DISCUSSION PAPER

REACH: is such regulation WTO consistent?

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Introduction

This present study analyses the Regulation on Chemicals of the European Union – so called REACH, and some of its main features. Technical barriers to trade have become the new instrument of distorting international trade benefits and creating protection for domestic industry, on the basis of protection of human health and the environment. It aims at identifying REACH's most primary and controversial element and its consistency under the World Trade Organization System, in context of the Agreement on Technical Barriers to Trade.

A brief comparative study between REACH and the United States, Canada, and Japan's regulations on chemicals is also herein presented as a way of identifying other ways of reaching similar goals of protection. According to some Brazilian representatives of the chemicals industry, the Canadian CPM is a better cost-benefits model.

The present study also introduces a brief analysis of the ongoing discussions of mega regional agreements and the negotiations on REACH, which have raised an extended concern in the European Chemicals Agency that fears lowering of levels of protection for human health and the environment.

Last, but not the least, in order to understand REACH's application and to address some possible claims that might be raised - either on negotiations or under international tribunals - for inconsistency of that regulation with international trade rules and principles, the present essay makes an analysis of case law related to REACH, under the European Court of Justice and the European General Court, since there is no specific case law to be analyzed under the WTO system. Post conclusions, in an annex to the

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present work, a table of cases related to REACH, under the European dispute settlement system is available.

1 – REACH: definition and main features

REACH is the abbreviation for "Registration, Evaluation, Authorization and Restriction of Chemicals"[3]. It is a European Union Regulation of 18th December 2006, which came into force in June 2007. It addresses production and use of chemical substances and their potential impacts on human health and the environment, promoting alternative methods for the hazard assessment of substances to reduce the number of tests on animals[4]. Its latest consolidated version is dated 10th April 2014[5].

REACH applies to almost all chemicals produced or imported in the EU. The Regulation, as a whole, does not apply to radioactive substances, substances under customs supervision, non-isolated intermediates and carriage of dangerous substances, according to its Article 2.1. Some parts of REACH, such as Registration and Evaluation, do not apply to substances used in medicinal products, food and feedingstuffs, according to its Article 2.4 (b). However, food and feedstuff are under other parts of REACH. REACH, Title IV, (information in the supply chain) does not apply to medicinal products for human or veterinary use, cosmetic products, medical devices which are invasive or used in direct physical contact with the human body and food or feedingstuffs. Other substances within specific conditions (e.g. re-imported and on-site isolated intermediates, according to Article 2.7 and 2.8) are exempted from other parts of the Regulation. The burden of proof is on companies to comply with the regulation and they must identify and manage the risks linked to the substances that they manufacture and market in the EU.

REACH Regulation has 849 pages. It took seven years to pass in the European Parliament and Council and it is one of the strictest and most complex legislations in the European Union dealing with chemical substances. Theoretically, companies established outside the EU are not bound by the obligations of REACH, even if they export their products into the customs territory of the European Union. Under REACH Regulation, the responsibility for fulfilling the requirements, such as pre-registration or registration, lies with the importers established in the EU or with the only representative of a non-EU manufacturer established in the EU[6]. Nevertheless, the EU is one of the most important trade partners for most of the countries in the world, the burden of proof

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.
[4] See Understanding REACH, In: http://echa.europa.eu/web/guest/regulations/reach/understanding-reach (access in 23th June 2014).
[5] In: http://old.eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20140410:EN:HTML (access on 23rd June 2014).
[6] Ibid.

and many of its costs, in practice, lie on the exporter willing to export its products to Europe. Therefore, REACH affects industries all over the world.

One of the "creations" of REACH Regulation was the establishment of the European Chemicals Agency (ECHA) whose main duty is to manage scientific, administrative and technical aspects from its headquarters in Helsinki [7].

ECHA set three deadlines for registration of chemicals, which are determined by tonnage manufactured or imported: i) 1000 tons/a. being required to be registered by 1st December 2010 (for chemicals of higher concern or toxicity); ii) 100 tons/a. by 1 June 2013; and iii) 1 ton/a. by 1 June 2018.

Pre-registering was a policy undertaken by 1st December 2008 and around 143,000 chemical substances marketed in the European Union were pre-registered even though pre-registering was not mandatory. Substances supply to the European market that has not been pre-registered or registered is illegal and according to the wording in REACH, it is "no data, no market".

ECHA has a special policy for addressing the continued use of chemical substances of very high concern (SVHC)[8]. ECHA must be notified, since June 2011, of the presence of SVHCs in articles whenever the total quantity used is more than one ton per year and the SVHC is present at more than 0.1% of the mass of the article[9]. Some SVHCs may be subject to prior authorization and applicants have to make plans for substituting it with a safer alternative. When a safer substitute is not known, the applicant must work to find one. The identification of a substance as SVHC and its inclusion in the Candidate List is the first step of the authorization procedure. A Candidate List of SVHCs is published and updated often by ECHA. The last list was updated on 16th June 2014 and it contains 155 SVHCs for authorization[10].

Under REACH, it is not possible to register a substance if the "Only Representative" consultancy company is not based in the EU, unless it is subcontracted to an EU-based registrant. Only Representatives (O.Rs.) are EU based entities that must comply with REACH, according to Article 8, and should operate standard, transparent working practices. The O.R. assumes responsibility and liability for fulfilling obligations of

[7] In the ECHA Webpage: "ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern", in: http://echa.europa.eu/about-us (access in 23th June 2014).

[8] Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHCs). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorization List (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification) (access in 23th June 2014).

[9] REACH defines an article as an object which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition. According to REACH, articles are for example; t-shirts, flooring and plastic packaging.

[10] SVHCs Candidate List in http://echa.europa.eu/web/guest/candidate-list-table (access on 23th June 2014).

importers, in accordance with REACH, for substances being brought into the EU by a non-EU manufacturer.

2 – REACH's primary and most controversial element

The REACH regime is comprised of several elements. However, **its primary and most controversial element is its data gathering and registration requirement**[11] **and, for non-Community manufacturers, the obligation to hire an O. R. to fulfil it**.

This data gathering and registration requirement applies to EU manufacturers, EU importers or EU O.Rs., established within the European Community, that manufactures within or imports into the EU both existing or new substances (on their own, in preparation or in articles), unless otherwise exempt, in a volume of more than 1 ton per year.

An O. R. might be a natural or legal person established in the Community appointed as the non-Community manufacturer's only representative to fulfil the obligations related to registration of substances. The O.R. must comply with all obligations under the REACH Regulation and must have a sufficient background in the practical handling of substances and the information related to them and keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet, according to Article 8.2 of REACH[12].

The complexity of this data gathering and registration requirement put non-EU manufacturers at an economic disadvantage since their only option is to choose between an importer and an O.R. registration to protect their intellectual property and to carry on with the burdensome bureaucracy (additional registration costs and burdens, mainly for Small and Medium Enterprises – SMEs and non-EU chemical substance-based product manufacturers at a competitive economic disadvantage, because they are unlike multinationals that have a European presence or to know where to find a competent and reliable O.R.).

3 – The Precautionary principle under REACH

The REACH registration/data gathering requirement obeys the precautionary principle and reflects a shift on regulatory paradigm, reversing the burden of proof from regulator to producer or importer on the basis of a only substance's hazardous properties not

[11] L. A. Kogan. REACH and International Trade Law, 2013, at para12.11.

[12] See REACH O.R. Requirements at Article 8 (1,2,3), In: http://old.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20140410:EN:HTML (access on 23rd June 2014)

taking into consideration the actual risk that such substances poses on human health or the environment[13].

REACH implements a hazard-based version of the precautionary principle through its Preamble, paragraphs 9 and 69 and Article 1(3), which is informed by quasi - quantitative or qualitative risk assessments.

In REACH's preamble, it is disposed that:

(9) The assessment of the operation of the four main legal instruments governing chemicals in the Community, i.e. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (4), Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (5), Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (6) and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (7), identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field, and the need to do more to protect public health and the environment in accordance with the precautionary principle.

(69) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorization should be granted where natural or legal persons applying for an authorization demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorized if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

REACH, Article 1 (3) disposes that:

This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

As one recently released report observed, although the EU Commission's Communication on the Precautionary Principle provides that 'the precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data', it fails to discuss how serious the risk or its consequences must be in order to trigger the application of the precautionary principle. While ECJ case law is helpful, it does not appear determinative. According to the report, such case law holds, for example, that it is not sufficient to make a generalized presumption about a putative risk or to make reference to a purely hypothetical risk in the absence of scientific (data) support. The report concludes that, in the absence of further direction, 'it cannot be deduced that the precautionary principle only applies

[13] Kogan, supra note 9, para. 12.15.

where a potentially serious risk is identified' and consequently, 'the burden of proof necessary to justify such application may be lower'[14].

4 – Is REACH WTO consistent?

REACH can be described as a "behind-the-border" technical measure intended to address regional health and environmental concerns and impacts. It can also be appropriately classified as a type of non-tariff measure (NTM) that falls within the scope of the TBT Agreement because arguably it distorts and creates uncertainty surrounding international trade flows of chemical substance-based products[15].

As the WTO itself acknowledges, while the application of NTMs does not always restrict trade, they often result in unnecessary restrictions of undue barriers, which explains why they are referred to as non-tariff barriers (NTBs) and some WTO treaties have dealt with them; e.g. TBT and SPS Agreements.

REACH does affect international trade but the mere presence of effects on international trade is not sufficient for holding that REACH violates the EU's obligations under WTO law. It must be highlighted that some features of REACH might point out to an unlawful technical regulation on chemicals.

An analysis of REACH in light of TBT

REACH does not refer to specific substances unless they are placed on the SVHC "candidate and/or authorization lists" or they are subject to restrictions. Nevertheless, it probably qualifies as a "technical regulation" within the meaning of TBT Agreement[16], Annex 1, and, as such, it does fall within the coverage of that Agreement[17].

In US Clove Cigarettes, Mexico Tuna II and US COOL Requirements, Panels and Appellate Body have recognized that the TBT Agreement assures the right of WTO Members to regulate for the protection of human health and the environment at "their chosen level of protection", as far as that right is not exercised to employ such regulations in "a discriminatory manner or as unnecessary obstacles to trade" (wording from the Preamble of the TBT Agreement)[18].

A country might choose its level of protection as far as two conditions are met:

1) the regulation is not employed in a discriminatory manner;

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[14] Kogan, supra note 9, para. 12.45.
[15] Kogan, supra note 9, para 12.5
[16] It "probably qualifies" because it has never been analyzed by a Panel or Appellate Body of the WTO.
[17] Kogan, supra note 9, para. 12.24
[18] See Panel Report. United States-Measures Affecting the Production and Sale of Clove Cigarettes ('US-Clove; See Panel Report, United States-Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna; See Panel Report, United States-Certain Country of Origin Labelling ('COOL)Requirements ((18 November2011) WT/DS384R, WTIDS386R Products ('Mexico- Tuna 11') (15 September 201l) WT/DS381/R. Cigarettes') (2 September 2011) WT IDS406/R.

2) the regulation does not represent unnecessary obstacle to international trade.

Therefore, an analysis of REACH's "discriminatory power" has to be undertaken on two basis, under TBT: Art. 2.1 (and its "likeness" and "less favorable treatment" analysis) and Art. 2.2 (and its wording "unnecessary obstacles to international trade" and "more trade-restrictive than necessary").

The TBT Agreement, Article 2.1, provides that

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

The likeness of imported and domestic products should generally be determined on a case-by-case basis pursuant to four general criteria: a) the properties, nature and quality of the products; b) the end-uses of the products; c) consumers 'tastes and habits in respect of the products; and d) the tariff classification of the products[19].

An analysis of REACH based on "likeness", which focuses either on "finished articles containing chemical substances", chemical substances or mixtures, shows the importance of product-related process and production methods (PPMs) as a possibility of claiming trade discrimination. In other words, within the chemical industry, "how products are made is becoming almost as important as how products perform"[20]. Discrimination between products has been based on PPMs, under REACH.

