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PhD thesis

Industrial Chemical Regulation in the European Union and the United States: A Comparison of REACH & the Bipartisan TSCA Reform Bills

by

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AUTHOR'S DECLARATION

No portion of the work referred to in this dissertation has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Furthermore, this dissertation contains no materials previously written and/or published by another person, except where appropriate acknowledgment is made in the form of bibliographical reference, etc.

Ágnes Botos

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ABSTRACT OF DISSERTATION

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Industrial Chemical Regulation in the European Union and the United States: A Comparison of REACH and the Bipartisan TSCA Reform Bills

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The European Union can claim to have the most ambitious chemical legislation in the world, called REACH regulation. The EU is actively spreading knowledge of REACH around the globe, thereby encouraging foreign governments to contemplate the adoption of REACH. As a result, REACH is exerting influence on environmental policy discussions in many countries.

In the United States, the chemical industry, the authority, and environmental advocacy groups have expressed interest in modernization of the Toxic Substances Control Act (TSCA) of 1976, the major U.S. regulatory law applicable to industrial chemicals. It has been theorized based on 'California effect' that Europe may seek to export its stricter environmental standards under REACH to the United States. Thus, it is interesting to examine whether the environmental, health, and safety practices and values found in REACH are impacting the TSCA reform debate in the US.

There is a gap in the literature: a comparison of REACH and the bipartisan TSCA reform bills –S.1009, S.697 and H.R.2576 - from health and safety point of view has not been undertaken. I chose to focus the comparison on the following issues: data development, priorities for safety assessments, safety standards, restrictions on chemical use, and preemption of regulatory activity by lower levels of government.

There are three major findings. First, none of the TSCA reform bills implemented the EU's radical solution of putting the burden of data generation, risk assessment, and risk management on industry. Second, REACH is more precautionary in its design than the TSCA reform bills. All the TSCA reform bills left unchanged the current U.S stance that an existing chemical is presumed safe until it is proven unsafe by the government. Third, the TSCA reform bills are generally less strict than REACH in their requirements on industry.

I also analyzed REACH and TSCA through a comparative risk assessment case study. I conclude that, to effectively accelerate the number of existing chemicals subject to risk assessment, EPA should simplify the risk assessment process, perhaps in ways that are

already being implemented by EPA for new chemicals. The case study analysis found that the technical practices of risk assessment for new chemicals in the US are theoretically similar to what EU industry prepares for REACH registration of new and existing substances.

The EU and the US have started working on limited harmonization of chemical legislation through the Trans-Atlantic Trade and Investment Partnership (TTIP) and have identified four main areas for policy convergence. Out of these four areas, I made a detailed analysis of possible cooperation in the classification and labeling of industrial chemicals.

The attempt to export the stricter EU chemical standard in REACH failed in the case of USA, and US decision makers are unlikely to reform TSCA based on the REACH model. I can conclude that REACH's key principles and elements were not adopted in any of the bipartisan TSCA reform bills in the US.

Keywords: REACH, TSCA, TSCA reform, bipartisan bill, chemical legislation, risk assessment, safety standard, GHS

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LIST OF ABBREVIATIONS

ACC	American Chemistry Council
Art.	Article
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CAS	Chemical Abstract Service
CBI	Confidential Business Information
CEFIC	The European Chemical Industry Council
CEU	Central European University
ChemSec	International Chemical Secretariat
ChemSTEER	The Chemical Screening Tool for Exposures and Environmental Releases
Chesar	CHEmical Safety Assessment and Reporting tool
CICA	Chemicals in Commerce Act
CIEL	Center for International Environmental Law
CIEPA	Centre for International and European Policy Action
CLP	Classification, Labeling, and Packaging
CMR	Carcinogen, Mutagen, or Toxic to Reproduction
COC	Concentration of Concern
CSA	Chemical Safety Assessment
CSIA	Chemical Safety Improvement Act
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
ECHA	European Chemical Agency
ECOSAR	Ecological Structure Activity Relationships
E-FAST	Exposure and Fate Assessment Screening Tool
EHS	Environmental, Health and Safety
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
EU	European Union
GAO	Government Accountability Office

GDP	Gross Domestic Product
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HPV	High ProductionVolume
IFCS	Intergovernmental Forum on Chemical Safety
IOEL	Indicative Occupational Exposure Limit
IRIS	Integrated Risk Information System
IU	Indiana University
IUCLID	International Uniform Chemical Information Database
LC50	Median lethal concentration. The concentration causing 50 % lethality
LD50	Median lethal dose. The dose causing 50 % lethality
LOA	Letter of Access
LOAEC	Lowest Observable Adverse Effect Concentration
MOE	Margin of Exposure
MSDS	Material Safety Data Sheet
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organisation
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
OC	Operational Conditions
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OSHA	Occupational Safety and Health Administration
PAHs	Polycyclic Aromatic Hydrocarbons
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonate
PhD	Doctor of Philosophy
PMN	Premanufacture Notices
PNEC	Predicted No Effect Concentration
PPORD	Product and Process Orientated Research and Development
QSAR	Quantitative Structure-Activity Relationships
R&D	Research and Development

RCR	Risk Characterisation Ratio
RMM	Risk management measures
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
SAICM	Strategic Approach to International Chemicals Management policy framework
SCL	Specific Concentration Limits
SCOEL	Scientific Committee on Occupational Exposure Limits
SDS	Safety Data Sheet
SIDS	Screening Information Data Sets
SIEF	Substance Information Exchange Forum
SME	Micro, Small and Medium-Sized Enterprise
SNUN	Significant New Use Notice
SNUR	Significant New Use Rules
SOCMA	Society of Chemical Manufacturers & Affiliates
SVHC	Substance of Very High Concern
SWCNT	Single-Wall Carbon NanoTubes
TBT	Technical Barriers to Trade
TCE	Trichloroethylene
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act (1976)
TTIP	Trans-Atlantic Trade and Investment Partnership
U.S.	United States
UN	United Nations
UNEP	United Nations Environmental Program
USA	United States of America
vPvB	Very Persistent and Very Bioaccumulative

TSCA REFORM BILLS ABBREVIATIONS:

H.R. 6100	1. TSCA reform bill: H.R. 6100 Kid-Safe Chemicals Act of 2008 was introduced in 2008 in the House of Representatives in the Committee on Energy and Commerce by Representative Solis, Hilda L (D-CA).
S.3209	2. TSCA reform bill: S. 3209 Safe Chemicals Act was introduced in 2010 in the Senate by Senator Frank Lautenberg (D-NJ) in the Environment and Public Works Committees.
S. 847	3. TSCA reform bill: S. 847 Safe Chemicals Act was introduced in 2011 in the Senate by Senator Frank Lautenberg (D-NJ) in the Environment and Public Works Committees
S.696	4. TSCA reform bill: S. 696 Safe Chemicals Act was introduced in 2013 in the Senate by Senator Frank Lautenberg (D-NJ) in the Environment and Public Works Committees.
S.1009 (CSIA)	5. TSCA reform bill (bipartisan): S. 1009 – Chemical Safety Improvement Act bipartisan bill was introduced in the Senate by Senator Frank Lautenberg (D-NJ) in 2013 in the Environment and Public Works Committees. Co-sponsors (26)David Vitter (R-LA)
Boxer CSIA	6. TSCA reform bill: Chemical Safety Improvement Act bill was introduced by Senator Barbara Boxer (D-CA) in 2014
CICA	7. TSCA reform bill: Chemicals in Commerce Act (CICA) bill was introduced in the House of Representatives by Representative John Shimkus (R-IL) in 2014 in the Environment and the Economy Subcommittee.
S.697 Udall-Vitter bill	8. TSCA reform bill (bipartisan): S. 697 Frank R. Lautenberg Chemical Safety for the 21st Century Act bipartisan bill was introduced in the Senate by Senator Tom Udall (D-NM) and David Vitter (R-LA) in 10th of March 2015 in the Environment and Public Works Committees.
Boxer-Markey bill	9. TSCA reform bill: S. Alan Reinstein and Trevor Schafer Toxic Chemical Protection Act was introduces in 12th of March 2015 by Barbara Boxer (D-CA) and Edward Markey (D-MA)
H.R. 2576 Shimkus bill	10. TSCA reform bill (bipartisan): H.R. 2576 "TSCA Modernisation Act of 2015" bill was introduced in the House by Representative John Shimkus (R-IL) in 26th of May 2015 in the Energy and Commerce Committees.

PREFACE: WHY DID I CHOOSE THIS TOPIC?

Writing a PhD allows me to collect information on changes in American legislation as well as get a deeper and wider knowledge about chemical and environmental regulations, which is crucial for my current job as a chemical management consultant in Hungary.

For the entirety of my career I've worked for industry: 10 years as an environment, health, and safety (EHS) specialist at General Electric and 7 years as an independent REACH consultant. For this reason it's my job to support the industry by ensuring it is in compliance with EHS legislations, with the aim to protect the environment and the health and safety of employees. From this work I've seen that we can better protect the environment, the industries' employees, and the public by the continuous improvement of chemical legislations, by learning more and more about the toxicological, eco-toxicological, and environmental fate of chemicals and their hazards and risks. Responsible EHS managers or EHS consultants, even though they work for and see the limits and issues of the industry, have similar values to environmentalists': to decrease the environmental and health impacts of hazardous chemicals and to continuously improve EHS systems. The industry is often very proud of their EHS results, and I have no doubt that a well written and strict chemical legislation can support not just the environmentalists' and the public's interest but the industry's interests as well. For this reason, I have chosen the environmental, health, and safety point of view through my research. Environmental, health, and safety values are more strongly present in the opinions of environmental groups and individual US states. However, the authority and the industry often have the same strict values, as will be demonstrated in this thesis, since their interests are to gain the trust of the public. I believe strict EHS principles give motivation, both to the industry and authority, for continuous improvement to better solve EHS challenges.

I received a scholarship for a month to learn more about the interaction of American and European chemical legislation at Indiana University (IU) in 2011 and in 2014. The result of my first US trip is a common article with Indiana University's researchers: "Regulating industrial chemicals: lessons for US Policy makers from the European Union's REACH program."[1]

[1]The article was issued in January 2012 in Indiana University Press, in a shorter version in November 2012 in the Environmental Law Reporter News & Analysis (Vol 42, No.11) and some part of it was issued in November 2013 in "The European Union REACH regulation for chemicals" book of Oxford University Press edited by Lucas Bergkamp. Team members of the article: Dr. John D. Graham, Adam D.K. Abelkop, Dr. Lois R. Wise and myself Agnes Botos

In our research in 2011 we assumed, as a thought experiment, that US legislators are considering whether to replicate some (or all) aspects of REACH in the United States. We suggested a variety of reforms for consideration by US policy makers that might make a REACH-like system less burdensome and more effective in the USA. Our primary purpose for this first article was to inform the US legislative debate about the modernization of the Toxic Substances Control Act of 1976. The major findings of the report were summarized in a table. I am going to use some parts of this article, with the permission of the IU team members, in my dissertation cited as (Abelkop *et al.* 2012). In 2011 we got financial support for our research from the American Chemistry Council, Dow and DuPont. This means that in 2011 the American industry was not against REACH but wanted to learn from it, and would even consider supporting a REACH-like system in the United States if it proved to be practical, not overly burdensome, and effective.

Today, in 2015, it is clear that a REACH-like system will not be implemented in the USA. The biggest oppositional stakeholder of REACH is the American industry, but it is undeniable that some values and principles of REACH have an effect on TSCA reform bills. My second research in 2014 examined the impact of REACH on TSCA reform debate. IU's team members continued to support me, both professionally and financially, in this research as well.

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Industrial Chemical Regulation in the European Union and the United States: A Comparison of REACH & the Bipartisan TSCA Reform Bills

INTRODUCTION

It is impossible to imagine a life of comfort and many of the latest technologies without the existence and usage of chemical substances. As global production, trade, and use of chemicals increases, fundamental change is needed for societies to manage chemicals, to reduce risk, and have chemicals used more safely (UNEP 2006). One important consequence of the widespread use of chemicals is that countries need to prepare chemical management policies in order to minimize damage to the environment and human health. Environmental and health concerns from the industrial chemical emissions are interpreted differently by various countries, and these differences can manifest themselves in their chemical management policies (Abelkop *et al.* 2012).

Chemical control policies should ensure a high level of protection of human health and environment. Chemical legislations are important steps towards regulating the use of chemicals. Different countries have different chemical legislations and these chemical legislations can interact with each other. Environmental policy in one nation or region is often shaped by, or influences, policies adopted in other countries or regions, as regulators often learn from one another.

The European Union can claim to have the most ambitious chemical legislation in the world (ECHA 2015 c): the REACH regulation (Registration, Evaluation, Authorization and Restriction of Chemicals 1907/2006/EC). The European Chemical Agency (ECHA) shares experience with an increasing number of regulatory authorities in countries that are revising their chemicals legislation. Some countries are adopting chemical safety legislation similar to REACH (Taiwan, for example), while some countries simply learn from REACH. It is undeniable that the EU's REACH regulation is already exerting influence on environmental policy discussions around the world, including the United States (Abelkop et al. 2012).

In the United States the chemical industry, government agencies, individual states, and environmental communities have expressed interest in the modernization of the Toxic Substances Control Act (TSCA) of 1976. Soon it is expected that U.S. decision makers will make consensus and able to issue the revised TSCA since in 2015 summertime Senate will vote on S.697 TSCA reform bill and House of Representatives will vote on H.R. 2576 TSCA reform bill, which is a big step further to issue the final bill. Although currently still no consensus exists on the final bill, there are broad discussions in the USA about other nations` chemical legislations. Similarly to the EU, environmental NGOs, animal rights activists, U.S.

states, and the industry constantly lobby policy makers to see their interests in the new legislation.

Research area and scope

My dissertation will compare REACH and the proposed TSCA reforms in order to determine similarities and differences. In the course of identifying differences, the dissertation also looks for promising areas of harmonization. Intellectually, this work will show how social science theories predict differences in EU and US chemical policies, and compare those predictions to what has happened. Practically, the dissertation will offer insight for US policy makers engaged in TSCA reform, as well as other countries, that are seeking to draw the best lessons from REACH and TSCA reforms. In this way, the dissertation contributes to global improvements in the safe use of industrial chemicals by minimizing damages to public health and the environment.

It is well known that the EU is actively spreading knowledge of REACH around the globe, thereby encouraging foreign governments to contemplate the adoption of REACH. As a result, REACH is exerting influence on environmental policy discussions in many countries. There are two relevant theories here: one is "race to the bottom" where jurisdictions compete for industry by offering lower (less strict) environment standards; the other is "race to the top" where jurisdictions compete with each other for the reputation as the "greenest" country by enacting stricter environmental standards (Vogel 1995 and 2012). The California-effect theory is actually a third – and less prominent – theory that is based in political economy, the notion that a "green" trading partner will use environmental regulation to upgrade the environmental standards of their partner in trade. Since the EU and the US are major partners in trade, it has been theorized that Europe may seek to export its stricter environmental standards under REACH to the United States through its control of access to the European market by companies based in the United States. Thus, it is interesting to examine whether the environmental, health, and safety practices and values found in REACH are impacting the TSCA reform debate in the US.

There are some studies about the strengths and weaknesses of REACH and TSCA (1976) and about their interactions, but there is a gap in the literature. A comparison of REACH and the bipartisan TSCA reform bills –S.1009, S.697 and H.R.2576 - from health and safety point of view has not been undertaken. Mainly environmental NGOs and academics refer to REACH as a potential example during the TSCA reform debate, but these

NGOs and academics have not yet made a comprehensive and rigorous study about REACH and TSCA reform bills. Trans-Atlantic Trade and Investment Partnership (TTIP)[2] negotiators also deal with this topic, but currently just in a much generalized way.

I have obtained information about REACH and TSCA through multiple methods: personal interviews in the US and EU, focus groups with practitioners, questionnaires, document reviews, and case studies of specific chemicals. The methods are employed to help learn how the EU's chemical policy is – and is not - diffusing in the USA. My US trips and the interviews with US and EU stakeholders and government officials helped me gain a better understanding of the US experts' views about REACH and TSCA reform, to make a comparison between REACH and bipartisan TSCA reform bills, and to discover their potential harmonization.

My research question is the following: What are the similarities and differences between REACH and the proposed reforms of TSCA, and are there some promising areas for harmonization?

The introduction discusses the background and scope of the research and gives an overview of the drivers for the development of chemical policies, especially focusing on environmental, health, and safety perspectives. This view will be used throughout the entirety of the research. It also addresses the following question: what differences would be expected between REACH and TSCA reform theoretically, based on the differences in political culture, institutions, and interest-group power structure? This chapter will show how social science theories predict differences in EU and US chemical policies.

The first chapter examines relevant literature about chemical policy development, the improvement possibilities of REACH, the impact of REACH on the rest of the world, and a comparative analysis of literature on REACH, TSCA, and/or TSCA reform bills. More articles, hearings, and testimonies of TSCA reform bills will be incorporated in the later analysis.

The second chapter displays the research question and objectives, theoretical framework, data collection and analysis, and the validity and the limitations of the study. The dissertation provides background information on the TSCA reform bills, and briefly analyzes their tendency from an environmental health and safety point of view.

The main part of the dissertation deals with the comparison of REACH with the bipartisan TSCA reform bills, the S.1009 bill, the S.697 bill, and the H.R.2576 bill. Since REACH and TSCA reform bills are complex laws, I chose to focus the comparison on the

[2] See it in detail in the Harmonization of chemical legislations chapter

following issues: data development, priorities for safety assessments, safety standards, restrictions on chemical use, and preemption of regulatory activity by lower levels of government. Different argumentative interpretations of various stakeholders are shown for each issue: environmental NGOs, industry, states, and authorities. The dissertation uses a case study for the comparison of REACH and TSCA's risk assessment process, both for existing and new chemicals. This comparative risk assessment case study is seeking to understand how the technical aspects of risk assessments are conducted in the US and the EU. I am interested in whether there is any significant difference if the industry prepares the risk assessment (EU) or the authority prepares it (USA) from a health and environmental point of view.

The dissertation displays possible future interactions for the harmonization of chemical legislation since the EU and the US have started working on limited harmonization of chemical legislation through the Trans-Atlantic Trade and Investment Partnership (TTIP) and have identified four main areas for policy convergence. Out of these four areas, I made a detailed analysis of possible cooperation in the classification and labeling of industrial chemicals.

The analysis of similarities and differences between REACH and the proposed TSCA reforms offer insight for US policy makers engaged in TSCA reform, as well as other countries, that are seeking to draw the best lessons from REACH and TSCA reforms. Annexes and references can be found at the end of the dissertation.

Expected theoretical differences between REACH and TSCA

When considering the question: "What differences between REACH and TSCA reform would be expected theoretically, based on the differences in political culture, institutions, and interest-group power structure?" two possible hypotheses can be found. These are:

- TSCA reforms should, to some degree, reflect REACH reforms because the policy diffusion literature predicts that policy makers can learn from the experiences of other governments and because EU policy makers will seek to protect the competitiveness of the European chemical industry by persuading other countries to enact REACH-like systems.
- REACH will likely be more precautionary in its design and more prescriptive about the generation of data (no data, no market). The precautionary principle is well accepted in Europe; indeed it is embedded in the Amsterdam Treaty that founded the EU. The US

government does not recognize a universal precautionary principle, and indeed gives entrepreneurs and companies substantial discretion to take risks in a capitalistic economic system. As a result, the US is sometimes tolerant of risky decisions/technologies that are supported by only limited safety data.

Policy diffusion: Do the TSCA reform bills reflect to some degree the REACH reforms?

I expect TSCA reforms should, to some degree, reflect REACH reforms, as the policy diffusion literature predicts that policy makers can learn from the experiences of other governments and because EU policy makers will seek to protect the competitiveness of the European chemical industry by persuading other countries to enact REACH-like systems.

According to Shipan and Volden (2008), policy diffusion is the spread of innovations from one government to another. One of the mechanisms of policy diffusion is learning from earlier adopters. This makes the task of the decision makers simpler, since they have chosen an alternative that has proven successful elsewhere. Policy makers cannot learn about policies that have not yet been tried. The learning hypothesis states that the likelihood of a government adopting a policy increases when the same policy is adopted broadly by other governments (Shipan and Volden 2008). "There is also an accumulation effect: if more countries have previously undergone processes of rationally learning, it is easier for additional countries to see the attractiveness of the reform more quickly, and implementation is likely to be easier domestically" (Baturo and Gray 2009, 140).

Learning is considered a horizontal mechanism of diffusion, and can be rational or bounded (Meseguer 2005). Both in rational and bounded learning, the politicians want to understand and find a solution for a particular problem. Rational learning is a diffusion mechanism where policy makers observe all available information in the world, regardless of its origin, evaluate its relevance, and adopt it if deemed appropriate (Baturo and Gray 2009). However, if the conclusion of learning has both positive and negative outcomes and prior beliefs are strong, then the learned and evaluated experiences carry less weight in the formation of posterior beliefs. If the conclusion of learning has only a positive outcome, regardless of prior beliefs, policy makers will converge on their posterior beliefs which are dominated by learned and evaluated experiences (Meseguer 2005.) At rational learning analytical skills are the most important.

In contrast with rational learning at bounded learning, policy makers, rather than evaluating all information, just look at those ones which are relevant or which are easily

accessible (Meseguer 2005). Politicians do not attach weight to all information: "governments may imitate what peer countries do simply because they are peers, or governments may imitate what apparently successful countries do simply because they are high-status countries that are considered to know best" (Meseguer 2005, 73). With bounded learning it is also possible that politicians share the same biases: beliefs or ideas that prevail over observed and evaluated experience of learning. In bounded learning, analytical skills are not so important and are subject to biases. This dissertation will determine how US policy makers learn from EU experiences and, whether, TSCA reform bills reflect, at least to some degree, REACH reforms.

Diffusion does not always occur through the mechanism of learning. Political economy theories urge consideration of how one jurisdiction can advance its economic interests by persuading another jurisdiction to enact a particular regulatory framework (Noll and Owen, 1983).One of the overarching goals of REACH is to protect the competitiveness of the European chemical industry, a goal that is more readily accomplished if the EU persuades other governments around the world to enact similarly stringent requirements on production and use of industrial chemicals. If European industry faces competitors from other regions of the world with lower costs of regulatory compliance, then European industry could be placed at a competitive disadvantage in the global marketplace. Thus, if the EU can persuade the US and other countries to adopt a REACH-like regulatory system, then the goal of protecting the competitiveness of the European chemical industry will be easier for the EU to accomplish.

At first glance, it might seem that U.S. chemical producers would see competitive opportunity in the EU's unilateral decision to impose higher compliance costs on its chemical industry. However, large multinational chemical producers based in the US (e.g., Dow Chemical Company, Exxon Chemical, and DuPont) also do significant business in Europe. Since multinationals are already compelled to comply with REACH, they may find it in their competitive interests to advocate for a stronger REACH-like system in the US, so that small- and medium-sized companies in the US do not acquire a competitive advantage over multinationals. Thus, there may also be some economic forces at work in the US that lobby for stricter industrial chemical regulation in response to the EU's enactment of REACH.

