the US by stating that REACH would have a disproportionate impact on SMEs and that the OR provision could discriminate against non-EC companies, placing higher costs on non-EU producers and manufacturers.[24] In this regard, the US and Australia have been underlining that many SMEs were being forced to reformulate their products or stop supplying certain substances to the EC market not because the substances had been found by ECHA to pose a risk, but rather due to the expenses associated with the registration process.

Another concern regarding SMEs has been raised by the Russian Federation attending to WTO TBT Committee with an observer status. According to this concern, with regard to SIEF, it was noted that that high volume producers had to submit their registration dossiers to ECHA by the end of 2010, while smaller volume of chemical producers could submit their registration dossiers until 2018. As a result, big producers were allowed to share data and classify substances by the end of 2010, without consultations with smaller producers and that would discriminate against SMEs. [25]

[23] Minutes of the Committee on Technical Barriers to Trade Meeting, 9 November 2007, G/TBT/M/43, published on 21 January 2008 at p.21.

[24] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-6 November 2008, G/TBT/M/46, published on 23 January 2009, p.31.

[25] Minutes of the Committee on Technical Barriers to Trade Meeting, 18-19 March 2009, G/TBT/M/47, published on 5 June 2009, p.43.

Generally, regarding these concerns, the EC responds that SMEs are also a vital part of the EU chemicals industry. However, safety was a concern, regardless of company size, the REACH information requirements were related to production volumes, uses and properties of chemicals and not to the turnover or the number of employees in a company. On the other hand, the EC endeavours to make the regulation work for them (through lower registration fees for instance). According to the EC, the structure of the regulation itself (on volumes) would help SMEs as these enterprises, by their nature, produced lower volumes of chemicals, they would be required to generate less information and hence would benefit from lower cost and lower associated fees.

3.1.2 Data Sharing Concerns Through SIEFs

As mentioned in the previous section, SIEFs or formation of consortia play facilitative role to gather data, which is one of the costly elements of registration requirement of REACH. According to the system, one substance has one SIEF, which was assigned after pre-registration period and all related data regarding the substance in question are collected in SIEF data sharing pools. The first registrant of the substance becomes "lead registrant" bearing all the costs necessary to collect data for registration. Therefore, "lead registrant" gains the right to charge 50 per cent of the total cost for sharing information with relation to tests on vertebrate animals from each of the subsequent registrants upon their property rights.

According to many non-EU WTO developing countries, the system is disadvantageous for their chemical industries since "lead registrants" of substances would be most likely to reside in the EU or other developed countries. Moreover, this high amount of

charge upon their property rights would seriously restrict the production and export to the European Communities of relevant products of SMEs in developing countries.

India has been one of the countries in WTO criticizing the SIEF system in REACH sharply. According to India, by creating such bodies, which are primarily controlled and dominated by the EU domestic industry, and are beyond the control of any regulatory oversight, the EU is placing exporters particulary SMEs of developing countries at a disadvantage. Furthermore, the challenges to SMEs are not only limited to data sharing costs, there also exists other issues such as high membership fees for joining SIEFs, non-uniform rules of SIEFs, penalties for late joining, yearly maintenance fees, refusal of members to admit participants, and the prohibitive cost of letters of acceptance. [26] Furthermore, European Commission is leaving it up to the industry to organize all these cost arrangements in the SIEF therefore the absence of clear rules for the fair allocation of costs by SIEF members is another matter of concern. There exists only Article 30 of REACH, which obliges participants to share cost in a fair, transparent and non-discriminatory manner.[27]

Lastly, high numbers of SIEFs become unworkable currently. The US argued that due to the lack of clarity and transparency of REACH, many companies had decided to pre-register every chemical substance to the ECHA. As a result, there were approximately three

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[26] Minutes of the Committee on Technical Barriers to Trade Meeting, 3-4 November 2010, G/TBT/M/52, published on 10 March 2011, p.22.

[27] REACH Regulation Article 30:…Within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facili- tated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 77(2)(g). If they cannot reach such an agreement, the cost shall be shared equally.

million pre-registrants of over 140,000 substances, which was much larger than what ECHA forecasted. These large numbers of pre-registrants would make the SIEFs unworkable and extremely expensive, especially for SMEs in both developed and developing countries who in many cases would have to pick and choose which substances they would continue to produce and use since they would not be able to participate in all of the SIEFs.[28]

3.1.3 Concerns regarding the broad scope, uncertainities and frequent revision of some of REACH provisions

Most of the countries outside the EU have remained concerned about the potential adverse impact of such a complex and broad regulatory initiative on international chemical and downstream trade. As Motaal (2009) states that several WTO Members have criticized REACH for its excessively broad coverage, calling on the EU to 'prioritize' the chemicals that are of greatest concern using a risk-based approach. Criticisms have been made of the use of the 'volume threshold' as the trigger for registration, with the argument being that volume is an imperfect surrogate for risk. [29] REACH is a kind of technical regulation, which is basicly designed at the very beginning but evolved in time by extension of its scope, or interpretation and explanation of its provisions in detailed REACH Implementation Guidelines published by ECHA and EC. However, there still remain many provisions and terms used in REACH that needs precise definitions.

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[28] Minutes of the Committee on Technical Barriers to Trade Meeting, 3-4 November 2010, G/TBT/M/52, published on 10 March 2011, p.39.

[29] Doaa Abdel Motaal (2009), Reaching REACH: The Challenge for Chemicals Entering International Trade, *Journal of International Economic Law 12(3),* pp.650-651.

To exemplify the uncertainities of REACH in several provisions, it might make sense to look at some of the terms, which are difficult to define but used in "authorization" process such as "adequate control", and "socio-economic benefits" that determines authorization to be granted or not. The absence of exact explanations of these terms could result in disagreements since two similar substances undergoing the same evaluation might have different outcomes or results. Furhermore, due to this possibility for different interpretations of the terms, it could happen that substances might be withdrawn from the EU market for economic, rather than safety reasons, since the companies or manufacturers could feel that the costs outweighed the profits. As a result, ambiguous concepts could lead to arbitrary decisions when applying the regulation in practice.

Another example of the uncertainities in REACH is about registration of substances "intentionally releasing" from the article. As Motaal (2009) underlines it has been argued that it is impossible to determine with certainty the articles from which there may be 'release'. [30] The fear is that liability provisions could take effect for situations in which producers genuinely did not know about the possibility of release.

Besides these specific uncertainities as described above, in general most of TBT members seem to have concerns about the unpredictability of REACH due to its frequent evolutionary structure. Most of them have been constantly explaining the fact that REACH constituted an unnecessary barrier to trade, especially for developing countries' SME exporters due to difficulties in understanding the rules and the disproportionate, needless costs

[30] Doaa Abdel Motaal (2009), Reaching REACH: The Challenge for Chemicals Entering International Trade, *Journal of International Economic Law 12(3),* p.651.

associated with compliance. They support their arguments with the fact that the text of the REACH Regulation is extensive and complex and subject to constant revision, and that the 52 supplementary guidance documents have not improved this situation, since they are often even more extensive and again subject to multiple revisions.

As Argentina reiterated in TBT Committee Meeting held in September 2011, the lack of transparency that results from the complexity of REACH, as well as, the frequent amendments to the legislation has led to great uncertainity in non-EU countries.[31] Since it was enacted in 1st June 2007, REACH has been amended nineteen times, six modifications of which have been introduced within the past four months of 2011 and some of which are highly critical for chemical industry such as adding new substances subject to authorization or restrictions as well as adjustments in implementation time-frame. [32]

Even though the EU has been referring to its REACH explanatory guidelines trying to facilitate the understanding of REACH amendments, but as these guidelines have been

[31] Minutes of the Committee on Technical Barriers to Trade Meeting, 15-16 June 2011, G/TBT/M/54, published on 20 September 2011, p.31.

[32] REACH amendments published in EUR-Lex in 2011: Regulation no. 143/2011, which added six substances to Annex 14 of REACH, that referred to substances requiring marketing and use approval from ECHA; Corrigendum of Regulation no. 143/2011 modifying the time-frame for the procedure; Regulation No. 252/2011 modifying Annex 1 to adjust classification criteria in other provisions of Regulation 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures; Regulation 253/2011 modifying Annex 13 containing the criteria to identify the persistent bio-accumulative and toxic substances as well as very persistent and very bio-accumulative substances; Regulation No. 366/2011 modifying Annex 17 - Restrictions to the manufacturing, marketing and use of specific substances, mixtures and dangerous articles, introducing new provisions on the particular substance called aklomide; and Regulation No. 494/2011 modifying Annex 17 as well - restrictions to the manufacturing, marketing and use of specific substances, mixtures and dangerous articles, banning as from 2012, cadmium in jewellery, plastics and welding bars. (http://eur-lex.europa.eu/en/index.htm) (Last visited on 20 December 2012)

constantly updated, it is clearly seen that the exporters to the EU market faced scarce predictability and transparency in their commercial operations.

Regarding this issue, the EC only states that the frequent revision of the REACH and guidance documents were the results of the need for adding more information related to specific problems arised and questions received. [33]

3.1.4. Lack of uniform implementation of the Regulation throughout the EU

Although REACH procedures have been implemented throughout the EU since 1st June 2007, WTO members have also remained concerned regarding the uniform implementation of the Regulation thoroughout the EU.