Based on a comparison of product characteristics and consumer tastes and habits, which include actual and perceived product-related health risks, groups of imported SVHC products may be distinguished from groups of domestic non-SVHC products, to the extent that they would not be deemed "like products"[21]. Thus 'like products' would become 'different products' merely on the substitution of a substance that would be deemed to be of very high concern, even though the rest of components and the performance of the product itself do not change.

That "likeness" would depend, however, on whether ECHA and/or EU Member State competent authorities, when classifying the substances incorporated within such products and later reviewing technical and substance dossiers, employ(s) a semi-quantitative or qualitative rather than a quantitative risk assessment approach. Semi-quantitative or qualitative analyses tend to focus mostly on the health hazards (based on intrinsic substance characteristics) posed by SVHC or non-SVHC products, which entails a lower threshold of potential harm, as compared to a strictly quantitative risk assessment approach. A quantitative approach instead focuses on the health risks

[19] US Clove and EC Asbestos Cases.
[20] Kogan, supra note 9, para.12.26
[21] Ibid., para.12.27.

engendered by such products, which necessarily takes into account exposure, dosage and actual use[22].

As such, some might reach a conclusion that a discrimination claim against the EU, under the TBT Agreement, Article 2.1, would have a greater chance of succeeding if it focused on groups of imported substances that are not SVHCs, not incorporated within articles, and not shown to pose empirical health or environmental risks[23]. Nevertheless, it could be different on a "less favorable treatment" analysis.

There is evidence that shows that EU Member State implementation of REACH's registration/data gathering and notification requirements imposes a higher cost structure upon, and thus impairs the competitiveness of "like" chemical substance-based product imports in EU markets. "It does so by subjecting groups of imported non-REACH registered SVHC-containing articles to treatment less favorable than that accorded to like groups of REACH-registered domestic articles and substances"[24]. Higher costs and higher bureaucracy (as identified in the list of Specific Trade Concerns) count for a 'less favorable treatment' for like imported products. Among other factors, EU based manufacturers do not have to contract an O.R. to represent them.

On the other hand, the TBT Agreement, Art. 2.2 provides that

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective taking account of the risks non-fulfillment would create.

Assessing the risks of non-fulfillment of these objectives, there can be found relevant considerations related to available scientific and technical information, related processing technology, or intended end-uses of products[25].

Having a look at REACH's primary objective ('ensuring a high level of protection of human health and the environment consistent with sustainable development') one might note that it probably qualifies as a 'legitimate objective'. The risk of a chemical substance toward human health and the environment does not necessarily have a proportionate relationship with the volume of production. However, volume is used as a proxy for exposure, since it allows a clear, enforceable priority setting for registration which also gives "legal certainty". Moreover the REACH registration/data gathering and notification requirements' default reliance upon a volume (hazard)-based exposure proxy can be respected as reflecting the EU's chosen level of protection[26]. Under REACH, the volume of production was the chosen level for protection in the EU.

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[22] Ibid., para. 12.28.
[23] Kogan, supra note 9, para. 12.29.
[24] Ibid., para. 12.30
[25] Ibid., para. 12.32.
[26] Ibid., 12.11

However it is doubtful whether 'volume' is the right proxy for measuring up protection for human health and the environment.

Nevertheless, the REACH registration process may be seen much more as "a system of data collection and warehousing than a procedure for protecting the public and the environment from exposures to hazardous substances (…) A majority of the data submitted under the REACH registration process may never be evaluated"[27].

A report published by the EU Commission indicates that REACH registration-related costs for EU and non-EU industries were more than twice the amount previously estimated[28]. There were identified several classes of expenditures, such as human resource, ECHA registration, data gathering, supply-chain communication, notification and external consultant costs – a part of all that was due to excessive vertebrate animal testing that resulted in significantly higher than estimated animal testing costs (an approximate €2.1 billion of costs, in general). These substantially "higher-than-anticipated registration costs" have generated a negative impact on chemicals international trade flows. The report reached a conclusion that such a high bureaucratic cost was the main reason for many large and SME chemicals companies to reduce substance production volumes to a "lower and less expensive tonnage band", effectively shrinking their EU market share. The report strongly suggests that these responses to REACH and the cost of REACH compliance could very well lead to fewer available substances, somewhat higher prices, and a potentially more concentrated and less competitive EU chemicals market.

It might be said that REACH's registration/data gathering and notification requirements, which includes O.R.'s costs and bureaucracy, are more trade restrictive than necessary to achieve REACH's legitimate objectives, considering the real benefits that REACH, according to the EU Commission itself, has provided.

Therefore, as far as the TBT Agreement is concerned, a violation might be found in distinct situations:

1) **Whenever it is possible to ascertain that the compared products - EU domestic and imported - are "like products**", under TBT, Art. 2.1, imported products should receive 'no less favorable treatment'. The argument that two compared products are not 'like products', based only on a hazard-approach of product-related process and production methods (PPMs) should not convince on the basis of the TBT preamble, since Art. 2.1 should also obey the rule not to create 'unnecessary obstacles to

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[27] ADK Abelkop, Á Botos, LR Wise, and J D Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program' (January 2012)
School of Public and Environmental Affairs, Indiana University, 24
In.: http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf (accessed 25th June 2014).

[28] See Centre for Strategy and Evaluation Services, 'Interim Evaluation: Functioning of the European ChemicalMarket After the introduction of REACH' (2012), iii-iv, 39-40, 45-46, 49, 78, 97, 101, 102, table box 4.1, table 4.16and 105;
In: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf (access on 25th June 2014);

international trade' and the rule that measures should not be 'applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade'.

2) **Whenever it is possible to ascertain that compared products are not "like products"** on a basis of product-related process and production methods (such as SVHC products), TBT preamble and Art. 2.2 should be applied and the rule that 'technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective' should be complied with. A country should not 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' (from the preamble wording). Nevertheless, such measures are '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' (from the preamble wording). It might be said that, under REACH, the volume of production was the chosen level for protection in the EU. However it is doubtful whether 'volume' is the right proxy for measuring up protection for human health and the environment.

3) **In general, technical regulations should not be prepared, adopted or applied whenever they create unnecessary obstacles to international trade**. From Article 2.2 wording, technical regulations create unnecessary obstacles ever since they are more trade-restrictive than necessary to fulfill a legitimate objective. Moreover such rule also is under TBT preamble. From REACH, it is very clear that its high bureaucracy and registration costs are more than necessary to fulfil the legitimate objectives established in its preamble. Moreover, a majority of the data submitted under the REACH registration process may never be evaluated and the EU Commission has indicated that the registration-related costs were more than twice the amount previously estimated, generating a negative impact on international trade flows of chemicals.

5 – REACH and comparative regulation: the United States, Canada, and Japan

After the launch of REACH, the United States Congress, in 2007, prepared a document in which it pointed out some of the basic differences in approach between REACH and the US Toxic Substances Control Act (TSCA), 1976[29].

The US document highlights that the TSCA places the burden of proof on the Environmental Protection Agency (EPA) to demonstrate that a chemical poses a risk to

[29] US Government Accountability Office, 'Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals', Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007.

human health or the environment even before EPA regulate such a chemical's production or use. REACH, instead, generally places a burden on chemical companies to make sure that chemicals do not represent such risks or, if they do so, that there are identified ways for handling them in a safe way.

The EPA may regulate a substance if it shows that there is a reasonable basis to come to a conclusion that it presents or will present an unreasonable risk. The TSCA requires the EPA to find a regulatory measure that is least burdensome but that, at the same time, mitigates the unreasonable risk. Nevertheless, the EPA has declared how difficult it is to regulate under this standard[30]. On the other hand, REACH requires chemical companies to obtain authorization to use chemicals that are in a list of 'substances of very high concern'. In order to obtain such authorization, companies need to show that they can control risks posed by the substance or they must make sure that the substance is safe for use. The companies, under REACH, must provide and develop information on the physical and chemical properties of the substance and the health and environmental effects of its use for new and existing chemicals produced on certain volumes.

Moreover, under REACH, regulators must require companies to undertake additional test data and information whenever they need to make an evaluation of the risk that a substance poses to human health and the environment. The TSCA, in contrast, puts the burden on the EPA to demonstrate that information on health and environmental effects are needed before requiring chemical companies to develop the data. The TSCA requires companies to make a notification to the EPA before producing or importing a new substance, but it does not require companies to develop and provide data on health and environmental effects unless the EPA sets out a rule requiring them to do so[31].

The TSCA and REACH both have clauses to protect information that is confidential or sensitive for companies. However, REACH requires a much more public disclosure of certain information, such as primary chemical properties, which includes even melting and boiling points. Moreover REACH restricts substantially the sort of information that the chemical industry may consider confidential[32].

REACH requires companies to develop and share with government regulators data on the effects that the substances produce on human health and the environment. The TSCA generally does not.

One of the most notable differences between REACH and TSCA is that TSCA requires the EPA to demonstrate that substances represent a risk to human health or the environment before controlling risks related to their production, distribution or use. REACH, instead, is based on the principle that companies are responsible to demonstrate that the chemicals they market, distribute, or use do not adversely affect

[30] US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007.
[31] Ibid.
[32] Ibid.

human health or the environment. Moreover, under REACH, companies have to obtain authorization to carry on with the use of a substance of very high concern, such as a substance for which there is scientific evidence of likely serious health or environmental effects. In order to obtain such authorization, companies need to demonstrate that it can adequately control risks posed by the substance. The EPA, instead, under TSCA, has distinct bodies to make the control of risks posed by new and existing chemicals. Whenever there is a new chemical, the EPA can restrict the production of such substance or its use if it understands that there is insufficient information to allow a calculated evaluation of the health and environmental effects of that substance. On that matter, EPA, according to TSCA, may choose the least burdensome requirement on the chemical industry that will adequately protect against the risk[33].

The TSCA does not require the chemical industry to develop hazard information for existing chemicals. EPA, instead, uses regulatory and voluntary programs to raise data on certain substances. The TSCA does not command the chemical industry to develop information on the harmful effects of existing chemicals for the human health or the environment. On this matter, EPA may request a test rule, that is, it may require such information on a case-by-case basis. Nevertheless, REACH demand companies to make a declaration of hazard information for new and existing chemicals that are within specific production and toxicity levels. On behalf of that command, REACH conceived a sole system for the regulation of new and existing chemicals and it requires companies to provide the registration of substances produced or imported at 1 ton or more per producer or importer per year with the European Chemicals Agency. Under REACH, the amount of information to be included in the study summaries based on the chemical's production volume must be specified (i.e., how much of the chemical will be produced or imported each year). The data collection requirements may be fulfilled through a variety of ways, including existing scientific modeling or testing[34].

In general, the TSCA requires the EPA to demonstrate that substances will cause unreasonable risk. Such a burden of proof, under REACH, is on the chemical industry, which must demonstrate that the substance has adverse chemical effects.

REACH requires companies to ask for authorization in order to use some hazardous substances and to point out safer substitutes. Moreover, to control chemical risks, REACH creates procedures for both authorizing and restricting the use of chemicals. Under REACH, authorization procedures have three different steps: i) publication of a list of substances that need authorization before they can be used, by the European Chemicals Agency ('the candidate list')[35]; ii) the European Commission will determine

[33] US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007.
[34] Ibid.
[35] 'The chemical agency will determine which chemicals to place on the candidate list after it has reviewed the information that chemical companies submit to the agency at the time the chemicals are registered under REACH and after considering the input provided by individual EU member states and the European Commission. In making this determination, the agency is to use criteria set forth in REACH, covering issues such as bioaccumulation, carcinogenicity, and reproductive toxicity' (US

the substances, on the candidate list, that will require authorization and which of them will be exempted from the authorization requirements[36]; iii) once a substance has been chosen to require authorization, companies will have to apply to the European Commission for an authorization for each use of that substance[37].