Precautionary principle: Are TSCA reform bills going to be "less precautionary" than REACH?

REACH is more precautionary in its design than the TSCA reform bills, and more prescriptive about generating data (no data, no market). The precautionary principle is well

accepted in Europe; indeed it is embedded in the Amsterdam Treaty that founded the EU. The US government does not recognize a universal precautionary principle, and is sometimes tolerant of risky decisions/technologies that are supported by only limited safety data (Vogel, 2012; Wiener et al, 2011).

The precautionary principle was stated in the 1992 Rio Declaration on Environment and Development: "where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." (SOCMA 2015 a)The EU accepted the precautionary principle in "Article 174 of the Amsterdam Treaty of the European Union: 'Community policy on the environment […] shall be based on the precautionary principle'" (Martuzzi 2007).The EU also incorporated the precautionary principle into REACH Regulations, which "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" (REACH, art. 1).

There is no universally accepted definition of the precautionary principle, but many variations were found in the literature review.

"Weak" definitions of the precautionary principle are the following:

- Lack of full certainty is not a justification for preventing an action that might be harmful (Morris 2000).
- Innocent until proven guilty? (Belt 2003)
- Safe until it is proven unsafe?
- "Regulators faced with scientific uncertainty about a risk are justified in acting to prevent it. It gives permission for action when faced with uncertainty and it does not say what risk management action should be taken" (Rogers 2003, 374).

"Strong" definitions of the precautionary principle are the following:

- Take no action unless you are certain that it will do no harm (Morris 2000).
- Guilty until proven innocent? (Belt 2003)
- Unsafe until it is proven safe (Yoshiko 2010).
- "Regulators faced with scientific uncertainty about a risk are required to act to prevent it. It obliges action and it does not say what risk management action is necessary." (Rogers 2003, 374)

The "strongest" definition of the precautionary principle is the following:

- "Regulators faced with scientific uncertainty about a risk should require the risk-generator to demonstrate that the risk level is either acceptable or justified by proposed risk management procedures before the activity is approved. It transfers the onus of proof concerning acceptable risk levels from the regulator to the risk-generator, a so-called reversal of the burden of proof and it does not say what risk management action is required" (Rogers 2003, 374).

Of these three definitions, REACH implemented the "strong" version, that a chemical is presumed to be unsafe until it is proven safe (Yoshiko 2010), and the "strongest" version that "REACH is based on the principle that chemical manufacturer and importers have the responsibility to demonstrate that the chemicals they manufacture or place in the market or distribute, or use do not adversely affect human health or the environment" (GAO 2009, 12).In the EU approach, the precautionary principle is compatible with classical risk analysis: risk assessment (scientific evaluation), risk management, and risk communication (Renn and Elliott 2011). But, the information about chemicals and the corresponding need to collect data (no data, no market) is necessary in order for the industry to overcome precaution by making an evidence-based case for safety (Rogers 2003).

Of the three precautionary principle definitions, TSCA implemented the "weak" version for existing chemicals. That is, that a chemical is safe until is proven unsafe, since "TSCA mainly places the burden on EPA, and generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks related to their production, distribution, or use" (GAO 2009, 12). In the US, the EPA has started to make "risk-based" decisions, which could have "successfully kept some new chemicals from coming into market, not because they were proven to be hazardous, but because the evidence proving their safety was inadequate and they resembled other chemicals known to be hazardous" (Renn and Elliott 2011, 251).

In order to appreciate why TSCA is less precautionary than REACH, it is important to appreciate that the tort liability system, which is based in common law, places greater burdens on the chemical industry in the US than it does in Europe. The primary mechanism that the US uses to encourage precautionary actions is tort law, not regulatory law. In contrast, the EU uses regulatory law as the primary means of safety protection. One of the reasons that the US has become interested in TSCA reform is a growing perception that tort law is not always

effective in protecting public health, safety, and the environment from the risks of chemical releases and exposures (Renn and Elliott 2011).

Arguably, the real issue is not whether the EU or US is "more precautionary," but how regulatory decision makers can strike the most appropriate balance between risk and precaution (Renn and Elliott 2011). This question, if REACH is more precautionary than the US bipartisan TSCA reform bills, will be further analyzed throughout this dissertation.

California effect: Are TSCA reform bills going to be less strict than REACH?

Vogel's *race to the top* or *California effect* means that it can be in the strategic interest of governments to promote stricter health and environmental foreign standards for less regulated governments in order to encourage them to adopt similar higher standards. The EU is actively spreading knowledge of REACH around the globe, thereby encouraging foreign governments to contemplate the adoption of REACH. Why would non-EU countries adopt the strict REACH regulation (Heyvaert 2010)?

According to Princen (1999), there are at least three ways of exporting strict standards: requiring producers to conform to certain standards, requiring other countries to conform to certain standards, and having national standards harmonized in an international organization. In each of these three cases the result can be a success or failure. When it comes to the success and failure of exporting strict standards, *legal*, *economic*, and *political* factors are the most important (Princen 1999).

Out of these three factors, economic size and economic power are the most salient. For the legal factor, Princen mentions how a country regulates its trade rules. For economic factors, he outlined that a big and wealthy country that has an attractive market has more opportunities to impose its strict standard (EU shares of US chemicals export is 25 % in 2012 according to US Census). However the market size of a country with less strict standards is also important. An economically more powerful country (like the USA) can use its market power to withstand the pressure or to adopt a greener standard. Finally, the political factors refer to the strength of pressure groups of the country that has to accept the stricter standard. This is important, since countries are more likely to introduce stricter standards if they have strong public interest groups (e.g. environmental groups or trade unions) that lobby for a strict standard. Vogel (1995, 55) mentions that the "removal of nontariff barriers and the strengthening of health and safety regulations requires a strong international authority." His thesis is that the stronger the international authority, the more likely a California effect is to

take place. Genschel and Plümper (1997) argue that strict standards are more likely to spread if the benefits relative to the costs of adopting them increase (Vogel and Kagan 2004). This question, whether TSCA reform bills will be less strict than REACH, will further be explored in this thesis.

Drivers for chemical policies development

It is also important to mention the general and concrete drivers for the development of chemical policies, and why these drivers of modernization of TSCA were not strong enough to amend the law for almost 40 years. Environmental advocacy groups, chemical industry, governmental agencies, trade unions, and other civil organizations have made important contributions to the promotion of chemical safety. However, progress in chemicals management has not been sufficient globally, which is why impairing the health and welfare of millions due to chemical exposure and the chemical contamination of the air, water, and land is still significant. The global production, trade, and use of chemicals are increasing, which makes fundamental changes inevitable in the way societies manage chemicals (UNEP 2006).

The 2002 World Summit on Sustainable Development, held in Johannesburg, agreed that the main goal of the United Nations is to ensure that by 2020, chemicals are produced and used in ways that minimize significant adverse impacts to the environment and to human health (UNEP 2006). Nations set out to meet these challenges through the development of their chemical policies. The United Nations Environmental Program is a primary driving force in the world for international activities related to the sound management of chemicals in order to achieve sustainable development (UNEP 2015). The EU adopted the ground-breaking REACH regulation in 2006 as its enabler for reaching that world summit goal (ECHA 2015). "In the United States the Louisville Charter for Safer Chemicals represents one important public statement about accomplishing federal reform by 2020. (…) It requiring safer substitutes and solutions; phasing out persistent, bioaccumulative, or highly toxic chemicals; giving the public and workers the full right to-know and participate; acting on early warnings; requiring comprehensive safety data for all chemicals; and taking immediate action to protect communities and workers" (Ditz 2007, 4).

International pressure for sound chemical management notably increased through three programs of the United Nations, such as the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), the Intergovernmental Forum on Chemical

Safety (IFCS), and International Chemicals Management policy framework (SAICM). The European Union plays a dominant role in all three of these programs (Uyesato *et al.* 2013).

EU's REACH program is considered worldwide to be a fundamental change to how we manage chemicals. Anna-Sofie Andersson, Director of ChemSec, an environmental non-profit organization with the vision of a world free of hazardous chemicals, said the following statement on Helsinki Chemical Forum in 2014 May: "REACH is the only system that can be used as a model for chemicals management!" Her justification was the following: REACH is based on core principles (the precautionary principle, no data no market principle, substitution principle to foster innovation, right to know principle, polluter pays principle), identifies properties for substances of very high concern, uses hazard and risk based system, uses available information from ECHA (hazard and exposure data and identified SVHCs), and REACH's candidate list drives innovation (ChemSec 2014). The ChemSec environmental non-profit organization also concluded the following for the cornerstones for chemical management:

- Basic set of legislation (based on the core principles, clear division of responsibilities between authorities and the industry, the possibility to restrict and ban groups of chemicals, the possibility to implement international agreements)
- Basic administration – enforcement
- Part of all relevant national policy areas (Co-ordination with other legislations)
- The implementation of GHS, including Safety data sheet (SDS) requirements
- Focus: Upstream chemicals control

Here we will see that US American Chemistry Council (ACC), who represents the American leading companies in the chemical industry, thinks differently: REACH is not the only system that can be used as a model for chemicals management (ACC 2014). However, the TSCA debate focuses around those cornerstones which were set out by the ChemSec NGO above.

Drivers of REACH

REACH is Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals, which came into effect on June 1st, 2007. REACH is an EU *regulation* which means it is applicable and binding in all Member States directly. It does not need to be passed into national law by the Member States, although national laws may need to be changed to avoid conflicting with the regulation (EC 2012).It has been translated to all EU languages. It is the

highest level legal act in the EU. REACH was developed based on detailed assessments of what worked and what didn't work under previous chemical controlling legislations. 6000 opinions were submitted through an internet consultation about the draft legislation of REACH. This contentious and emotional political debate took almost 10 years.

There are three main drivers and two additional drivers for REACH development (Hansen 2013): The first is the lack of publicly available toxicological, ecotoxicological, and environmental fate data on existing chemicals.[3] In 1999, a review showed that only 20% of existing chemicals had full test data defined by the OECD Screening Information Dataset (Williams *et al.* 2009). This resulted in the lack of trust that substances were being used safely, since 90% or more of the total volume of all substances on the market were existing substances which had no data (Bergkamp and Penman 2013).

The second main driver is the slow and resource-intensive progress made under previous legislation (Dangerous Substances Directive), with respect to existing substances. Authorities from Member States of the EU were responsible for prioritizing the existing substances, and making a full risk assessment and risk management process. However, only less than 200 hundred have been completely assessed (9 chemicals /y (Hansen and Penman 2013, 377), which showed lack of commitment and lack of resources from authorities (Hey *et al.* 2007). During the debate, they concluded that faster and less resource-intensive progress could be made if the industry generated the comprehensive intrinsic property database rather than the authority. This is a top-down approach to information requirements.

The third main driver is the fact that the burden on proof was on authorities and not on the polluters. There was a political will to implement 'polluter pays principle' which means "those who manufacture and use chemical substances must be made responsible for generating sufficient data, and based on that data, they must carry out a safety assessment, and then identify and implement the necessary risk reduction measures. (Hansen 2013, 18)"

The fourth, additional, driver of REACH development is that before REACH there was a huge difference between the new substances (non-phase-in) and the existing (phase-in) substances' testing requirements, since new substances (marketed in the EC after 1981) have to be notified and tested extensively. These new substances' notification and testing requirements have inhibited research and development, and encouraged the use of old existing substances (Hey *et al.* 2007). This is due to the fact that these tests were very expensive, and

[3] Existing substances are chemicals included on the EINECS list, the 'European Inventory of Existing Chemical Substances' available at ECHA homepage

only a few companies could afford to invest money in it. Finally, the fifth driver of REACH development is to allow free movement of chemicals on the EU market.

Drivers of TSCA modernization: Why has the USA been waiting more than 40 years with the TSCA reform?

The current Toxic Substances Control Act (TSCA), 15 U.S.C. §2601 et seq., was enacted by US Congress in 1976. This is the US federal chemical law which gives the US Environmental Protection Agency (EPA) the right to regulate chemicals manufactured[4] or processed in the United States, to ensure that they are safe for their intended use. In the late 1960s and early 1970s, the American public and government leaders became increasingly concerned (ChemHeritage 2010) about the improper handling of chemicals, mainly pesticides, which impaired the health of chemical industry workers and caused toxic effects on wildlife due to the dumping of chemicals into rivers. In 1976 TSCA was one of[5] the strictest standards in the world (Yoshiko 2010), so it influenced EU chemical policy and other nations' chemical policies. However since 1976, for almost 40 years, it has not been officially modernized. Since 2008, ten TSCA reform bills were issued and just three, the *S. 1009 Chemical Safety Improvement Act – 2013*, the S.687*Frank R. Lautenberg Chemical Safety for the 21st Century Act -2015*, and the *H.R.2576 TSCA Modernisation Act – 2015*, had bipartisan support. Unfortunately, none of them could yet become law. While, in Europe, during the past 40 years the chemical directives have been amended several times and in the end strict REACH regulation was issued. [6]

The main drivers of REACH development and the main drivers of TSCA development are identical. Lack of data on existing chemicals resulted lack of trust from American public that the chemicals are used safely similar like in Europe. The second driver that the prioritisation of existing substances and making a full risk assessment and risk management process by the U.S Environmental Protection Agency are very slow is a real problem in the USA as well. The third driver that the polluter pays principle is not implemented since not the manufacturer and users of chemicals generate data and carry out safety assessments is also true for the USA.

The two additional drivers of REACH is slightly different in the USA, new chemical notification – the Premanufacture Notice (PMN) - is not inhibiting research and development,

4 TSCA's definitions of 'manufacture' includes 'import'
5 Japan issued a Chemical Substance Control Law in 1973 earlier than TSCA (Abelkop et al. 2013)
6 REACH regulation was amended several times since 2006 as well.

according to the U.S industry rather accelerate it. The fifth driver the free movement of chemicals on the market, is also not such a big problem in the other side of the ocean as it was in EU before REACH.

Why has the USA been waiting more than 40 years with the TSCA reform even though they have the same main drivers like in EU? Why were the drivers of modernization of TSCA not strong enough to amend the law, even though in the last years calls for reform have emerged from the general public, the nonprofit-sector, the EPA, Congress, and the industry?

As a general explanation, the slow pace of TSCA reform can be seen as a reflection of the balance of power between industry and environmental groups, with the balance tilted strongly toward industry in US political culture. Although environmental advocacy groups have significant influence in the US, two features of the US political system cause industry to have relatively more power in the US than in Europe: the multiple power centers in US lawmaking creates more obstacles to reform, and the orphan status of TSCA makes reform more challenging.

The law-making processes in the USA and EU are significantly different. The United States Congress consists of two houses: the Senate and the House of Representatives. For a reform bill to become law, both houses must agree to identical versions of the bill (Wikipedia 2015). The US has a two party system where industry, though more influential in the Republican Party than the Democratic Party, has significant ties to both parties. In recent years the influence of environmental lobbies has been primarily in the Democratic Party. The partisan majorities in the Senate and the House are quite often controlled by different parties. This makes an agreement on any environmental reform bill difficult. An extra disadvantage is that a bill, once introduced, is eligible for enactment for only one congressional period of two years. If a bill is not passed in one period and Congress starts a new period, then the bill must be re-introduced and the process starts again at the beginning. Through the legislative process, the president exerts influence, in part because the president possesses the power to veto a reform bill passed by Congress.

In the EU, the law-making process is not limited to two years, and the European Commission (EC) proposes new laws. The agreement of 14 Commissioners out of 28 is enough to write draft legislation, which is then sent to the European Parliament and Council to be adopted (EU 2015). There are multiple political parties in the EU, and environmental and industry groups have ties to multiple parties. The Parliament and Council can amend

legislation, but procedures exist to facilitate resolution of differences, and the Commission – as a proposer of a new law – has strong incentives to facilitate dialogue and acceptable compromises.

The main reason for the long period without TSCA reform is the 'orphaned' status (ChemHeritage 2010) of the TSCA: there was no political leadership within the US Congress that shared the views of the leadership of EPA that TSCA needed to be modernized. After each two-year election cycle, membership on committees could change, which helps explain why some champions of reform in the House and Senate were lost. None of the U.S. presidents since 1976 have made TSCA reform a high legislative priority. And the U.S. Congress has become increasingly plagued with partisan disagreements, causing opportunities for collaboration to wane.

TSCA's orphan status has also extended to NGOs, since many environmental groups were indifferent to TSCA reform and no individual group, until recently, made TSCA reform their first-tier legislative priority. (In the last few years, the Environmental Defense Fund, a moderate pro-environment group, has championed the cause of TSCA reform). Environmental NGOs in the US have given higher priority to other issues such as clean air, clean water, and climate change.

TSCA was orphaned by the public as well. There was very little support from the outside public to modernize the TSCA, and the industry has historically opposed legislative reform of the TSCA, fearing that reform would bring more regulatory burdens and more compliance costs.

Today, this orphan status of TSCA has changed; more and more stakeholders are getting involved in TSCA reform and important changes are being made to the TSCA. According to almost all of my interviewees, if REACH had never been enacted the momentum behind TSCA reform would be weaker. Hence, we can say one of the drivers for the acceleration of TSCA modification in the USA was the enactment of the REACH regulation. The impact of REACH on TSCA reform debate will be examined, and REACH and the proposed TSCA reforms will be compared in order to determine similarities and differences, including some opportunities for harmonization.

1. LITERATURE REVIEW

This chapter examines relevant literature on comparison literature of REACH, TSCA, and/or TSCA reform bills. The chapter does not address the larger literature that reviews REACH or TSCA alone, though some of this literature is cited later in the dissertation.

1.1. REACH's role in environmental policy worldwide

The environmental revolution in the United States occurred in the late 1960s and early 1970s, when policymakers enacted major environmental statutes such as the Clean Air Act (1970), the National Environmental Policy Act (1970), Clean Water Act (1972), Endangered Species Act (1973) and Toxic Substances Control Act (1976). The wave of new legislation was a response to urgent problems, such as urban rivers regularly catching fire, consistent smog alerts in big cities, and birds dying off due to the unconstrained use of certain pesticides (Blais 2014). In the 1970s and 1980s, the American environmental legislation tended to be more stringent than that seen in individual European countries. However, starting in the late 1980s, the EU gradually started to make environmental policy innovations, while the interpretation of the *precautionary principle* caused many transatlantic political disputes (Jordan 2005).

Currently, according to David J. Vogel, the environmental revolution is more prominent in the EU than in the US, as EU environmental policy is progressing aggressively, while US environmental policy remains stagnant. "The EU has been characterized as having some of the most progressive, strongest, and innovative environmental policies in the world. (…) EU environmental policy has become 'one of the best known aspects of the EU'" (Smith 2005).

Kelemen and Vogel (2007) explain why the EU replaced the US as an international environmental leader; "the stronger the domestic political influence of environmentalists, the more stringent are domestic standards and the more it becomes in the interests of business to support treaties that could impose those standards on foreign competitors". In the US, the political influence of environmental lobbies weakened during the early 1990s, as the significant expansion of government regulation from 1960-1990 resulted in strong criticism from small and large businesses and Mayors and Governors concerned about economic development.

In the United States, bitter divisions about environmental policy also developed along party lines. In the early 1970s, Democrats supported, on average, approximately twenty

percent more environmental measures than Republicans. In 1995, Democrats supported 89% of environmental measures while Republicans supported just 11 %. Gradually the Democrats became the 'environmental party', and Republicans the 'anti-environmental party'. Public support for new regulation also declined during this time. In 1994, the majority of the American public believed that environmental protection is good or excellent in the US. Since 2000, the survey data show an increase in public dissatisfaction with the regulatory status quo (Kelemen and Vogel 2007).

Skepticism about US environmental regulation was intensified by the insights from analytic tools such as risk assessment, comparative risk assessment, risk-tradeoff analysis, cost-effectiveness analysis and cost-benefit analysis. Although the design of US regulations were often well intended and somewhat effective in protecting the environment, analysts found that the regulations were sometimes based on poor science, weak economic analysis, and insufficient consideration of regulatory alternatives. For example, some regulations designed to reduce air pollution indirectly caused an increase in water pollution. Likewise, economists showed that, through use of market-based instruments, regulators could accomplish more protection of the environment, and at less cost to the economy, than occurs under traditional command and control standards (Graham and Wiener 1995).

In Europe, the opposite occurred. Environmental movements flourished across Western Europe in the 1970s and European environmental activists became gradually involved in electoral politics. At the end of the 1990s, 11 EU member states had Green parties in their government. These Green parties supported strict domestic environmental standards, and expanded their commitments to international environmental cooperation. At the same time, the European Commission and the European Parliament saw the promotion of EU environmental policy as a powerful way to build support among European citizens for the EU (Kelemen and Vogel 2007).

The early 1970s are often described as the 'dark ages' of EU environmental policies since political leaders paid little attention to environmental problems and environmental pressure groups were not yet present. The first Programme of Action on the Environment was introduced in 1973, although a few legal measures on chemicals were implemented beforehand in 1967. Between 1989 and 1991, the EU issued more environmental legislation than in the previous 20 years combined, as the greener member states started to push EU environmental standards that were as high, or even higher, than their own national standards (Jordan 2005).

Vogel's *race to the top* or *California effect* means that it can be in the strategic interest of governments, once they have enacted strict health, safety, and environmental standards, to promote the enactment of similar standards by less regulated governments. The California effect gained its title because California and other environmentally progressive states often enact stricter environmental health and safety standards ahead of the federal government, and then encourage other states – or even the federal government -- to enact similar elevated standards.

In the EU, Sweden, Austria, Finland, Germany, the Netherlands, Denmark and Norway are infamous for their strict environmental health and safety regulations. Andersen and Liefferink (1997) call these countries the pioneers or forerunners, as they push other EU members to adopt stringent environmental policies.

Policy-making in the EU is a two-level game, but not necessary simultaneous. On the one hand, there are 'Brussels politics' in which different EU institutions are involved and, on the other hand, there are domestic politics that influence the official positions of member states in the European Council and in the European Parliament. Negotiators are often misinformed about other countries' domestic environmental politics. However, policy experts from the most strictly regulated member states tend to exert stronger influence on EU decisions than experts from less regulated member states (Andersen and Liefferink 1997).

The EU plans to be in compliance with the international goal for chemicals by 2020, requiring that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment (UNEP 2006). In the EU there are four general environmental principles: The polluter pays principle, the precautionary principle, the principle of producer responsibility, and the principle of sustainable development. These principles are implemented into REACH legislation. I will address these principles in a later chapter.