The issue first arised in TBT Committee when some EU member states (Belgium and the Netherlands) requested pre-registration numbers of the chemicals during their importation to the EU despite the fact that REACH did not clearly stipulate such a practice. This practice has shown that there were inconsistencies in REACH implementation among different EU member states and there is a problem of treatment of pre-registration number information in customs clearance when EC member States import. The US has criticized this seeking evidence of pre-registration implementation due to two reasons in TBT Committee Meeting held in March 2009. First, given that REACH allowed six months from the date of import or first manufacture for companies to submit late pre-registrations or for ORs to add new downstream users, these actions could block legitimate trade. Second, pre-registration numbers supplied for purposes of customs clearance could be transmitted to downstream

[33] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-6 November 2008, G/TBT/M/46, published on 23 January 2009, p.37.

users, who could use them to decipher information about product formulations. Both of these potential problems would affect imports.[34]

The lack of clarity and uniformity in penalties of non-compliance with REACH among EC member states has been another matter of concern. Even though the responsibility for the formulation of penalties under REACH fell under the competences of each EU Member State, there are also some concerns on the lack of clarity on penalties for non-compliance with REACH. Chile argued in TBT Committee Meeting held in December 2009 that only Spain, Sweden, Germany and the United Kingdom provided information about the penalties of non-compliance with REACH and urged the EC to clarify what were the penalties for non-compliance with REACH.[35] Regarding the problems that might be derived from the lack of uniformity in sanctions, Mexico also expressed its concern through bringing to the attention of the TBT Committee a recently approved French law, which established criminal and monetary sanctions for non-compliance with REACH. Furthermore, Mexico stated that those sanctions were far too high and were not consistent with WTO provisions.[36]

Besides those concerns, different interpretation of REACH provisions across the EC member States is another issue that is brought to the attention of TBT Committee by the US by exemplifying the issue that the ECHA guidance on "notification obligations for substances

[34] Minutes of the Committee on Technical Barriers to Trade Meeting, 18-19 March 2009, G/TBT/M/47, published on 5 June 2009, p. 40.

[35] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-6 November 2009, G/TBT/M/49, published on 22 December 2009, p.15.

[36] Minutes of the Committee on Technical Barriers to Trade Meeting, 18-19 March 2009, G/TBT/M/47, published on 5 June 2009, p. 39.

in articles" noted that producers needed to check with each member State regarding how it would interpret the notification obligations.[37]

Finally, same problems are likely to arise in relation to the evaluation process, and it is commonly stated that there could be inconsistencies from one EU member state to another, since member states needed to carry out their own evaluation.

Regarding the issue of inconsistent application by EC member States, which could lead to uncertainty and trade barriers, EC has been emphasizing that since the legal instrument chosen as a Regulation, it would be directly applicable in Members States applied uniformly throughout the European Communities. Furthermore, ECHA had been given the power to take decisions in certain cases, and to ensure consistency, particularly in the registration and evaluation elements of REACH. The Agency would also have a forum for exchange of information on enforcement where Members States could discuss these issues. In order to promote consistent interpretation of REACH, guidance for authorities would be provided and an appeal would be possible both to the Agency and to the European Court of Justice (ECJ), which is the only institution that has the competence to provide a definitive interpretation of its provisions. As a result, the EC strongly believes that REACH would improve consistency of enforcement within the European Union and facilitate trade flows.[38]

[37] *Ibid*, at p.40.

[38] Minutes of the Committee on Technical Barriers to Trade Meeting 1-2 July 2008, G/TBT/M/45, published on 9 September 2008, p.11.

3.1.5 Concerns Regarding Substitution System and Authorization List

One of the most debated parts of REACH is the authorization or restriction requirement for certain chemicals. The main purpose behind that is to substitute them gradually in time after the placing substances on the authorization candidate list (known as black list).

Regarding the concern, the US noted that the ECHA was expected to issue a candidate list of those substances that would be subject to authorization on account of them potentially being SVHC. However, the US has been concerned that this list was hazard-based, where substances would be placed on the candidate list without evidence that the substances posed 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. Moreover, it was pointed out that the evaluation of all the chemicals on the candidate list could take decades, and that the status of such chemicals would remain uncertain for the foreseeable future. In light of the significant additional reporting requirements associated with using substances subject to authorization and the potential restrictions on their use, many companies believed the candidate list of substances for authorization would be used as a "black list," causing companies to discontinue using substances on the list before the ECHA had evaluated the information necessary to determine whether the substance posed a risk. If purchasers demanded products free of candidate list substances, product suppliers could find themselves

obliged to undertake costly reformulations, despite the lack of scientific evidence justifying such a change. [39]

Regarding substitution, EC has been underlining that REACH encouraged the substitution of dangerous substances. This was particularly relevant to: CMRs Categories 1 and 2, PBTs, vPvB and Substances of equivalent concern (on a case-by-case basis, e.g. hormone disturbing substances). Progressive substitution was, in the view of the EC, a proportionate measure to protect health and environment if the risk could not be adequately controlled and a suitable alternative existed.

Regarding authorization, it was generally stressed by the EC that the authorisation system would only address substances of very high concern and, in this sense, the system was built to prioritize according to the likelihood of risk: substances with the greatest potential exposures and being produced in high volumes had to be registered earlier. Moreover, the authorisation system would be tailored to apply to the highly hazardous substance, for instance with respect to substances already known to be carcinogenic, mutagenic or toxic to reproduction (CMRs).

As a result, it seems that the authorisation system was seen as both risk-based and proportional because of the two ways in which an authorisation could be obtained. First, authorisations could be granted if the applicant was able to demonstrate adequate control of risks. Second, authorisation could also be granted if there was no alternative substance or technology (even if the risks were not adequately controlled) and socio-economic benefits

[39] Minutes of the Committee on Technical Barriers to Trade Meeting, 18-19 March 2009, G/TBT/M/47, published on 5 June 2009, at p.42.

outweighed the risks. The system also took into account risks of alternative substances and research activities considered. Moreover, it was pointed out that the authorisation would be associated with a review period based on substitution plans.

3.2. Legal Concerns Expressed Under TBT Committee

Considering the increasing concerns of non-EU WTO members at TBT Committee and the significance of maintaining their competitiveness in the EU market, some implementations of REACH are likely to be challenged legally under WTO Dispute Settlement Mechanism (DSM).

If REACH is to be subject to DSM, recalling the Appellate Body's interpretation of "technical regulation" in *EC-Asbestos case,* REACH is likely to fall under the category of a "technical regulation" since it lays down the product charactheristics and their related processes and production methods for an identifiable group of products. Furthermore, compliance to these rules set in REACH Regulation is mandatory. [40] Finally, the process of evaluating technical dossiers submitted with registration applications by ECHA is likely to be an example of a conformity assessment procedure (CAP) within the meaning of the TBT Agreement. Consistent with the definition of CAP, evaluation of dossiers determines whether the REACH requirements for registration have been fulfilled.

[40] EC-Measures Affecting Asbestos and Asbestos Containing Products, Appellate Body Report, WT/DS135/AB/R, 12 March 2001, at para. 67-70.

First, as Palmer (2004) noted that under WTO rules, the EU is entitled to have chosen a high level of protection for its people and the environment from harm caused by industrial chemicals. Considering the Panel and Appellate Body Reports of previous cases such as *Gasoline, Hormones, Salmon* and *Asbestos* cases, the EU's chosen level of protection cannot be challenged under the TBT Agreement or the GATT.[41] In other words, every WTO member is free to determine the level of protection of its human health or environment.

However, there still exist some main concerns that might be examined legally under some of TBT provisions as follows:

3.2.1. REACH Rules Conflicting with TBT Article 2.1.

The first specific concern regarding REACH is that its possible violation of "national treatment rule" under TBT Article 2.1. As a provision, which merges WTO non-discrimination principles (MFN and national treatment) into TBT Agreement, Article 2.1 reads as *"Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country."*[42]

[41] Alice Palmer, *"REACH and 'Proportionality' under WTO rules"* Briefing for WWF, FIELD, June 2004, p.5.

[42] There exist different interpretations regarding the relationship between TBT Article 2.1 and GATT Article III:4. According to some, even though TBT Article 2.1 might look like GATT Article III:4 at the first sight, there are some main differences. The major ones are: 1-) The scope of "*like product*" under TBT Article 2.1 is interpreted narrower than the one under GATT Article III:4 in which "accordion approach" is applied. 2-) There is no emphasis on TBT Article 2.1 "so as to protect domestic industry" while there is a strong emphasis on it in Article III:4 of the GATT. (For further explanations, see Andrew Guzman and Joost Pauwelyn (2009) International Trade Law, Aspen Publishers Kluwer Law International, p.533.)

3.2.1.a Concerns under TBT Article 2.1.

According to those concerns related with TBT Article 2.1, although the requirements of the REACH are designed to be applied to both EU and non-EU producers and thus non-discriminatory legally *(de jure)*, it could still be discriminatory in practice *(de facto*), as non-EU producers and suppliers would face greater difficulties in complying with the complex requirements as compared to their EU counterparts.

In fact, there have been some specific examples given to support this "discrimination" argument. As a net importer country to the EU, Australia stated in TBT Committee Meeting held in June 2005, by referring to Article 2.1 of the TBT Agreement, that although the REACH legislation required registration of chemical products regardless of origin, the fact that substances already registered in the European Communities were not required to be re-registered when bought by a downstream producer in the European Communities was likely to put imported products at a competitive disadvantage. EU producers that used chemical substances were more likely to source substances that had already been registered from within the European Communities, rather than to source the substance from outside the European

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However, in the last *US- Clove Cigarettes* AB Report, the interpretation of TBT Article 2.1 by considering contextual elements of GATT Article III:4 was underlined. According to para.100 of the AB Report:

"The national treatment obligations of Article 2.1 and Article III:4 are built around the same core terms, namely, "like products" and "treatment no less favourable". We further note that technical regulations are in principle subject not only to Article 2.1 of the *TBT Agreement*, but also to the national treatment obligation of Article III:4 of the GATT 1994, as "laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use" of products. The very similar formulation of the provisions, and the overlap in their scope of application in respect of technical regulations, confirm that Article III:4 of the GATT 1994 is relevant context for the interpretation of the national treatment obligation of Article 2.1 of the *TBT Agreement*. We consider that, in interpreting Article 2.1 of the TBT Agreement, a panel should focus on the text of Article 2.1, read in the context of the TBT Agreement, including its preamble, and also consider other contextual elements, such as Article III:4 of the GATT 1994."