A recent study concludes that a majority of the data submitted under the REACH registration process may never be evaluated[38].

Alternative regulation on chemicals management strategies were issued in Canada ('Canada's risk prioritization-based Chemicals Management Plan') and Japan ('Japan's risk prioritization-based chemical substance control law – so called Kashinho Law'), each of which feature 'an iterative screening approach that permits regulators to 'set aside a vast array of substances/uses at the beginning if they are unlikely to cause unacceptable risk', may qualify as less burdensome alternatives to REACH, in a different way from the TSCA. Such experts have come to a conclusion that an iterative screening approach focuses on a substance's potential for 'risk' rather than 'hazard, it would probably reduce costs and administrative burdens associated with substance registration while ensuring the same high level of protection of human health and the environment pursued by REACH[39].

Unlike the hazard-based REACH registration/data gathering provision, however, the multiple-level screening mechanisms of Canada's CMP and Japan's Amended Kashinho focus mostly on the exposure risks posed by substances rather than on merely a substance's hazardous intrinsic properties.

Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007).

[36] 'According to the Environment Counselor for the Delegation of the European Commission to the United States, some chemicals may be exempted from authorization requirements because, so far, sufficient controls established by other legislation are already in place' (US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007).

[37] 'The application for authorization must include an analysis of the technical and economic feasibility of using safer substitutes and, if appropriate, information about any relevant research and development activities by the applicant. If such an analysis shows that suitable alternatives are available for any use of the chemical, then the application must also include a plan for how the company plans to substitute the safer chemical for the chemical of concern in that particular use. The European Commission is generally required to grant an authorization if the applicant meets the burden of demonstrating that the risks from the manufacture, use, or disposal of the chemical can be adequately controlled, except for (1) PBTs; (2) very persistent, very bioaccumulative chemicals (vPvBs); and (3) certain other chemicals including those that are carcinogenic or reproductive toxins. However, even these chemicals may receive authorization if a chemical company can demonstrate that social and economic benefits outweigh the risks' (US Government Accountability Office, Highlights of GAO-07-825, A report to Congressional Requesters, August, 2007).

[38] ADK Abelkop, Á Botos, LR Wise, and J D Graham, 'Regulating Industrial Chemicals: Lessons For US Lawmakers from the European Union's REACH Program' (January 2012)
School of Public and Environmental Affairs, Indiana University, 24
In.: http://www.indiana.edu/~spea/faculty/pdf/REACH_report.pdf (accessed 25th June 2014).

[39] Ibid.

According to representatives of the Brazilian chemicals industry, the Canadian CMP offers a better cost-benefit, within a context of national policy for safety in chemicals[40]. The CMP is based on the Domestic Substances List – DSL, which contains around 24 thousand substances. From the DSL, 4,300 substances were separated for analysis up to 2020, under a criterion of prioritization. A key element in the CMP is data collecting on properties and uses of about 200 substances identified in the prioritization procedure. Such policy is so termed 'Challenge'. Industry and interested parties might contribute with additional information, which can be used in the assessment of risk and in the development of better practices for managing risk and substances[41].

Nevertheless, none of the three chemicals-management regulatory regimes (REACH, CMP, and Amended Kashinho) - besides the amended US TSCA[42] - have been in operation for more than a few years, and therefore continue to evolve. Consequently, it is probably too soon to draw any definitive conclusions regarding their relative effectiveness such that the CMP or Amended Kashinho can be justified as a less trade-restrictive alternative to REACH that can, partially or completely, fulfill REACH's legitimate objective to the same extent as REACH[43].

An absence of a risk threshold for action within the EU REACH's precautionary principle would seem to explain the difference between the Canadian CMP prioritized screening approach informed by a quantitative risk assessment-focused precautionary principle and the REACH hazard-based pre-registration/data gathering approach informed by a hazard assessment qualitative risk-focused precautionary principle. Under REACH, the precautionary principle appears already to have been applied in requiring the pre-registration of tens of thousands of substances for which risk assessments have not yet been performed (i.e. at a pre- risk assessment stage), premised only on a 'volume-based exposure proxy' (annual substance manufacturing and import volumes) and, perhaps, also on some qualitative risk data informed by socio-economic analysis ('general scientific acceptance'). By comparison, under the CMP, the precautionary principle would appear to be applied at the risk management stage once a risk assessment has been performed on a medium or high priority substance and has revealed a high likelihood of harm (exposure) to human health or the environment under particular exposure scenarios[44].

Moreover, Japan's legislation amendment was phased in over a two-year period and effectively facilitated Japan's shift from a hazard-based to a risk-based chemical substance management framework.

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[40] MOURÃO, Nicia Maria Fusaro; ZANATTA, Fernando, 2013.
[41] MOURÃO, Nicia Maria Fusaro; ZANATTA, Fernando.
[42] TSCA is still under scrutiny in the US Congress.
[43] Kogan, supra note 9, para. 12.55.
[44] Ibid., para. 12.46.

6 - REACH and Mega- Regional Trade Agreements

Regulation on the chemical sector has become more dynamic. Over the past decades, legislators have decided to take different approaches for regulation and dismiss their trade partners' approaches. Different legislation to be fulfilled in each part of the world generates high costs for chemical companies since they must comply with similar requirements more than once ever since they decide to put their products on foreign markets. Identified barriers are, inter alia, different methods for assessment of chemical substances since each partner country has its own method of assessing them. There have been suggestions for harmonization and for avoidance of duplication without compromising some of the protection standards, which include inter alia administrative obligations, reporting requirements and data generation and capture[45].

Besides, in the application and implementation of laws, there are fields where duplication can be reduced with no real effects on protection standards. Efforts have been made to include mutual recognition in the actual agreements negotiations.

The Transatlantic Trade and Investment Partnership (TTIP) is different from other free trade agreements negotiated earlier[46] since the two trading partners - The US and the EU - have considered to make a commitment on regulatory cooperation related to trade barriers which might be eliminated and at the same time maintaining the same levels of environmental and consumers protection[47].

Since non-tariff barriers have been identified as the main aim of Mega Regional Agreements, mutual recognition has become one of the main objectives of TTIP and has been feared mainly by the European Environmental Bureau that are afraid of negotiations pushing standards to the bottom in the name of harmonization and mutual recognition[48]. That might be the most difficult issue to negotiate mainly under the TTIP. However it is still difficult to know how legislation like REACH might be affected before the final draft is released.

It is not easy to identify concrete proposals from the chemical industry for regulatory cooperation. TTIP has to deal with a big gap in the chemical sector since US and EU have completely different approaches for regulation on chemicals - REACH in the EU and the U.S. Toxic Substances Control Act (TSCA). Therefore mutual recognition is difficult to be envisaged, although cooperation is possible on other basis.

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[45] VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.

[46] Such as the Trans-Pacific Partnership and the former negotiations for the Free Trade Area for the Americas.

[47] VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.

[48] See R. Trager, Fears free trade agréments will hamstring chemical legislation, In: http://www.rsc.org/chemistryworld/2014/04/fears-free-trade-agreements-will-hamstring-chemical-legislation (access on 10th July 2014).

The European Chemical Industry Council (CEFIC) and the U.S. American Chemistry Council (ACC) have proposed some steps for reducing duplication and for getting convergence within time, which include, inter alia:

a) Cooperating in the prioritization of chemicals that need to undergo assessment;
b) approximation of methods in chemical assessment;
c) intensive exchange of information and finding out about possibilities how to cooperate in newly arising topics (e.g. regulation of nanomaterials, combination effects of chemicals, endocrine active substances);
d) cooperation and exchange of information for data between public agencies in charge of chemicals;
e) an effort to handle the classification and labeling of chemicals in a similar manner and to implement the already agreed United Nations GHS classification and labeling system uniformly;
f) protection of registration data and of confidential business information and of trade secrets[49].

There is also a fear that sustainable agriculture and food policies might be endangered under these free trade agreements, since some of their negotiations focus on sanitary and phytosanitary restrictions[50]. Countries have been allowed to set their own standards for animal and plant health and food safety that are not based on science under the precautionary principle and REACH has made it its main language.

US companies have described REACH as 'the biggest trade barrier they face'[51]. On this behalf, the European Environmental Bureau fears that TTIP could threaten REACH by 'introducing confidentiality clauses that would make relevant safety data even harder to obtain, or by creating a system of 'mutual recognition' that would mean approval of a chemical in the US would mean it was automatically approved in the EU, where chemical regulation is tighter'[52].

One of the fears, mainly from the European side, is that there is already precedent for chemical industries using free trade agreement clauses, such as the North American Free Trade Agreement (NAFTA), to challenge legislation that infringe their expected profits.

In 1997, the US chemical company Ethyl Corporation successfully challenged a Canadian ban on import and inter-provincial trade of the gasoline additive MMT, a suspected neurotoxin that car makers claim interferes with vehicles' onboard diagnostic systems. Preliminary tribunal judgments against Canada led its government to repeal the MMT ban, issue an apology to the company and settled out of court with Ethyl for $13 million (£7.8 million). In 1998, the US waste disposal firm SD Myers challenged a temporary Canadian ban on the export of waste polychlorinated biphenyls. The tribunal awarded the company C$6 million compensation. A few years later, Crompton, a US-based agro-chemical company, now part of Chemtura, unsuccessfully challenged the Canadian government ban on the sale and use of lindane, an agricultural pesticide now banned under the Stockholm Convention on Persistent Organic Pollutants. Currently, Lone Pine Resources, a US oil and gas company, is challenging a Quebec government ban on hydraulic fracturing in the St Lawrence River basin and seeking damages of C$250 million, also under NAFTA[53].

TTIP has been accused as an excuse to 'water down' REACH in Europe. Nevertheless, as a matter of fact, negotiations have already pointed out that there will be no mutual

[49] VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.
[50] Trager, supra note 104.
[51] Ibid.
[52] Ibid.
[53] Trager, supra note 104.

recognition of REACH and TSCA, since they are too different regimes for chemicals management and their protection standards are quite distinct from each other. Regarding REACH and TSCA, there might have a more intensive data exchange between the chemicals agencies[54].

It has also been discussed to what extent TTIP threatens the WTO system. On this subject, there are positions that point out that WTO, in fact, lays 'the foundation for how to negotiate multilaterally – somewhere down the road – the many new topics which will be parts of TTIP' and, therefore, 'the results of the agreement should be open to third parties too', which would 'further multilateral trade liberalization', in general[55].

7 – Globalization and multiplication of REACH-likes

REACH has become a pattern that has been replicated worldwide. In the chemicals word, the 'order of the day' is, more and more, 'globalization of REACH'. It is interesting to note that compliance with REACH has become much more common place than complains against REACH. What exactly was the convincing European speech to make that happen?

Mourão and Zanata (2013) make a comment on a Press Release of the European Union (MEMO/06/488), which is based on some few questions: i)'Will REACH become the world standard for controlling chemicals?' The answer to this question is that the EU has effectively assumed the constructive role of international leader on chemicals safety and REACH has potential to inspire legislation all over the world; ii) 'How have European companies and third countries reacted to this European's desire to 'globalize' REACH'? The answer would be that many European companies have approved such globalization of the EU chemicals regulation since they are not penalized in face of other markets[56].

In fact, with such globalization, the European companies keep their competitiveness and, for the rest of the world, REACH might be a good investment as the European market is a large consumer's market. Moreover, adopting the high standards of REACH might result in substantial gains for all, but mainly for developing countries that will be able to have technological support and investments to adequate their markets under the Stockholm Convention on Persistent Organic Pollutants. The adoption of REACH in a multilateral level brings also gains to all since it reduces the duality of having to comply with different standards[57]. Nevertheless, REACH has also its bitter taste.