EU environmental policy is developed by the European Commission through its environmental action programs. The programs set out broad policy objectives for the future. The slogan of the EU's 7th environmental action program: *'Living well, within the limits of our planet'.* It fills gaps and identifies overlaps with the view of achieving 2050 vision and setting priority objectives for 2020.

> *"In 2050, we live well, within the planet's ecological limits. Our prosperity and healthy environment stem from an innovative, circular economy where nothing is wasted and where natural resources are managed sustainably, and biodiversity is protected, valued and restored in ways that enhance our societies resilience. Our low-*

carbon growth has long been decoupled from resource use, setting the pace for a safe and sustainable global" (EC 2014a).

The ultimate goal is set to achieve a prosperous economy, resource efficiency, non-toxic environment and non-toxic product cycles, which put additional demands on the Chemicals Policy. The 7th Environmental Action Program sets out to meet these challenges through the development of EU strategy for a non-toxic environment, supported by a chemical knowledgebase by 2018. The chemical companies should become a chemical knowledge company, which means that the companies who know their substances, know the uses and understand safety -hence invest in innovation- are ensuring environment and health protection and have a competitive advantage. For 2015, the EU would like to ensure the safety of nanomaterials, minimize exposures to endocrine disrupters, appropriate regulatory approaches to mixtures and minimization of exposures to substances in articles. For 2018, the EU plans to develop an EU strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions (Hansen 2014).

Societies around the world have become concerned about the perceived hazards of chemicals. Both in the US and in Europe, there has been a tracking of the presence of heavy metals and persistent organic compounds in citizens. The rapid development in analytical chemistry allowed us to measure smaller and smaller concentrations of chemicals in the environment and in the human body. The public belief is that there is an inadequate database on the adverse health effects of chemicals. This placed pressure on regional, national and international regulatory authorities to gather data (Williams *et al.* 2009).

According to Moules (2011) there are six main ways in which public law regulates and protects the environment. All the six ways are used in chemical legislation in both the EU and in the US. First, standards are set in relation to toxicological, ecotoxicological, and environmental fate tests. Second, conditions are set for the issuance of permits, which authorize manufacturers or importers of chemicals to engage in commercial activity. Third, civil liability may be created, such as penalizing environmentally harmful activity such as using a banned chemical. Fourth, public law regulation may identify certain species that must be protected or certain human subpopulations (e.g., children). Fifth, public law regulation may lead to the banning of certain activities. For example, banning or restricting the use of a substance of very high concern. Finally, public law may require particular procedures to be carried out before an activity may be undertaken. A good example of this is the requirement for chemical risk assessment (Moules 2011).

Public participation is a theme of the modern environmental revolution and it was crucial in both REACH and TSCA reform. The definition of public participation, according to Renn and his colleagues, is "forums for exchange that are organized for the purpose of facilitating communication between government, citizens, stakeholders and interest groups and businesses regarding a specific decision or problem" (Renn at al. 1995, 2). Public participation has different formats. In TSCA reform, the public hearing involving different stakeholders has been most relevant. Meanwhile, in the REACH debate, the internet consultation format is used now quite often. The purpose of public participation can also vary. It can facilitate conflict and power redistribution, reveal collective conscience, and/or help to improve decision-making through using comprehensive information. The values for the evaluation depend on which side the evaluator is on. The public will evaluate the process in terms of how well their interests are reflected in the final outcome. This is a process that must have winners and losers. The problem lays in the evaluation, where one groups places value above all others (Renn at al. 1995). "The public is not a homogenous entity. Decision makers are faced with competitive claims, values, opinions from experts, pressure groups and so on" (Le Guen 2007, 106). Thus public participation does not necessarily bring public consensus, since reaching joint agreement and building trust is very difficult (Renn 2007 a).

Technical risk assessment identifies the hazard associated with the substance and the likelihood of that hazard's occurrence. The expertise of the risk assessor is crucial. One factor that complicates discussion of risk is the difference between public perceptions of risk and scientific analyses of risk. Some believe that at least some part of the risk can be explained to the public in a simplified way. Others believe the public perception of risk is very subjective, since hazards meaning different things to different people but an unfamiliar risk may lead to a greater concern than a familiar risk. Media attention is a heuristic for determining whether the problem is serious. This helps explain why different cultures, stakeholders and people are frightened of different things, since they hear different reports from the relevant media of what is hazardous. To allow greater public participation in environmental decision making can decrease the tension between the public perception and the scientific analysis. (Holder and Lee 2007, 15 -16, 58)

The risk assessment on a chemical is examined when exposure is combined with hazard. According to Richardson, risk assessment has four aspects: hazard identification, risk characterization, exposure assessment and risk estimation. Quantification of risk assessment requires dose-effect and dose-response relationships in likely target populations (Richardson 1992). The results of risk assessment often depend on data which are not scientifically

complete or perfectly relevant, which is why risk assessment can never be an exact science. Risk can be minimized, but rarely can be eliminated and reduced to zero. The absence of an observable effect level does not guarantee that there are no effects. (Richardson 1988, 7)

Thus, decisions about risk acceptance must always be taken in a situation of some uncertainty. The procedure of risk assessment is nonetheless of critical importance since the process is the ultimate guarantee of public safety and, thus, must inspire confidence. Risk management is an active hazard control process relating to a potential hazard. Risk management selects the optimal regulatory response (e.g. exposure control) for safety from that hazard (Richardson 1992). Actions to reduce risk and control the hazard cost money.

Ortwin Renn (2007) prepared a risk governance framework that includes societal context and a new categorization of risk. It goes beyond the generic elements of risk assessment, risk management and risk communication. Hazard includes the "inherent properties of the risk agent and related processes". Risk is the "potential effects that these hazards are likely to cause on the ecosystem or on human organisms and their related probabilities" (Renn 2007, 15). The risk governance framework has three main phases: pre-assessment, risk appraisal and risk management. The purpose of the pre-assessment phase is to determine what is going to be addressed as risk by different actors, including a screening the potential risks. The risk appraisal's first component is the risk assessment, which includes hazard assessment, exposure assessment, and risk estimation. The risk assessment is confronted with three major challenges: complexity, uncertainty and ambiguity. The second component of risk appraisal is concern assessment, which deals with the stakeholders concerns, questions, emotions, hopes and fears. Risk characterization and risk evaluation aims to judge the tolerability and acceptability of risks. The risk management phase implements the actions required to tackle risks, thereby accomplishing tolerability or acceptability of risk. Risk communication enables stakeholders and the public to understand the results and decisions of the risk appraisal and risk management phases. Effective risk communication, when based on a two-way communication between laypeople and elites, helps create trust and prepares the society to cope with the risk (Renn 2007).

Part of the EU risk assessment is calculating the Derived No-Effect Level, or DNEL. The DNEL is the level of exposure to the substance above which humans should not be exposed (threshold level). The DNEL measures the potential of the substance to cause adverse health effects. DNELs do not have the same purpose and same status as Occupational Exposure Limits (OELs), even though in some circumstances an existing OEL can be used as a DNEL and DNELs have the same units as OELs. DNELs are merely meant to be compared

to exposure levels in order to a derive risk characterization ratio (RCR). If the exposure level is higher than the DNEL, risk reduction measures should be applied (Boogaard *et al*. 2011).

Schenk (2014) and her team compared the long-term inhalation worker-DNELs, which was calculated by industry based on a REACH guidance document and Swedish occupational exposure limits (OELs), which was calculated by the authority based on SCOEL guidance. On average, industry‘s Worker-DNELs were the same as the Swedish OELs, but the variation was enormous. The reason for these discrepancies is that there are many arbitrary choices (key studies, dose descriptors, assessment factors) that influence the calculation of DNEL (Schenk *et al.* 2014).

In another article, she explained that the worker–DNELS will be defined in practically each hazardous substances registered over 10 tonnes /y, so many more substances will have worker-DNELs than health-based OELs set by SCOEL or regulatory agencies. “This leads to the question on whether further work on deriving OELs is really needed” since industry started to handle worker- DNELs as OELs (Schenk and Johanson 2011).

Hansen and Blainey authored an article concerning how the REACH regulation was constructed; the main issues raised in the three years of intense negotiations and the solution found for these issues. Reading his article, it was evident that the pre-REACH EU legislation[7] had very similar issues like current TSCA in the USA. In the previous EU substance regulation programme, the authorities had to demonstrate based on a comprehensive risk assessment that information was needed from the industry. This is the ’bottom-up’ approach to data generation. "This burden required significant resources from the Member State authorities, and was only possible after having proven that the substance may present a serious risk. In addition, such decisions could often only be made if good exposure information was available” from manufacturers, importers and downstream users (Hansen and Blainey 2008, 111).

Before REACH was issued, a lobbying campaign was organized by European and American chemical manufacturers to the opposition to the European efforts to issue REACH. Why should the American industry oppose a burden to its competitor? According to Lorenz “the opposition to REACH could have been caused by the fear of spillover leading stricter regulation of the chemical sector in the US as well rather than by its financial impact on US exports” (Lorenz *et al.* 2012, 21).

[7]Regulation 93/793/EEC and 67/ 548/EEC

Why the EU industry is no longer against a stricter regulation and why we do not find widespread dissatisfaction with REACH? The answer is that a stricter chemical regulation gives an opportunity to the industry to rebuild public confidence in its products, and so enhances sales and the reputation of the chemical industry (Lorenz *et al.* 2008).

Chemical companies who wish to prepare a REACH registration dossier must use the IUCLID 5 and REACH-IT program. There are two different forms of registration: individual submission and joint submission. Individual submission is restricted by ECHA since 'one substance one registration' principle should be used in the SIEFs. In case of a joint submission, the SIEF members must choose a lead-registrant company, who is responsible for collecting the minimum required data set. First, the lead-registrant must submit the registration dossier. The rest of the companies can submit their co- registration dossier following lead registrant's submission. After the lead-registrant finalizes the preparation of the „full" dossier, the co-registrants must pay for a „token" number, which serves as the identification number. The SIEF member is able to use this "token" number to certify that they are able to use the toxicological tests of the lead registrant so the 'one substance one registration' principle is ensured with the token. Through this process, one can understand that the submission date of the co-registration dossier can only occur after the lead-registrant submits a full dossier (Botos n.d.).

There are some articles which are dealing with how REACH may be improved to protect the environment and human health. One of them is the article of Lee (Lee *et al.* 2013) who made a comparative study of Denmark's and South-Korea's lead exposure levels. During his research he concluded that the exposure scenarios of REACH do not include background exposures from historically accumulated chemicals. REACH does not contain cumulative risk assessments that are closer to real exposure situations and include differences in territorial environmental quality. Data from environmental monitoring and Pollutant Release and Transfer Register may be used to derive total background human exposure and should be taken into consideration in REACH.

The head of ECHA, Geert Dancet, in his annual presentation to the Environmental Committee of the European Parliament said that REACH dossier's information requirements section should be amended due to legal uncertainties. ECHA cannot effectively require data about nanomaterials and endocrine disruptors. Currently, ECHA sends individual information requests to companies if they register a substance in the nanoform, but companies often appeal it, and once an appeal has been made, the information request is suspended and the ECHA cannot learn more about the impact of nanos. Endocrine disrupting chemicals have a

similar story. He also urged to have an EU criterion for endocrine disrupters. The Commission, before making any decision on changing the REACH annexes' information requirement section, needs to clarify the costs for companies that work in this highly innovative area, especially for SMEs (CW 2015 d).

ECHA organized a workshop on how a read-across within REACH dossiers could be improved in order to reduce uncertainties associated with the use of alternative approaches. Checking the REACH dossiers, the ECHA found three typical issues that impact the acceptance of the read-across prediction, the first is the experimental data used in the read-across, the second is the chemical similarity on which the analogue or category is based, and the third is the weight-of-evidence supporting the categorization scheme employed. During this workshop, the interested stakeholders were enabled to clarify many misconceptions (Patlewicz *et al.* 2013).

During our 2012 interviews with EU REACH experts (Abelkop *et al.* 2012), we did not find widespread dissatisfaction with REACH as a whole but we concluded that REACH has some flaws that may require some refining in the years ahead. One of our recommendations was that additional rules are needed on the formation and operation of SIEFs and consortia, since REACH registration is a collaborative process among companies. Such rules, which could be provided through ECHA guidance, may reduce transaction costs for companies, while providing more predictability in the registration process. As more small and medium-sized companies are brought within the registration system, the value of additional rules regarding data sharing, data compensation, and SIEF operation will become even more important. ECHA also recognized this flaw of REACH and plans to issue a new data sharing guidance document in 2016 to support the SMEs.

As a REACH consultant, who works with many SMEs, it is noticeable that data compensation is one of the flaws of REACH, which the SIEF members really depend on concerning whether the lead registrant calculates the Letter of Access (LOA) price in a fair, transparent and non-discriminative way. If not, then ECHA is not able to support the SMEs in an effective way against the lead registrant. ECHA's opinion is that registrants of the same substance are obliged to be part of the same joint submission, and registrants must therefore make sure that they comply with their joint submission obligations. Otherwise, they may be subject to enforcement actions by their national enforcement authorities. In 2016, the REACH process will be restricted and no individual registrations for the same substance will be allowed (pers. comm.). Therefore, SIEF members with an unfair lead registrant can pay much more for a LoA, than an individual submission, which would no longer be reasonable.

However, in order to increase transparency in SIEFs, ECHA has appointed an Ombudsman in order to more closely monitor individual cases and offer a platform for redress to SMEs. ECHA also appointed an SME ambassador to review SME needs for 2018 when the most SMEs will register its substances (Gubbels *et al.* 2013).

When REACH regulation places all major responsibilities on the chemical companies rather than on administrative bodies, it is nothing less than a paradigm shift in the regulatory approach (Führ and Bizer 2007) or with other name "the reverse burden of proof" (Hansen and Blainey 2008), or the implementation of polluter pays principle. Industry has three types of direct costs in REACH: the cost for testing substances which is paid by the lead registrant through the Letter of Access (LoA), the cost of registering which is paid to the authority (ECHA), and the cost for the REACH consultants to help prepare the REACH registration. Industry has indirect costs in some cases, such as risk management measures or replacement of products that include substances of high concern.

The direct cost of complying with REACH is payable as a one time, 1 USD compliance cost per 100 USD of sales per year (Lorenz *et al.* 2008). Angerer and his team agree that REACH is affordable for even chemical companies in new European Member States (Poland, Hungary). Charging the chemical industry with the REACH implementation cost would erode its 11 year turnover by 0.13% and its 11 year profit by 4.4%, which means that the "cost burden remains far below critical thresholds and will not harm the strong international competitive position of Europe's chemical industry, nor trigger relocation of downstream industries outside Europe (Angerer *et al*. 2008, 646)."

Gubbels and her team argue that there are serious concerns with how SMEs could cope with REACH registration, even though they have to pay lower fees to the authority. The lead registrants usually ask the same amount for a LOA from each SIEF members in the given tonnage range,[8] but SMEs deal with lower volumes of chemicals than do larger companies, resulting in a higher cost per unit. ECHA recognized this issue and has appointed an SME Ambassador in order to review SME needs for 2018, when the most SMEs will register its substances (Gubbels e*t al.* 2013).

However, without a doubt, REACH has benefits, like the creation of new knowledge on chemical properties and risks of the registered substances, communication of this information along the supply chain, improvement of risk management, and occupational health and safety.

[8]During my practise I have seen just once that the lead registrant sold the LOA proportionally with the volume of sales.

The EU is actively spreading knowledge of REACH around the globe, thereby encouraging foreign governments to contemplate the adoption of REACH. Adoption of REACH in non-EU countries could happen in two ways: full assimilation, or approximation of rules (Heyvaert, 2010). A good example for the first model of full assimilation is Norway, Lichtenstein, and Iceland, who are EEA members. These countries implemented REACH regulation similarly to other EU-countries, and accepted the normative and procedural content of REACH. In these three countries, ECHA will administer their registration files, perform completeness checks, receive registration fees, and assign registration numbers. "For countries outside of EEA, full assimilation to REACH is not a plausible scenario. They are much more likely to approximate the REACH format in domestic legislation" (Heyvaert 2010, 231), and they would most likely export the registration part of REACH. Non-EU countries will more likely copy the basic REACH principles rather than the entire REACH framework (Fisher 2008). "A domestically differentiated version of REACH may perform as well as, or even better than, the EU example as a health and environmental protection instrument, but could forfeit the trade liberalization and competitiveness benefits that the globalization of norms seek to attain" (Heyvaert 2010, 235).

REACH regulation has an impact on many countries who want to reform their chemical legislations. I will address some of these countries in this chapter. If non-EU manufacturers want to sell their chemical materials in the EU, they face the regulatory barriers created by REACH. During trading to the EU, countries can monitor and study REACH easily, and can make a decision if they want to implement any element of REACH into their chemical legislation.

ECHA has cooperation agreements with regulatory agencies in four countries: Australia, Canada, Japan and the US. These activities are focused on exchanging information, best practices, and scientific knowledge. The ECHA regularly delivers explanatory presentations on EU chemical legislation for non-EU audiences, both for authorities and industry. Priority is given to the authorities in countries that are revising their chemical legislation. The ECHA is doing regulatory and trade dialogues between the EU and its main partners such as China, South-Korea and the Russian Federation, and other countries as well. (ECHA 2015 d).

As a candidate for EU membership, Turkey started the process of introducing REACH into its own legislation in 2011. The implementation project ended in 2013 with a draft

regulation called the Turkish version of REACH. The registration part of it is scheduled to occur between 2016 and 2018. There is no separation of deadlines like in the EU, in Turkey manufacturers can register their substances at any time by end of 2018 (CW 2014 a).

Moldova is planning to implement REACH into their new chemical law. The EU is going to support them to undertake further technical steps. Moldova has no chemical manufacturers, which is why REACH implementation is not expected to have an extra burden on Moldovan enterprises. (CW 2014 c)

South Korea developed "Korean-REACH" in less than three years. The adoption of EU REACH in South-Korea is not full assimilation because Korean REACH is not identical to European REACH. Rather, it implemented the following part of EU REACH: registration, pre-registration, data sharing, joint registration, evaluation, restriction, authorization, article notification and only-representative system. The registration deadlines are from 2015 to 2020. (Uyesato *et al.* 2013) Using REACH data to register substances in South Korea is currently a hot topic since, in theory it should save money and reduce the need for animal testing. In practice, some EU data may not be accepted by Korean authorities because of differences between REACH and Korean REACH, such as good laboratory practice certification. "Some REACH registrants have voiced concern that, if they share data with the South Korean authorities, it may leak into the public domain and, thus, lose its financial value" (CW 2015 b, 1).

Russia, Belarus, and Kazakhstan are in the process of adopting a new set of common chemical regulation. During this reform they take into consideration the REACH regulation however the three countries would like to adopt REACH differently (CW 2014 b). Kazakhstan would like efforts in aligning its chemical rules with REACH Regulation to be considered in their new chemical legislation. However, Russia and Belarus do not agree with this design, since Russia and the EU currently have a diplomatic conflict (CW 2015 c).

Japan did not introduce a REACH-like chemicals management regime for three reasons. First, they do not want to put a financial burden on the Japanese industry. Second, the Japanese government traditionally does not rely on risk assessment carried out by industry. Finally, the Japanese government does not want to implement legislation that can cause disputes with companies. Although a REACH-like system is not implemented in Japan, it provided the Japanese government with many ideas on how to develop and refine the Japanese 'Chemical Substance Control Law' (Uyesato *et al.* 2013).

China is not going to adopt REACH wholesale into Chinese law. REACH is referenced in Chinese laws by name, but it does not mean that there is the adoption of

REACH in China. However, understanding of REACH and doing policy assessment about REACH means that they can consider the key aspects of REACH when drafting a chemical law. China has a REACH Helpdesk to support Chinese companies with information on REACH. There are a lot of legal and technical exchanges[9] between Europe and China in order to enhance Chinese officials and industry decision makers' opportunities for exposure to European environmental law (Uyesato *et al.* 2013).

REACH is exerting influence on environmental policy discussion in the United States as well. This dissertation looks for the similarities and differences between REACH and the proposed reforms of TSCA. In the course of identifying differences, the dissertation also looks for promising areas of harmonization. I can conclude that REACH's influence is to raise the level of awareness of chemical risks in almost all countries, even in those which have not implemented any element of REACH.

1.2. Comparison of REACH, TSCA and TSCA reform bills

Koch and Ashford (2006) examine REACH from the perspective of how it might offer insight into more effective implementation of TSCA. They describe two kinds of risk management errors: Type I error "when a substance is regulated which later on turns out to be either not hazardous or less hazardous than expected," and a Type II error "when a suspected hazardous substance is not regulated and it turns out to be more hazardous than expected" (Koch and Ashford 2006, 34). The avoidance of Type I errors is that we assume that a substance is safe, until the opposite has been shown. The avoidance of Type II error is the precautionary principle.

The United States Government Accountability Office (GAO 2007) compared selected provisions of REACH and TSCA to support recommendations that might strengthen TSCA. Those provisions were: enactment date, definition of new and existing chemicals, number of chemicals covered by legislation, notification requirement, method use to prioritize chemicals for further review, notification of significant changes in uses of existing chemicals, requirement of chemical companies to complete risk assessment, encourages minimizing animal testing, requirement for the disclosure of production quantities, downstream users

[9]In 2012 I was a trainer in a seminar on EU regulatory system EU GHS and EU REACH in China in Jingzhou. It was a program organised by the EU in order to support China's Sustainable Trade and Investment system. It was a project funded by the European Commission. 150 Chinese industry people and authority staff participated on this training.

responsibilities, regulation of hazardous chemicals, enforcement mechanisms, substitution requirement, protection of confidential business information, public availability of chemical information, and requirements addressing the health of children.

GAO made three recommendations to strengthen TSCA: obtaining additional chemical information from the industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and enhance the public's understanding of the risks of chemicals to which they may be exposed. At that time, EPA did not agree with GAO's recommendations. EPA states in the GAO report: "TSCA is a fully implemented statue, that has withstood the test of time, while REACH is not yet in force, and there is no practical experience with any aspect of its implementation" (GAO 2007, 30).

Denison (2007) of the Environmental Defense Fund, made a detailed comparative analysis of Canadian, European Union, and United States policies on industrial chemicals. Denison's main topics were the following: prioritizing chemicals of concern, tracking chemicals, their production and use, requiring the generation and submission of risk-relevant information, risk management for existing and new chemicals, disclosing information, and protecting confidential business information. TSCA and REACH will be analyzed herein utilizing on the same key topics (expect confidential business information), but the TSCA reform bipartisan bills will also be added to the analysis with a focus on the technical aspects. Denison compared REACH, TSCA, and the Canadian Environmental Protection Act (CEPA) rigorously and found the best practice for each topic, of which many were included into the TSCA debates. For chemical prioritization he recommended a clear criteria, which is hazard- and exposure-specific, as well as risk based. For tracking of chemicals, the government should require regular reporting of chemical manufacturer and downstream users use, exposure information, and any significant changes. The government should have broad authority to request additional information if it is needed to demonstrate potential or actual risk. All new chemicals should be reviewed and existing chemicals should have a transparent risk assessment process within a reasonable time frame. The burden on governments to manage the risks of existing chemicals should not be higher than for new chemicals. He prepared a table about the minimum data sets for REACH and current TSCA and CEPA. The Canadian part has been deleted from his table (see it in Annex III), however it will be referred to later when discussing minimal data sets.