Communities. This raised concerns as to whether the European Communities was acting consistently with its national treatment obligation under the TBT Agreement.[43]

Another example of the discriminatory implementation of REACH was raised by Korea in TBT Committee Meeting held in July 2007, by stating that it would be more difficult for non-EU manufacturers to comply REACH than for EU manufacturers especially in the case of producers of articles and manufacturers of polymers. According to REACH, even though the manufacturers outside Europe registered the basic substances, non-EU manufacturers in the same supply chain were also responsible for the registration of that substance, whereas EU manufacturers in the same supply chain did not have any responsibility for registration. [44] There seems to be an extra registration burden for non-EU manufacturers in the same supply chain while this is not applied to EU manufacturers in the same supply chain.

In line with the concern of Korea above mentioned, regarding the registration of monomers in polymers, which has been discussed frequently in TBT platform, Japan has also raised its concern in TBT Committee Meeting held in March 2008. Under REACH, an importer of polymers into the European Communities was requested to register the constituent monomers of the polymers from outside the European Communities. According to Japan, in such cases, there could be problems related to possible leakage of data to manufacturing competitors. In contrast, in the European Communities, the monomers were

[43] Minutes of the Committee on Technical Barriers to Trade Meeting 16-17 June 2005, G/TBT/M/36, published in 4 August 2005, p.4.

[44] Minutes of the Committee on Technical Barriers to Trade Meeting 5 July 2007, G/TBT/M/42, published on 6 August 2007, p.15-16.

registered directly by the monomer producers and the polymers manufacturers in the European Communities were not requested to register the composite of monomers. Therefore, information on their composition did not have to be shared with competitors. As Japan was concerned, this difference in the registration process could lead to a disadvantage for polymer manufacturers outside the European Communities.[45]

Regarding all these technically detailed specific concerns, the EC has responded generally by stating that the revised REACH proposal is fully compatible with Article 2.1 of the TBT Agreement, as products are treated the same way and REACH applied equally to EU and non-EU-producers. EC also reiterates that most WTO Members has also some national legislation in place with respect to risks of chemicals to health and safety, which non-national manufacturers including the ones in the EU had to comply with.

Besides some technical discriminatory treatment to the advantage of the EU manufacturers and importers in REACH, there also exist different effects of REACH on non-EU producers in terms of increasing their costs while decreasing their competitiveness. As underlined in the previous section, REACH has a wide coverage and a horizontal structure, which involved more than 30,000 chemical products and relevant downstream products. Considering that procedures of registration, evaluation and authorization were complex, burdensome and costly, the import and export cost of many non-EU enterprises would inevitably rise and that might result in some products becoming uneconomic to produce and hence being withdrawn from the EU market, most probably by Small and Medium Sized

[45] Minutes of the Committee on Technical Barriers to Trade Meeting 20 March 2008, G/TBT/M/44, published on 10 June 2008, p.25.

Enterprises (SMEs) exporting products of big volume, but of a low value in developing countries.[46]

Perhaps the most costly and disadvantageous part of REACH in terms of competitiveness for non-EU manufacturers is that under REACH the registration of their substances can only be made by their "Importers" or "Only Representatives" (hereafter ORs) which both have to be established in the EU territory. The main disadvantage behind the selection of "importer" option for the non-EU based suppliers has been raised as the disclosure of chemical formulations for purposes of registration that might lead to some problems regarding the protection of their intellectual property rights. Another disadvantage of this option was raised by the US in TBT Committee Meeting held in March 2008, that a non-EU manufacturer relied on multiple EU importers to export its substance to the EU market, each importer had to separately register the substance, while companies established in the EU could register substances on their own which would create a discriminatory benefit to EU producers. [47]

While designing REACH, most probably considering the side effects of registration via "importer", the EU created another option for the non-EU manufacturers, which is known as the appointment of ORs to register their substances on behalf of non-EU companies. However, as the US and other non-EU countries have been highlighting that according to their chemical industry, the benefit of the ORs provision was undermined on account of its

[46] The specific effects of REACH on SMEs are discussed in detail further.

[47] Minutes of the Committee on Technical Barriers to Trade Meeting 20 March 2008, G/TBT/M/44, published on 10 June 2008, at p. 22.

potential to disrupt global supply chains, especially SMEs within those supply chains, and to allow for potentially discriminatory treatment between EU and non-EU member state actors.[48]

Of particular concern was also the confidentiality of registration documents submitted by manufacturers located in third countries to their ORs located in the EU. However, EC has been avoiding deliberately for providing a list of "ORs" registered or accredited in the European Communities that had received adequate training in confidentiality, or monitoring their operations so as to ensure that confidential documents were duly protected during the registration process. EU seems not to be involved in any type of interactions between non-EU producers and ORs by declaring that appointment of an OR was purely voluntary and the relation between the entity and the OR itself was not governed by REACH and thus "the relation between these entities was contractual in nature and subject to private law".[49]

Another concern that has come true after the implementation of REACH in 2008 was that the extra burden of OR fees on non-EU suppliers which were at the beginning was extremely high since there was no market price set for this new and unknown "service" in the EU. For most of the developing countries and their SMEs, the costs associated with the appointment of an OR have substantially increased the costs of exporting to the EU market. Although, the EU has been stating that OR is just one of the options for the non-EU producers, due to the disadvantages of registration via importer outweighs the one via OR, the main trend among non-EU countries has been the selection of the OR option.

[48] Minutes of the Committee on Technical Barriers to Trade Meeting 20 March 2008, G/TBT/M/44, published on 10 June 2008, p.23

[49] Minutes of the Committee on Technical Barriers to Trade Meeting 24-25 March 2010, G/TBT/M/50, published on 28 May 2010, p.16.

In addition to the aforementioned concerns regarding OR, there had been uncertainities regarding the functioning of the mechanism. For instance, there is no provision in REACH explaining whether non-EC manufacturers could continue their exportation using the information and data already submitted even once their OR designated would go bankrupt. With regard to questions on the possibility of changing the OR, the EC noted that a transfer of the registration would be possible by submitting an update of the earlier dossier and stated that the former OR would have to agree with the change and that it would therefore be advisable that these aspects were covered in the private arrangements between the non-EU manufacturer and the OR.[50]

In addition to "only representative" fee concern, another problem for non-EU manufacturers is that the costs of all tests that the registration process required were listed in Euro; this has been also found clearly disadvantageous for third country producers whose national currencies are less valuable than the Euro. Lastly, European Communities had set up several Help Desks within the EU Member States functioning with the direct cooperation of ECHA to grant technical assistance to the EU chemical industry. Based on the principle of national treatment, some developing countries such as Chinese Taipei requested that the Commission provide similar arrangements to other WTO Members so as to enable these Members to respond to problems in a timely and efficient manner since otherwise this seems to be discriminatory approach against non-EU manufacturers. [51] Regarding the request to

[50] Minutes of the Committee on Technical Barriers to Trade Meeting 24-25 March 2010, G/TBT/M/50, published on 28 May 2010.

[51] Minutes of the Committee on Technical Barriers to Trade Meeting 9 November 2007, G/TBT/M/43, published on 21 January 2008, p.8.

have REACH Help Desks in third-countries, the EC representative took note of the request made in TBT Committee Meeting held in November 2007 but no steps have been taken in this manner yet.

3.2.1.b. Analysis of the Concerns under TBT Article 2.1.

Considering the concerns mentioned above in detail, most probably, the first and the main concern that is likely to be challenged under Article 2.1 is to lay down whether REACH discriminates between imported and domestic (manufactured in the EU) "*like*" chemicals. Before discussing the determination of likeness under TBT, it is reasonable to underline that the REACH regulation applies equally to all "*like"* products, whether domestic or imported *prima facie*.

As Harrell (2006) states that REACH will result in increased costs for the chemical industry worldwide and manufacturers from all countries must meet the same requirements and submit the same types of data for approval of their products and recalls the Appellate Body has previously indicated that regulations that result in burdens shared equally across national lines will not violate the national treatment requirement. [52] In fact, in the *Gasoline* case, the import requirements were found to be discriminatory, but the Appellate Body noted that the discrimination could have been avoided by "imposing a uniform statutory baseline on refiners and importers alike."[53] From this perspective, REACH, therefore, might not be found in conflict with the national treatment requirement under TBT Agreement *prima facie*.

[52] Sarah, Harrell (2006), "Beyond REACH? An Analysis of the European Union's Chemicals Regulation Program Under World Trade Organization Agreements" *Wisconsin International Law Journal,* p. 511.

[53] Appellate Body Report on "United States - Standards for Reformulated and Conventional Gasoline"

However, that does not change the existence of discriminatoy effects of some REACH provisions, which supports the concerns over infringement of non-discrimination principle. As Bronckers and Charro (2005) underlines that the language of these provisions are neutral, and they do not discriminate *de jure* against imported like substances, however the indirect effects of REACH on imported like products *de facto* should be taken account during the analysis. [54] In fact, this type of argument brought to Dispute Settlement Body through *Chile-Taxes on Alcoholic Beverages* case. In this case, tax rates depending on alcoholic content applied for both domestic and imported products. Thus, at the first stage, the technical legislation seemed to be in line with non-disrimination principle. However, the tax rates increased steeply, not proportionally, for the alcoholic drinks having high alcoholic content, which clearly hit the imported alcoholic drinks since they had high alcohol content mostly. Since domestic and imported products were found comparable, the tax rate scheme was found to be in violation with national treatment principle.[55]

The argument stating that not only *de jure* but also *de facto* discrimination of any technical regulation should be taken into account in its compatibility analysis under TBT Article 2.1, might be supported by the statement of Ehring (2002) underlining that even though there is no legal discrimination, "any asymmetry in practice between the treatment of domestic and imported substances could still amount to a violation of national treatment

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WT/DS2/AB/R 29 April 1996 p.25.