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[54] VCI Verband Der Chemischen Industrie . V. Wir Gestanten Zukunft. TTIP: Questions & Answers from the Chemical Industry. April, 2014.
[55] Ibid.
[56] MOURÃO, Nicia Maria Fusaro; ZANATTA, Fernando. A Globalização da regulação e suas forças motrizes: o caso do REACH. In: Revista Químicos e Derivados, 2013.
[57] Ibid.

Despite all these European assumptions that a REACH globalization might bring gains to all, Small and Medium Enterprises (SMEs), which have low technical knowledge and less access to investments, have faced many difficulties in complying with REACH. In Europe itself, such difficulties with compliance have led many SMEs to sell their plants to large companies – a process that is conducting Europe and other markets around the world to concentration, less competition and changes in chemicals overall prices[58].

Heyvaert (2009), Professor of International Environmental Law, at the London School of Economics and Political Science, argues that the importation of foreign regulatory norms and procedures might put pressure on local regulatory priorities, cultures and practices. She identifies five challenges that rules-importing countries are likely to face:

> First, there is the risk of a mismatch between global norms and local regulatory priorities. The second and third challenges address the risks generated by increasing regulatory uniformity, namely, the development of 'regulatory monocultures' and the amplification of both strengths and weaknesses of a dominant regulatory approach. The fourth and fifth challenges consider the process of rules importation as a first step in the development of transnational regulatory governance and contemplate some of the trade-offs between regulatory sovereignty and transnational recognition of domestic rule making[59].

REACH was constructed in such a way that it has become a 'desirable product' to be exported to the rest of the world. The rest of the world seems to be keen to 'buy it'. It represents a chemical regulation that has been promoted as a global standard, probably under the European belief 'in its inherent superiority as a regime to foster innovation and competitiveness on the chemicals market, while guaranteeing an acceptable high level of health and environmental protection'[60].

Nevertheless, there are other clear motivations, besides public health and environment that are at the front level of this globalization of REACH. 'If regulatory cost cannot be avoided entirely, then at least the affected industry can try to ensure that none of its competitors escape it, leading it to put pressure on government, first, to strive for uniformity in product regulations and, second, champion the adoption of equally costly regulations abroad, so that local rules do not adversely affect the global competitive position of the domestic industry'[61]. This is clear-cut a matter of keeping the EU's competitiveness on the global market.

Moreover, taking REACH beyond EU's borders legitimatizes its high standards procedures, joining together EU's allies for that matter. Heyvaert adverts that it would be much more difficult to argue that REACH's risk management regime is not necessary, or that it is unfair or disproportionate if it is ratified by a considerable share of the world population[62].

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[58] Ibid.
[59] HEYVAERT, Veerle. Globalizing Regulation: Reaching Beyond the Borders of Chemicals Safety. In: Journal of law and Society, v. 36, N. 1, March, 2009, at 111.
[60] Ibid., at 113.
[61] Ibid., at 114.
[62] Ibid., at 116.

However, as the primary goals of REACH are the protection of public health and the environment, all the burdensome costs and bureaucracy that it causes would be considered legitimate if it achieves its goals. 'A number of leading scientists in Europe take a discouragingly dim view of the quality of the information that will be generated in compliance with the REACH prescriptions as a basis for better health and environmental decision making. For instance, the decision to exclude substances produced below one tonne pm/py causes unease, since production volume is a plausible but still highly imperfect heuristic for expected exposure. A considerable range of chemicals that pose unacceptable risks may continue to escape out notice as they are produced in below-threshold volumes. Even more damningly, the chemical tests prescribed for toxicity and ecotoxicity assessment are no longer state-of-the-art, and can only give the most rudimentary insight into a chemical's toxicity'[63].

In fact, according to representatives of the Brazilian chemicals industry, the registration procedure of REACH has not brought up surprises or added any value to the scientific knowledge so far that could justify its strictness in the name of protection of human health and the environment[64].

8 - Specific Trade Concerns on REACH[65]

After the notification of REACH regulation to the TBT Committee, thirty four non-European WTO-Members expressed Specific Trade Concerns (STC) about REACH, most of them comprising of REACH's registration/data gathering and notification obligations. Some of the main concerns raised in the last years were based on the following arguments:

a) SMEs – high costs and bureaucracy for Small and Medium Enterprises; distorting market effects competition; market concentration since these SMEs have been absorbed by large companies;
b) Developing countries – no available technologies and difficulties to fulfil REACH requirements;

[63] Ibid., at 123.
[64] MOURÃO, N. M. F.; ZANATTA, F., 2013.
[65] 'The Committee on Technical Barriers to Trade ("TBT Committee") was established with the purpose of "affording Members the opportunity of consulting on any matters relating to the operation of this Agreement or the furtherance of its objectives, and shall carry out such responsibilities as assigned to it under this Agreement or by the Members". Since its first meeting, Members have used the TBT Committee as a forum to discuss issues related to specific measures (technical regulations, standards or conformity assessment procedures) maintained by other Members. These are referred to as "specific trade concerns" and relate variously to proposed measures notified to the TBT Committee in accordance with the notification requirements in the Agreement, or to measures currently in force. Committee meetings, or informal discussions between Members held in the margins of such meetings, afford Members opportunity to review trade concerns in a bilateral or multilateral setting and to seek further clarification'. In: WTO, G/TBT/GEN/74/Rev.9, 17 October 2011, Note by the Secretariat.

c) Distinct interpretations of REACH terms – as the implementation of REACH is due in each country of the EU, there have been multiple interpretations of REACH terms, such as 'articles' and, therefore, there is an urgent need to harmonize REACH interpretation in Europe;
d) Nanomaterials – proliferation of registries among the State Members of the EU;
e) SIEF (Substance Information Exchange Fora – arbitrary and opaque functioning, including costs related to it; large companies have become owners of data within the SIEF system;
f) ORs (Only Representatives) – discrimination on foreign importers and producers, since they cannot register their products without contracting an European O.R.;
g) SVHCs (Substances of Very High Concern): lack of a pattern on notification of SVHCs; each EU country proceeds in a different manner[66].

Nevertheless, REACH has not been challenged at the WTO Dispute Settlement System so far. There have been identified possible nine reasons for that:

1) the EC's submission to the TBT Committee of an "early notification" under TBT Agreement, Article 2.9.1 acquainting Members with the proposed REACH regulation; 2) the EU's almost simultaneous hosting of a public internet-based consultation that received up to 6,500 comments in response to the REACH proposal; 3) the EU's granting of a 60-day extension to the REACH comment period; 4) the EU's willingness to respond in writing and in person to WTO Member's numerous concerns at several TBT Committee meetings and to engage in private bilateral consultations with some WTO Members; 5) considerable WTO Member government and non-EU industry lobbying; 6) the EU's willingness to incorporate at least some of the comments and criticisms received into a partial revision of REACH prior to its adoption; 7) the passage of time deemed necessary for the purpose of accurately assessing whether the adopted REACH registration/data gathering obligation has been applied in a WTO-consistent manner; 8) a dedicated *cadre* of academic, civil society and industry advocates/lobbyists who have labored to defuse accusations of REACH WTO non-compliance; and 9) the EU's likely comprehensive review of the Panel and AB decisions in WTO Shrimp-Turtle case[67].

In case of a dispute under the WTO system, the EU is "likely to emphasize that it had engaged in prior efforts to ensure that REACH was complementary to international initiatives, such as the International Council of Chemicals Management" and also that they have undertaken "good faith diplomatic efforts to negotiate with other WTO Members, including those which have raised objections to the proposed measure, for the purpose of concluding bilateral or multilateral agreements that address the perceived (health, environment etc.) threat in a more consensual manner, prior to enforcing said measure"[68].

However, after eight years of implementation of REACH, we understand that new STCs can be raised on the following basis:

i) Many Small and Medium Enterprises (SMEs), in Europe and in the rest of the world, have sold out their business to large companies, which has led the

[66] WTO, Minutes G/TBT/N/EU/131, G/TBT/N/EEC/52 (+Adds.1-7) G/TBT/N/EEC/52/Add.3/Rev.1, G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, G/TBT/N/EEC/297/Rev.1, G/TBT/N/EEC/297/Rev.1/Add.1; G/TBT/N/EEC/333, G/TBT/N/EEC/333/Add.1, G/TBT/N/EEC/334, G/TBT/N/EEC/334/Add.1; G/TBT/N/EEC/335, G/TBT/N/EEC/335/Add.1; G/TBT/N/EEC/336, G/TBT/N/EEC/336/Add.1; G/TBT/W/208.
[67] Kogan, supra note 9, para. 12.17.
[68] Ibid., para. 12.18.

chemicals market worldwide to concentration, less competition and changes in chemicals overall prices[69].

ii) As REACH has been 'exported', the importation of foreign regulatory norms and procedures might put pressure on local regulatory priorities, cultures and practices[70].

iii) Increasing regulatory uniformity leads to the development of 'regulatory monocultures' and consequently the amplification of both strengths and weaknesses of a dominant regulatory approach[71].

iv) Leading scientists in Europe have had a discouragingly view in relation to the quality of data that has been generated in compliance with REACH's prescriptions for better health and protection of the environmental[72].

9 - Case Law on REACH in the European Court of Justice

Since there is no case law under the WTO system specifically related to REACH, it is important to analyze some of the disputes that have been brought before the European Court of Justice and the European General Court[73] on this issue.

In an annex to the present work, there are some other disputes that have been listed, which comprise of similar discussions to the ones herein analyzed.

9.1 - Case C-558/07: S.P.C.M. SA and Others v Secretary of State for the Environment, Food and Rural Affairs[74]

The European Court of Justice interpreted the scope of Article 6(3) of the REACH Legal Text and declared Article 6(3) valid in the European Court of Justice ruling on monomers C-558/07 of 7 July 2009.

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[69] MOURÃO, Nicia Maria Fusaro; ZANATTA, Fernando, 2013.
[70] HEYVAERT, 2009.
[71] Ibid.
[72] Ibid.
[73] The European General Court (EGC) is a constituent of the European Union's Court of Justice. The EGC hears actions taken against the institutions of the European Union by individuals and Member States, although certain issues are reserved for the European Court of Justice (ECJ), which is the highest court in Europe. Decisions of the General Court can be appealed to the ECJ, but only on a point of law. Prior to the coming into force of the Lisbon Treaty on 1 December 2009, it was known as the Court of First Instance. In: http://curia.europa.eu/ (access on 22nd July 2014).
[74] See in http://curia.europa.eu/juris/document/document.jsf?text=&docid=77548&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=524647 (access on 10th July 2014).

The case concerned a request from the High Court of Justice (England & Wales), Queen's Bench Division - Administrative Court, regarding the interpretation and validity of REACH, Article 6(3).

REACH, Article 5, entitled 'No data, no market', provides:

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

REACH, Article 6, entitled 'General obligation to register substances on their own or in preparations', provides as f[1] HEYVAERT, 2009.

[1] Ibid.

ollows:

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the [European Chemicals] Agency.
(…)
3. Any manufacturer or importer of a polymer shall submit a registration to the [European Chemicals] Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain, if both the following conditions are met:
a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

Moreover, Article 8 of REACH states:

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.
2. The representative shall also comply with all other obligations of importers under this Regulation.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.'

For a preliminary ruling, two questions were raised by the UK High Court: 1) clarification of the concept of 'monomer substance', as used in Article 6(3) of the REACH Regulation; and 2) whether Article 6(3) of the REACH Regulation is invalid in so far as it requires manufacturers and importers of polymers to submit an application for registration of monomer substances.