Can the industry be trusted to generate reliable data? Denison deals with this question in detail. If the industry generates risk data, this supports the "green chemistry" initiative because if the industry integrates safety considerations into new chemicals and products, it

produces incentive for the industry to design safer chemicals. "If government is sufficiently resourced to conduct detailed reviews and to address any deficiencies in industry's assessments and management, industry generated risk data may succeed. If government is insufficiently resourced industry's assessments and self-designed risk management plans are better than none" (Denison 2007, I-9). Data generated by the government, or by independent laboratories, can be better trusted and the industry can provide the financial support. According to Denison (2007, I-9): "it is evident that a strong government capability dedicated to chemical risk assessment and management is an essential element of any sound chemicals policy. Clear rules are needed that ensure transparency and accountability for the generation of data, its assessment and the resulting actions, regardless of who conducts these activities."

Due to cost minimization, animal welfare concerns, and efficiency objectives, both industry and the government are using alternative methods to generate toxicological and ecotoxicological data. If alternative methods can be applied, then unnecessary animal testing may be avoided. These alternative methods usually cost 10% of a real in vivo test's price, therefore the considerable benefits of these methods are reducing both cost and animal use (Denison 2007).

Alternative models are used for grouping chemicals into categories, identifying, and filling (eco-)toxicological data gaps for the hazard assessment of chemicals (Denison 2007). The "read-across" is the most commonly used alternative approach for data gap filling. Those substances whose physicochemical, toxicological, and ecotoxicological "properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity", may be considered as a group or category of substances (OECD n.d. 2). Read-across entails the use of relevant information from analogous substances (the 'source' information) to predict properties for the 'target' substance under consideration (ECHA RAAF 2015). The other most commonly used approaches for data gap filling is the Quantitative Structure-activity relationship (QSAR). QSARs are methods for estimating properties of chemicals from its molecular structure through a mathematical model. ECHA supports training to use the OECD QSAR Toolbox, which is the most comprehensive, widely recognized, and freely available platform for data gap filling in regulatory hazard assessment.

However alternative tests have limitations, for instance in their accuracy and reliability, which is why we cannot always rely on them. One of the main limitations of these alternative tests is that they are highly dependent on having a robust and expanding underlying data set of values derived from in vivo testing. This basically means that these alternatives test results will only be as good as the in vivo data that underpin them. The other

limitation is that "QSAR reliable models are available for only a subset of relevant endpoints" (Denison 2007, A-7). Denison raises two concerns related to QSAR models. The first is whether and when QSAR-generated estimates can reliably replace experimental data and hence serve as a scientifically sound alternative to testing. The second concern is that QSAR estimates generated through different softwares may not be accepted universally by all countries (Denison 2007, A-8). Denison saying that read-across or QSAR-derived information will be sufficient only in relatively rare cases, and that the model shortcomings and the justification of the use of it should be clearly communicated in order to reliably replace experimental data with QSAR or read-across methods.[10]

Hazard is largely inherent in a substance, and does not fundamentally change over space or time, or with the use of the chemical. However, exposure changes with place, use, and time, which results in the periodical reassessment of exposure by the industry. The variable nature of exposure poses a major challenge to exposure and risk assessment. Detailed and replicable test descriptions are available for the conducting of hazard tests (see Annex II), in contrast to the conducting of exposure tests for which there is no internationally accepted consensus. The common limitation of exposure assessments are how to examine cumulative and aggregate exposures (Denison 2007). ECHA developed a model called the Chesar tool to predict exposure. The Chesar tool[11] carries out exposure assessment and risk characterization, and generates Chemical Safety Reports and exposure scenarios for communication.

John Applegate (2008) called REACH Anti-TSCA since REACH adopts several techniques that reverse the TSCA approach. The most important techniques are that in REACH there is no distinction between new and existing chemicals and that REACH shifts both the burden of generating new information and the burden of the proof of safety to the industry. Applegate (2008) suggests four practical principles for TSCA reform with respect to REACH innovations. The first one is that chemical regulations should be preventative, and its restrictions proportionate, to the risk presented. He suggests a risk-based regulation which is preventative, because it addresses probabilities of harm, rather than actual harm. The second principle is that chemical regulation should aim for progressive improvement in chemical safety, so the US should identify and eliminate the worst chemicals and direct innovation toward safer chemicals. Applegate's third principle is precaution, that the lack of full information should not be a barrier to preventative action. To achieve it, the regulatory

[10] REACH registration dossiers make widespread use of read across and QSAR methods.

[11] https://chesar.echa.europa.eu/

apparatus of TSCA should be far more nimble in order to generate the needed information more effectively. The fourth principle is transparency, meaning that the public should be provided with full chemical safety information, and simplicity which means procedural complexity should be limited.

In the previously mentioned 2011 Indiana University study (Abelkop *et al.* 2012) it was assumed, as a thought experiment, that US legislators are considering whether to replicate some (or all) aspects of REACH in the United States. A variety of reforms were suggested for consideration by US policy makers that might make a REACH-like system less burdensome and more effective in the USA. We thoroughly described the most important elements of the REACH regulation and we explored reforms for each of the four parts of the REACH program: registration, evaluation, authorization, and restriction. Since we have not performed a detailed analysis of each reform proposal, we were suggesting the reforms in the spirit of options for consideration and further analysis, and not as firm recommendations. Our primary purpose, with this first article, was to inform the US legislative debate about modernization of the Toxic Substances Control Act of 1976. The major findings of the report are summarized in Table 1.

Table 1. Summary of Potential Reforms to REACH if the US chose the REACH model (Abelkop *et.al* 2012)

Registration
1. Accomplish better priority setting
2. Reduce registration requirements for intermediates
3. Offer more explicit guidance on information technology tools
4. Offer more explicit guidance on data sharing, compensation, joint registration
5. Publicly disseminate identity of lead and joint registrants
6. Publicly disseminate Chemical Safety Reports unless specific passages are approved exclusions to protect confidential business information
7. Integrate registration and authorization obligations
8. Eliminate need for “only representative” to reduce trade barriers
9. Provide more clarity on the continuing obligation to update registration dossiers
10. Consider cross-Atlantic recognition of registration dossiers
Evaluation
1. Consider merging compliance check and substance evaluation
2. Provide for public nomination of substances for dossier and substance evaluation
3. Provide for a more targeted compliance check process
4. Consider contracting evaluation to external experts
Authorization
1. Increase role of the regulatory authority in listing of candidates
2. Merge candidate list and authorization list into a single list
3. Establish a public nomination process for consideration of substances for authorization
4. Consider eliminating notification requirement for articles
5. Consider listing specific uses rather than chemical substances
6. Clarify decision response time to applications for authorization
Restriction
1. Integrate or replace the restriction process with the other elements of REACH

In 2011, our research team received financial support from the American Chemistry Council, Dow and DuPont. This means that in 2011 the American industry was not against REACH but wanted to learn from it, and would even consider supporting a REACH-like system in the United States if it proved to be practical, not overly burdensome, and effective. Today, in 2015, it is clear that a REACH-like system will not be implemented in the USA, and that the biggest oppositional stakeholder of it is the American industry. However, it is undeniable that some values and principles of REACH have had an effect on TSCA reform bills.

Lucas Bergkamp edited a book about The European Union's REACH regulation for chemicals, which includes a chapter about the REACH's impact on the rest of the world (Uyesato et al. 2013). This article analyzed the three first TSCA reform bills in two pages (H.R. 6100, S.3209, S.847). The current study will focus on the analysis of the TSCA reform bills after 2013. In those earlier bills "the most significant borrowing from REACH was the proposed use of the precautionary principle" (Uyesato et al. 2013, 343). US manufacturers and processors should prove that their products are safe by using a risk-based safety standard. There are significant differences between REACH and TSCA reform bills until 2011. In REACH, in the Substance Information Exchange Forums, manufacturers and importers need to cooperate in the preparation of a registration dossier and chemical safety report (CSR). In TSCA bills there is no requirement about that kind of cooperation. Each manufacturer should submit a minimum dataset (without joint submission); the EPA would determine which one is a duplicate, and reimburse the original data submitter. Under REACH downstream users have regulatory obligations, while TSCA reform bills ignore downstream users. The TSCA reform bills do not contain the REACH regulatory concept of substances of very high concern (SVHCs), except if the prioritization into three classes will deal with exposure reduction of the highest priority chemicals. There are no provisions about SVHCs in the article or requirements about authorization for SVHCs in TSCA reform bills until 2011.

Keller and Heckman LLP, in 2013, issued the amended version of the TSCA if the S. 1009 Chemical Safety Improvement Act were to become law. It is the comparison of the two legal texts but does not contain any interpretation of the bill (Keller and Heckman 2013).

The Center for Progressive Reform (CPR 2013) issued a short report where they made a comparison of TSCA, S.696, and S. 1009 bills based on four criteria: testing, standard of review, deadlines, and preemption. They stated in their analysis that the S. 1009 bill would add more procedural requirements for the EPA to require basic testing on untested chemicals, which could cause further delays. The S. 1009 bill will rely on the EPA to set priorities, but is

an unnecessary step since Congress could consult with academics, federal and state officials, and stakeholder experts to develop a workable list of a few hundred chemicals of highest concern based on REACH restrictions and authorization lists, the Stockholm Convention list, Superfund law, other federal statutes, and high production volume chemicals. The S. 1009 bill's "unreasonable risk" standard would be the same as under the TSCA, "the burden of proof would remain on EPA and courts would still subject EPA's analysis to a high 'substantial evidence' review which is harder to the agency to meet than the 'arbitrary and capricious' standard" (CPR 2013 , 6).The S. 1009 bill does not include statutory deadlines for reviewing all chemicals, despite the fact that deadlines are the best way to ensure the EPA acts in a timely manner. S. 1009 would establish EPA safety determination as a regulatory "ceilings," and states have the opportunity to apply for waivers from preemption restrictions through juridical review. For TSCA reform, the Center for Progressive Reform mentions two key principles. The first principle is that industry should have the burden of proving that the risks meet the safety standard designed by EPA. The second is that the new TSCA should have a precautionary regulation, "better safe than sorry," whereby agencies focus on preventing harm rather than waiting for harm (CPR 2013).

Abelkop and Graham, from Indiana University, continued our first research (Abelkop et al. 2012) and made a detailed comparative analysis of Canadian, European Union, and United States policies on industrial chemicals in 2014 (Abelkop and Graham 2015). Their analysis is limited to existing substances, since chemical legislations usually treat new substances with greater scrutiny. They did not compare the different bipartisan TSCA reform bills, however they did make several recommendation for TSCA reform. The article's main topics are prioritization, screening in risk assessment, and the burdens of data generation and safety determination. They also offer several suggestions for TSCA reform based on European and Canadian experiences (Abelkop and Graham 2015). The first is that US decision makers should consider applying the Canadian approach to prioritization. In Canada high-priority chemicals are identified for risk assessment based on alternative models (read-across and QSAR approach). If the industry does not agree with this estimation result, they can respond by generating additional animal or alternative data. In this way, in contrast with the EU, the US could avoid the extra, and perhaps redundant, work of collecting data about low-priority chemicals[12]. The rate of error is likely to be relatively small if the screening model is conservative, as well as health and environmentally protective in their design, meaning that the exercises would be generally biased in favor of pushing borderline cases in

[12] The EU is required to collect minimal data about almost all chemicals due to precautionary measures

the high-priority category. REACH data collection also uses screening/modeling (read-across and QSAR) techniques, and not just animal test data (Abelkop and Graham 2015).

The second suggestion of Abelkop and Graham is that US decision makers should consider applying European-style chemical registration only to high-priority substances, placing the burden of generating data and proving the safety of specific uses, on the industry. "If manufacturers or downstream users must affirmatively show that the ways in which they use chemicals meet a legislated safety standard, then they have an added incentive to generate additional information beyond that provided by marketplace competition and duties of care under tort law. If the burdens of producing data and proving unacceptable risk rest with the government, then manufacturers and downstream users may be inclined to refrain from making scientific investments in data generation until they are compelled to do so" (Abelkop and Graham 2015, 54).This US registration of high-priority chemicals could be based on the EU principles of "one substance one registration" and "no data, no market." The US registration program could be similar to the EU's. While it is not necessary to be exactly the same, the presumption should be in favor of international harmonization. EPA could review the US industry's safety determination and require additional data if necessary. Risk assessment should be separated from risk management decisions (Abelkop and Graham 2014).

The current dissertation builds on the work of the scholars mentioned above, on the comparison of REACH and TSCA legislation and bipartisan TSCA reform bills, the TSCA reform hearings, the opinions of interviewees, other articles connected to the topic, and my REACH experience. There has been no previous, rigorous comparison of the bipartisan TSCA reform bills and REACH regulation, which is why this study is a unique intellectual contribution.

2. RESEARCH DESIGN

2.1. Research question and objectives

Many countries are, today, making plans to create or amend their chemical regulatory systems. Among chemical control policies, REACH is categorized as the "most ambitious" chemical legislation in the world (ECHA 2015 c). This is why it has an important role in international chemical risk regulations: other nations may find it attractive and want to adopt it entirely, or just selected elements of it. Not just different nations' government officials follow chemical legislation changes; environmental NGOs and the industry also do, in order to lobby policy makers to see their interests in new legislation.

The *practical purpose* of this study is to compare REACH and the US bipartisan TSCA reform bills -S. 1009, S.697, and H.R. 2576 - in order to determine similarities and differences, including some opportunities for harmonization. Practically, the dissertation offers insight to U.S. policy makers engaged in TSCA reform as well as other countries that are seeking to draw the best lessons from REACH and TSCA reforms. In this way, the dissertation contributes to global improvements in the safe use of industrial chemicals, by minimizing damages to public health and the environment. During the research I would like to understand the process of the movement of the different chemical legislations. The research problems addressed in this study seek to examine how social science theories predict differences in EU and US chemicals policies. Since this research will be conducted after the first and second REACH registration deadline (2010, 2013) and during the TSCA debate in the USA, it has the potential to make a contribution to chemical policy at a formative stage, and may influence the TSCA reform discussion, the design of TSCA reform as well as the implementation of TSCA reform.

As shown in the literature review no rigorous comparison of REACH and bipartisan TSCA reform bills, from a health and safety point of view is seen in the literature. Mainly environmental NGOs refer to REACH as a good example during the TSCA reform debate. TTIP negotiators deal with opportunities for harmonization, but in a very general way.

In order to address this research gap, the following research specific question has been developed. It is broken down to specific objectives to provide the operational focus for this research. The function of this research question is to explain specifically what the study will attempt to understand, and to help focus and guide the research.

In qualitative research usually they use three kinds of research questions (Maxwell 1996).*Descriptive* research questions ask about what actually happened in terms of observable

behavior or events. *Interpretive* research questions ask about the meaning of things for the people involved: their thoughts, feelings, and intentions. *Theoretical* research questions ask about why these things happened, how they can be explained. The main research question belongs in the descriptive category, but during interviews and evaluation many interpretive and theoretical questions were asked and explored.

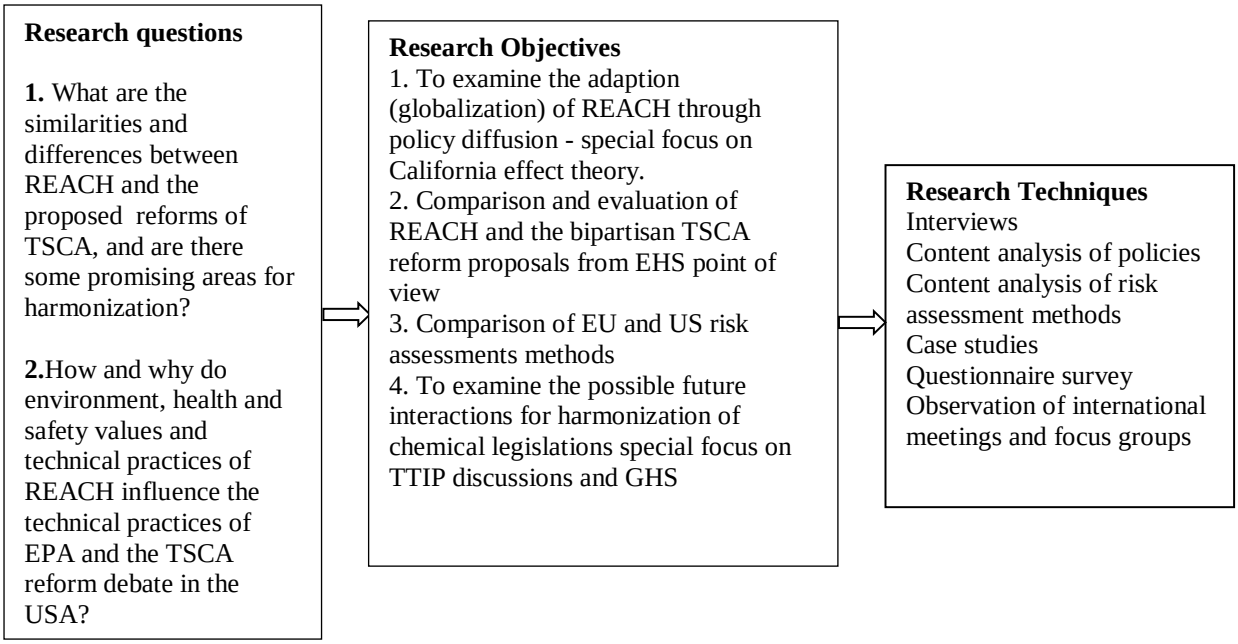


Fig. 1. Research questions, objectives and techniques

Overall, this research aims to explore the impact of REACH, as the most ambitious chemical legislation in the world, on debate about TSCA reform in the US. Hence, the research question is as follows: What are the similarities and differences between REACH and the proposed reforms of TSCA, and are there some promising areas for harmonization? Through the comparison of REACH and TSCA reform bills, I wanted to discover the answers to the following research question: How and why do environment, health and safety (EHS) values and technical practices of REACH influence the technical practices of EPA and the TSCA reform debate in the USA?

EHS values of REACH: strong precautionary principle (A chemical is presumed to be unsafe until it is proven safe.), polluter pays principle, responsibility of producer principle, right to know principle, substitution principle, one substance one registration principle, no data no market principle, minimum safety related dataset implementation, identification of substances of very high concern, hazard and risk based system.

Technical aspects refer to the following: Hazard assessment (minimum dataset, DNEL, PNEC), Exposure assessment (exposure, PEC), Risk assessment (RCR), safety data sheets and exposure scenarios, GHS classification and labeling, IUCLID and REACH-IT softwares.

To answer the research questions and to analyze this policy reform, policy diffusion, globalization, and the California effect theories will be used. The similarities and the differences between REACH and TSCA will be addressed and how the different stakeholders see the adoption of REACH's values into the revised TSCA reform bill. Secondly, the S.1009, S.697 and H.R. 2576 bipartisan TSCA proposals will be analyzed from the point of view of environmental health and safety. The comparison is structured around several key issues which have been important to public debate in the US: data development, priorities for safety assessments, safety standards, restrictions, and preemption. I do not address in detail some important issues that are worthy of future study such as confidential business information, judicial review, endocrine-disrupting chemicals and persistent, bioaccumulative and toxic chemicals.

The different argumentative interpretations of the different stakeholders will also be highlighted, including those of environmental NGOs, industry, and authorities. In the case of REACH adoption, environmental NGOs and the industry have totally different opinions which are not unsurprising, given the organizations they represent. Two controversial views, expressed at EU and US conferences, will be discussed, and later more similar views will also be apparent.

Anna-Sofie Andersson, Director of ChemSec, an environmental non-profit organization which has the vision of a world free of hazardous chemicals, said the following statement on Helsinki Chemical Forum in 2014 May**:** "REACH is the only system that can be used as a model for chemicals management!" Her justification was the following: REACH is based on core principles, identifies properties for substances of very high concern, is a hazard and risk based system which uses available information from ECHA (hazard and exposure data and identified SVCHs), and REACH's candidate list drives innovation (ChemSec 2014).

Cal Dooley, President & CEO of the American Chemistry Council, had a different opinion on REACH. In his speech at the GlobalChem conference in 2014 he declared that REACH should not be used as a model for chemical management, and that it is an unfortunate trend that some Asian countries base new chemical regulation on Europe's REACH model.

The USA needs to demonstrate that a risk- and science-based approach to chemical management is a better alternative to REACH. He did not dispute that the USA has an important opportunity to apply the lessons learned from REACH, and other programs, in order to ensure that the United States' new chemical regulatory program would become the most modern, effective, and sound chemical regulatory approach in the world. The USA would like to create, through TSCA reform, a gold standard in effective chemical management systems that would be a model for the rest of the world (AAC 2014).

The risk assessments describe under which manufacturing and use of a substance is considered to be safe. Whether there are any measurable or significant differences, from a health and safety point of view, in a risk assessment prepared by the industry (EU) or the authority (USA) will also be analyzed. The technical comparison of risk assessments shows the similarities and differences between EU and US risk assessments' practices and examines the areas for modifications of technical practices and not just policy frameworks.

The possible future interactions for harmonization of chemical legislations will also be examined, which will particularly focus on TTIP discussions. A detailed analysis of possible cooperation in the classification and labeling of industrial chemicals (GHS) will be prepared since this is the most promising area for cooperation and for a full harmonization between the EU and US.

Finally, what other nations in the process of revising their own chemical policies can learn from TSCA reform debates or from REACH, in order to improve their chemical legislations will be discussed.

This dissertation is intellectually multi-faceted. It is partly predictive, especially with respect to how TSCA reforms and REACH should be expected to differ based on different theories, partly descriptive when describing similarities and differences of chemical policies, partly prescriptive with regard to possibilities for harmonization, and partly technical when comparing how risk assessments are performed under REACH and TSCA.

Through the following techniques the mechanism of the EU's chemical policy diffusion in the USA is explored: interviews, focus group discussions, questionnaire surveys, document reviews, and case studies. I will discuss research techniques in more detail later. A better understanding of US experts' view about REACH and TSCA reform has been gained through trips to the US and interviews with both US and EU stakeholders and government officials, making it easier to draw a comparison of REACH and bipartisan TSCA reform bills.

2.2.Theoretical framework: Globalisation of REACH?

2.2.1. Policy diffusion and policy convergence

Among chemical control policies[13], REACH is categorized as the "most ambitious" chemical legislation in the world. For this reason it has an important role in international risk regulations and is why it can be a "soft power" of the EU (Yoshiko 2010), as other nations may find it attractive and want to adopt it either fully or partially.