[54] Marco, Bronckers and Pablo, Charro (2005) "REACH Reviewed under WTO Law", *Journal for European Environmental and Planning Law*, Vol.2 Issue:3, p.187.

[55] Appellate Body Report on "Chile - Taxes on Alcoholic Beverages" WT/DS87.110/AB/R 1999.

principle."[56] Hence, considering some of its special requirements set for non-EU countries during the factual implementation, REACH is more likely to be subject to TBT Article 2.1 because of its infringement of *de facto* discrimination criteria.

In fact, there are some inevitable results deriving from the implementation of REACH provisions leading to adverse and discriminatory effects for non-EU WTO members. As mentioned in the previous sub-section in detail; asymmetric implementations in the registration of the "like" chemicals in the same supply chain depending on their origin, problems deriving from registration of chemicals only through importer or OR for non-EU chemicals, both formation and flow of information in SIEFs to the advantage of EU producers as well as absence of any dispute settlement mechanism for non-EU states etc. are likely to be challenged under TBT Article 2.1 due to their *de facto* competition distorting effects .

Leaving all these broader potential legal interpretations aside, turning back to the determination of "likeness" of products under TBT would make sense to analyse the issue more in depth. Thus, when REACH is subject to DSM based on its violation of TBT Article 2.1, the first thing to be analyzed is whether the chemical products in question are "like products".

According to some interpretations in the academia, one of the things that differentiates TBT Article 2.1 from GATT Article III:4 is that the interpretation of "likeness" in TBT is narrower than the one in GATT. As Marceau and Trachtman (2002) noted since justifications under GATT Article XX are not available to violations of TBT Article 2.1, the scope of "like products" is not the same as that under GATT Article III:4. As they claimed, "the sixth

[56] Ehring, Lothar (2002): "De *Facto* Discrimination in World Trade Law: National and Most- Favoured-Nation Treatment-or Equal Treatment", *Journal of World Trade.* 36, p. 921-977.

preambular paragraph of TBT Agreement [57] combined with the necessity requirement of Article 2.2 [(to be discussed in detail further)] may suggest that a narrow interpretation of like products is appropriate in the context of Article 2.1"[58] In other words, the absence of GATT Article XX-type exception is the main reason behind the interpretation of Article 2.1 more narrowly than GATT Article III:4.

This argument might be supported by considering the fact that even in *Asbestos case* which was analyzed under GATT III:4, the interpretation of "likeness" of asbestos and alternative fibers by the Appellate Body was so narrow. Appellate Body recalled four classic criteria derived from *Border Tax Adjustment* case. [59] However, in the *Asbestos case*, Appellate Body stated that these criteria do not exhaust inquiry.[60] Other closely related factors or evidence were taken into consideration in this case such as health risks of these two substances which was used to determine that those products are not "like products".

From this "narrow interpretation of likeness" perspective, it would be reasonable to presume that any inquiry of "like products" under TBT Article 2.1 is to take into account all

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[57] TBT Agreement 6th paragraph of the Preamble: *Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;*

[58] Gabrielle Marceau and Joel P. Trachtman (2002), "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tairffs and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods", *Journal of World Trade* 36(5): p.822.

[59] See Working Party Report, Border Tax Adjustments, adopted 2 December 1970, BISD 18s/97. These criteria are set as (i) physical properties of the products in question; (ii) their end-uses, (iii) consumer taste and habits vis-à-vis those products (iv) tariff classification.

[60] Appellate Body Report, *EC –Asbestos*, WT/DS135/AB/R, at para 101.

related factors in a more stringent manner than the one in *Asbestos Case,* which was analyzed under GATT Article III:4. For the REACH case, to determine the likeness of two chemicals, which one is domestically produced in the EU and the other is imported, the Panel would not only take into account the traditional likeness criteria, but also examine in detail other evidences or factors such as their health risks which might be proved by scientific studies or their competitiveness or substitutability. Thus, the probability of the likeness of these two chemicals in question found under TBT Article 2.1 seems to be less than the one that can be found under GATT Article III:4 since there is no exhaustive list set of these related factors used in likeness determination under TBT.

In fact, the Appellate Body report on *US-Clove Cigarettes* has brought new dimension to the determination of likeness issue under TBT Article 2.1. In its interpretation, it is remarkable that GATT Article III:4 and its contextual elements are taken into account substantially for the interpretation of TBT Article 2.1. In this case, the Appellate Body considered that the determination whether products are "like" within the meaning of TBT Article 2.1 is a determination about the competitive relationship between the products based on an analysis of traditional "likeness criteria", namely, physical charactheristics, end-uses, consumer tastes and habits and tariff classification. The Appellate Body also considers that the regulatory concerns underlying a measure such as health risks associated with a given product [as it was in *Asbestos Case*] may be relevant to an analysis of the "likeness" criteria under

GATT Article III:4, as well as under TBT Article 2.1, to the extent they have an impact on the competitive relationship between and among the products concerned. [61]

This recent interpretation of "likeness" blended with "competitiveness" notion in DSM might put the EU into trouble in terms of defending its possible arguments that the chemicals are not "like" so as to prove that REACH is non-discriminatory under TBT Article 2.1. Without leaving aside some implementations of REACH putting non-EU producer's chemicals in disadvantage position in terms of competition as discussed above, it is more likely that would be an issue especially under REACH's authorization or restriction of chemicals.

As it was described in the previous sections, REACH promotes the substitution of SVHC chemicals by authorization or restriction mechanism based on their risk assessment results. However, even a chemical is found as SVHC, REACH might only allow the use of these chemicals as long as they are "adequately controlled" or their "socio-economic benefits outweigh their risks". These vague wording in REACH reflects the subjectivity of the perception in the EU regarding a chemical, which is proved scientifically to be risky.

Before the release of the interpretation of likeness in *US-Clove Cigarettes,* regulatory concerns lying under any technical measure such as health risks were accepted as sufficient including four traditional likeness criteria to determine the likeness of the products concerned as it was in *EC-Asbestos*. Therefore, in such a challenge under TBT Article 2.1, the EU was likely to manipulate the decision of "likeness" of the Panel by underlying differing health risks of two chemicals by using its subjective definitions of risk to prove that these chemicals are not "like"

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[61] Appellate Body Report on "US- Measures Affecting the Production and Sale of Clove Cigarettes" WT/DS406/AB/R, at paras. 111, 119, 120 and 136.

chemicals so as to avoid from any violation of TBT Article 2.1. However, with the recent interpretation of the Appellate Body in *US-Clove Cigarettes,* the regulatory concerns of the EU under REACH might be taken into account to the extent it affects the competitiveness of these two chemicals (one produced in the EU, one in abroad) in the EU market. Thus, only by underlying the health risks of non-EU produced chemical, which is subject to different treatment, is not sufficient if there exists a competitive relationship among them. Proving the lack of competitive relationship between two chemicals seems more difficult than verifying the regulatory concerns that leads to differential treatment under REACH.

Even the likeness is determined under TBT Article 2.1; another criterion has to be met which is the proof of the existence of "less favorable treatment." As it was stated in Marceau and Trachtman (2002) by referring *Korea-Various Measures on Beef* case, "a formal difference in treatment between imported and like domestic products is thus neither necessary, nor sufficient, to show a violation of [GATT] Article III:4." As they state that "less favorable treatment" decision might be given based on the probability of the detrimental and modifying effect of the measure in question in terms of competition to the disadvantage of imported like product.[62]

In fact, the recent Appellate Body Report on *US-Clove Cigarettes* also confirmed similar approach regarding the interpretation of "less favorable treatment" by taking into account previous findings of the Appellate Body in the context of GATT Article III:4 which are

[62] Gabrielle Marceau and Joel P. Trachtman (2002), "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tairffs and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods", *Journal of World Trade* 36(5): p.820-821.

found to be "instructive in assessing the meaning of less favorable [treatment]".[63] In this case, Appellate Body clearly states that "…where the technical regulation at issue does not *de jure* discriminate against imports, the existence of a detrimental impact on competitive opportunities for the group of imported vis-à-vis the group of domestic like products is not dispositive of less favourable treatment under Article 2.1." By clearly underlining the significant role of "detrimental impact" in "less favorable treatment" analysis, the Appellate Body notes that "…a panel must further analyze whether the detrimental impact on imports stems exclusively from a legitimate regulatory distinction rather than reflecting discrimination against the group of imported products. In determining whether a measure has detrimental impact on imports constitutes less favorable treatment, a panel must carefully scrutinize the particular circumstances of the case, that is, the design, architecture, revealing structure, operation, and application of the technical regulation at issue, and, in particular, whether that technical regulation is even-handed, in order to determine whether it discriminates against the group of imported products."[64]

The similar approach might be applied under TBT Article 2.1 in terms of REACH. Instead of proving differential treatment of two "like" chemicals, it would make sense to prove to what extent this differential treatment leads to any deterioritation in the competition power of the like imported chemical in the EU market. Under such an analysis, a Panel might consider the discriminatory and competitive distorting design and application of REACH. Thus, based

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63 Appellate Body Report on "US- Measures Affecting the Production and Sale of Clove Cigarettes" WT/DS406/AB/R, at para 180.

64 See Appellate Body Report on "US- Measures Affecting the Production and Sale of Clove Cigarettes" WT/DS406/AB/R, at para 182.

on this interpretation of less favorable treatment, some implementations of REACH such as registration of non-EU chemicals via impoter or OR or their disadvantaged position in SIEFs might be found as having detrimental impact on competitive opportunities for domestic and imported like chemicals.