It must be first clarified that unreacted monomers must, according to Article 6(1) and (2) of the REACH Regulation, be registered inasmuch as they constitute substances on their own. By contrast, polymers are, in accordance with Article 2(9) of that regulation, excluded from the registration obligation. According to Article 3 (5), polymers are composed of monomer units, which are defined as monomer substances in a reacted form. As it can be observed, Article 6(3) of the REACH Regulation concerns monomer substances or any other substances which are constituents of polymers. Therefore, given

the definition of polymer as stated in Article 3(5) of the REACH Regulation, registration concerns reacted monomer substances and the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are incorporated in polymers. As such, it is not polymers which are affected by the registration obligation but only monomer substances with their own characteristics as they existed before polymerization. Despite polymers are exempted from registration because of their large number, according to Article 138(2) of the REACH Regulation, that situation is liable to be reviewed as soon as it is possible to establish a practicable and cost-efficient way of selecting polymers.

The ECJ's ruling answered the first question by reaching a conclusion that the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are integrated in polymers.

As for the second question, the ECJ found it important to have a look at the principle of proportionality. Under EC Law, the principle of proportionality requires that measures implemented through Community provisions should be appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it[75]. The ECJ found that it was necessary to examine whether the obligation to register monomer substances constitutes a proportionate means to achieve the objectives of that regulation – that is, to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation, as set in Article 1of the REACH regulation.

In the preamble of REACH, the method to achieve this objective is the registration obligation imposed on manufacturers and importers, which includes the obligation to generate data on the substances that they manufacture or import, to use those data to assess the risks related to those substances and to develop and recommend appropriate risk management measures. Therefore, the obligation to register monomer substances, which are less numerous than polymers, makes information available not only on the risks specific to those substances but also on those of monomers found as residues after polymerization or in monomer form after the possible degradation of the polymer[76]. The ECJ understood that the registration of reacted monomers in polymers obeyed the precautionary principle and that it is an appropriate means by which to realize the objectives of the REACH Regulation[77].

It remains to be determined whether that obligation goes beyond what is necessary. As it was applied for Community manufacturers and importers of monomer substances alike, preventing distortion of competition, the ECJ reached a conclusion that the

[75] Case C-491/01 British American Tobacco (Investments) and Imperial Tobacco [2002] ECR I‑11453, paragraph 122 and the case-law cited.
[76] Ibid, para. 53.
[77] Ibid., para. 58.

regulation does not go beyond that which is necessary to meet the objectives of the REACH Regulation[78].

In the proceedings before the UK High Court, the applicants claimed the proportionality of that registration obligation, taking into account that importers are faced with heavier practical difficulties that arise mainly from the fact that first, they do not know the composition of the imported polymer and, second, that the costs of the registration procedure are disproportionate in relation to the results achieved and the quantities of substances concerned[79].

Regarding such concerns, the ECJ pointed out that 'the procedure is identical whether the products are manufactured in the Community or outside it and, consequently, the burden is not heavier for manufacturers not established in the Community or importers than it is for Community manufacturers'[80] and therefore, 'taking account of the limited number of potential monomer substances, the 12-year period of validity for a previous registration of substances, as provided for in Article 27 of the REACH Regulation, and the possibility of sharing information in order to reduce costs, the burden deriving from the obligation to register reacted monomer substances in polymers does not appear to be manifestly disproportionate in the light of the free movement of goods on the internal market open to fair competition. It follows that Article 6(3) of the REACH Regulation is not invalid on the ground that it infringes the principle of proportionality'[81].

It was also discussed under the UK High Court that there was an infringement of the principle of equal treatment, since Community manufacturers of polymers were in a position to register those substances more easily than were importers because they know the composition of their products, whereas importers are subject to the good will of their suppliers outside the Community. Regarding such a concern, the ECJ ruled that 'the identical treatment required in those different situations is objectively justified by compliance with the competition rules applicable in the internal market' and that 'no infringement of the principle of equal treatment can be found and, therefore, that Article 6(3) of the REACH Regulation is not invalid on the ground that that principle has been infringed'[82].

9.2 - Case C-358/11: Lapin elinkeino-, liikenne- ja ympäristökeskuksen liikenne ja infrastruktuuri -vastuualue v Lapin luonnonsuojelupiiri ry, Judgment of the Court of 7 March 2013[83]

[78] Ibid., para. 63.
[79] Case 491/01, Ibid., para. 64.
[80] Ibid., para. 67.
[81] Ibid. para. 71-72.
[82] Ibid. para 78-80.
[83] See in: http://curia.europa.eu/juris/document/document.jsf?text=&docid=134608&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=557970 (access on 10th July 2014).

In 2008, the *Liikenne ja infrastruktuuri -vastuualue* decided to repair the 35 km track between *Raittijärvi village* and the nearest road, part of which crosses a Natura 2000 zone. The repair work was to consist in laying down wooden duckboards to facilitate the passage of quad vehicles in wetland areas outside the winter season besides other provisions. Those duckboards are supported by structures made up of old telecommunications poles which, for their previous use, were treated with CCA solution. The *Lapin luonnonsuojelupiiri*, which is the applicant association in the main proceedings, took the view that those poles constitute hazardous waste and requested the *Lapin ympäristökeskus* (the body responsible for environmental protection) to prohibit the use of those materials. Following the rejection of that request, that association brought an action before the *Vaasan hallinto-oikeus* (Administrative Court), which annulled that decision in 2009. The case was raised before the *Korkein hallinto-oikeus* (Supreme Administrative Court), which brought the requests before the ECJ for a preliminary ruling, as following[84]:

'1 Is it possible to deduce directly from the fact that waste is classified as hazardous waste that the use of such a substance or object has overall adverse environmental or human health impacts within the meaning of Article 6(1), first subparagraph, point (d), of … Directive 2008/98/EC? May hazardous waste also cease to be waste if it fulfils the requirements laid down in Article 6(1) of Directive 2008/98?
2. In interpreting the concept of waste and, in particular, assessing the obligation to dispose of a substance or an object, is it relevant that the re-use of the object which is the subject of the assessment is authorized under certain conditions by Annex XVII as referred to in Article 67 of the REACH Regulation? If that is the case, what weight is to be given to that fact?
3. Has Article 67 of the REACH Regulation harmonized the requirements concerning the manufacture, placing on the market or use within the meaning of Article 128(2) of that regulation so that the use of the preparations or objects mentioned in Annex XVII cannot be prevented by national rules on environmental protection, unless the restrictions [envisaged by those provisions] have been published in the inventory compiled by the Commission, as provided for in Article 67(3) of the REACH Regulation?
4. Is the list in Point 19(4)(b) in Annex XVII to the REACH Regulation of the uses of CCA-treated wood to be interpreted as meaning that that inventory exhaustively lists all the possible uses?
5. Can the use of the wood at issue as underlay and duckboards for a wooden causeway be treated in the same way as the uses listed in the inventory referred to in Question 4 above, so that the use in question may be permitted on the basis of Point 19(4)(b) of Annex XVII to the REACH Regulation if the other conditions are met?
6. Which factors are to be taken into account in order to assess whether repeated skin contact within the meaning of Point 19(4)(d) of Annex XVII to the REACH Regulation is possible?
7. Does the word "possible" in the provision mentioned in Question 6 above mean that repeated skin contact is theoretically possible or that repeated skin contact is actually probable to some extent?'[85]

As a preliminary observation, it should be noted that despite the telecommunications poles under stake were treated with a dangerous substance, for the application of REACH, it remains the fact that, under that regulation, such treatment does not preclude, under certain circumstances, the use of those wooden poles for certain purposes that may include duckboards for the track concerned, where appropriate. It should also be observed that, according to REACH, Article 2(2), waste, as defined in Directive 2008/98, is not a substance, mixture or article within the meaning of Article 3 of that regulation.

[84] Case C-358/11, para. 22-23.
[85] Ibid., para. 26.

Moreover, REACH, Article 67(1) and (3) states:

'1. A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. …
(…)
3. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by 1 June 2009.'

First, the ECJ examines the third question

So far as Article 67(3) of the REACH Regulation is concerned, while it authorizes a Member State to maintain existing and more stringent restrictions than those in Annex XVII, this is to be done on a transitional basis, until 1 June 2013, and subject to the condition that those restrictions have been notified to the Commission, something which the Republic of Finland, moreover, acknowledges that it has not done. The transitional and conditional nature of that measure cannot call into question the harmonization carried out by Article 67(1) of the REACH Regulation.

Therefore, if a Member State intends to make the preparation, placing on the market or use of a substance which is the subject of a restriction under Annex XVII to the REACH Regulation subject to new conditions, it may do so only in accordance with Article 129(1) thereof, in order to respond to an urgent situation to protect human health or the environment, or in accordance with Article 114(5) TFEU on the basis of new scientific evidence relating inter alia to the protection of the environment. The adoption of other conditions by the Member States is incompatible with the objectives of that regulation (see, by analogy, Joined Cases C‑281/03 and C‑282/03 Cindu Chemicals and Others [2005] ECR I‑8069, paragraph 44) [86].

The ECJ concluded that, under those circumstances, the answer to the third question is that Articles 67 and 128 of the REACH must be interpreted as meaning that European Union law harmonizes the requirements relating to the manufacture, placing on the market or use of a substance such as that relating to arsenic compounds which is the subject of a restriction under Annex XVII to that regulation[87].

The ECJ goes on to analyze the fourth and fifth questions. The provisions of Annex XVII, point 19(4), to the REACH set out the situations in which there may be a derogation from the provisions of point 19(3) prohibiting the use of arsenic compounds for the protection of wood. Regarding these questions, Annex XVII states, in point 19, column 2, concerning 'Conditions of restriction' that:

3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.
4. By way of derogation from paragraph 3:
(a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorized in accordance with Article 5(1) of Directive 98/8/EC. Wood so treated shall not be placed on the market before fixation of the preservative is completed.

[86] Case C-358/11, para. 36-37.
[87] Ibid., para. 38.

(b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:
– as structural timber in public and agricultural buildings, office buildings, and industrial premises,
– in bridges and bridgework,
(…)
– as electric power transmission and telecommunications poles,
(…)
(d) Treated wood referred to under point (a) shall not be used:
– in residential or domestic constructions, whatever the purpose,
– in any application where there is a risk of repeated skin contact,
(…)
5. Wood treated with arsenic compounds that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.
6. Wood treated with CCA type C that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4:
– may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d),
– may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
7. Member States may allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007:
– to be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d),
– to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).'

The ECJ makes a first point that the provision mentioned in these questions has an exhaustive list and must be necessarily subject to strict interpretation[88]. It remains the question whether the use of the telecommunications poles at issue as an underlay for duckboards does in fact come within the scope of the applications listed in that provision. The ECJ understands that it would come within the scope of REACH 'where there is a risk of repeated skin contact', which 'must be interpreted as meaning that the prohibition at issue must apply in any situation which, in all likelihood, will involve repeated skin contact with the treated wood, such likelihood having to be inferred from the specific conditions of normal use of the application to which that wood has been put'[89].

For the present essay, it is not important to go through the ECJ' s reasoning on the first question. Nevertheless the second question is also related to REACH. The ECJ's answer to second question is therefore that REACH, Annex XVII, 'in so far as it authorizes the use, subject to certain conditions, of wood treated with CCA solutions, is, in circumstances such as those in the main proceedings, relevant for the purpose of determining whether such wood may cease to be waste (…)'[90].

[88] Case C-358/11, para. 41-43.
[89] Ibid., para. 52.
[90] Ibid., para. 64.

Article 2(2) of the REACH Regulation provides that it does not apply to waste. However, it would not be consistent to understand from Article 13 of the Waste Directive requirements concerning the use of waste which the holder does not discard or intend to discard, or no longer discards or intends to discard, which are more stringent than those for identical substances which are not waste. An inconsistency of that kind must in any event be avoided if rules for such substances exist that have a similar objective. It must be reminded that the purpose of the REACH Regulation, under Article 1(1), is to ensure a high level of protection of human health and the environment. Despite that objective, it is not all uses of substances, mixtures or products that would be permissible under that regulation; it is necessarily also to be regarded as permissible recovery of waste, particularly hazardous waste. REACH covers a large number of substances, mixtures and products, but specifically regulates their use in certain cases, which are distinguished by particularly serious risks to human health and the environment. The Member States may restrict the use of such substances to protect workers, human health and the environment unless it has been harmonized under the regulation. According to REACH, such harmonized rules for the use of CCA-treated wood already exist. Such an assessment must serve as guidance on how similar waste may be used[91].