In this dissertation, the issue of *interaction* between US and EU chemical control policies is addressed. There are many modes of regulatory interactions: regional trade agreements, harmonization, mutual recognition, and globalization of regulation (Yoshiko 2010).[15] The European Commission promotes the *globalization* of REACH approach to chemical safety beyond EU borders. A good example for this promotion is the annually organized Helsinki Chemicals Forum, where journalists and chemical management experts from NGOs, academics, authorities, and industries are invited from all over the world to learn about REACH, and discuss key issues of global relevance regarding chemical management and the control of chemical safety (HCF 2014). REACH can be a model for non-EU countries in reforming their chemical management policies. Countries such as Switzerland, Japan, Canada, South-Korea, Taiwan, New Zealand, and China have apparently expressed a keen interest in learning from REACH (Abelkop *et al.* 2012).

As Yoshiko (2010) argues, there are 4 main factors for the globalization of REACH. The first one is the market force or export interests, which means non-EU countries have an interest in exporting to the EU. Non-EU producers can meet stricter export standards, so they can pressure their home governments to have their domestic regulations fall in line with the stricter EU regulations. EU shares of US chemicals export was 25% in 2012, so the EU is a very significant market for USA (US Census 2012). SOCMA, an industry association, in their testimony in March 2014 recommended for consideration "to authorize EPA to consider

[13] The term 'policy' is used differently by researchers. In the dissertation the Wenting and Boons definition will be used: "when the aim is to compare the instruments adopted by public officials regarding certain subject in different countries, policy is defined as an object that delineates a specific problem and provides a solution to that problem" (Wenting and Boons 2014, 18,). Policy transfer theory studies the process "by which knowledge of policies, administrative arrangement, institutions and ideas in one political system is used in the development of policies, administrative arrangements, institutions and ideas in another political system." (Wenting and Boons 2014,19)

robust summaries of test data prepared under REACH, since this would be an efficient way to leverage available data without having to confront complex concerns arising under research contracts and data ownership agreements" (SOCMA 2014, 4).

The second factor that explains globalization of REACH is the institutional similarity between the EU and non-EU countries. Norway, Liechtenstein, and Iceland, all who implemented REACH similarly as any EU member states, are good examples of this second factor even though they are not among the EU 28, but rather are closely associated with EU through its membership in the European Economic Area in context of being a European Free Trade Association member. The US political culture and institutions are quite different from the EU, which is why the USA would not be expected to implement REACH like any EU member states.

The third factor that can affect the globalization of REACH is solving similar problems at the domestic and international levels. Lessons learned from EU regulations that could be applied in a non-EU country, international agreements, or institutions re-engaged in similar problem-solving actions (OECD, SAICM)) could support REACH globalization. The US tries to learn from REACH while they criticize it at the same time.

The fourth factor is the role of non-governmental actors (e.g. CIEL, ChemSec) and international organizations who pressure consumers to demand similar standards like in the EU, in order to reduce the use of toxic chemicals for products sold in their domestic markets. We can see the environmental NGOs lobby in the TSCA reform as well.

A key concept that underpins this research is the *diffusion* proposed by Rogers (1995,1): "diffusion is the process in which an innovation is communicated through certain channels over time among members of a social system," and the *policy diffusion* proposed by Elkins and Simmons (2005, 39): "the actions and choices of one country affecting another, but not through any collaboration." Another concept which underpins this research is *policy convergence*, the possible effects and the outcome of a cross-national policy diffusion which mainly deals with the following questions (Heinze 2008): to what extent have policies in different states become more similar over time, and what factors account for these developments? What are the underlying mechanisms causing diffusion and convergence effects and what are the factors accounting for the differential impact of these mechanisms?

The globalization of REACH and the impact of REACH on TSCA reform can be studied through the concept of *policy diffusion* (the process) *or policy convergence* (the outcome of the process). Policy diffusion scholarship discusses the mechanisms of the spread of policy. "The concept of 'policy diffusion' is defined as 'the actions and choices of one

country affecting another, but not through any collaboration.' More precisely, under the concept of diffusion, governments are independent in the sense that they make their own decisions without cooperation or coercion but interdependent in the sense that they factor in the choices of other governments" (Yoshiko 2010, 176).

It is important to understand why policy convergence does not always occur. Basically, one can distinguish three groups of factors influencing the functioning of the identified diffusion mechanisms: international and transnational, country-specific, and policy-specific factors (Knill and Lenschow 2005).[23] "The more dissimilar the cultural, institutional, and socioeconomic characteristics of countries the less diffusion between these countries can be expected." (Heinze 2008).

According to Shipan and Volden (2008), policy diffusion is the spread of innovations from one government to another. They distinguished four mechanisms of policy diffusion: learning from earlier adopters, economic competition, imitation, and coercion.

With reference to the first mechanism, policy makers can learn from the experiences of other governments. This makes the task of the decision makers simpler, since they have chosen an alternative that has proven successful elsewhere. Policy makers cannot learn about policies that have not yet been tried. The learning hypothesis states that the likelihood of a government adopting a policy increases when the same policy is adopted broadly by other governments (Shipan and Volden 2008). "There is also an accumulation effect: if more countries have previously undergone processes of rationally learning, it is easier for additional countries to see the attractiveness of the reform more quickly, and implementation is likely to be easier domestically" (Baturo and Gray 2009, 140).

Learning is considered a horizontal mechanism of diffusion, and can be rational or bounded (Meseguer 2005). Both in rational and bounded learning, the politicians want to understand and find a solution for a particular problem. Rational learning is a diffusion mechanism where policy makers observe all available information in the world, regardless of its origin, evaluate its relevance, and adopt it if deemed appropriate (Baturo and Gray 2009). However, if the conclusion of learning has both positive and negative outcomes and prior beliefs are strong, then the learned and evaluated experiences carry less weight in the formation of posterior beliefs. If the conclusion of learning has only a positive outcome, regardless of prior beliefs, policy makers will converge on their posterior beliefs which are dominated by learned and evaluated experiences (Meseguer 2005.) At rational learning analytical skills are the most important.

In contrast with rational learning at bounded learning, policy makers, rather than evaluating all information, just look at those ones which are relevant or which are easily accessible (Meseguer 2005). Politicians do not attach weight to all information: "governments may imitate what peer countries do simply because they are peers, or governments may imitate what apparently successful countries do simply because they are high-status countries that are considered to know best" (Meseguer 2005, 73). With bounded learning it is also possible that politicians share the same biases: beliefs or ideas that prevail over observed and evaluated experience of learning. In bounded learning, analytical skills are not so important and are subject to biases.

The second mechanism of policy diffusion is economic competition (emulation), where the hypothesis is that the likelihood of adopting a policy decreases when there are negative economic spillovers from that adoption and the likelihood of adopting a policy increases when there are positive spillovers(Shipan and Volden 2008). Emulation is driven by motivations other than problem solving. "Because governments emulate following certain trends, emulation becomes a symbolic act whereby politicians seek to enhance their status, credibility, or 'modernity'" (Meseguer 2005, 76). Emulation is a 'blind' action compare to learning, however "emulation has driven the adoption of a wide range of economic and social policy reforms" (Meseguer 2005, 79).

The third diffusion mechanism is imitation, where the crucial question is: what did the first government do and how can the other government appear to be the same? With imitation it is not important to learn about consequences, just simply aspire to be like the other government. The imitation hypothesis is that the likelihood of a government adopting a policy increases when its nearest bigger neighbor adopts the same policy (Shipan and Volden 2008). However politicians also seek a reputation for innovation, which works in favor of divergences rather than convergence. A politician is not seen as innovative if they simply copy the policy innovation of a neighboring jurisdiction. U.S. environmental NGOs's incentive is to be different than REACH or go beyond REACH in order to demonstrate their innovativeness. This is a possible barrier to convergence as well. Multinational corporations are involved in both REACH and TSCA reform, but there are many smaller chemical producers and users in the US who have no experience with REACH and are likely to be skeptical of European regulatory schemes.

The forth mechanism is coercion, when countries or international institutions (like the United Nations) can coerce a country through trade practices and economic sanctions to take actions that meet common expectations. However many times countries sidestepping the

international agreements. The coercion hypothesis is that the likelihood of a state adopting a policy decreases when the federal government adopts a similar policy that covers the state. Preemption belongs to the coercive diffusion mechanism (Shipan and Volden 2008).

If policymakers are interested in knowing the political and policy consequences of the adoption then it may take a longer time, even years, to evaluate the effectiveness of a policy (Shipan and Volden 2008). Learning and economic competition are likely to exhibit longer-term effects than imitation or coercion. Larger and economically powerful countries are more capable of learning from others. US policymakers, through TSCA hearings and studying other nations' chemical policies, have chosen this careful and slow learning adoption.

In the Advocacy Coalition Framework prepared by Sabatier (2011), there are two hypotheses concerning policy change: First, the key components of a governmental policy program will be considerably altered or revised during the timeframe the subsystem advocacy coalition that created the program remains in power, unless change is mandated by a higher power (Sabatier 2011, 106). Secondly, the key components of a governmental policy program will be altered if changes happen for example in socio-economic conditions, public opinion and system-wide governing coalitions (Ibid, 106). Interest group leaders and legislators frequently engaged in attempting to direct public policy. Furthermore, agency officials, researchers, journalists, consultants, and scientists are not always impartial and are often associated with advocacy coalitions (Sabatier 2011).

Diffusion mechanisms can only rarely be observed and measured directly. This requires finding adequate indicators. The question is: under which conditions can different types of diffusion be expected? These conditions should be based on international, national, and policy-specific factors that might set off and influence the functioning of the different social mechanisms (Heinze 2008). Some example for international level are: number/proportion of adopters, action of reference countries, development of international norms, specification and number of competing international norms, degree and institutionalization of international networking, economic interlinkages and integration, economic and trade relevance of policy sector, situation of uncertainty and crisis, negative incentives of international organizations, and positive incentives of international organizations. In my thesis I will show some of these factors through concrete examples in the next chapter.

There is further theory which deals with the question of why non-EU countries would adopt REACH. Heyvaert (2010) discuss the desire of countries to improve their health and environmental domestic legislations. The EU is actively spreading the knowledge of REACH

around the globe. Large chemical industries located outside the EU may put pressure on their government to lift local standards to EU level. Vogel's race to the top or *California effect* means that it can be in the strategic interest of governments in order to encourage them to adopt similar higher standards. For a 'race to the top' to occur, first, the country upholding the more stringent standards must be able to close its borders to products that do not meet its regulatory prescriptions (Jonathan 2000).[17] In 1976 TSCA was one of the strictest standard in the world,[14] so it influenced the EU chemical policy. Now it is the opposite: EU chemical policy is the stricter standard, so it influences TSCA reform (Yoshiko 2010). "The country with the toughest regulation must constitute a desirable export market. In the case of REACH, both conditions are fulfilled: the EU is a highly desirable export market for chemicals, and REACH provisions apply both to domestically manufactured and imported goods" (Heyvaert 2010, 230). It is in the interest of non-EU exporters to lobby for the adoption of identical, or at least compatible, standards domestically. Specifically, non-EU exporters wish to avoid different internal and external regulatory standards. This aversion can result in pronounced inefficiencies in industrial production and management. Furthermore, non-EU exporting companies want to preserve market leverage over their global counterparts within their domestic market, in addition to other export markets outside the EU, as a consequence of their more relaxed regulatory standards (Heyvaert 2010). The indirect economic advantage are opportunities for exchanges of expertise and technology and helping countries secure international funding for chemical safety capacity building projects (Ibid).

Currently the US industry does not lobby for the implementation of a REACH-like legislation in the US, since they do not want any additional testing costs and risk management costs. This would raise the cost of producing chemicals and puts US plants at an economic disadvantage, which is why Heyvaert's theory does not fit in this case. U.S. industry is advocating for a Canadian-style system, that, if enacted, could serve as a unified North American alternative to REACH (Abelkop and Graham 2015). However US states (e.g. California) lobby for adoption of their stricter standards in the TSCA reform, so in that case Heyavert's theory works, but the U.S. industry may see TSCA reform as a weapon to use against state stricter regulatory programs.

According to Princen (1999), there are at least three ways of exporting strict standards: requiring producers to conform to certain standards, requiring other countries to conform to certain standards, and having national standards harmonized in an international organization.

[14] Japan issued a Chemical Substance Control Law in 1973 earlier than TSCA (Abelkop et al. 2013)

In each of these three cases the result can be a success or failure. When it comes to the success and failure of exporting strict standards, *legal*, *economic*, and *political* factors are the most important (Princen 1999). Out of these three factors, economic size and economic power are the most salient. For the legal factor, Princen mentions how a country regulates its trade rules. For economic factors, he outlined that a big and wealthy country that has an attractive market has more opportunities to impose its strict standard (EU shares of US chemicals export is 25 % in 2012 according to US Census). However the market size of a country with less strict standards is also important. An economically more powerful country (like the USA) can use its market power to withstand the pressure or to adopt a greener standard. Finally, the political factors refer to the strength of pressure groups of the country that has to accept the stricter standard. This is important, since countries are more likely to introduce stricter standards if they have strong public interest groups (e.g. environmental groups or trade unions) that lobby for a strict standard. This was discussed in the introduction as "orphan status" of TSCA pulled back the TSCA reform for years. Vogel (1995, 55) mentions that the "removal of nontariff barriers and the strengthening of health and safety regulations requires a strong international authority." His thesis is that the stronger the international authority, the more likely a California effect is to take place. Genschel and Plümper (1997) argue that strict standards are more likely to spread if the benefits relative to the costs of adopting them increase (Vogel and Kagan 2004). This question, whether TSCA reform bills will be less strict than REACH, will further be explored in this thesis.

Adoption of REACH in non-EU countries could happen in two ways: full assimilation, or approximation of rules (Heyvaert, 2010). Good examples for the first model for full assimilation are Norway, Lichtenstein, and Iceland, who are EEA members. These countries implemented REACH regulation similarly to EU-countries, and accepted the normative and procedural content of REACH. In these three countries ECHA will administer their registration files, perform completeness checks, receive registration fees, and assign registration numbers. "For countries outside of EEA, full assimilation to REACH is not a plausible scenario. They are much more likely to approximate the REACH format in domestic legislation" (Heyvaert 2010, 231), and they would most likely export the registration part of REACH. Non-EU countries will more likely copy the basic REACH principles rather than the entire REACH framework (Fisher 2008). "A domestically differentiated version of REACH may perform as well as, or even better than, the EU example as a health and environmental protection instrument, but could forfeit the trade liberalization and competitiveness benefits that the globalization of norms seek to attain" (Heyvaert 2010, 235).

The REACH regulation is about 250 pages, and contains XVII. annexes and about 2000 pages of guidance documents to help interpret REACH. It can be concluded that REACH is difficult, tedious, frustrating, and labor intensive for both industry and governmental authorities, which makes it harder for the cross-national diffusion of this legislative innovation. Halffman and Bal (2009) discuss the growing complexity of regulatory regimes: First, the complexity of regulation can create a situation where only companies capable of maintaining a large staff of regulatory specialists can participate. "For these reasons, the largest players in a market with complex regulation may even support increasing regulation, as it allows them to take control. (Halffman and Bal 2009, 10)." Smaller firms and regulatory agencies are concerned about the ability to complete. Growing complexity also implies a threat of growing regulatory cost. Complexity in chemical regulation is also likely to increase, because the experts continue to research new pathways, continue to develop new tests, or further refine exposure models. (Halffman and Bal 2009).

Complex regimes like REACH favor big companies over small ones. The US has a much larger and more vibrant small business sector than EU does, and the small business sector is well organized for political action in the US through groups such as the National Federation of Independent Businesses. There is no plausible reason for most small businesses that make or use chemicals to favor a REACH-like system, since small companies lack the resources to operate under a REACH-like system. Indeed, it is reported that large companies under REACH have exploited smaller companies during the registration process.

My experience as a chemical legislation consultant is that the complexity of REACH was somewhat eased by the detailed, clear and logical guidelines and great IT tools issued by ECHA.

This research starts from the assumption that it is extremely unlikely that the REACH program would be adopted wholly in the United States, as the process of *policy diffusion* tends to operate in a partial and idiosyncratic manner. "Scholars of the transformative perspective on policy insist that policies tend to mutate when they move from one country to the next. Those mutations, which are called refinements, modifications, or reforms, may result from a variety of contextual factors, such as different traditions of political institutions, unique socio-economic factors in a particular country or region, distinct preferences of key legislative actors, and different distributions of power between different branches of government and the private and public sectors"(Abelkop et al. 2012, 10). We should not expect to find diffusion and convergence in every detail, rather on a system level.

Now that the theories relating to the current topic have been reviewed, the following section will deal with the research techniques.

2.3. Interviews, focus group discussions, surveys, case studies

Research design is described as the main element of the research strategy that identifies who, what, where, and how the topic will be analyzed (Denzin and Lincoln 1998).In accordance with the above, the simple questions of what, who, where, and how were applied to the needs of research that focuses on chemical management policies in US and EU (Kulauzov 2007).Research design includes research strategies, data collection techniques, data analysis strategies, time schedule, and site and sample(Marshall and Rossman1989).

The overall nature of the dissertation is on the border of descriptive and explanatory studies, but more so descriptive of the similarities and differences between REACH and possible TSCA reforms. The comparison is structured in analytic dimensions that correspond to the several main issues that are a focus in the TSCA reform debate. For each issue, the different argumentative interpretations of different stakeholders are shown: environmental NGOs, industry, and governmental authorities. The dissertation is multifaceted because it is partly predictive, since predictions are made for how TSCA reforms and REACH should be expected to differ based on different theories; partly descriptive, since similarities and differences of chemical policies are described; partly prescriptive with regard to possibilities for harmonization; and partly technical, since comparisons are made concerning how risk assessments are performed under REACH and TSCA.

In this section, the most important methods are described and defended. They include: content analysis of policy documents from primary sources (e.g. legal texts and official guidance documents), content analysis of chemical dossiers (e.g. the chemical-specific registration dossiers submitted by industry to ECHA under REACH), and personal interviews, structured and informal, with key individuals who have access to in-depth information about REACH and TSCA.

Content analysis of policy documents from primary and secondary sources was the starting point, to acquire an overview of the policy situation and to understand the degree of policy convergence and divergence between the two bodies of legislation. Primary sources are the EU REACH regulation, ECHA guidance documents under REACH, the TSCA, the TSCA reform proposals and official testimony related to the proposals, and various EPA technical and policy documents related to TSCA implementation. Secondary sources are seen in the detailed literature review of both policies, especially focusing on the comparison literature. As part of the content analysis, safety information about the same chemical (trichloroethylene) was checked in EU registration dossiers and in EPA data collections. Also, the risk

assessment process and the GHS implementation process of the EU and US were examined. During content analysis, the following four points are the focus: design and procedural structure of the policy, the origins and drivers of the policy, issues and concerns with the policy among stakeholders and academics, and possible effects of the policy.

With regard to the personal interviews of experts, both structured interviews guided by a questionnaire and informal unstructured interviews were conducted to gather information. My participation in several international chemical management conferences provided me an opportunity to learn more about EU and non-EU chemical management policies, and to meet EU and non-EU chemical legislation experts. During the conference, with the help of the snowball technique, key EU and non-EU experts were found for personal interviews (structured and unstructured). The snowball technique relies on the fact that the experts in the area can suggest further experts, therefore due to the chain reaction a good overview of the whole field is achieved (Miles and Huberman 1994).

Based on the results of content analysis of policy documents, a questionnaire was prepared for a structured interview with key individuals who have access to in-depth information. Cresswell (1994) summarized the strengths and weaknesses of *structured interviews*, which involve direct personal contact with an informant who is asked to answer pre-established questions relating to the research problem. The strengths are the following: the researcher can obtain large amounts of expansive and contextual data quickly, it allows for immediate follow-up questions and clarification, it is useful for discovering complex interconnections in social relationships, and it facilitates quantifiable analysis and validity checks. Weaknesses include the following: it requires personal interaction and cooperation, the questions and answers may be misunderstood, interviewees may not always be truthful, interviewer bias can occur, and one cannot capture nuances of social reality. A face-to-face interview can last longer, but the researcher needs to take into consideration tiredness or impatience on the part of the respondent, which can affect the quality of answers. In some cases, the respondent was more comfortable with an informal, unstructured interview, particularly when met during a break or at lunch at a conference. Most of the personal interviews were structured, but some were more informal.

After collecting the necessary data, a significant part of the research was to analyze the data and translate it into useful, applicable information. After analyzing the data, a clear picture of the EU and US systems emerged. The Miles and Huberman(1994) interactive structure for data analysis was used: data reduction (editing, segmenting, summarizing data, coding and memoing, finding themes, clusters and patterns, conceptualizing and explaining),

data display (organizing, compressing and assembling information), and drawing and verifying conclusions. I found it most useful to categorize the data into broad themes and issues related to my research question and compare responses within those themes and issues.

While preparing interview questions, how particular interview questions will actually work in practice were anticipated: how people will understand them and how they are likely to respond (Maxwell 1996).

When undertaking qualitative research involving interviews with experts, it is hard to define and obtain an unbiased sampling frame. Consequently, a purposeful sampling, or so-called criteria-based selection, is often used. This is a strategy in which particular settings, persons, or events are selected deliberately in order to provide important information that cannot be as easily obtained with standard survey techniques. In qualitative interview studies, samples are not used at all, but rather people who are expert in an area (Maxwell 1996).

To learn about the TSCA reform debates, 15 stakeholders and government officials were interviewed in the US who were familiar with one or more parts of the TSCA program in 2014 (see their names and organizational affiliations in Annex I.). In the regulated community, interviewees included industry representatives, law firms, and consultants who advised the regulated industry. Key officials in EPA were also interviewed, as well as selected NGOs and academics linked to NGOs who are tracking TSCA reform. In 2011, 20 EU stakeholders and government officials were interviewed with a US team in the frame of another research project. Those interviews helped enrich my professional knowledge base as a technical REACH consultant.

My approach to interviews was to encourage candor by ensuring each interviewee that we would not assign specific viewpoints to specific individuals. All interviewees and their organizational affiliation have been documented for inspection by readers. In addition to these more structured interviews, which occurred by phone or in person, I attended the 2014 GlobalChem Conference and TSCA workshop in Baltimore, Maryland (USA). At those meetings, I heard formal presentations and panel discussions on a wide range of TSCA reform issues, and I networked informally and individually with many of the more than 300 participants in the three days of the meetings. Before each structured interview began, I introduced myself, the purpose of my research, and disclosed my affiliations with CEU and IU. I also explained the ground rules about how their responses would be used in my investigation.