Finally, even though it has been rejected by the WTO Appellate Body in *Japan-Alcoholic Beverages* case[65] and it is not mentioned among the three elements required for violation of the national treatment obligation under TBT Article 2.1 in the recent *US- Clove Cigarettes*,[66] even if both like product and less favorable treatment requirements are proved, the Panel might also use "aim and effect test" to some extent while determining the violation of TBT Article 2.1. As Hudec (1998) notes that "Although it is true that the aim of a measure may not be easily ascertained, nevertheless its protective application can most often be discerned from the design, the architecture, and the revealing structure of a measure".[67] According to that approach, if the impact of any REACH implementation to like foreign product is proved to be more detrimental than the legitimacy of its aim, which is high level of protection of human health and environment, than it is more likely to prove the violation of REACH under Article 2.1. Here it is reasonable to state that the power of REACH in such a challenge under TBT Article 2.1 derives from the legitimacy of its aim. To sum up, even all the criteria of the

[65] See Appellate Body Report, Japan-Alcoholc Beverages II, WT/DS8/AB/R at p.27.

[66] Appellate Body Report on "US- Measures Affecting the Production and Sale of Clove Cigarettes" WT/DS406/AB/R, at para 87.

[67] Robert E. Hudec (1998) GATT/ WTO Constraints on National Regulation: Requiem for An Aims and Effects Test, 32 *International Lawyer*, p. 619.

violation are met, when the measure is subject to "aim-and-effect test", it would be highly challenging to prove that REACH implementation precisely violates Article 2.1.

3.2.2. REACH Rules Conflicting with TBT Article 2.2.

Another significant concern that might be challenged legally under TBT is that REACH is found to be more trade restrictive than necessary by many WTO member countries, which is related with TBT Article 2.2 requiring that members must 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"* and that *"technical regulations…not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create."* It also provides "*a non-exhaustive list of legitimate objectives for which technical measures may be enacted such as national security, prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment."* Another non-exhaustive list is also provided for the assessment of risks deriving from non-fulfillment of the measure such as available scientific and technical information, related processing technology or intended end-uses of products.

3.2.2.a Concerns under TBT Article 2.2.

REACH is accepted as the most comprehensive legislation regarding chemicals since the scope of registration is wider than the systems of other countries' chemical management regulations, including Canada and Japan. Thus, registration of all chemicals exceeding 1 ton/per year has the risk potential of becoming an excessive burden for importers of chemicals.

Most of the countries that would be affected adversely from the system due to its volume-based approach instead of the one only based on risk since some countries have been providing chemicals to the EU market in high volumes with low risks. Considering the legitimate objectives pursued under REACH, most countries in WTO criticized REACH as being more trade restrictive than necessary since it is designed upon a volume-based approach and it did not focus on substances that presented the greatest risk. Furthermore, due to its volume-based approach, REACH has brought extra transaction costs for the exporters outside the EU. Additionally, the same product is required to be registered separately for each of its specific use. Considering the structure and the different compositions of the complex chemicals, that seems to become highly repetitive and bureaucratic.

On behalf of APEC countries, Japan raised its concerns regarding the infringement of TBT Article 2.2 at TBT Committee Meeting in November 2006. Japan's concern was about the registration of reacted monomers in polymers, which did not harm the environment while the polymers were exempted from registration. According to Japan, the obligation to register the reacted monomers in polymers was not appropriate and might not be in line with Article 2.2 of the TBT Agreement. A simple notification might be required if the ECHA needed to understand the material composition of polymers for reference. [68] However, EC responded that two principles had been used in this area. First, polymers were exempted from registration. Second, monomers had to be registered because even though they reacted fully to create polymers, free monomers and oligomers would be left creating the hazard profile of

[68] Minutes of the Committee on Technical Barriers to Trade Meeting, 9 November 2006, G/TBT/M/40, published on 26 January 2007, p.11.

polymers. It was pointed out that many oligomers were bioavailable and posed a risk. Monomers would be used to assess the risks of polymers.[69]

Besides these scope of registration concerns, some countries such as Mexico had raised its concerns that the requirement of an OR was contrary to the provisions of the TBT Agreement. In fact Mexico has been noting that it would be possible to find alternative systems to ORs by having the EC conduct inspections extra-territorially, in the exporting country instead, so that exporters would then be able to register the chemicals by themselves.[70] However, on the proposal of inspections outside the EC territory, the representative of the European Communities stated that such a provision would be in violation of basic principles of international law since the EC could only impose its laws in territories under its jurisdiction.[71] Lastly, considering the burdensome procedures that are required to find and establish an OR, many non-EU countries emphasized that would lead European importers to begin sourcing their inputs domestically instead.

Regarding all these concerns in general, EC has been responding that the revised REACH proposal is fully compatible with Article 2.2 of the TBT Agreement and REACH is not overly restrictive, as taking into account the objectives which are pursued by REACH: a high protection of the consumer, of human health and life, and of the environment. Furthermore, the EC states that individual registrations were necessary and that, as designed,

[69] Minutes of the Committee on Technical Barriers to Trade Meeting, 9 November 2006, G/TBT/M/40, published on 26 January 2007, p.16.

[70] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-6 November 2008, G/TBT/M/46, published on 23 January 2009, p.32.

[71] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-6 November 2008, G/TBT/M/46, published on 23 January 2009, p.35.

the authorization procedures were limited in scope, workable, and that the decision were taken based on risk.

3.2.2.b. Analysis of the Concerns under TBT Article 2.2.

When REACH is subject to TBT Article 2.2, the analysis would begin with the proof of the legitimacy of the REACH's objectives, one of which is ensuring a high level of health and environmental protection through the application of the precautionary principle. As it is noted in Appellate Body Report in *EC- Asbestos Case,* "it is undisputed that WTO members have the right to determine the level of protection of health that they consider appropriate in a given situation." [72] In this manner, the objective of REACH is in line with the legitimate objective rule under TBT Article 2.2.

After ensuring the legitimacy of the REACH's objective, it would be essential to examine whether any REACH requirement in question creates an unnecessary obstacle to international trade and be more trade restrictive than necessary to reach its legitimate objective. Thus, a "necessity test" should be applied to the measure so as to lay down the "proportionality" between measure and its objective. The test is also significant for the search of "least trade restrictive alternatives" of REACH rather than its requirements.

During the analysis, first of all, one should take into account that "the necesity test" to be applied under TBT Article 2.2 is different than the one applied under GATT Article XX(b) because the one to be conducted under TBT is also based upon "risks of non-fulfilment"

[72] Appellate Body Report on *EC- measures Affecting Asbestos and Asbestos- Conaining Products,* WT/DS135/AB/R, adopted on12 March 2001, para 168.

criteria which is not available in analysis under GATT. [73] Under TBT, "risks of non-fulfilment" of the measure determines whether the measure is an unnecessary obstacle to trade and more trade restrictive than necessary or not. Thus, for instance, if the non-fulfillment of any REACH measure, non-registration or non-authorization of a chemical, creates risks for human health and environment protection and that can be proven by an available scientific and technical information, whether it reflects the majority's scientific opinion or not, then the measure in question is likely to be adopted as "necessary" and not creating unnecessary obstacle to trade by being more trade restrictive than necessary.

As Marceau and Trachtman (2002) affirms while applying "proportionality" test under TBT 2.2 on the basis of "risks of non-fulfilment", it is reasonable to expect that "the magnitude and probability of risk become relevant."[74] Indeed, in *Hormones case*, the WTO's Appellate Body has affirmed the need to take into account the magnitude of "risks of non-fulfilment" issue by stating "that responsible, representative governments should commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned."[75] Thus, as Palmer (2004) states that "it is reasonable to conclude that it is 'the actual potential for adverse effects on human health in

[73] One of the most critical provisions of the GATT regarding REACH is Article XX (b) related with general exceptions through which measures prohibited can still be justified. *Article XX(b) reads with chapeau:* "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:….(b): necessary to protect human, animal or plant life or health;…"

[74] Gabrielle Marceau and Joel P. Trachtman (2002), "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tairffs and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods", *Journal of World Trade* 36(5): p. 831.

[75] Appellate Body Report on *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R WT/DS48/AB/R, adopted on 16 January 1998, para 124.

the real world where people live and work and die' that should be taken into account in assessing the risk addressed by REACH". [76] Hence, under TBT analysis, it is not only enough to lay down the risks of non-fulfillment but it must also indicate the likelihood of risks to be occurred and their predatory impact. As might be seen, the analysis of the availability of risks under TBT Article 2.2 is quite strict and the more probable and predatory of the risks of non-fulfillment, the more it is found to be legitimate and necessary.

Besides "risks of non-fulfillment" approach, it is also likely that Panel might take into account the interpretation criteria of "necessity" under GATT XX(b). As Palmer (2004) states, by referring to various cases held in WTO, even though GATT and the TBT Agreement are separate agreements expressing similar rules in different ways, "it is, however, likely that the provisions in both Agreements would be interpreted 'harmoniously', with a view to avoiding any conflict between them.[77] Thus, in the absence of any guidance on how TBT Article 2.2 should be interpreted, it is also likely assume that "the necessity" under TBT Article 2.2 would be read in a manner consistent with the term 'necessary' under GATT Article XX (b) without excluding its specific "risks of non-fullfilment" criteria. Marceau and Trachtman (2002) also affirm that "the risk of non-fulfillment can also be viewed as part of the analysis

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[76] Alice Palmer, *"REACH and 'Proportionality' under WTO rules"* Briefing for WWF, FIELD, June 2004, p.6.

[77] Alice Palmer, *"REACH and 'Proportionality' under WTO rules"* Briefing for WWF, FIELD, June 2004, p.15.