On first and second question, the ECJ ruled that the answer to be given to Questions 1 and 2 is that, under Article 6(4) of the Waste Directive, 'hazardous waste is no longer to be regarded as waste if it is to be presumed that the holder no longer discards or intends or is required to discard it because its recovery corresponds to a use which harmonized rules for the purpose of Article 128(2) of the REACH expressly permit for identical substances which are not waste'[92].

9.3 - Cases C-625/11P and C-626/11P: Polyelectrolyte Producers Group (PPG) and SNF *v.* ECHA, Judgment of the Court in Case C-625/11P and in Case C-626/11P, both of 26 September 2013

The first case concerned ECHA's inclusion of a substance on the list of 'candidate substances'. PPG (Polyelectrolyte Producers Group GEIE) is a European economic interest grouping which represents the interests of companies that are producers and/or importers of polyelectrolytes, polyacrylamide and/or other polymers containing acrylamide, established in Brussels . SNF is one of its member companies, established in Andrézieux-Bouthéon, France.

In 2009, the Netherlands submitted to ECHA a dossier concerning the identification of acrylamide as a substance fulfilling the criteria set out in Article 57(a) and (b) of REACH, which sets out the substances which may be included in Annex XIV to that regulation, entitled 'List of substances subject to authorization' and letters (a) and (b) of

[91] Ibid., para. 92-96.
[92] Ibid., para. 97.

Article 57 list the substances which meet the criteria for classification as carcinogenic and mutagenic substances under certain categories.

In the contested decision, ECHA identified acrylamide as fulfilling the criteria set out in Article 57 of REACH and included acrylamide on the candidate list of substances, which was published on the ECHA website, in accordance with Article 59(10) of the REACH Regulation. According to Article 59 of that regulation, entitled 'Identification of substances referred to in Article 57', paragraph (10) establishes that ECHA shall publish and update the list that identifies substances meeting the criteria referred to in Article 57 and establish a candidate list for eventual inclusion in Annex XIV ('candidate list of substances').

PPG and SNF brought an action against that decision and, according to ECHA and the European Commission, the complainants failed to observe the time-limit for bringing an action. On the basis of the alleged failure to comply with the time‑limit for bringing an action, the General Court, at first instance, dismissed the action brought by PPG and SNF as inadmissible without considering the other pleas of inadmissibility raised by ECHA and the Commission[93].

Leaving aside the time-limit procedural discussions of the case, which were the main issue, it is important to make reference to an interpretation of the ECJ related to the fact that 'it is not disputed that a decision of ECHA concerning the inclusion of a substance on the list of candidate substances constitutes a challengeable act. Article 94(1) of the REACH Regulation provides that an action may be brought against a decision of ECHA, in accordance with the Treaty on the Functioning of the European Union (TFEU), Article 263, where, inter alia, no right of appeal lies before the Board of Appeal of ECHA. That is the case in respect of decisions taken under Article 59 of the REACH Regulation[94].

Regarding the main issue, without raising the grounds for that finding, it is important to note that the ECJ overruled the first instance decision, considering that it was not observed the proper procedural time-limit for the complainants to bring an action against ECHA on the grounds that a substance was included in the 'candidate list'[95]. This case makes a point for the possibility of challenging ECHA's decision of including a substance in the candidate list, since it operates within the procedural limits.

In the second Case C-626/11P, an action was brought for annulment prior to the publication of acrylamide on the candidate list of substances of very high concern. ECHA, on 27 November 2009, agreed on the identification of acrylamide as a substance of very high concern, because it fulfilled the criteria set out in Article 57(a) and (b) of the REACH Regulation and, On 7 December 2009, ECHA published a press release announcing it. The candidate list of substances would be formally updated in January

[93] Case C-625/11P, para. 20.
[94] Ibid., para. 28.
[95] Ibid., para. 35.

2010. On 30 March 2010, the candidate list of substances, including acrylamide, was published on the ECHA website[96].

PPG and SNF raised an appeal on the basis that the General Court erred in law in the interpretation and application of the REACH by finding that the identification of a substance as one of very high concern by the ECHA Member State Committee, according to Article 59(8) of REACH, does not constitute a decision intended to produce legal effects vis-à-vis third parties before the publication of the candidate list of substances including that substance[97]. They claimed that it is clear, from the various references to 'identification' and 'inclusion' in the provisions of REACH defining the obligations regarding information, that the European Union regulation 'intended to create such obligations arising from the identification of a substance at an earlier stage than its inclusion on the candidate list of substances'[98].

According to Article 59 of REACH, entitled 'Identification of substances referred to in Article 57':

'1. The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV ('candidate list of substances'). ...
(…)
3. Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to [ECHA].… [ECHA] shall make this dossier available within 30 days of receipt to the other Member States.
4. [ECHA] shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. [ECHA] shall invite all interested parties to submit comments within a specified deadline to [ECHA].
5. Within 60 days of circulation, the other Member States or [ECHA] may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to [ECHA].
6. If [ECHA] does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. …
7. When comments are made or received, [ECHA] shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.
8. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, [ECHA] shall include the substance in the list referred to in paragraph 1. …
(…)
10. [ECHA] shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.'

On the one hand, under the ECHA, whenever a procedure involves several stages, only measures that lay down the institutional position at the completion of the procedure is a contestable measure. Therefore, according to ECHA, in the present case, the inclusion of acrylamide on the candidate list of substances, published on 30 March 2010, is the only measure that creates potential legal effects and, as such, the agreement of the Member State Committee is a 'preparatory measure' that cannot not produce any legal obligation in itself[99].

[96] Ibid., para. 7-10.
[97] Ibid., para. 24.
[98] Ibid., para. 25.
[99] Case C-626/11P, para. 26.

The Commission itself has found that 'whenever an unanimous agreement of the Member State Committee allows no discretion as to the inclusion of a substance on the candidate list of substances does not mean that that agreement constitutes the final, challengeable measure and is substitutable for the decision of ECHA taken under Article 59(8) of the REACH Regulation'[100].

On the other hand, the Commission also understands that no provision of REACH point out to a distinction between the 'identification of a substance' and 'its inclusion on the candidate list of substances'. From Article 59 of REACH, it can be understood that substances are identified as 'substances of very high concern' for the sole purpose of being included on the candidate list[101].

On first instance, the General Court was right to find that the legal obligations that arise from the measure identifying a substance as being of 'very high concern', resulting from the procedure referred to in Article 59 of REACH, only bind the persons concerned after publication of the candidate list of substances, which contains that specific substance, just as provided for in Article 59(10), because only then it is possible to ascertain unequivocally what are those person's rights and obligations in order to take the necessary measures accordingly[102].

The ECJ ruled that the General Court was wrong to conclude that an 'application was inadmissible on the ground that it had been brought before the date of publication of the contested decision by means of the inclusion of acrylamide on the candidate list of substances on the ECHA website, initially scheduled for 13 January 2010, but which finally took place on 30 March 2010' and, in the light of the foregoing, the appellants' appeal was upheld. The case went back to the General Court, since the state of the proceedings does not allow the ECJ to give final judgment in such a matter[103].

10 - Cases under the General Court

10.1 Case T-93/10: Bilbaína de Alquitranes, SA and Others v ECHA, Judgement of the General Court of 7 March 2013

The case T-93/10, under the European General Court, consisted of an action raised by Bilbaina de Alquitranes, established in Spain, and others, for the partial annulment of the decision of ECHA, which was published on 13 January 2010, to identify pitch, coal tar, high temperature (so called CTPHT) as a substance among the carcinogenic substances (category 2) on account of its persistent, bioaccumulative and toxic properties ('PBT properties') and its very persistent and very bioaccumulative properties ('vPvB properties'), meeting the criteria set out in Article 57(a), (d) and (e) of

[100] Ibid., para. 27.
[101] Ibid., para. 28.
[102] Ibid., para. 31-32.
[103] Ibid., para. 41, 44.

REACH. The applicants brought an action for partial annulment of the decision of the ECHA, regarding specifically their substance concerned.

ECHA argues inadmissibility of the action because it says that the contested decision is not of direct concern to the applicants. It is not disputed that the applicants, who are the suppliers of a substance provide the recipient of the substance in question with a safety data sheet where that substance meets the criteria for classification as 'dangerous'(CTPHT has been classified among the carcinogenic substances - Category 2). Nevertheless, it is disputed that the identification of CTPHT as a substance of very high concern, resulting from application of the procedure provided for by Article 59 of REACH, on the ground that that substance has PBT or vPvB properties, constitutes new information capable of triggering the obligation referred to in that provision; that is, the updating of the safety data sheet, with the result that the contested decision directly affects the legal situation of the applicants[104].

The identification of CTPHT as a 'substance of very high concern', on the grounds that it has PBT or vPvB properties, constitutes new information, regarding hazards identification and composition/information on ingredients. The ECHA's argument that 'the dangerous nature of the substance at issue is caused by its inherent properties, which the applicants should have assessed and should have been aware of before the adoption of the contested decision, first, it must be observed, that the ECHA refers to the discussions held in a subgroup of the European Chemicals Bureau (ECB) on the question whether the substance at issue met the PBT and vPvB criteria. While it is true that the hazards caused by a substance are the result of its inherent properties, those dangers must be assessed and determined in accordance with defined rules of law. In its argument concerning the discussions held in that subgroup, the ECHA does not indicate the rules of law which allowed that subgroup to determine the PBT and vPvB properties. Moreover, the ECHA does not state that the conclusions of that subgroup were binding on the applicants. On the other hand, the applicants pointed out that the conclusions concerning CTPHT were disputed. Second, the ECHA states that the applicants should have assessed the inherent properties of CTPHT and should, as a result, be aware of the PBT and vPvB properties of that substance. As is apparent from the case-file and as the applicants confirmed at the hearing, it is precisely the PBT and vPvB properties of CTPHT which they dispute. Thus they did not conclude, in the context of their assessment concerning CTPHT, that that substance had PBT and vPvB properties'[105].

Regarding the 'hazard identification' of the safety data sheet, the identification of CTPHT as a 'substance of very high concern', on the ground that that substance had PBT or vPvB properties, consisted of new information which could allow users to take measures for the protection of human health and safety at work and for the protection of the environment. Such an identification amounts to new information that is capable of

[104] Case T-93/10, para. 39-40.
[105] Case T-93/10, para. 47.

affecting the risk management measures, or new information on hazards and, as such, the applicants were obliged to update the safety data sheets concerned. Therefore, the contested decision directly affects the legal situation of the applicants. According to REACH, any actor in the supply chain of a substance must communicate new information on hazardous properties, regardless of the uses concerned, to the next actor or distributor up the supply chain. Therefore it is uncontestable that the contested decision is of direct concern to the applicants [106].

Moreover, ECHA has argued that the action is inadmissible because the contested decision is not a 'regulatory act'[107]. It is true that the contested decision does not constitute a legislative act since it was not adopted according to EU legislative procedure. However the contested decision is an act of the ECHA adopted on the basis of Article 59 of REACH and, as such, the General Court found that it constitutes a regulatory act[108].

It was submitted by the applicants that the identification of CTPHT as a 'substance of very high concern' breaches the principle of equal treatment. It is alleged that that substance is comparable, concerning its content of chemical substances and of competition on the market, to other UVCBs containing anthracene and other polycyclic aromatic hydrocarbons ('PAHs'). Nevertheless, ECHA, with no objective justification, identified only CTPHT, and not those other substances, as a 'substance of very high concern'[109].