The questionnaire (see it in Annex II.) contained factual questions about the respondent, such as their educational background, title, and organizational affiliation,

including a probe about how much experience the person had on chemical legislations. The questionnaire contained both closed-ended questions and open-ended questions. Open-ended questions were primarily used to allow respondents to express their beliefs in their own words. Likert-type questions were also used. "A Likert item is simply a statement which the respondent is asked to evaluate according to any kind of subjective or objective criteria; generally the level of agreement or disagreement is measured" (Tandon *et al*. 2009, 238).

To check the validity of the gathered information and conclusions, Singleton and Straits' (1999) suggestion was utilized, which was to look at the data from different perspectives and triangulate it. That was accomplished by using different sources of data collection such as public documents, literature review, and interviews. Specifically, the information provided by the interviewees was checked against other types of data, and any inconsistencies were explored and clarified (Miladinova 2008). "The main threat to valid description is the inaccuracy or incompleteness of the data (Maxwell 1996, 89)." If the descriptions of the interviews conducted are invalid, then any interpretations or conclusions drawn from these descriptions are questionable (ibid). Audio recording of structured interviews was undertaken to enhance the completeness and accuracy of the data collection. As I am not a native English speaker and my degree of fluency with the English language is imperfect, the interviews were transcribed by an American environmental student at IU. Transcript Divas, an official transcribing company, was hired to type a TSCA history video for the same reason.

A main threat to valid interpretation is imposing one's own meaning, rather than understanding the perspective of the people studied. There are several ways this can happen: not listening for the participants' meaning, misconstruing a participant's response, or not giving participants ample opportunity to express their viewpoints. Such interviews of experts are different from interviews of laypeople, in part because the expert may provide more complex and nuanced answers to structured questions. Experts may also be more comfortable with open-ended questions than closed-ended questions, since some have a distaste for opinion polls.

The first two interviews were conducted in collaboration with IU Professor John D. Graham, my US consultant, who has several decades of experience conducting expert elicitations on a wide range of topics. After each interview, he critiqued my performance and made suggestions as to how the interview might have been improved. Before these interviews I tried to understand US environmental law concepts, and only after I had some basic knowledge of TSCA and US environmental legislations did I start conducting

interviews alone. As I have more than 17 years of experience with chemical legislations, I am confident that I was able to understand and properly interpret what the interviewees were saying.

One important threat to the validity of qualitative conclusions is the tendency of the researcher to interpret the data in a way that fits the researcher's theory or point of view. It was difficult for me to not be biased as I am European, an expert on aspects of REACH regulation, and I think REACH is a logical and workable regulatory system. Indeed, as a citizen I prefer strict environmental legislation such as that embodied in REACH. It was therefore somewhat difficult for me to stay objective, to listen and understand the American way of thinking toward regulation, which is often skeptical of government, skeptical of the value of strict business regulation, and skeptical of European regulatory concepts. After each of the first two interviews, Professor Graham and I debriefed with each other for over an hour, reflecting on what we had heard and I asked a variety of clarification questions about what was said.

A diverse range of individuals was interviewed in order to understand various aspects of TSCA reform and various perspectives: NGOs, academics affiliated with NGOs, practitioners from the industry, lawyers, consultants, scientists, and authority staff. No one from the US Congress could be interviewed but that is not surprising since the TSCA reform issues were being actively negotiated at the time of my interviews. Nor was I able to interview European experts who negotiate with Americans about TTIP, to understand what kind of issues and difficulties they see during these negotiations.

On the other hand, the number of interviews that I conducted was, if anything, somewhat larger than is typical of expert elicitations in the environmental field (Graham 2015). When combined with my participation in several conferences and informal personal interviews, I am confident that I have an excellent grasp of the similarities and differences between REACH and the possible TSCA reforms.

2.4. Analysis of the interviews with U.S. chemical legislation experts

The following subchapter analyzes data collected through interviews and translates the data into useful applicable information. Based on the results of content analysis of policy documents, a questionnaire (See Annex II.) was prepared for a structured interview of key individuals who have access to in-depth information on TSCA reform. The interviews lasted roughly 1 hour per person, conducted through telephone, Skype or in person in 2014 in the USA.

To explore and analyze the TSCA reform debates, 15 stakeholders and government officials from the US were interviewed who had familiarity with one or more parts of the TSCA program in 2014 (see their names and organizational affiliations in Annex I.). In the regulated community, interviewees included 3 industry representatives, 2 members of law firms, and 1 consultant who advised the regulated industry. 3 key officials from the EPA were also interviewed, as well as 1 selected environmental NGO and 5 academics linked to NGOs involved in tracking TSCA reform.

My approach to the interview process focused on encouraging candor and openness by ensuring each interviewee of privacy and discretion by not assigning specific viewpoints to particular individuals. Before each structured interview began, I introduced myself, the purpose of my research, and disclosed my affiliations with Central European University and Indiana University. I also explained the ground rules concerning how responses would be used in the study.

The questionnaire (see Annex II.) contained factual questions about the respondent, such as their educational background, title, and organizational affiliation, including a probe about how much experience the person had in the field of chemical legislations. The questionnaire contained both closed-ended and open-ended questions. Open-ended questions were primarily utilized to allow respondents to express their beliefs using their own words. Likert-type questions were also employed to generally evaluate the level of agreement or disagreement of a given statement. However, virtually all interviewees were more comfortable with open-ended questions, and explained why they agreed or disagreed with the given Likert-type statements.

The first open-ended question was the following: *In general terms, what would you say has been an impact of REACH – the legislation itself and the implementation process – on the TSCA reform debate in the United States?* It was concluded from these answers that American stakeholders have widely criticized TSCA on multiple occasions since 1976.

However, there has not been enough momentum, reason, or common agreement to make substantial reforms. Once REACH established itself as the most ambitious standard globally, and started to influence other nations' chemical policy, Americans began to analyze it. Responses included both positive and negative aspects, since "some US people see REACH as a positive model, but others see REACH as a negative model. As a result, REACH raised issues to be debated". "REACH helps guide the TSCA reform discussion. REACH's implementation is causing American people to think carefully about how to move forward in TSCA reform so we can say that "one of the main drivers was REACH, which TSCA reform is again on the table in the USA". "One of the big impacts of REACH is to know that it is possible to demand tests from industry," so it is possible to implement the 'polluter pays principle' when the manufacturer and end-user of chemicals are generating sufficient data. Due to REACH shifting burdens on the EU industry, the U.S. industry is more willing to entertain the idea of revising TSCA.

However, reactions to REACH in the US were not primarily positive. One example of a negative view is the following: "There is reluctance among certain members of industry and certain members of Congress to adopt anything that resembles EU policies. So some pragmatic ideas that are in REACH, like put the burden on industry to collect data and prove the safety of the chemicals, are perceived as European. There is a reversion (resistance) in Congress to these ideas, precisely because they are European; some in Congress want to do reform an American way".

Research also revealed that there is a strong desire not to replicate REACH in the USA. This opinion is a very important political obstacle to policy convergence. It is also a good example of bounded learning (a diffusion mechanism) that was mentioned earlier in the dissertation. With bounded learning, it is possible that politicians share the same biases, in this case that the European way is not as good as the American way. Also, this discussion showed that the Canadian chemical legislation design looks closer to the U.S. bill than to REACH, and that Americans think that REACH is too complex, and would like to avoid complexity within TSCA reform.

Do you see any part of REACH that should be followed in TSCA reform? From this question I wanted to know which REACH values had a chance to be followed in TSCA reform. More interviewees mentioned that the radical EU solution to put the burden of data generation, risk assessment, and management on the industry would be advisable to follow in TSCA. Some interviewees expressed positive views in that REACH compels manufacturers

and importers of substances to supply regulators with a minimum safety-related dataset for existing and new chemical substances. The 'one substance one registration' principle of the EU was also mentioned along with beneficial IT tools that helped to meet clear deadlines. Data generated by REACH, which is available to the public on ECHA's website, could be used in TSCA reform. The candidate and authorization list is stimulating EU industries to substitute SVHCs with safer alternatives. A candidate list would be useful for TSCA reform as well, since chemicals on the candidate list create a strong signal for stakeholders to remove these substances. However after reading the proposed reforms of TSCA, I can conclude that none of these mentioned elements of REACH were adopted in any of the bipartisan TSCA reform bills in the USA.

Do you see any part of REACH that should not be followed in TSCA reform? From this question, I surmised that prioritizing chemicals based on volume should not be followed in TSCA, according to the view of some of my interviewees. REACH applies to chemicals that are manufactured or imported over 1 t/y. However, it is possible that a chemical manufactured below 1 t/y can be even more risky and dangerous to human health and/or the environment than chemicals manufactured more than 1 t/y. Therefore, it would be important not to limit TSCA based on tonnage requirement. In REACH regulation, companies have to fulfill registration, notification and/or communication requirements related to substances in articles. However, this requirement should not be followed in TSCA reform since downstream users do not collaborate with each other to provide information about substances contained within articles. One particular interviewee did not support the EU radical solution to place the burden of data generation, risk assessment, and management on the industry, as the industry is not as objective as the authority. Therefore, the industry should not be the evaluator of safety determination. Another interviewee did not support the fact that REACH has a strong emphasis on animal testing. Interestingly, this part of REACH is set to be amended. The European Commission has issued changes to the REACH testing requirements for consultation in order to introduce the possibility of waiving in vivo tests, if sufficient information can be generated by alternative methods (CW 2015 e).

According to your opinion what is the weakest point of REACH legislation? This question is not as important to the overarching research as it is not the aim of this dissertation to suggesting REACH modification. However, from this question, I could comprehend that REACH's image in the Use's very complicated, overly burdensome, expensive, and the quality of dossiers are not sufficient, resulting in a negative effect on innovation. Seeing these

thoughts (prejudices) I could better understand why there is a strong desire to not replicate REACH in the US.

According to your opinion what is the weakest point of current TSCA legislation? This question was very important from my research point of view, since it assisted me in understanding what the primary priority is in TSCA reform by a set of key chemical legislation specialists. Since the chemical industry, the authority, and environmental advocacy groups have expressed interest in modernization of the TSCA, and nearly every interviewee expressed their perception that it is fundamentally flawed, there is no significant divergence between what different stakeholders see as the weakest point of TSCA. Almost all interviewees mentioned that the existing chemicals program is a key problem. Specifically, the EPA has limited authority to require toxicity testing of existing substances. To require these tests, the EPA must provide evidence that the chemical may pose an unreasonable risk of injury to health and/or the environment, due to concerns about toxicity or exposures. Therefore, the burden of proof is on the EPA to demonstrate the need for safety testing and their authority is not effective enough to obtain the information necessary to justify restrictions.

What is the impact of the concern that 'REACH has too much complexity' on the TSCA reform debate in the USA? In them, when REACH was first introduced, it represented a piece of "too complex" legislation, which is difficult to understand and implement. I wanted to know whether or not that characteristic of REACH is spreading in the US. However, from the answers, I could see that this question was not significant since the interviewees provided general answers involving REACH's complexity, supporting a desire to keep TSCA simpler than REACH.

What is the impact of REACH 'location of burden of proving safety (industry versus government)' on the TSCA reform debate in the USA? In the EU, to place the burden of data generation, risk assessment, and management on the industry was a radical solution. EU leaders pushed this solution since they were not able to achieve real progress at existing chemicals' risk assessments, and thus wanted to implement the 'polluter pays' principle. EU industries actively lobbied to block this radical change. Therefore, my expectation was that in the USA, the situation would be similar. Interestingly, from these answers, I discovered that the EPA leadership believes that the industry is not as objective as the authority (EPA), and the industry should not be the judge of the final safety determination. However, the authority also believes that manufacturers need to have increased responsibility for providing hazard

and exposure data. It was interesting to see from the industry representative's answer that the overall industry does not disagree, and that there is a sense of responsibility for industry to carry that burden. The voluntary EPA High Production Volume (HPV) Challenge Program is a good example of this. Specifically, companies sponsored more than 2200 HPV chemicals and collected publicly available EHS data about these existing chemicals. Meanwhile, some people see the safety determination as the government's job in the USA and others believe that the burden should be on the industry to prove that the chemical is safe. However, none of the TSCA reform bills enacted dictate that the industry should prove safety. Thus, the radical change of REACH was not implemented.

What is the impact of REACH 'publicly available test data' on the TSCA reform debate in the USA? The first main driver of REACH is the lack of publicly available toxicological, ecotoxicological, and environmental fate data on existing chemicals (Hansen 2013). This resulted in the lack of trust that substances were being used safely. To solve this issue, much of the toxicological, ecotoxicological and environmental fate data generated by REACH are made publicly available on ECHA's website. The companies also have the right to treat some extra part of the REACH registration dossier as confidential, for an extra cost. However, the final decision lies in ECHA's hands. Regulators outside of the EU are able to make use of, and rely on, that EU information, which is disseminated on the ECHA homepage when assessing chemical safety in their jurisdiction (Yoshiko 2010). I wanted to know how Americans wish to solve this issue, and whether the US is going to utilize and rely upon REACH data.

Almost all stakeholders –including those within industry- agree that the seemingly limitless claims of confidential business information should be changed towards a more strict direction in the TSCA reform bill (SOCMA 2013a). The interpretation of *principle of public participation* is different in the EU and in the US. The biggest setback to implementation of this principle is confidential business information. ECHA disclose the majority part of the registration dossiers on ECHA homepage. "TSCA's Confidential Business Information (CBI) provision allows companies to make nearly unlimited claims of CBI, without requiring any upfront justification or EPA review, and without any date of expiration or requirement for periodic renewal and justification of such claims" (Beinecke 2011, 5).

One of the interviewees stated that roughly 16,000 chemicals have been claimed to get CBI in the public inventory, and it is a real problem if it is a carcinogen or endocrine disrupter, because with these chemicals the public is now aware of the risk when the identity

of the chemical is also confidential. The EPA's current interpretation creates uncertainty about whether chemical names are confidential when they are contained in health and safety studies (SOCMA 2013).TSCA reform Principle No. 5 of the EPA says that provisions assuring transparency and public access to information should be strengthened, which means "data relevant to health and safety should not be claimed or otherwise treated as CBI. The EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety". As I understood from another interviewee, quite often the government does not have a comprehensive understanding of the real value of a CBI, even though the industry shows good substantiation. Due to this reason, the government cannot do an adequate job of judging this complex issue.

SOCMA represents many U.S companies and explained why CBI is a real value, especially for SME companies, who produce specialty chemicals (SOCMA 2013 a). These companies, through extensive research, are deeply involved in developing greener chemicals. In case of a disclosure of the chemical identity of the new chemical, a potential competitor – many times outside of the USA- easily reveals it, and gets a free-ride on the innovation. A patent is not a solution for U.S companies because it does not help against nations where patent enforcement is weak. This is why most companies protect chemical identity by hiding it as a trade secret. The incentive to develop greener chemicals largely disappears if manufacturers know that the risk is high for having their invention revealed. However, SOCMA agrees that companies have over-claimed CBI in the past, and the companies should provide a reasonable justification to get a CBI approval from the EPA, and should periodically renew it. They agree to disclose the chemical identity via generic, structurally-descriptive names, since the functional groups on a substance can indicate the chemical and toxicological properties sufficiently. However, the precise chemical identity –chemical name, molecular formula, and CAS number is not an essential element of health and safety studies, and must continue to be protected against public access. "The EPA should be permitted to share CBI with other Federal agencies and with state and foreign governments that, in practice, provide protections equivalent to those provided by EPA. (SOCMA 2013 a, 1)"

In the TTIP discussion, the EU Commission identified four main areas in which a higher degree of convergence may be sought to increase efficiency and reduce costs. The fourth area of cooperation between the EU and the US is enhanced information sharing and protection of confidential business information (CBI). One of my interviewees said that it would be ideal if the EPA could take all of the REACH dossiers and review the information in

them, and then determine if they need additional information. However, due to legal difficulties, this is currently not a realistic solution.

Another interviewee mentioned that collection of publicly available information is more seamless from ECHA's user-friendly webpage than from the US EPA dissemination website. In the USA, one must repeatedly make an official request for information, otherwise it is not available.

What is the impact of 'cross-Atlantic recognition of registration dossiers' on TSCA reform debate in the USA? In our first article in 2012, (Abelkop *et. al* 2012), one of our findings was to consider cross-Atlantic recognition of REACH registration dossiers. One of my interviewees replied to another question that it would be ideal if the EPA could take all the REACH dossiers and use the information in it, and then determine if they need additional information. However, due to legal difficulties, this is currently not a realistic solution. Another interviewee mentioned that this topic is in the TTIP discussion. This interviewee mentioned that under a US Pre-manufacturing Notice (PMN) 85% of applications for PMN at the EPA have no toxicity data, and if the EU is going to recognize a notification that contains no data, then it undermines the EU "no data no market" principle, and Europe cannot accept it. Therefore, if the US implements a minimum data set requirement (similar to REACH) in TSCA reform, then Europe could accept this information sharing.

What is the impact of REACH 'precautionary principle' on the TSCA reform debate in the USA? My interviewees recommended further literature about this topic that is analyzed in the introduction.

What is the impact of REACH 'Transatlantic Trade and Investment Partnership (TTIP)' on the TSCA reform debate in the USA? Many of my interviewees are not involved in TTIP discussion. However, the one interviewee who was involved mentioned that if TSCA reform would come after TTIP, then it would appear more like REACH. He thinks TTIP has an impact on forcing the industry to try to achieve TSCA reform before TTIP is concluded because, if TTIP would be concluded, then decision makers could push TSCA reform to have a more similar structure to REACH. They claimed they would finish TTIP by end of 2015, before Barack Obama leaves the presidential office. They tried to accomplish this in 2 years. This would have a large effect on TSCA reform, an effect on how it is implemented. If TSCA reform does not happen, then it will have a bigger effect on how any sort of TSCA reform happens in the future. This places a great amount of pressure on TTIP. Other interviewees said that TTIP discussion will have a minimal impact on TSCA reform since, in the TSCA

reform debate people are not talking about TTIP. I analyze the TTIP discussion in the seventh chapter in this dissertation.

What is the impact of REACH 'no distinction between new and existing substances' on the TSCA reform debate in the USA? The fourth additional driver of REACH development is that, before REACH, there was a huge difference between the new substances (non-phase-in) and the existing (phase-in) substances' testing requirements, since new substances (marketed in the EC after 1981) have to be notified and tested extensively. These new substances' notification and testing requirements have inhibited research and development, and encouraged the use of old existing substances (Hey *et al.* 2007). This is due to the fact that these tests were very expensive, and only a few companies could afford to invest money in them. The REACH 's solution was 'no distinction between new and existing substances' since REACH compels manufacturers of substances, producers of articles, and importers to supply regulators with a minimum safety-related data set for existing, as well as new, chemical substances. This sparked my curiosity in whether or not the US is going to implement this solution in the TSCA reform bills. My interviewees explained that in the TSCA reform bills, there is a sharp distinction between new and existing chemicals, and since the industry believes that the new chemical program works well and supports innovation, there is no hope to change it. Environmentalists and civil society would like to have a minimum dataset for all chemicals, and there was a debate about this in the previous TSCA reform bill, but the minimum dataset request is currently ignored.

What is the impact of REACH 'one substance one registration' on the TSCA reform debate in the USA? I wanted to know if the US is going to implement the 'one substance one registration' principle of REACH. However, I received the same answer from most of my interviewees. Specifically, that the US is not going to implement a registration process. From this response, I concluded that the Americans call the registration process the European process when the industry collects data through registration dossiers and makes a safety determination. However, I believe the REACH 'one substance - one registration principle' or in this case 'one substance-one dataset' is used in the US, just that the EPA takes a "lead-registrant" role, and the EPA collects all test data from the concerned companies, from literature, or through alternative methods and makes a safety determination for all new substances and for high –priority existing substances.

What is the impact of REACH 'publicly available data like PNEC and DNEL' on the TSCA reform debate in the USA? According to my opinion, the determination of DNEL

(Derived No Effect Level) human health hazard threshold limit value and PNEC (Predicted No Effect Concentration) environmental threshold limit value is the biggest EHS achievement of REACH regulation. These concrete limits -if it is implemented and calculated well- can provide substantial support for the EHS leaders' job in the industry. Only those interviewees who are involved in risk assessments had an opinion about this question. One of the interviewees stated that since DNELs works like Occupational Exposure Limits (OEL), that it is the reason why there are several fears that these levels are too strict and too conservative. Another interviewee said that the quantification of low-level limit (DNEL), will automatically raise questions about how it is scientifically determined and will thus raise a debate around the definition of an adverse effect and low-level exposure.

What is the impact of REACH 'use-specific registration' on the TSCA reform debate in the USA? One of the interviewees stated that part of the US debate involves how to assess risk on certain uses and how to address them. When the EPA prepares a chemical assessment, they do it for certain uses and a significant new use notice (SNUN) is required if the use changes. Some use categorization could be advantageous. One of the interviewees hopes to avoid use-specific registration, since it is a problem with REACH.

What is the impact of REACH 'exposure scenarios' on the TSCA reform debate in the USA? Under REACH, "the information on the conditions under which a substance is manufactured and used is called the exposure scenario" (ECHA 2009, 5). The exposure scenarios can be prepared with exposure estimation models (e.g. Chesar tool). In the final exposure scenario, the risk is under control, which means that the Risk Characterization Ratio (RCR) calculated by the model is less than 1 (RCR<1). Therefore, the use written in the exposure scenario is safe under the operational conditions (OC) and the risk management measures (RMM) specified in the exposure scenario. The 'conditions of use' (OC + RMM) represent the minimum requirements that a downstream user should implement. In practice, conditions of use at downstream users are likely different from the scenario, yet the risk still may be adequately controlled (RCR<1) if the downstream user is able to be in compliance with the minimum requirements of the exposure scenario. The exposure scenarios are attached to safety data sheets, which the consumers receive with the first supply of the chemical. The content of the exposure scenarios should be implemented with chemical downstream users and manufacturers similar to the safety data sheets' content. Many companies do not attach the exposure scenario to the safety data sheet, or oppositely, they attach it for all uses and not just the specific uses of their supplier, by creating a safety data book with more than 100

pages instead of a safety data sheet (SDS). The incorrectly interpreted and implemented exposure scenarios cause many misinterpretations in the EU. As expressed by the interviewees, while the EU relies on generic assessments (calculated with Chesar model), the EPA will rely on factual information and will not use exposure scenarios for assessment. The EU assumes that these "fake" exposure scenarios show the actual exposure, but it does not show low-level exposure.

What is the impact of REACH 'authorisation and restriction' on the TSCA reform debate in the USA? TSCA Section 6 is essentially the authorization / restriction part of US chemical legislation. This is one of the weakest points of TSCA (See Corrosion Proof Fittings Case when the authority could not ban the use of asbestos). Slow and resource intensive risk assessment, risk management, and slow prohibition or restriction of chemicals to address the evaluated risk is one of the main drivers of TSCA reform. The TSCA reform bill will be structurally different than REACH, but the end result of risk assessment to justify prohibiting certain chemicals may not vary.