Also see *See Korea - Definitive Safeguard Measure on Imports of Certain Dairy Products,* Appellate Body Report para 81, WT/DS98/AB/R, adopted on 12 January 2000; *Gasoline* p. 23 on 'principle of effective treaty interpretation'. *See* also *Indonesia – Certain Measures Affecting the Automobile Industry,* Report of the Panel adopted 23 July 1998, WT/DS54/R; WT/DS55/R; WT/DS59/R; WT/DS64/R para 14.28 and *Turkey - Restrictions on Imports of Textile and Clothing Products,* Panel Report paras 9.92 ff, WT/DS34/R, Panel Report and Appellate Body Report adopted on 19 November 1999 re 'presumption against conflict'.

of two of the [balancing test] criteria: the importance of the values and policies protected by the measure and the extent to which a specific measure contributes to the end pursued."[78]

Hence, for any REACH requirement in question, it would be reasonable to apply the "balancing test" or "cost-benefit test" laid down in *Korea-Various Measures on Beef Case* by the Appellate Body including risks of non-fulfillment criteria. According to that, the interpretation of "necessary" is found to be closer to "indispensable for the aim" than it is to "make a contribution to the aim".[79] Under this provision, when there exists a lack of proportionality between the measure and its aim after this weighing and balancing approach including the application of "risks of non-fulfillment" criterion, the measure is likely to be defined as "unnecessary technical obstacle to trade as well as more trade restrictive than necessary". Thus, for instance, the registration or substitution of any chemicals under REACH is expected to be almost indispensable because it should make strictly "material contribution" to the aim of the protection of human health and environment and otherwise non-fullfillment of the measure would create in risks for the realization of the objective.

Considering the risks of non-fulfillment criteria, there are some requirements of REACH that might be categorized as "more trade restrictive than necessary" for non-EU producers because the risks of non-fulfillment can not be laid down objectively and thus might be subject to Article 2.2 violation. For instance, it is difficult to legitimize the need for

[78] Gabrielle Marceau and Joel P. Trachtman (2002), "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tairffs and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods", *Journal of World Trade* 36(5): p. 831.

[79] Appellate Body Report on *Korea-Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, adopted on11 December 2000, para 161.

registration of constituent monomers of the polymers imported from outside the EC, while in contrast, constituent monomers of the polymers produced in the EC, are not required to register the composite of monomers. If there is a risk of non-registration of the same chemical, the measure should be applied to all producers without discrimination or creating unnecessary barrier for non-EU countries. This implementation might lead to misperceptions about the availability of risks for non-EU WTO members and might be subject to Article 2.2 with the claim that there are no risks of non-fulfillment and thus this is designed as unnecessary obstacle to trade outside from the EU.

Whether REACH is 'proportionate' to its aims – namely, whether it is more trade-restrictive than necessary to achieve a high level of health and environmental protection – is also likely to depend on whether there are alternative measures reasonably available to the EU which are less trade restrictive while providing an equivalent contribution to the achievement of the objective pursued by REACH without being unduly burdensome for the EU. Under TBT Article 2.2 the search of less trade restrictive measure is broader than the one in GATT Article XX(b). When any REACH requirement is subject to Article 2.2, it is likely to be expected that all other alternatives, which are fulfilling the same legitimate objective at the equivalent level without causing extra burden or costs to the regulating state are to be examined strictly.

To exemplify how significant and difficult it might be to demonstrate the less trade restrictive alternatives strictly under TBT, the *Asbestos* case, which was examined under GATT, might be given as an example to show that even under GATT, the alternative proposals were examined strictly. In that case, France's chosen level of protection was to halt

the spread of asbestos-related health risks through a ban on white asbestos, subject to exceptions. However, Canada argued that 'controlled use' of white asbestos was a reasonably available alternative, which would be less trade-restrictive than the French ban, while serving the same end. However, the Appellate Body observed that the efficacy of controlled use had not been demonstrated by Canada, justifying a conclusion that controlled use would not allow France to achieve its chosen level of health protection. It also added that "…Moreover, even in cases where "controlled use" practices are applied "with greater certainty", the scientific evidence suggests that the level of exposure can, in some circumstances, still be high enough for there to be a "significant residual risk of developing asbestos-related diseases." [80]

The findings in the *Asbestos* case could be contrasted to the conclusions reached in *Thai Cigarettes* case which examined cigarette import restrictions aimed at protecting the public from harmful ingredients in imported cigarettes, and to reduce the consumption of cigarettes in Thailand. In that case, strict, non-discriminatory labelling and ingredient disclosure regulations were considered an appropriate alternative measure that would allow the Thai government to control and inform the public of cigarette content. A ban on cigarette advertising combined with restrictions on supply was considered appropriate alternative means by which to control cigarette consumption. These measures, the Panel found, were 'reasonably available to Thailand to control the quality and quantity of cigarettes smoked' which could achieve the same health policy goals of the Thai import ban.[81]

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[80] Appellate Body Report on Appellate Body Report on *EC- measures Affecting Asbestos and Asbestos-Containing Products,* WT/DS135/AB/R, adopted on 12 March 2001, paras. 173-174.

[81] *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes,* Report of the Panel adopted on 7 November 1990, BISD 37S/200 ('Thai *Cigarettes'),* paras. 85-87.

In this manner, there are some WTO members such as Mexico that has been proposing alternative measures for some requirements of REACH. However, these measures are not laid down analytically and they might be easily refuted by the EC and if subject to TBT Article 2.2 by the Panel or Appellate Body, if they are not well designed and in line with TBT 2.2 rules. For instance, Mexico has been noting that it would be possible to find alternative systems to ORs by having the EC conduct inspections extra-territorially, in the exporting country instead, so that exporters would then be able to register the chemicals themselves. On the other hand, the EC stated that such a provision would be in violation of basic principles of international law since the EC could only impose its laws in territories under its jurisdiction.

Considering all these criteria to check whether REACH is compatible with TBT Article 2.2, the EU's desire to protect health by limiting market access to chemicals that are shown to be safe is a legitimate interest. Regarding risks of "non-fulfillment" criteria, in fact risk assessment is an inherent part of the REACH Regulation because the system is based on it. In addition to that, REACH does not affect a total ban on its target products, as was the case in the *Asbestos* case, instead of this, REACH aims to ensure that risk assessment is employed for all chemicals used in the EU.

Hoewever, one of the main objections regarding REACH under TBT Article 2.2 is that REACH could result in banning of products with no proof of any hazard. In fact, as Harrell (2006) affirms that the requirement that each manufacturer submit quantitative data about its product's risks guarantees that products will not arbitrarily be banned. Thus, it is not wrong to say that the incorporation of risk assessment eliminates the possibility of arbitrary

bans. Furthermore, if the scientific data do not show proof of hazard related to a product's use, the product is presumed safe. Even if some hazards are shown, the use of a product will not be precluded if the benefits of use outweigh the risks or it is "adequately controlled". [82] Therefore, this objection would likely to fail.

Furthermore, there are some chemicals, which are covered by REACH Regulation under the category of SVHC (e.g. boric acid and its derivatives categorized as CMRs) and their risk of harm on human health has still been a subject of debate among scientific experts. One might challenge that even though there is no certain scientific proof of their harms on human health, these chemicals cannot be subject to "authorization or restriction" requirements of REACH. However, it is significant to recall the Appellate Body's approach to this issue in *Asbestos* case. Appellate Body has found that WTO Members are not required to rely on majority scientific opinion when taking account of risks under TBT Article 2.2 or GATT Article XX. In the *Asbestos* case, the Appellate Body stated by referring to *EC-Hormones* case examined in the context of SPS Agreement: "[i]n justifying a measure under Article XX(b) of the GATT 1994, a Member may ... rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion."[83] Although the Appellate Body's observations in the *Hormones* case were limited to the SPS Agreement, the *Asbestos* case subsequently applied relevant

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[82] Sarah, Harrell (2006), "Beyond REACH? An Analysis of the European Union's Chemicals Regulation Program Under World Trade Organization Agreements" *Wisconsin International Law Journal,* p. 513.

[83] Appellate Body Report on Appellate Body Report on *EC- measures Affecting Asbestos and Asbestos-Containing Products,* WT/DS135/AB/R, adopted on 12 March 2001, para. 178.

elements of the Appellate Body's reasoning to GATT Article XX(b). Thus, it would be likely to expect that consistent reasoning would also be applied to an analysis of 'risk' under Article 2.2 of the TBT Agreement. Thus, even though the results of scientific study does not reflect the majority's opinion, still it might be used to justify a measure as being no 'more trade-restrictive than necessary' to fulfil its objective under the TBT Article 2.2.

On the other hand, the most vulnerable part of REACH requirements to a challenge under TBT 2.2 is that meeting the criteria of the least-restrictive-means requirement of the Article even though the challengers of REACH have not been able to demonstrate an alternative measure yet to reach the same objective at the equivalent level. On the other hand, as Harrell (2006) notes that the WTO is inclined to defer to its members' choice of the measure to achieve its protection level and considering the fact that there exist no international standard or framework to respond the objective of the EU at the same level as REACH does, WTO is likely to find REACH "necessary" as the only reasonable alternative to achieve EU's goal. [84] Thus, it is likely to expect that REACH would survive a least-restrictive-means challenge.