REACH, Article 59, sets out an identification procedure that does not confer on ECHA the power to choose the substance to be identified. Nevertheless, if a dossier on a substance is prepared by a Member or, at the request of the Commission, by the ECHA, the latter must proceed to identify that substance in accordance with the conditions set out in that article. The Great Court understood that the identification procedure was observed and that, in identifying CTPHT and not the allegedly comparable substances as a substance of very high concern, the ECHA did not breach the principle of equal treatment[110].

There was also a plea alleging an error of assessment or an error of law in the identification of a substance as PBT or vPvB on the basis of its constituents. The applicants pointed out that the dossier presented by ECHA for CTPHT did not comply with the requirements set out in Article 59(2) and (3) and in Annexes XIII and XV of REACH because it was not based on 'an assessment of the substance itself but on an assessment of the properties of its constituents'. Besides that, the rule that a substance must be identified as 'having PBT or vPvB properties provided that it contains a constituent which has PBT or vPvB properties and is present in a concentration of 0.1%

[106] Ibid., para. 48-50.
[107] Ibid, para. 52.
[108] Ibid, para. 65.
[109] Ibid, para. 69.
[110] Case T-93/10, para. 72.

or more' is not provided for in Annex XIII to REACH and therefore has no legal basis[111]. The Great Court considered that ECHA did not therefore infringe those provisions[112] and that it based its approach on scientific reasons[113] because 'that CTPHT was not identified as having PBT and vPvB properties solely because a constituent of that substance has a certain number of PBT and vPvB properties, but that the proportion in which such a constituent is present and the chemical effects of the presence of such a constituent were also taken into account. The applicants' argument concerning the identification of CTPHT as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1% does not demonstrate that the contested decision is vitiated by a manifest error'[114].

It is also observed by the applicants that the assessment of the constituents of the substance at issue is not a 'sufficient basis' for its identification as having PBT or vPvB properties since those constituents have not been individually identified as having PBT or vPvB properties in a separate ECHA decision based on a thorough assessment for that purpose[115], but the General Court also rejected such a submission.

A third plea was brought up, alleging that the contested decision does not respect the principle of proportionality. REACH's objective is to ensure a high level of protection of human health and the environment. All the substances that could replace CTPHT also have PBT or vPvB properties. The applicants claim that ECHA could have taken other 'appropriate and less onerous measures', which could be 'the application of risk management measures on the basis of the chemical safety assessment in the registration dossier prepared by the applicants' or 'the presentation of a dossier concerning the substance at issue under Title VIII of REACH[116].

The principle of proportionality, which is a general principle under EU case law[117] and a principle invoked under WTO case law[118], requires that measures adopted by Members do not exceed the limits of what is supposed to be appropriate and necessary in order to reach the objectives pursued and whenever there is a choice between several appropriate measures, it should be chosen the least onerous one. Besides that, the measure at issue must not be disproportionate to the aims pursued.

Regarding the principle of proportionality, the General Court remarked that the 'ECHA is to recommend priority substances to be included' in the annex 'taking into account the opinion of the Member State Committee and specifying for each substance inter alia the uses or categories of uses exempted from the authorization requirement'. Therefore

[111] Ibid, para. 78.
[112] Ibid, para. 81.
[113] Ibid, para. 89.
[114] Ibid, para. 100.
[115] Ibid, para. 102.
[116] Case T-93/10, para. 113.
[117] See Case C‑15/10 Etimine [2011] ECR I‑0000.
[118] See US – Standards for Reformulated and Convention Gasoline (US-Gasoline), WT/DS2/9, adopted on 20 May 1996, Section III.B.

a substance may be subject to authorization only as a result of a decision by the Commission to include that substance in REACH, Annex XIV. For the purpose of identification of substances of very high concern, REACH lays down an authorization procedure[119]. On such reasoning, the applicant's argument was rejected.

Within the claim of proportionality, the applicants argued that the contested ECHA's decision exceeds the limits of what is necessary to achieve the objectives pursued, since other provisions could be less onerous and at the same time serve to provide a high level of protection of human health and the environment. It was argued that the ECHA could have waited for the presentation of the assessment in order to check the chemical safety report and the proposed risk management measures, instead of identifying the substance at issue as being of very high concern[120]. The General Court understood that 'the objective of the authorization procedure', under REACH, is part, inter alia, 'progressively to replace substances of very high concern with other appropriate substances or technologies, where they are economically or technically viable' and therefore 'the risk management measures' proposed under REACH 'do not constitute appropriate measures for the achievement of the objectives pursued'[121].

10.2 - Case T-94/10: Rütgers Germany GmbH and Others v ECHA, Judgement of the General Court of 7 March 2013

The case consisted of an action brought by Rütgers Germany GmbHfor, based in Germany, and others, for the partial annulment of the decision of ECHA to identify anthracene oil[122] as a substance of very high concern, under REACH**[123]**.

Germany submitted to the European Chemicals Agency ('ECHA'), on 28 August 2009, a dossier that it had prepared on the identification of anthracene oil, on behalf of its persistent, bioaccumulative and toxic properties ('PBT properties') and its very persistent and very bioaccumulative properties ('vPvB properties'). Following the procedure, ECHA stated that anthracene oil is classified as a 'carcinogenic substance' and met the criteria set out in Article 57(a) of REACH. Such an agreement was reached unanimously by the Committee.

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[119] Case T-93/10, para. 119-120.
[120] Ibid, para. 119-123.
[121] Ibid, para. 124.
[122] Anthracene oil is a combination of polycyclic aromatic hydrocarbons ('PAHs') obtained from coal tar, with an approximate distillation range of 300° C to 400° C and a composition primarily of phenanthrene, anthracene and carbazole. Such a substance is among the 'substances of unknown or variable composition, complex reaction products or biological materials ('UVCB substances'), because it cannot be fully identified by its chemical composition' and is used mainly as an intermediate for the production of carbon black, a pigment and a reinforcing filler in rubber products, especially tyres as well as an intermediate for the production of pure anthracene.
[123] Case T-94/10, para. 2.

One of the first applicants' argument was that it is disputed that the identification of anthracene oil as a substance of very high concern as a result of the procedure provided for by Article 59 of REACH, on the ground that that substance has PBT or vPvB properties, constitutes new information within the meaning of Article 31(9)(a) of REACH capable of triggering the obligation referred to in that provision, that is, the updating of the safety data sheet, with the result that the contested decision directly affects the legal situation of the applicant[124]. The discussion was similar to the one analyzed in the previous case, related to CTPHT.

There were five pleas in law raised in support of the present case: the first two pleas concerned alleged breaches of procedural requirements, related to Article 59(3), (5) and (7) of and Annex XV to REACH. The other three pleas alleged breach of the principle of equal treatment, an error of assessment or an error of law regarding the identification of a substance as having PBT or vPvB properties on the basis of its constituent ingredients and breach of the principle of proportionality[125]. All the pleas were rejected by the General Court and the action in its entirety was dismissed. The arguments were quite similar to the previous case discussed. Therein will be highlighted only the issues that distinguish the cases.

The applicants argued that Germany did not give information on alternative substances even though it had been informed by the applicants of the existence of such substances, namely petroleum-based preparations and ECHA accepted that dossier without alternative substances having been pointed out. According to the applicants, it can be taken into consideration that without that irregularity and if the fact that the alternative substances also contained PBT constituents had been known, the contested decision might not have been adopted and a different procedure might have been triggered[126].

The letter to the competent German authorities of 17 July 2009 from the Coal Chemicals Sector Group did not refer to any alternative substances, but they simply asked the German authorities to adopt 'a more balanced approach not penalizing a single industry sector', since the group pointed out that 'it is well known that many streams of petroleum conversion contain anthracene as well'. The Court understood that that letter makes reference to substances which, according to the group, present a 'comparable level of danger to that of anthracene oil' and not to substances which can be used as 'alternatives' because they are capable of being used instead of anthracene oil to perform the same function and therefore they found that the procedural requirements set out in REACH were respected. Therefore it does not seem the information on alternative substances is relevant as regards the outcome of that procedure[127].

[124] Ibid., para. 41.
[125] Ibid., para. 68.
[126] Ibid., para. 69.
[127] Ibid, para. 73-74 and 77.

In a second plea, the applicants observed that ECHA had no authority to make an amendment on the proposal made by the Germany concerning the inclusion of anthracene oil in the candidate list of substances, which was based solely on the fact that that substance had PBT and vPvB properties. According to that amendment, anthracene oil was identified as a 'substance of very high concern' on the basis not only of its PBT and vPvB properties as alleged, but also of its carcinogenic properties. Since that substance could not have been identified as being of very high concern on the basis of its PBT and vPvB properties, the reference to its carcinogenic properties remains the only reason for its inclusion in the candidate list of substances. The dossier prepared by Germany contained only the proposal to identify anthracene oil as a substance with PBT and vPvB properties – and as such of very high concern. It said nothing about its carcinogenic substance, which was an amendment of ECHA. It was argued that ECHA had no authority to amend the proposal. Such a plea was also rejected on the grounds that ECHA is in a position to put forward its point of view effectively and therefore it must be possible to incorporate the comments made by the ECHA in the contested decision[128].

The third plea, alleging breach of the principle of equal treatment[129] was similar to the previous case analyzed and the General Court upheld the position that such a plea should be rejected[130].

Moreover, very similar arguments to the previous case were: the fourth plea, alleging an error of assessment or an error of law in the identification of a substance as PBT or vPvB on the basis of its constituent. The Court upheld, as in the previous case, that ECHA bases its approach on scientific reasons. The applicants' argument concerning the identification of anthracene oil as having PBT and vPvB properties on the basis of its constituents present in a concentration of at least 0.1% does not demonstrate that the contested decision is vitiated by a manifest error[131].

The fifth plea of this case brought about the same discussion of the principle of proportionality discussed on the previous case and was also rejected by the General Court.

Conclusions

The European chemicals regulation policy, REACH, is a main concern for international companies entering into the European market. One of the main creations of REACH

[128] Ibid, para. 80-88.
[129] The identification of anthracene oil as a substance of very high concern breaches the principle of equal treatment. That substance is comparable, from the point of view of its content in chemical substances and of market competition to other UVCB substances containing anthracene. However, the ECHA, without any objective justification, identified only anthracene oil, and not those other substances, as a substance of very high concern (para. 90).
[130] Case T-94/10, para. 95.
[131] Ibid., para. 121.

was the European Chemicals Agency, which has been in charge of applying such regulation.

REACH's primary and most controversial element is its data gathering and registration requirement and, for non-Community manufacturers, the obligation to hire an O. R.to fulfil it. This has become an economic disadvantage for them since their only option is to choose between an importer and an O.R. registration to protect their intellectual property and to carry on with all the burdensome bureaucracy.

Many WTO Specific Trade Concerns have been raised and most of them comprise of REACH's registration/data gathering and notification obligations, mainly related to its costly and hazard-based approach, threatens to intellectual property rights and mandatory data sharing. Nevertheless, REACH has not been challenged at the WTO Dispute Settlement System. There are some identified reasons for that, which may consist of: the EC's submission to the TBT Committee of an "early notification", under TBT Agreement, acquainting Members with the proposed REACH regulation; the long period of discussions of that regulation and the EU's granting of a 60-day extension to the REACH comment period, although a 60 days period might count exactly in the opposite direction, which is too short a period for the complexity of REACH; considerable WTO Member government and non-EU industry lobbying; and a considerable group of academic, civil society and industry advocates/lobbyists who have labored to defuse accusations of REACH WTO non-compliance.