Likert-type questions were also employed to generally evaluate the level of agreement or disagreement of a given statement. In my Likert scale the participants could choose from 5 answers: strongly agree, agree, neither agree nor disagree, disagree, strongly disagree with the given statement. The interviewees used the *neutral* option when they were not familiar with the topic of the statement, or when they did not want to provide an opinion about the statement or when they did not like the wording of the statement.

The number of different stakeholders was not identical: I interviewed 3 industry representatives, 2 law firms, and 1 consultant who advised the regulated industry. 3 key officials in the EPA were also interviewed, as well as 1 selected environmental NGO and 5 academics linked to NGOs who are tracking TSCA reform.

Likert tests measure either positive or negative responses to the statement (Wikipedia 2015 a). It was interesting to see that there were only two statements out of twenty that resulted in an *agree* or *strongly agree* response, if the neutral answers are omitted. These statements were: "A better priority-setting procedure for regulating existing chemicals under TSCA needs to be established." 8 strongly agree, 3 agree and 4 neutral answers were given. The other was that "TSCA reform needs to have a strong emphasis on sound science and risk assessment." 10 strongly agree, 2 agree and 3 neutral answers were given.

There were a few statements where there was just 1 disagreement and the rest of the people agreed or were neutral: "TSCA reform needs to include a provision to encourage data

sharing between ECHA/REACH and EPA/TSCA." and "the cross-Atlantic recognition of REACH registration dossiers is feasible." and "if REACH had never been enacted the momentum behind TSCA reform would be weaker."

The different Likert scores show that TSCA reform is not black and white and every expert has a subjective opinion about this topic. However, almost all interviewees were more comfortable with open-ended questions and explained why they agree or disagree with the given Likert-type statement. That is why I do not find it important to analyze the scores. Also, even though these statements were not open-ended questions, it functioned in the same way as an open-ended question because they stimulated thoughtful reactions and elaborations from interviewees.

After analyzing the data, a clearer picture of the EU and US systems emerged.

3. REACH, TSCA AND THE BIPARTISAN TSCA REFORM BILLS

3.1. Overview

Since 2008, ten bills have been introduced to amend the Toxic Substances Control Act of 1976.[15] For a bill to become a law, both houses of Congress must agree on identical versions of the bill. When the Senate and House of Representatives' are controlled by majorities of different parties, the challenge of finding an agreement on the bill is even harder. Under most circumstances, a bill cannot be enacted without some bipartisan support from the two parties in Congress.

The *S. 1009 – Chemical Safety Improvement Act (CSIA-2013)* bill was introduced by Senator Frank Lautenberg (D-NY) and David Vitter (R-LA) in May 2013, for consideration by the Senate Committee on Environment and Public Works. It was the first TSCA reform bill to receive any bipartisan support, drawing co-sponsorship from eight Democratic and eight Republican Senators. It was not enacted by Congress in 2013-14 due to opposition from Senator Barbara Boxer (D-CA), who was chair of the Committee, and due to slow progress in

[15] TSCA bills:

H.R. 6100	1. TSCA reform bill: H.R. 6100 Kid-Safe Chemicals Act of 2008 was introduced in 2008 in the House of Representatives in the Committee on Energy and Commerce by Representative Solis, Hilda L (D-CA).
S.3209	2. TSCA reform bill: S. 3209 Safe Chemicals Act was introduced in 2010 in the Senate by Senator Frank Lautenberg (D-NJ) in the Environment and Public Works Committees.
S. 847	3. TSCA reform bill: S. 847 Safe Chemicals Act was introduced in 2011 in the Senate by Senator Frank Lautenberg (D-NJ) in the Environment and Public Works Committees
S.696	4. TSCA reform bill: S. 696 Safe Chemicals Act was introduced in 2013 in the Senate by Senator Frank Lautenberg (D-NJ) in the Environment and Public Works Committees.
S.1009 (CSIA)	5. TSCA reform bill (bipartisan): S. 1009 – Chemical Safety Improvement Act bipartisan bill was introduced in the Senate by Senator Frank Lautenberg (D-NJ) in 2013 in the Environment and Public Works Committees. Co-sponsors (26)David Vitter (R-LA)
Boxer CSIA	6. TSCA reform bill: Chemical Safety Improvement Act bill was introduced by Senator Barbara Boxer (D-CA) in 2014
CICA	7. TSCA reform bill: Chemicals in Commerce Act (CICA) bill was introduced in the House of Representatives by Representative John Shimkus (R-IL) in 2014 in the Environment and the Economy Subcommittee.
S.697 Udall-Vitter bill	8. TSCA reform bill (bipartisan): S. 697 Frank R. Lautenberg Chemical Safety for the 21st Century Act bipartisan bill was introduced in the Senate by Senator Tom Udall (D-NM) and David Vitter (R-LA) in 10th of March 2015 in the Environment and Public Works Committees.
Boxer-Markey bill	9. TSCA reform bill: S. Alan Reinstein and Trevor Schafer Toxic Chemical Protection Act was introduces in 12th of March 2015 by Barbara Boxer (D-CA) and Edward Markey (D-MA)
H.R. 2576 Shimkus bill	10. TSCA reform bill (bipartisan): H.R. 2576 "TSCA Modernisation Act of 2015" bill was introduced in the House by Representative John Shimkus (R-IL) in 26th of May 2015 in the Energy and Commerce Commitees.

the House of Representatives. Before the end of the session, Senator Lautenberg passed away.

In the November 2014 elections, the Republican Party captured a majority of seats in the U.S. Senate. Republican Senator James Inhofe of Oklahoma replaced Senator Boxer as Chair of the Senate Committee on Environment and Public Works. A second bipartisan TSCA bill, *S. 697, was named the 'Frank R. Lautenberg Chemical Safety for the 21st Century Act'*. S.697 and was co-sponsored by Senator Vitter (R-LA), Senator Tom Udall (D-NM) and a coalition of 15 additional Democratic and Republican Senators. Introduced for Committee consideration on March 10th, 2015, S. 697 was later approved by the Committee and, as of this writing, awaits consideration on the floor of the U.S. Senate.

A third bipartisan TSCA bill, *H.R. 2576 TSCA Modernization Act of 2015,* was introduced in the House in April 2015 for consideration by the Subcommittee on Environment and Economy of the Committee on Energy and Commerce. After revisions at both the Subcommittee and Committee levels, the main sponsor, Republican Representative John Shimkus (R-IL), mustered such widespread support in both parties that it passed the House of Representatives by a vote of 47-0 to 1. Compared to the two Senate bills, which are over 100 pages in length, the House bill is relatively short, only 40 pages.

The prospects of TSCA reform in 2015-2016 appear to be good, but three additional steps must be taken. The Senate must pass a TSCA reform bill. The Senate and House leaders of reform must negotiate a common bill that attracts sufficient support on both the House and Senate floors. And President Obama, who has indicated that he would like to see improvements to the House bill, must sign a TSCA reform bill, thereby making it a new law.

Legislative success on TSCA reform will require an 'art of compromise,' as it was said by the late Senator Lautenberg prior to his death (B&C 2015). Only bipartisan bills have a chance to be a common bill and later on a law, which is why the two bipartisan Senate bills, S. 1009 from 2013 and S. 697 from 2015, and the House bill, H.R. 2576 from 2015, are analyzed in this dissertation.

Policy makers, industry and some environmentalists were pleased with S. 1009 bill in 2013. Republican Senator Vitter, who introduced this bill, said: "Our bill strikes the right balance between strengthening consumer confidence in the safety of chemicals, while also promoting innovation and the growth of an important sector of our economy" (Vinyl n.d, 1). The American Chemistry Council's President Cal Dooley praised the bill, saying it "will put safety first, while also promoting innovation, economic growth and job creation" (Vinyl n.d, 1) Richard Denison, senior scientist of the Environmental Defense Fund said, "This bill is

both a policy and political breakthrough. It gives EPA vital new tools to identify chemicals of both high and low concern, and to reduce exposure to those that pose risks" (Vinyl n.d, 1). Even though this bill did not become a law, S. 1009 TSCA is used here for analysis, as it was the first bipartisan bill and the bills issued in 2015 continuously refer to this bill.

S. 697 bill of 2015 is a compromise bill that attracted a wider degree of bipartisan support than S. 1009. However, the support was not unanimous. According to Barbara Boxer, Senator of California, the S. 697 bill fails to provide the public health protections needed and is worse than current TSCA. At a public hearing on March 18, 2015, she showed the names of 450 organizations that oppose enactment of S. 697 (Boxer 2015). Senator Lautenberg's widow noted at the TSCA hearing that some states are still waiting for a different bill, but urged Congress not to let the interests of a few states undermine the interests of the rest of the country. "Do not allow the perfect to be the enemy of good," she stated ((B&C 2015, 1).

In the House, the senior Committee Democrat was Paul Tonko (D-NY). He argued that "The draft H.R. 2576 House bill of 2015 'represents a significant departure' from the S. 1009 bill (CW 2015 a,1). Tonko, Shimkus, and other co-sponsors argued that H.R. 2576 has several features that are superior to S. 697. At this writing, it is not known whether a common bill will be negotiated, and whether any final bill will look more like H.R 2576 or S. 697.

The REACH regulation was enacted in 2006 after a multi-year deliberative process, but the first bipartisan TSCA reform bill was not introduced until 2013. However, an earlier Democratic-sponsored TSCA reform bill, the Kid-Safe Chemical Act, was introduced in 2008 but did not attract any bipartisan support.

Did the enactment of REACH motivate the US to accelerate the TSCA reform effort after 2008, and thereby change the 'orphan status' of TSCA? Almost all interviewees agreed that, although TSCA reform is unlikely to resemble REACH, the REACH did contribute to an intensification of interest in TSCA reform. The EU's new ambitious and strict chemical management policy certainly brought attention to the weak points of TSCA. Almost all interviewees answered that, if REACH had never been enacted, the momentum behind TSCA reform would have been weaker.

American stakeholders have criticized TSCA many times since 1976, but there has not been enough momentum, reason, or common agreement to reform it. Before REACH, around 1976, TSCA was one of the strictest standards in the world, so it influenced other nations' chemical policies, including the EU. After REACH became the strictest standard in the world, and started to influence other nations' chemical policy, Americans started to analyze it. They

responded in both positive and negative ways, since "some US people see REACH as a positive model, but others see REACH as a negative model. As a result, REACH raised issues to be debated." (pers.comm). Two kinds of attitudes towards TSCA reform, from a REACH impact point of view, were made clear: a positive and a negative. Two examples of the positive impact are the following: "There have been some multinational companies, who have businesses in Europe, and that experienced the REACH registration process, have been more supportive of EU policies and EU ideas, and they see the benefit of having a REACH-like system in the USA, in order to avoid two different processes and duplication of the tests and to create efficiency (pers.comm)". The enactment of REACH was also seen as strengthening the hand of NGOs in the US, who could point to REACH and say "the EU is more protective than the US.(pers.comm)" Both of these answers are consistent with the 'California effect' theory.

Reactions to REACH in the US were not, however, primarily positive. One example of a negative view is the following: "There is a reluctance among certain members of industry and certain members of Congress to adopt anything that resembles EU policies. So some pragmatic ideas that are in REACH, like put the burden on industry to collect data and prove the safety of the chemicals, are perceived as European. There is a reversion (resistance) in Congress to these ideas, precisely because they are European; some in Congress want to do reform an American way. (pers.comm)" This opinion is a very important political obstacle to policy convergence. It is also a good example of bounded learning (a diffusion mechanism) that was mentioned earlier in the dissertation. With bounded learning it is possible that politicians share the same biases, in this case that the European way is not as good as the American way.

In the following sub-chapters, mainly through content analysis of policy documents (three bipartisan bills) and through the views of different US stakeholders (through testimonies at public hearings), the impact of REACH on TSCA reform is analyzed. The major issues concerning data development, prioritization for safety assessments, safety standards, restrictions, and preemption part of TSCA are covered, as each are a focus of the TSCA reform debate. How the European solution differs from the TSCA bills' solution from an environmental, health, and safety point of view will also be shown.

3.2. Data development requirements

Physical-chemistry, toxicological, ecotoxicological, and environmental fate data development are key technical requirements for sound chemical policy, since without good data it is very hard to evaluate a chemical substance for safe use. During the TSCA reform discussions, crucial issues were explored such as how much data are needed, what kind of data are needed, who should collect data, and how accessible and transparent should the data be to the government and to the public. The European answers to these questions will be shown, and compared to the answers under TSCA and the TSCA reform bills.

The lack of publicly available toxicological, ecotoxicological, and environmental fate data on existing chemicals[16] was one of the main drivers for enactment of REACH (Hansen 2013). 90% or more of the total volume of substances on the market were existing substances with no data (Bergkamp and Penman 2013), which resulted in the lack of trust of claims that substances were being used safely. The EU concluded that industry should generate a comprehensive database on the intrinsic properties of each substance, a process that was seen as faster and more cost-effective than relying on the governmental authority.

Gathering data on intrinsic properties, chemical uses, exposures, toxicity, and risks is a burdensome task that requires time, monetary resources, and technical expertise. REACH compels manufacturers of substances, producers of articles, and importers to supply regulators a minimum safety-related data set for existing as well as new chemical substances. Any company that wishes to manufacture or import chemicals in the EU in an amount of 1 ton or more per year must first register the chemical substance with the government. The registration "dossier" under REACH must contain a minimum set of data (see Annex III.), or the substance may not be manufactured or imported (Abelkop et al. 2012). The minimum data set varies depending on the tonnage range. REACH Article 119 describes which raw data generated by industry should be publicly available on ECHA's website.[17] However, some of the key analyses related to the safety of specific uses, which are included in the industry's chemical safety report, are treated as confidential business information. In that light, the primary concept underlying chemical registration in the EU is "no data, no market" (REACH Art.5).

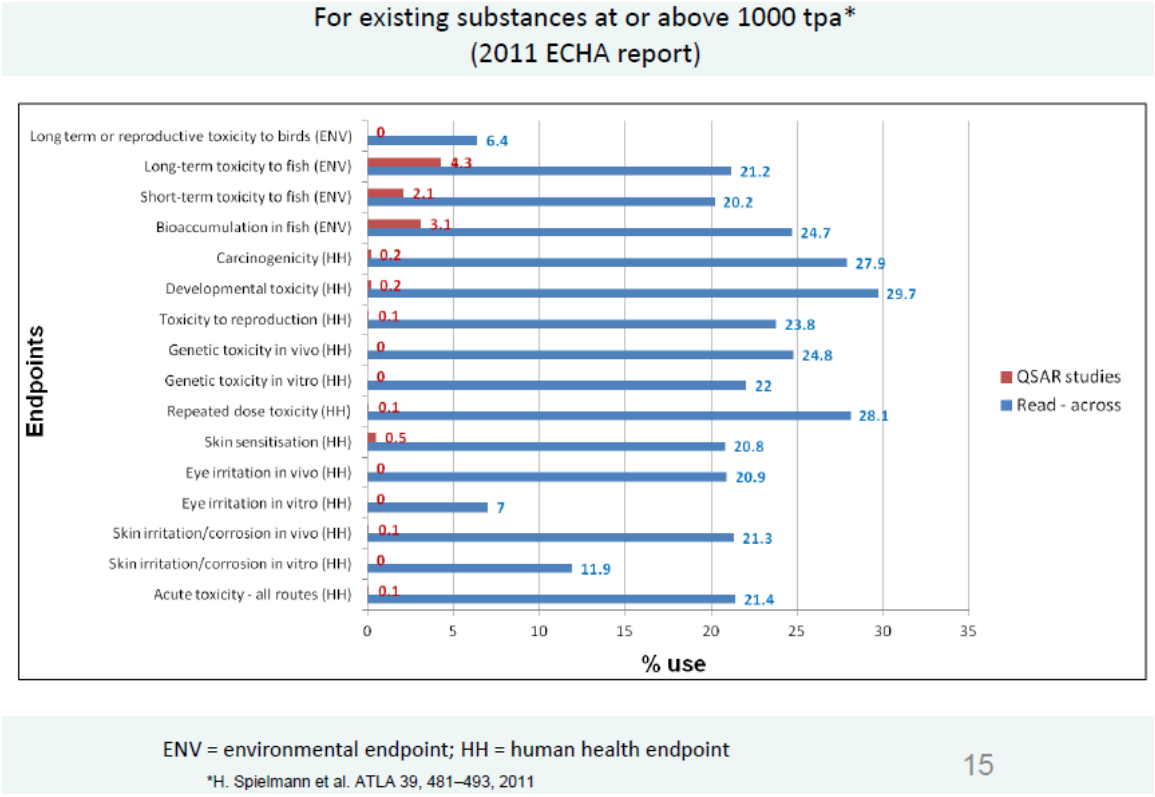
[16] Existing substances are chemicals included on the EINECS list , the 'European Inventory of Existing Chemical Substances'

[17] http://echa.europa.eu/information-on-chemicals

To reduce duplicative testing on animals and to save testing costs for manufacturers and importers, REACH legally requires companies that manufacture or import the same chemical substance to share data with one-another and to submit that data as part of one joint registration (REACH Art.11). This is the concept of "one substance, one registration" (REACH Art.11), and REACH is unique among the global suite of environmental regulations in this concept. Joint registration also eases ECHA's burdens of evaluating the registration materials by focusing much of the registration content from many companies into a single document. REACH's focus on the regulation of existing and new chemicals makes the EU legislation unique among regulatory approaches to industrial chemicals. As a part of the registration, the industry gathers data on the chemical properties of thousands of existing chemical substances. In REACH there is no difference between new and existing substances from a data-gathering point of view (Abelkop et al. 2012).

The industry has used alternative methods to generate toxicological and ecotoxicological data for REACH registration. The alternative methods usually cost 10% of the price of an in vivo test, so there are large benefits to industry in terms of lowered testing costs and diminished use of animals. The most commonly used alternative approaches for data gap filling are the 'read-across' and the Quantitative Structure-activity relationship (QSAR). Both were described in the literature review, including their limitations. About 6-30% of REACH lead dossiers of existing substances above 1000 t/y contained read-across and 0-4% contained QSAR data as can be seen from Table 2.

Table 2. QSAR and read-across based submissions to the ECHA for existing substances at or above 1000 t/y (ECHA 2015b)



ECHA offers training in the use of the OECD QSAR Toolbox, which is the most comprehensive, widely recognized, and freely available platform for data gap filling in regulatory hazard assessment. The Toolbox is widely used by industry as they prepare registration dossiers. Thus, it can be concluded that REACH is a data-generating regulation, as ECHA reported in 2014 that it had received a basic data set on more than 10,000 substances (ECHA 2014). Even more will be collected by 2018, which is the registration deadline for substances manufactured between 1-100 t/y.

Under current TSCA, there is no minimum required information for new or existing chemicals. “85% of the notices EPA receives for new chemicals contain no health data, and 95% contain no ecotoxicity data. The U.S. is not requiring a minimum set of data for new chemicals to assess their safety” (Beinecke 2011, 4). Regardless, the EPA may demand toxicological data if the substance "may present an unreasonable risk of injury to health or the environment, or is produced in very large volume and there is a potential for a substantial quantity to be released into the environment or for substantial or significant human exposure"

(CRS 2013, 2). EPA officials believe that demonstrating an unreasonable risk is a more stringent requirement than demonstrating a significant risk. Specifically, the process of establishing a significant risk, versus that of finding an unreasonable risk, requires an extensive cost-benefit analysis. "Since 1976, the EPA only issued regulations to control five existing chemicals that were determined to present an unreasonable risk" (GAO 2009, 2).[13] The EPA knows they need data to evaluate chemicals, but the agency perceives that it cannot effectively use the TSCA statute to get data. In addition to the legal problems with TSCA, some experts see organizational problems at EPA that exacerbate the problem of inadequate safety data (ChemHeritage 2010).

In order to appreciate why EPA perceives that TSCA is too weak to force generation of safety data, consider decision of the U.S. Court of Appeals (5th Circuit) in the Corrosion Proof Fittings case. EPA collected some data to support a ban on the use of asbestos in numerous applications, but the asbestos manufacturers (represented by Corrosion Proof) sued the EPA. The Court found that the EPA was required to collect data not only on the negative effects of asbestos but also on the positive effects, in order to support an unreasonable risk determination (Corrosion n.d.). The Court also ruled that the EPA must analyze asbestos on a use-by-use basis, rather than simply ban all uses of asbestos because the substance is hazardous.

This result seriously demoralized the EPA staff. This is a serious issue for the EPA, so the EPA started developing other ways to get data. In some cases, the EPA was able to accomplish what the TSCA set out to do, but they did not use the TSCA statue (ChemHeritage 2010). A good example is the voluntary High Production Volume (HPV) Challenge Program. Under this Program, companies were 'challenged' to make health and environmental effects data publicly available on chemicals produced or imported in the United States, if they are produced in volumes greater than 453 metric tons/year. All of this newly collected data allows HPV chemicals to become more widely understood by the EPA, stakeholders, and most importantly the public. As of June 2007, companies sponsored more than 2,200 HPV chemicals, but other chemicals remained unsponsored in the HPV Challenge Program. Therefore, the EPA is trying to collect basic hazard data for these unsponsored chemicals (EPA 2015).

The Toxic Substances Control Act (TSCA) section 4 test rules and section 8 rules have been used by the EPA in some cases to gather much needed data (EPA 2015). TSCA Section

8 provides that the EPA is to maintain the TSCA inventory of chemicals used in commerce. TSCA Section 8 requires reporting and record-keeping on existing chemical substances, which allows the EPA to request health, safety, and exposure data on existing chemicals (EPA 2015). The industry is required to inform the EPA if they obtain measurable evidence that a chemical substance was the result of significant harm to health and wellbeing of their employees (ChemHeritage 2010). However, in practice, companies may withhold significant information from the EPA on the grounds that injury may not occur. This is why the EPA has little to no information about chemical exposures, essential for a correct risk assessment.

In the current TSCA, the EPA must already have a body of information to document potential risk, toxicity, or exposure in order to require industry to generate new data (Denison 2007). The EPA must go through notice- and comment- rulemaking to require testing, which can take years. Since TSCA was enacted, the EPA has required testing for fewer than 200 chemicals (Denison 2007). Through TSCA reform, the EPA would like to change this process. The EPA has issued a TSCA reform principle about data development: manufacturers and downstream processors and users of chemicals should be required to provide sufficient hazard, exposure, and use data for a chemical. When manufacturers do not submit sufficient information, the EPA should have the necessary authority and tools, such as data call-in power, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals (both new and existing chemicals) (EPA 2015 a) .

Interestingly, some industry groups (SOCMA 2014) agree that EPA, through TSCA reform, should obtain the power to require downstream users to report use and exposure data, especially for consumer uses, since manufacturers currently have to make educated guesses on how a chemical they make is used. A customer or entity further downstream may not be inclined to share such proprietary information (SOCMA 2014 a), as disclosure of information about uses and exposure may help potential competitors.