On the other hand, there are still some parts of the REACH regulation that might be strongly challenged under TBT Article 2.2. For instance, under REACH, registration requirement is mostly based on the volume and the risk of chemicals. However, considering the registration time and required data schedule, it is predominantly based on volumes rather than risks since the required information for the registration of high volumes of chemicals is

[84] Sarah, Harrell (2006), "Beyond REACH? An Analysis of the European Union's Chemicals Regulation Program Under World Trade Organization Agreements" *Wisconsin International Law Journal,* p. 514.

more than the one requested for low-volume chemicals. Furthermore, the high tonnage chemicals are also required to be registered at the very early stages of REACH, as it was required for CMR substances. Thus, many chemicals presenting little or almost no risk to human health and environment have to be treated as if they are CMRs just because they are introduced to the EU market in high tonnages. Furthermore, as Bronckers and Charro (2005) truly states that "this volume-based approach does not really explain why foreign (or domestic) producers of substances, preparations and articles will have to register an imported (or domestic) substances even of the substance has already been registered by another manufacturer in the EU or by another importer into the EU."[85] Furthermore, due to its volume-based approach, REACH has brought extra transaction costs for the exporters outside the EU. Additionally, the same product is required to be registered separately for its each specific use. Considering the structure and the different compositions of the complex chemicals, that seems to become highly repetitive and bureaucratic.

Thus, judgement of the volume-based registration requirement as being indispensable to reach the high standard of objective is required as well as the search of availability of an alternative method for high volume but low risk chemicals which might require less onerous REACH procedures than registration and data generation by ensuring the same level of protection.

Addition to all that, as Bronckers and Charro (2005) state that even though it would be accepted that low risk and high volume chemicals are subject to the same strict requirements

85 Marco, Bronckers and Pablo, Charro (2005) "*REACH Reviewed under WTO Law*", Journal for European Environmental and Planning Law, Vol.2 Issue:3, p.190.

to which high risk chemicals are being subjected, the manageability of the huge amount of data generated for registration by the EC still remains as a matter of concern. Thus, "regulatory schemes that are incapable of achieving their stated objective can hardly be deemed to be proportional."[86]

To sum up, the WTO would likely consider that REACH is "necessary" if the EU is able to show that the regulation is the only practical means of achieving the stated goals relating to the protection of health.

3.2.3. REACH Rules Conflicting with TBT Article 2.3.

Article 2.3 reads, "*Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner."* Through this article, WTO members are required to give up their technical regulations in the case of changes in objectives and conditions leading to their adoption or a less trade restrictive method is found to address the same purpose.

This provision is significant so as to legitimize the use of less trade restrictive measure, in case it is to be laid down for any REACH requirement for any chemicals by a WTO member state. Due to the precautionary approach of REACH Regulation, there still exist many chemicals, which were categorized under SVHC list while their risks have not been scientifically proved yet. In the case that they are to be found risk free and this is scientifically

86 Marco, Bronckers and Pablo, Charro (2005) "*REACH Reviewed under WTO Law*", Journal for European Environmental and Planning Law, Vol.2 Issue:3, p.191.

proven, and if REACH still keeps applying the same strict requirements to the same chemical, that might be challenged under TBT Article 2.3.

3.2.4 REACH Rules Conflicting with TBT Article 2.4.

Another concern that might be challenged under TBT is regarding the incompatibility of REACH with relevant international standards. According to Article 2.4 of TBT *"Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."*

3.2.4.a. Concerns under TBT Article 2.4.

Many countries have called on the EC to harmonize REACH with existing regional and international standards or to await the outcome of certain harmonization efforts that are currently underway. There have been serious concerns that REACH would be incompatible with current international initiatives, such as the International Council of Chemical Associations (ICCA) High Production Volume Chemicals Program (HPV) and the UN's Globally Harmonized System for classification and labelling (GHS).

However, the EC has responded that REACH complements, rather than supplants, existing international and regional regulations, and that it has every intention of complying with these norms. For example, information generated under the HPV programme could be

used for REACH as long as registrants could demonstrate they had a right to use these studies. Information generated under other programmes could also be used if appropriate. The EC has also implemented GHS through its new CLP Directive EC 1248/2008. Moreover, REACH implemented a large number of the SAICM objectives (Strategic Approach to International Chemicals Management).

3.2.4.b. Analysis of the Concerns under TBT Article 2.4.

TBT Agreement aims to encourage WTO members to be stick to international standards as long as they are not "ineffective or inappropriate" for the fulfillment of the objectives pursued through its Article 2.4. Thus, the meanings of "ineffective or inappropriate" determine the necessity of the use of international standards as a basis for technical regulations. In *EC-Sardines Case*, agreeing with Panel's Report, the Appellate Body noted that "ineffective refers that something which is not having the function of accomplishing, having a result or brought to bear while "inappropriateness" means something which is not suitable, proper or fitting. Thus, the question of effectiveness bears upon the results of the means while the question of appropriateness relates more to the nature of the means employed."[87] In addition to that, Appellate Body also confirms that the legitimate objectives are also interpreted in the context of TBT Article 2.2. [88] Through this case, Appellate Body also clarified that due to the possibility of a measure being effective but inappropriate or vice versa, the complaining party, not the regulating party, has the burden of showing that

[87] Appellate Body Report on *EC- Trade Description of Sardines,* WT/DS231/AB/R, adopted on 26September 2002, para. 285.

[88] Appellate Body Report on *EC- Trade Description of Sardines,* WT/DS231/AB/R, adopted on 26September 2002, para. 286.

international standard is effective and appropriate. [89] Lastly, Appellate Body also clarified that consensus of the Regulating Party with any related international standard is not required for standards adopted by the international standardizing community thus a Regulating Party might be held to a standard that it did not consent to through this interpretation. [90]

In fact the language of *"inappropriateness or ineffectiveness to fulfill the legitimate objective pursued"* seems to create a room for maneuver and a possibility of deviation from related international standards for the Regulating Party while creating a challenge to the complaining WTO members to assert the contrary. Thus, this language enables technical regulations to be below or above international standards. As Marceau and Trachtman (2002) affirm that "if participation in international standards body setting and reliance on their work as basis is encouraged, deviations from international standards is not prohibited". [91]

It is of course open to question whether current international standards regarding chemicals such as Global Harmonized System (GHS) for Classification and Labelling, or Stockholm Convention on Persistent Organic Pollutants and Rotterdam Convention regarding the Trade of Chemicals and Pesticides, or the work of the OECD Task Force on Endocrine Disrupters, exist to achieve the goals of REACH. In fact, even though REACH

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[89] Appellate Body Report on *EC- Trade Description of Sardines,* WT/DS231/AB/R, adopted on 26September 2002, para. 289.

[90] Appellate Body Report on *EC- Trade Description of Sardines,* WT/DS231/AB/R, adopted on 26September 2002, para. 222.

[91] Gabrielle Marceau and Joel P. Trachtman (2002), "The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tairffs and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods", *Journal of World Trade* 36(5): p. 842.

has stricter rules for chemicals management comparing to international standards, EC has been underlining that REACH is complementary to such programmes to control chemicals risk, and, moreover, supportive of many of them. Furthermore, EC also clearly confirms that information generated under other international programmes could also be used if appropriate and effective. In addition to this, The EC has incorporate OECD's GHS system to REACH Regulation through its new CLP Directive EC 1248/2008, which is mostly parallel with OECD GHS System.

In line with the analysis, in case REACH is challenged under this provision, first complaining Party is to be expected to lay down any requirement under REACH is also covered by an international standard appropriately and effectively for the fulfillment of legitimate objective pursued by adducing sufficient evidence. Otherwise, as a Regulating authority, EU is likely to respond that REACH complements, rather than supplants, existing international and regional regulations, and that it has every intention of complying with these norms. On the other hand, EU might also claim as Harrell (2006) notes that there are several international programs regulating chemicals in some way, including some that are still in development stages and none of these, however, is a comprehensive program like REACH which is sufficient to fulfill the EU's goal of increased knowledge of the risks related to all chemicals being used within the Union and thus these agreements, therefore, may not be effective in reaching the EU's goals. [92] As a result, since TBT enables its members to deviate from international standards in the case of their inappropriateness and

[92] Sarah, Harrell (2006), "Beyond REACH? An Analysis of the European Union's Chemicals Regulation Program Under World Trade Organization Agreements" *Wisconsin International Law Journal,* p. 514.

ineffectiveness, EU is likely to legitimize its deviation from international standards in chemicals area.

3.2.5 REACH Rules Conflicting with TBT Provisions Regarding Conformity Assessment Procedures

There also exist some concerns regarding the conformity assessment procedures (CAPs) required by REACH that might challenged under related TBT provisions. Article 5.1.1 and 6.1 of TBT are designed to address the concerns regarding CAPs under REACH.

3.2.5.a. Concerns under TBT CAPs Related Provisions

Concerns have been raised, in particular by developing countries, about the extent to which the EC is likely to accept test data that are needed for registration generated outside the EC, and whether OECD's 'Good Laboratory Practice' (GLP) would be applied. According to Article 14(9) of the REACH Regulation, ecotoxicological and toxicological test and analysis were required to be carried out in compliance with the principles of GLP contained in Directive 2004/10/EC[93] or with other international standards recognized as equivalent by the Commission or the ECHA which the OECD GLP accredited laboratories are the only option. Therefore, one of the main critics towards the implementation of REACH system is that the strict attitude of the EC to accept the use of data, which is generated outside the EU and based on EC GLP Directive or OECD GLP Criteria which is the only recognized option by the EC.

On the other hand, there are many WTO members, especially developing countries, that have based their accreditation system on ISO standards instead of the ones set by OECD

[93] For EC GLP Directive visit http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:050:0044:0044:EN:PDF (Last visited on 21 March 2012)

and they claim that in accordance with the TBT Agreement, the European Communities should also accept the testing data provided by non-EC laboratories fulfilling ISO standards such as General Requirements for the Competence of Testing and Calibration Laboratories. Some also argue that especially in the case of chemicals that are well known with their simple physico-chemical characteristics, the EU authorities must accept data from internationally accredited regulatory bodies such as the ILAC (International Laboratory Accreditation Cooperation). Most developing countries consider that some kind of communicability between those different systems should be ensured pursuant with TBT Agreement Article 6.1 through mutual recognition agreements.