Nevertheless, an analysis of REACH in light of TBT shows that EU Member State implementation of REACH's registration/data gathering and notification requirements imposes a higher cost structure, and thus impairs the competitiveness of "like" chemical substance-based product imports in EU markets. It subjects groups of imported non-REACH registered SVHC-containing articles to treatment less favorable than that accorded to like groups of REACH-registered domestic articles and substances. Moreover, REACH's registration/data gathering and notification requirements , which includes O.R.'s costs and bureaucracy, are more trade restrictive than necessary to achieve REACH's legitimate objectives, considering the real benefits that REACH, has provided. It has been observed that the REACH registration process may be seen much more as a method of 'data collection and warehousing' than a procedure for protecting the public and the environment from exposures to hazardous substances. It is very true that most of the information submitted under the REACH registration procedure may never be evaluated, given the amount of data submitted.

Therefore, as far as the TBT Agreement is concerned, a violation might be found in the following situations:

1) Whenever it is possible to ascertain that the compared products - EU domestic and imported - are "like products", under TBT, Art. 2.1, imported products should receive 'no less favorable treatment'. The argument that two compared products are not 'like products', based only on a hazard-approach of product-related process and production

methods (PPMs) should not convince on the basis of the TBT preamble, since Art. 2.1 should also obey the rule not to create 'unnecessary obstacles to international trade' and the rule that measures should not be 'applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade'.

2) Whenever it is possible to ascertain that compared products are not 'like products' on a basis of product-related process and production methods (such as SVHC products), TBT preamble and Art. 2.2 should be applied and the rule that 'technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective' should be complied with. A country should not 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' (from the preamble wording). Nevertheless, such measures are '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' (from the preamble wording). It might be said that, under REACH, the volume of production was the chosen level for protection in the EU. However it is doubtful whether 'volume' is the right proxy for measuring up protection for human health and the environment.

3) In general, technical regulations should not be prepared, adopted or applied whenever they create unnecessary obstacles to international trade. From TBT, Article 2.2, technical regulations create unnecessary obstacles ever since they are more trade-restrictive than necessary to fulfill a legitimate objective. Moreover such rule also is under TBT preamble. From REACH, it is very clear that its high bureaucracy and registration costs are more than necessary to fulfil the legitimate objectives established in its preamble. The EU Commission has indicated that the registration-related costs were more than twice the amount previously estimated, generating a negative impact on international trade flows of chemicals.

Whenever REACH is compared to other regulation that also intends to protect human health and the environment from chemical substances (e.g. US's TSCA, Canadian CMP and Japanese Kashinho), it is clear that REACH's hazardous approach and the shift of burden of proof to manufacturers is too burdensome compared to what would be deemed necessary to reach its legitimate goals.

'Moves to require mandatory substitution or across the board uniform time limits would cause unnecessary market disruptions without clear environmental benefits. Registration and notification of substances embedded in articles when no potential risks have yet been identified could cause many entities including numerous SMEs from developing countries to forego the EU market without corresponding environmental benefit'[132].

[132] EU Economic Observer, in: http://euobserver.com/economic/21813 (access on 24th July 2014).

Although some may say that it might be too late to challenge REACH under the multilateral system or even under other international fora, an analysis of case law that have been brought before the ECJ's system provides evidence to the contrary. Many cases have been discussed either at the ECJ or at the General Court instances and they show that the highest tribunals in Europe are willing to verify the legality of REACH and its complexity under EU law, remarking that some outcomes have been in favor of the complainants.

The ECHA's most recent concerns around the mega-regional trade negotiations, fearing that agreements such as TTIP might lower the level of protection for human health and the environment, on the basis of regulatory cooperation and mutual standards recognition, is evidence that REACH can and might be challenged, either on tribunals or under international negotiations and that its "warehouse approach" may be dully considered an unnecessary barrier to international trade.

Last, but not the least, globalization of REACH – the multiplication of REACH-likes – has raised new concerns. New procedures of STCs can be raised, under the WTO TBT Committee, in the actual stage of implementation of REACH, under the following basis: i) many SMEs, in Europe and in the rest of the world, have sold out their business to large companies, which has led the chemicals market worldwide to concentration, less competition and changes in chemicals overall prices; ii) as REACH has been 'exported', the importation of foreign regulatory norms and procedures might put pressure on local regulatory priorities, cultures and practices; iii) increasing regulatory uniformity leads to the development of 'regulatory monocultures' and consequently the amplification of both strengths and weaknesses of a dominant regulatory approach; iv) leading scientists in Europe have had a discouragingly view in relation to the quality of data that has been generated in compliance with REACH's prescriptions for better health and protection of the environmental .

ANNEX

TABLE: CASE LAW ON REACH IN THE EUROPEAN SYSTEM[133]

Cases	Court	Outcome
Case C-558/07: S.P.C.M. SA and Others v Secretary of State for the Environment, Food and Rural Affairs	ECJ	This reference for a preliminary ruling concerns the interpretation and validity of Article 6(3) of REACH. The concept of 'monomer substances' in Article 6(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC relates only to reacted monomers which are integrated in polymers.
Case C-358/11: Lapin elinkeino-, liikenne- ja ympäristökeskuksen liikenne ja infrastruktuuri - vastuualue v Lapin luonnonsuojelupiiri ry	ECJ	This request for a preliminary ruling concerns the interpretation of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, such as REACH . European Union law does not, as a matter of principle, exclude the possibility that waste regarded as hazardous may cease to be waste within the meaning of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives if a recovery operation enables it to be made usable without endangering human health and without harming the environment and, also, if it is not found that the holder of the object at issue discards it or intends or is required to discard it within the meaning of Article 3(1) of that directive, this being a matter for the referring court to ascertain. The REACH Regulation, in particular Annex XVII thereto, in so far as it authorizes the use, subject to certain conditions, of wood treated with CCA solutions, is, in circumstances such as those in the main proceedings, relevant for the purpose of determining whether such wood may cease to be waste because, if those conditions were fulfilled, its holder would not be required to discard it within the meaning of Article 3(1) of Directive 2008/98.
Case C-625/11P :Polyelectrolyte Producers Group and SNF v ECHA	ECJ	By their appeal, Polyelectrolyte Producers Group GEIE (PPG) ('PPG') and SNF SAS ('SNF') seek to have set aside the order of the General Court of the European Union of 21 September 2011 in Case T‑268/10 PPG and SNF v ECHA [2011] ECR II‑6595 ('the order under appeal'), by which that Court dismissed as inadmissible their action for annulment of the decision of the European Chemicals Agency (ECHA), identifying acrylamide (EC No 201-173-7) as a substance meeting the criteria laid down in Article 57 of REACH. The ECJ Sets aside the order of the General Court of the European Union of 21 September 2011 in Case T‑268/10 PPG and SNF v

[133] See http://echa.europa.eu/web/guest/regulations/reach/legislation (access on 24th July 2014).

		ECHA, understanding that the General Court erred in law in finding that Article 102(1) applies only to measures published in the Official Journal of the European Union and thus declaring the action brought by PPG and SNF inadmissible.
Case C-626/11P: Polyelectrolyte Producers Group and SNF v ECHA	ECJ	The ECJ understood that the General Court was wrong to conclude that that application was inadmissible on the ground that it had been brought before the date of publication of the contested decision by means of the inclusion of acrylamide on the candidate list of substances on the ECHA website, initially scheduled for 13 January 2010, but which finally took place on 30 March 2010.
Case T-1/10: PPG and SNF v ECHA	General Court	Application for annulment of the decision of ECHA identifying acrylamide (EC No 201-173-7) as a substance fulfilling the criteria referred to in Article 57 of REACH. As the candidate list of substances exists only on the ECHA website, the inclusion of a substance in that list takes place when the updated list is published. It is, therefore, only upon inclusion in the candidate list of substances published on the ECHA website that the act identifying a substance as being of very high concern, resulting from the procedure set out in Article 59 of that regulation, is intended to produce legal effects.
Case T-93/10: Bilbaína de Alquitranes, SA and Others v ECHA	General Court	Action for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify pitch, coal tar, high temperature (EC No 266-028-2) as a substance meeting the criteria set out in Article 57 of REACH. In so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to REACH demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of REACH, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-94/10: Rütgers Germany GmbH and Others v ECHA	General Court	Action for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil (EC No 292-602-7) as a substance meeting the criteria set out in Article 57 of REACH. in so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to Regulation No 1907/2006 demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of Regulation No 1907/2006, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-95/10: Cindu Chemicals BV and Others v ECHA	General Court	Action for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil, anthracene low (EC No 292-604-8) as a substance meeting the criteria set out in Article 57 of REACH. in so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to REACH demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was

		carried out in accordance with the procedure set out in Article 59 of Regulation No 1907/2006, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-96/10: Rütgers Germany GmbH and Others v ECHA	General Court	ACTION for the partial annulment of the decision of the ECHA, published on 13 January 2010, to identify anthracene oil (anthracene paste) (EC No 292-603-2) as a substance meeting the criteria set out in Article 57 of REACH. In so far as the applicants argue that the information contained in the dossier concerning a proposal for a restriction measure pursuant to Annex XV to REACH demonstrates that the identification of the substance at issue was not necessary, it is sufficient to point out that such identification was carried out in accordance with the procedure set out in Article 59 of REACH, which constitutes a different procedure from that set out in Title VIII of the same regulation. In the light of the foregoing considerations, it cannot be concluded that the contested decision breached the principle of proportionality.
Case T-268/10: PPG and SNF v ECHA	General Court	Application for annulment of the decision of ECHA identifying acrylamide (EC No 201-173-7) as a substance fulfilling the criteria referred to in Article 57 of REACH. It follows from the foregoing that the action must be dismissed as inadmissible and that it is unnecessary to consider the other pleas of inadmissibility raised by ECHA and the Commission.
Case T-89/13: Calestep v ECHA	General Court	Available only in French and Spanish: ‘une demande de sursis à l’exécution des rappels de paiement des 23 janvier et 8 février 2013 adressés par l’ECHA à la requérante au motif que celle-ci ne remplissait pas les conditions pour bénéficier de la réduction des redevances prévue pour les petites entreprises. La demande en référé doit être rejetée comme irrecevable’.
Case T-346/10: Borax Europe v ECHA	General Court	Application for annulment of the decision of the ECHA, published on 18 June 2010, identifying boric acid (EC No 233-139-2) and disodium tetraborate, anhydrous (EC No 215-540-4) as substances meeting the criteria referred to in Article 57 of REACH. It is apparent from all of the foregoing that the Court is in a position to rule on the action without ordering measures of inquiry. Furthermore, since the contested decision has been published on the ECHA’s website and produced by the applicant in an annex to the application, this request is irrelevant. The applicant’s request for a measure of inquiry must therefore be refused, and the action dismissed in its entirety.
Case T-368/11: Polyelectrolyte Producers Group and Others v Commission	General Court	Available only in French and Spanish: ‘une demande d’annulation du règlement (UE) n° 366/2011 de la Commission, du 14 avril 2011, modifiant le règlement (CE) n° 1907/2006 du Parlement européen et du Conseil concernant l’enregistrement, l’évaluation et l’autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH), en ce qui concerne l’annexe XVII (acrylamide). Le recours dans son intégralité doivent être rejetés
Case T-456/11: ICdA and Others v Commission	General Court	Application for partial annulment of Commission Regulation (EU) No 494/2011 of 20 May 2011 amending REACH of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals

		(REACH) as regards Annex XVII (Cadmium) (OJ 2011 L 134, p. 2) in so far as it restricts the use of cadmium pigments in plastic materials other than plastic materials in which that use was restricted before the adoption of Regulation No 494/2011. the first part of this plea in law must be upheld. In the light of the foregoing considerations, and without there being any need to rule either on the second part of this plea in law or on the other pleas in law raised by the applicants, the action must be upheld and the contested regulation must be partly annulled in so far as it restricts the use of the cadmium pigments at issue in mixtures and articles made from plastic materials other than those in respect of which that use was restricted before the adoption of that regulation. On the other hand, the action must be rejected as inadmissible as to the remainder.