Thus, European Communities has been asked many times to clarify what alternatives to accreditation systems for test methods were available for laboratories and to provide examples of accredited laboratories which were not accredited by the OECD GLP but were acceptable to the EC. However, EC responded that ISO standards could not provide the equivalent level of assurance for EC authorities. Therefore, any such tests had to come from laboratories – also outside the EU – that had obtained a certificate indicating that they applied GLP.

3.2.5.b. Analysis of Concerns under TBT Provisions related with CAPs

TBT requires "national treatment" and "less trade restrictive means" principles to be applied not only in technical regulations but also in conformity assessment procedures (CAPs). Thus, TBT Article 5.1.1 lays down that CAPs are prepared, adopted and applied in a "no less favorable" manner for the suppliers of "like products" of other WTO members.

Regarding this provision, REACH might be challenged by some non-EU and non-OECD member WTO states due to its mandatory data generation requirement under OECD's GLP or related EC Directive standards. Even though domestic (manufactured in the EU) chemicals are also subject to the same GLP Criteria as they are applied to the like products, and there is no discrimination *de jure,* there might be *de facto* discrimination to the advantage of EU members and OECD states. However, it is likely that such a challenge might be weakened by the EC due to the absence of legal non-discriminaton.

However, REACH might still be challenged under TBT Article 5.1.2 due to its mandatory requirement regarding data generation under OECD GLP standards. According to Article 5.1.2. CAPs are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. Article 5.1.2 goes on"… *This means, inter alia, that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.*" As it is interpreted under TBT Article 2.2, the risks that might be occurred from non-conformity of these CAPs play a major role in determining their necessity as it played in Article 2.2 for technical measures. Thus, it is reasonable to expect that complaining party has to lay down the lack of necessity of the required CAPs by proving the lack of its proportionality and risks of non-conformity considering their magnitude and predatory impacts as well as going further by proposing a less trade restrictive CAPs responding the objective at equivalent level with less burden on the Regulating Party.

As described in the previous section, some WTO members, especially developing countries might challenge the requirement of GLP Testing Methods since most of them have based their accreditation system on ISO standards instead of the ones set by OECD. If these WTO members might be able to lay down that their ISO testing standards could provide the equivalent level of assurance for EC authorities in terms of data generation without giving extra burden on the EC as well as laying down the risks of non-conformity with GLP testing standards do not outweigh the risks of non-conformity with ISO testing standards, the GLP based data generation requirement of REACH is likely to be found in violation with Article 5.1.2.

As a complementary to this challenge, as long as WTO members using ISO testing standards might be able to prove the appropriateness of these tests with the aim of REACH, they might also claim that acceptance of ISO standards as well as OECD standards is possible pursuant to TBT Article 5.4 regarding harmonization of CAPs. [94] Thus, EC might be triggered to also accept the testing data provided by non-EC laboratories fulfilling ISO General Requirements for the Competence of Testing and Calibration Laboratories or data from internationally accredited regulatory bodies such as the ILAC (International Laboratory Accreditation Cooperation).

[94] TBT Agreement Article 5.4: In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate for the Members concerned, for, inter alia, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

Furthermore, TBT Article 6.1 also enables the communicability between those different CAPs "provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures." This provision paves the way to implement "mutual recognition" principle for conformity assessment procedures so as to prevent their potential to be an unnecessary obstacle to trade. As mentioned in the previous section, Canada and Mexico have been calling for mutual recognition agreements enabling that their CAPs might be valid for REACH data generation process and thus minimizing their registration costs. As long as these WTO members might be able to prove that their testing methods and standards are equivalent to the EC's OECD based GLP standards, than the insistence of the EU regarding GLP testing standards is no longer legitimized.

3.2.6 REACH Rules Conflicting with TBT Articles Special and Differential Treatment for Developing Countries

From the very beginning of REACH proposal, considering the costly and complex structure of the REACH Regulation, EU has been criticized sharply regarding the lack of incorporation of special and differential treatment, as well as, technical assistance programmes for developing countries in particular for their SMEs. This concern might also be brought under related TBT provisions.

3.2.6.a Concerns Under Related TBT Provisions

Most of the developing countries view that the costs brought by REACH would disproportionably affect producers in developing countries exporting to the EU, putting them at a disadvantage over their competitors, especially in developed countries. Those countries

including China considers that European Communities had not conducted a sufficient impact assessment of the negative effects of REACH on the chemicals industry in developing countries, given the huge gap between the European Communities and developing countries in production technology and production level of chemicals. Furthermore, recalling TBT Art. 12.3 [95] and stressing the negative impacts on developing countries of REACH Regulation, China also states that REACH could trigger the transfer of many raw material-type industries, characterized by low added value but high pollution, to developing countries, hence confronting developing countries with the risk of "chemical pollution".

Chinese concerns seem to be shared by other developing countries including Mexico since this WTO member has been stressing for so long the need for technical assistance pursuant with Article 11 and special and differential treatment pursuant with Article 12 of the TBT Agreement. [96] In fact, developing countries' level of technological development in the chemicals industry is low and mostly companies in the developed world hold the data needed for registration of chemicals. Therefore, firms in developing countries would have to pay high fees for such data for registration leading to increases in costs in chemical production and trade. Moreover, the cost of importing chemicals from the European Communities would also rise. Thus, technical assistance and especially extension of the timeframe of the

[95] TBT Agreement Article 12.3 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.

[96] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-7 June 2006, G/TBT/M/39, published on 31 July 2006, p.11.

implementation for developing countries has been the main proposals brought to the EU by developing countries.

Regarding these concerns, the European Communities has been recalling that the primary objective of REACH was the protection of human health and environment; no exceptions for developing countries could therefore be provided for requirements such as the pre-registration/registration obligation. [97] However, the EC also recognizes its obligations under TBT Agreement and agreed that guidance was needed for the stakeholders, to ensure consistent, cost effective, and smooth implementation of REACH. In fact, extensive guidance material has been prepared and that appropriate technical assistance, and capacity building activities to industry and authorities in developing countries have been conducted so far. Additionally, the representative of the European Communities has invited Members having specific needs for such technical assistance programs, to direct their requests to the respective delegations of the European Commission in their country.[98]

3.2.6.b. Analysis of the Concerns under Related TBT Provisions

REACH Regulation might be challenged by developing and less developed countries due to its costly, complicated and *de facto* discriminatory structure under TBT Article 12.3. According to this provision *"Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special*

[97] Minutes of the Committee on Technical Barriers to Trade Meeting, 5-6 November 2008, G/TBT/M/46, published on 23 January 2009, p.38.

[98] Minutes of the Committee on Technical Barriers to Trade Meeting 1-2 July 2008, G/TBT/M/45, published on 9 September 2008, p.12.

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."

However, when these developing WTO states challenge REACH under Article 12.3. they might not be able to gain any benefit considering the *EC- Biotech* Panel Report which was prepared under SPS Agreement. Interpreting a similarly worded provision in the SPS Agreement, the *EC-Biotech* Panel noted that "taking into account" does not prescribe a specific result to be achieved, and that in weighing and balancing the various interests at stake, the needs of a developing country did not have priority over, for instance, other legitimate interests. [99] Thus, the same approach might be applied to TBT Agreement in case REACH was challenged under this TBT provision.

Conclusion

REACH is one of the most complex, comprehensive legislation from the last two decades of the EU history and it has created reactions among producers both in chemicals and other sectors not only in the EU first, but also in the world then since the new EU chemicals legislation is cross-cutting with other sectors and affecting all the actors in global supply chains in terms of their competitiveness and ability to access in EU market.

[99] Panel Report on *EC-Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R WT/DS292/R WT/DS293/R, adopted on 29 September 2006, para. 7.1621.

Therefore, REACH has been on WTO TBT Committee Agenda since the end of 2003. Even though the EU has made substantial changes in its REACH proposal since its first notification to the WTO in 2004, it has not succeeded to appease the concerns of non-EU WTO member states yet. In fact it is clearly seen that the more REACH Regulation is applied into practice with its most criticized requirements such as registration and authorization, the sharper criticism it gets. The critics are ranging from the adverse effects of REACH on SMEs to its lack of uniform implementation throughout the EU. However, the critics are usually clustered around its national treatment infringing and unnecessary obstacles to trade creating potentials.

That intensified concerns and criticism brings into mind the question whether REACH is likely to survive any possible challenge under TBT Agreement in the future. As a technical legislation which is based on a moderate application of the precautionary approach that specifically incorporates risk assessment, REACH has a legitimate objective of protection of human health and safety at high level in terms of TBT Agreement. Thus, it is clear that REACH completely fulfills the legitimate objective criteria of TBT.

However, what is less clear for the compatibility of REACH with TBT Agreement is its negligence in fulfilling the requirement of the Agreement that a WTO member state treats other member states' *like* products in line with national treatment principle and use the least trade restrictive means in meeting this legitimate objective. While REACH does not favor the EU products to the detriment of other nations *de jure,* due to some of its complicated requirements, REACH might easily be perceived as if it is infringing national treatment

principle *de facto.* Furthermore, some of its extremely stringent requirements lead to the questioning of whether it is the least trade restrictive measure to reach its objective.

The environment and human health related cases brought to the WTO DSM in the last decade has illustrated the willingness of the WTO DSM to recognize each member nation's right to choose its level of protection, along with the growing acceptance of the precautionary principle regarding environmental and health concerns internationally. Thus, even though REACH still has many aspects to be judged under TBT Agreement, considering its leverage of legitimate objective and the lack of alternative measures proposed in line with TBT rules of complaining parties, it is also likely that REACH is to be upheld by the WTO DSM.

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