Through TSCA reform, industry has also requested that submission of non-adverse data under Section 8 (e) be required, and that EPA be required to take it into account such data when prioritizing and evaluating chemicals for safety. Current TSCA Section 8e is biased towards adverse data and does not explicitly recognize non-adverse data, since the EPA only requires adverse data from the industry. By requiring submission of both types of data, EPA

understanding of chemical hazards would improve, (SOCMA 2014 a) and the public database on existing chemicals would not be biased towards 'bad news' (SOCMA 2014 b).

A third request that industry has made for reform of TSCA Section 8 is that the Inventory of existing substances be updated periodically by placing chemicals in active and inactive categories (SOCMA 2014 b). Currently, many chemicals listed on the TSCA Inventory are no longer used commercially.

Section 4 of TSCA gives the EPA authority to require testing of existing chemical substances and mixtures once certain criteria are met. The major shortcoming in this section is procedural, since the EPA is required to go through a rulemaking process to require testing (SOCMA 2014 b). A 'rule'must go through all sorts of procedural requirements like public notice (a draft rule must be published in the US Federal Register), then consideration of public comments, and publication of a final rule. If an individual or company believes that EPA exceeded its authority or that its actions are unjustified, that person or company can take the EPA to court. The industry reform recommendation is that, instead of a rule, the EPA should require tests by industry through 'order', since an 'order' does not have to go through rulemaking procedures. "In giving EPA such 'order' authority, however, Congress should not authorize unnecessary blanket or one-size-fits-all testing requirements" (SOCMA 2014 b, 3), which means the industry does not agree to having a uniform, minimum required dataset for all chemicals. Rather, industry believes that testing approaches should be tiered and targeted: they should start off at a screening level and focus on uses where exposures are most likely to be significant. If a screening level analysis shows that the risk is likely to be sufficiently low, additional test data would not be necessary. The industry also believes alternatives to animal testing (QSAR, read-across) should be authorized and encouraged. The tiered system industry is advocating was adopted by Canada in 2006 and has proven to be feasible and less burdensome than REACH (Abelkop and Graham, 2015). The industry also believes that EPA should be required to review a minimum number of chemicals annually via a risk-based prioritization process. EPA has some of the required expertise to do so, but agency needs additional resources to do this job (SOCMA 2014 b).

Environmentalists in the U.S. tend to have different views than industry concerning how TSCA reform should address the need for data development. The Driving Innovation paper of Center for International Environmental Law (CIEL 2013) states that the minimum data set is the most significant distinction between the US new chemical 'notification' and EU

registration system'. In the US, if a company intends to manufacture a new chemical substance for commercial purposes, the company must submit a Premanufacture Notice (PMN) 90 days before the date of intended start of production or importation (EPA 2015 b). During that 90-day review period, the EPA assesses whether the new substance may present an unreasonable risk to human health or the environment. After the PMN review, the new chemical is then added to the TSCA inventory. However, 85% of PMNs contain no health data, and more than 95% contain no eco-toxicity data. Half of all PMNs are submitted without any test data (Lynn 2015). CIEL seeks to generate information about hazardous properties in all chemicals, similar to the required data under REACH registration. There are also some industry groups that favor more required data from manufacturers. For example, US producers of consumer products and retailers value safety data about chemicals, in order to make better decisions to select a chemical for their products and to protect their workers, customers, and brand name.

Environmentalists are also concerned that EPA is relying too much on Structure Activity Relationships (QSAR, read-across) modeling tools. The models can give a trustworthy prediction if the input data are trustworthy. But, half of all PMNs are submitted without any test data (Lynn 2015), so in these cases the EPA can only make assessments based on data for similar substances, and not on valid data about the substance of interest. One of the main limitations of alternative methods is that they are highly dependent on having a robust and expanding underlying dataset of values derived from in vivo testing, which basically means these alternative results will only be as valid as the in vivo data that underpin them. The other limitation is that "QSAR reliable models are available for only a subset of relevant endpoints" (Denison 2007, 125).

A PMN review is usually a personal meeting of industry scientists with eight to ten EPA staff members. By the end of the meeting, the company knows if they need to generate any extra data regarding to a new substance. If the EPA says that the new substance may present an unreasonable risk to human health or the environment, then Section 5 gives the EPA the ability to require additional tests or other measures to control the risks. Environmentalists strongly criticize the new chemical approval system due to lack of minimum data sets.

With regard to data development, the bipartisan TSCA reform bills are modeled more after the Canadian system than Europe's REACH regulation. As we shall see below, the

TSCA reform bills contain no mandatory registration system with minimum data requirements.

S. 1009 CSIA -2013 does not require development and submission of a minimum dataset for new or existing chemicals. Instead of a minimum required dataset, the S. 1009 bill requires adequate data and information for safety assessment and determination. The development of such test data and information is the responsibility of the manufacturers and processors. Industry must give the Administrator the scientifically reliable data through voluntary agreements, and the EPA is to evaluate the quality of such information, analyze it, and make a determination whether additional data and information are required. The EPA still needs to demonstrate a need for extra data, which makes their task more difficult than it is for ECHA under REACH.

S. 1009 also requires EPA to transparently consider both positive and negative findings about safety, not just the negative ones, and make the data available for public comment. The EPA can collect data not just from the industry, but also from the public, university scientists, and governmental bodies in the US and abroad. Information about structure-activity relationship (grouping of chemicals or read-across) models and other publicly available information sources (including REACH data on ECHA's website) must be considered before EPA requires additional tests. EPA may use a rule, testing consent agreement, or an order to obtain additional data from industry, assuming the EPA has made available a written justification of the need for additional data. EPA may request data pertaining to acute toxicity, subchronic toxicity, chronic toxicity, carcinogenicity, genotoxicity, developmental toxicity, neurotoxicity, bioaccumulation, persistence, presence of the chemical in human blood, fluids, tissues, and aggregate exposure to the chemical from multiple sources. Failure of industry to submit any required information is a prohibited act and subjects the manufacturer and/or processor to penalties.

The S. 697 - 2015 Senate bill is similar to the S. 1009 Senate bill from a data development point of view. S.697 does not require development and submission of a minimum dataset for new or existing chemicals; indeed, the bill explicitly prohibits the EPA from requiring minimum data sets. The Administrator may require the development of new information only if it is necessary to establish the priority of chemical substances.

The EPA first requests voluntary information prior to issuing an order, if testing is necessary for prioritization. S. 697 enhanced the EPA's authority by ensuring the EPA can require testing of new chemicals and to inform prioritization of existing chemicals (Lynn 2015). The bill eliminated TSCA's unreasonable risk finding requirement, which environmentalists call a catch-22 (CIEL 2014): that the EPA has the authority to require data submission for chemicals which may present an unreasonable risk of injury to health or the environment, however regulators cannot compel manufacturers to generate the health and safety data needed to demonstrate unreasonable risk. S. 697 allows the EPA to issue orders to require testing instead of going through a rule making, which is a step forward for EPA compared to TSCA .

House bill H.R. 2576- 2015 is similar to the two bipartisan Senate bills from a data development point of view. The bill does not require development and submission of a minimum dataset for new or existing chemicals. This bill also solves the Catch-22 issue of the TSCA since it adds a new provision stating simply that EPA can seek data whenever that data is "necessary to conduct a risk evaluation" (SOCMA 2015). It clarifies that cost and benefit considerations are relevant only in deciding what risk management measures should be imposed to ensure that the use of substance does not pose unreasonable risks" (ACC 2015, 3) House bill -2015 allows the EPA to issue orders (SOCMA 2015) to require testing instead of going through rulemaking, which would be a far more time-consuming process.

Reading all the three bipartisan TSCA reform bills, it can be seen that there is no plan for minimum dataset requirements, such as those contained in the REACH registration system. But, the reform bills make it easier for EPA to justify a required data collection, and the collection may be the same or similar to the kinds of data required under REACH. Thus, theoretically, the TSCA reform bills can lead to data-collection requirements that are as strict as those in REACH.

A key question is whether the EPA will have enough capacity to do make the necessary justifications for data and not fail in implementation as in the case of the current TSCA, where EPA has required testing for fewer than 200 chemicals (Denison 2007). In the EU thousands of chemicals were registered with supporting data. Since there is no required minimum dataset and computer modeling may not always give a trustworthy answer under TSCA reform, the EPA may be compromised in its ability to make safety determinations based on valid data.

Another key difference between REACH and TSCA reform is REACH's 'one substance - one registration principle,' or in the US the 'one substance-one dataset' principle. Under TSCA reform, EPA takes the 'lead-registrant' role, collecting all test data from the concerned companies and applies the read-across and QSAR models. This data collector task (which in the EU is led by industry, the so-called lead registrant) is not simple and often requires extra production-related information about substances that is only available from industry. Unless industry works closely with EPA under TSCA reform, the data development process, including the process of deciding whether additional tests are necessary, will be quite difficult for EPA to complete in a timely and competent manner.

A related question is whether industry can be trusted to generate reliable safety data. Denison (2007) deals with this question in detail. If the industry generates risk data, it may support the 'green chemistry' movement because the industry may be inclined to integrate safety considerations into the design of new chemicals and products. "If government is sufficiently resourced to conduct detailed reviews and to address any deficiencies in industry's assessments and management, industry generated risk data may succeed. If government is insufficiently resourced, industry's assessments and self-designed risk management plans are better than none" (Denison 2007, I-9). If data are generated by the government or by independent laboratories, it can be better trusted and the industry will simply be expected to pay the bill (Denison 2007).

In the EU, in the Evaluation under the 2013 REACH Progress Report, Geert Dancet, the executive director of ECHA, declared that ECHA checked all or parts of about one third of the substances covered by the registrations submitted for the 2010 deadline, and they find that the information quality and the consistency of registration data still need to improve (ECHA 2014). In a compliance check, 61% of the checked dossiers had some kind of shortcoming, but since the selection criteria are intended to find cases with high potential for compliance issues and only a small portion are selected randomly, these 61% cannot be taken to indicate the overall quality of the whole registration database (ECHA 2014). Based on this ECHA report, we can see that the industry may prepare a technically weak registration dossier. Since the ECHA and the EU member states conduct detailed reviews, the quality of REACH dossiers are continuously improving.

Schenk (2014) and her team compared the long-term inhalation worker-DNELs which was calculated by industry based on REACH guidance document and Swedish occupational

exposure limits (OELs) which was calculated by the authority based on SCOEL guidance. On average, industry‘s Worker-DNELs were the same as the Swedish OELs, however the variation was huge. The reason of these discrepancies, is that there are many arbitrary choices (key studies, dose descriptors, assessment factors) that influence the calculation of DNEL (Schenk *et al.* 2014).

However, an unanswered question is whether industry-supplied safety assessments can achieve more, less, or the same trustworthy quality as a dossier prepared by a government agency.

Like the Canadian system, the TSCA reform bills depend on development of a coherent risk framework, adequate governmental expertise and capacity, and read across and QSAR tools. The models can give trustworthy predictions if the input data are trustworthy. In the EU, when the burden was left on the authority to collect safety data, government failed, which is why REACH made a fundamental change to put the burden of data collection on industry. Thus, the three bipartisan TSCA reform bills are not a fundamental change from a data development point of view compared to current TSCA, as still EPA collects the data and still needs to demonstrate the need for data (though without a catch-22 burden). One has to question whether the US EPA will be able to do a much faster and stricter job in data collection than the EU accomplished prior to REACH. The Canadian experience provides a more optimistic precedent for government-led development of safety data (Abelkop and Graham, 2015).

3.3. Prioritization for safety assessments

The TSCA Inventory currently contains over 84,000 chemicals (not all of them are actively produced right now), and substances on the Inventory are considered 'existing' chemicals in the US, and substances not on the TSCA Inventory are considered 'new' chemicals. A new chemical substance is added to the TSCA Inventory through a Premanufacture Notice (PMN). A chemical must be on the TSCA Inventory prior to commercial manufacture, import, or processing (TSCA Sec 8 (b). In 1976 TSCA grandfathered without any evaluation the 60,000 chemicals that were in commerce at that time. TSCA did not provide adequate authority or resources for the EPA to reevaluate all of these existing chemicals, even as new concern arose as to their safety (Jones 2015).

In the near term, preparing safety assessments for 84,000 chemicals is not feasible. This is why, during the TSCA reform discussions, it was considered crucial to consider how to prioritize chemicals for safety assessment: which chemicals should be subject to detailed safety assessments, which are of lesser concern and can wait for safety assessments until a later time, and which should be eliminated from the TSCA inventory list. REACH and TSCA reform both address prioritization but they do so in different ways.

3.3.1. REACH Prioritization

As explained in the previous section, REACH requires a minimum data set for all substances (see Annex III.), but still tries to lessen the burden on the industry, depending on the characteristics of the chemical. The nature and/or timing of the data requirements vary depending on three factors: whether the substance is an existing substance ('phase-in substance') or a new substance ('non-phase-in substance'); whether the substance has the potential to cause harm to persons or the natural environment (toxicity); and how much the substance is used (imported or manufactured).

Pre-registration provides a distinction in the process for existing and new substances. Through the benefit of pre-registration process, companies can take advantage of extended registration deadlines (See Table 3).

Table 3. REACH Registration Deadlines (Abelkop *et al.* 2012)

Extended Registration Deadlines for phase-in substances	***Substance Criteria***
November 30, 2010	quantity imported or manufactured ≥ 1000 tonnes / yr/ legal entity CMR category 1 & 2 ≥ 1 tonne / yr / legal entity very toxic to aquatic organisms ≥ 100 tonnes / yr / legal entity
May 31, 2013	quantity imported or manufactured ≥ 100 tonnes / yr / legal entity
May 31, 2018	quantity imported or manufactured ≥ 1 tonne / yr / legal entity

Fewer amounts of information and less tests are required for chemicals that are manufactured or imported in lower volume. For hazardous chemicals exceeding 10-tonnes, a Chemical Safety Report (CSR) must be prepared also. REACH provides registration

exemptions or reduced registration requirements for certain categories of common low risk substances (e.g. polymers and intermediates) (Abelkop *et al.* 2012).

The above distinctions are completed by the EU industry, but EU authority also undertakes prioritization when they determine which chemicals appear on the candidate list,[18]which ones go to the authorization list (REACH Annex XIV), and which ones go to the restricted chemicals list (REACH Annex XVII).

REACH regulation is based on both hazard and risk, but in the USA the general opinion about REACH is that it is a hazard-based regulation. It is true that the first step under REACH is a requirement for companies to assemble a minimum dataset about the intrinsic properties of the chemicals, especially the hazards of the chemicals. But, in the second process of the chemical safety assessments, companies analyze the extent of exposure and risk associated with each of the uses of chemicals. If risks are available, they are subject to risk management measures in order to ensure adequate control of exposure. The authorization and restrictions procedures under REACH are also risk-based, since industry and government have the opportunity to consider the risks and benefits of chemicals on a use-by-use basis.

3.3.2. TSCA prioritization

Current TSCA is lacking a mandate for the EPA to screen efficiently existing chemicals for potential data needs. There exists a unilateral opinion amongst actors and stakeholders that the EPA should conduct the prioritization of existing chemicals in a risk-based fashion, however TSCA legislation does not require this process. Over the years, various U.S. administrations have failed in their attempt to prioritize chemicals due to lack of funding for such programs. This has "hampered progress on the review of existing chemicals" (SOCMA 2013, 5). In the TSCA reform principles advocated by EPA, the fourth point is about prioritization: "Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner, which means that EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations" (EPA 2015 a, 1). In other words, EPA would prefer a risk-based prioritization scheme to one that is based on hazard alone, a view that is shared by industry: "Congress should remove obstacles to more comprehensive EPA evaluation of

[18] http://echa.europa.eu/candidate-list-table

Inventory chemicals by mandating EPA to review a minimum number of chemicals annually via a risk-based prioritization process. SOCMA 2013, a, 2)"

Most interviewees agreed that a system of priority-setting for existing chemicals under TSCA needs to be established. One interviewee even mentioned that the absence of clear priority setting guidance and clear deadlines is one of the biggest gaps in TSCA, and has contributed to the failure of the current law. Another mentioned that REACH's prioritizing chemicals based on volume should not be followed in TSCA reform, as chemicals below 1 t/y can sometimes be far more dangerous to human health and the environment than chemicals of which more than 1 t /y are produced (pers.comm). The challenge for TSCA reformers is how to incorporate priority setting into new legislation.

S. 1009 directs the Administrator to establish a risk-based screening process for identifying existing chemical substances into two groups, high priority or low priority, for safety assessment and determination. In this screening process, only the active substances should be taken into consideration; inactive substances should not since no exposure or risk is expected. The screening process should be completed by EPA in a timely manner; and the list of chemical substances being considered for prioritization should be published for public comment. An initial list is authorized, but the S. 1009 does not require putting a concrete number of substances on the list, even though some previous TSCA reform bills required a minimum of 300 substances.[19] The screening criteria shall consider: the recommendation of a State agency, the hazard and exposure potential of the substance, the use of the substance, the manufactured or processed volume, and the volume change in recent years. When limited data are available about a substance, it should be categorized as a high-priority substance. The Administrator shall write a brief explanation about the reasons for prioritization. The Administrator shall remove a chemical substance from the high-priority list, after an adequate safety determination is completed and published. The EPA can collect data for screening processes not just from the industry but from the public, governmental bodies (e.g., the REACH database on ECHA's website), structure-activity relationship (grouping or read-across) models, and from other publicly available information sources.

With regard to a decision about need for additional tests, the EPA is expected to integrate relevant information from multiple sources into a two-tiered testing framework (CRS 2013). TIER 1 contains a screening level exposure assessment (including modeling if appropriate), and a screening analysis for hazards. TIER 2 calls for additional tests if the TIER 1 tests and modeling do not provide adequate information for a decision. TIER 2 tests

[19] S. 3209 Safe Chemicals Act 2010 and H.R. 6100 Kid-Safe Chemicals Act 2008

may include exposure assessments and toxicological tests for specific biological endpoints, but the Administrator is required to minimize the number of new animal tests. Under S. 1009, the Administrator is required to prepare a report every five years about progress in the prioritization of existing chemicals.

The prioritization part of S. 697 is similar to S.1009 bill, as S. 697 directs the Administrator to establish a risk-based screening process for existing chemical substances that places each chemical into one of two groups: high priority or low priority for a safety assessment and determination. A high-priority substance is one that both high hazard and widespread exposure; a low-priority substance has "information sufficient to establish that the chemical substance is likely to meet the applicable safety standard (S.697)"Lack of data is a sufficient basis for designating a chemical as high priority. The EPA can require testing to inform prioritization decisions where data are lacking (Denison 2015). The initial list should contain at least 10 high-priority substances (including five on the TSCA Work Plan chemical list) and 10 low-priority substances. In three years after the date of enactment, the goal is that 20 low-priority substances, and in five years 25 low-priority substances, should be designated. In three years after the date of enactment, the goal is to have completed safety assessments for at least 20 high-priority substances, and in five years 25 high-priority substances.

The slow pace of the safety assessment process under S. 697 is a source of controversy. Environmentalists, States, and academics strongly criticized that "S. 697 would only require 25 high priority chemical reviews be underway within five years of enactment (…), which means EPA could take a century or more to review the most dangerous chemicals in commerce" (Cook 2015, 5)

The 2015 draft bipartisan bill in the House does not contain a prioritization provision for existing chemicals, which means that EPA would have discretion to determine priority setting. Interestingly, both the industry and EPA criticized that prioritization is missing from the House reform bill. James Jones, Assistant Administrator at EPA, testified that the House bill should give the EPA authority to set priorities for conducting safety assessments on existing chemicals based on relevant risk and exposure considerations (Jones 2015 a). Beth Bosley from SOCMA said that the most notable omission from the House bill is detailed risk-based prioritization for existing chemicals (SOCMA 2015). She believes that the crucial issue is whether the EPA can get sufficient tools and adequate resources to do this huge task. Revised H.R. 2576.requires EPA to complete at least 10 chemical assessments per year for existing substances.

Thus, the Senate and House reform bills differ in how prioritization of existing chemicals is addressed. It is unclear how much data the EPA will collect from tests and modeling in order to complete prioritization, since there is no minimal dataset. The EPA can easily make a 'Type II error': when suspected hazardous substances are not prioritized for safety assessment, and later on turn out to be more hazardous than expected ((Koch and Ashford 2006). However, if this Type II error is recognized, EPA can make the substance a priority and regulate it later on.

In this section it was shown that both REACH and the bipartisan Senate TSCA reform bills address prioritization for existing chemicals, though in different ways. The House bill contains no explicit prioritization provisions. The California effect theory, predicting that the stricter standard will be adopted by another government due to policy convergence, has not happened. In the US, the burden of collecting information and prioritizing them remains with the EPA rather than the industry, and this fundamental change that has occurred under REACH is not likely to happen soon in the US. In this respect, it can be concluded that REACH had no practical impact on how the bipartisan TSCA reform bill addressed the prioritization process, even though REACH was mentioned many times in the TSCA debate by different stakeholders.

4. SAFETY STANDARDS, RESTRICTIONS, AND PROHIBITIONS

4.1. Safety standards, restrictions, and prohibitions in EU

Safety assessments, safety standards, risk threshold, risk assessments, and risk characterization describe the conditions under which manufacturing and use of a substance is considered to be safe. The safety assessment can be risk-based or intrinsically hazard based. Risk is determined as a function of a chemical's intrinsic hazard, its use, and expected level of exposure (CIEL 2014). Hazard is largely inherent to a substance, and does not fundamentally change over space, time, or how the chemical is used. On the other hand, exposure changes with place, use, and time, which means that exposure must be periodically reassessed by industry. The variable nature of exposure poses a major challenge to exposure and risk assessment. Detailed and replicable test descriptions are available to conduct hazard tests (see them in Annex III.). In contrast there is no internationally accepted test for exposure measurements or models. The common limitation of exposure assessments are how to examine cumulative and aggregate exposures (Denison 2007).

4.1.1. Safety determination in EU: Chemical Safety Assessment (CSA)

"Under REACH the Chemical Safety Assessment (CSA) is the process that describes the conditions under which the manufacturing and use of a substance is considered to be safe" (ECHA 2009, 5). The CSA is prepared by the industry as part of the REACH registration dossier, and then is subject to review for completeness and quality by ECHA.

The lead registrant may include the Chemical Safety Report (CSR) in the joint submission of a registration dossier for multiple manufacturers, processors, and users. If not, each co-registrant must attach their own CSR to their mini dossier.

There are three major steps in the CSA process: hazard assessment, exposure assessment, and risk characterization. CSA is the hazard and risk based safety assessment in the EU prepared by the industry as part of REACH registration dossiers. The so-called hazard based safety assessment in the EU is the Authorization (Annex XIV) and the Restriction processes (Annex XVII), which are led by EU authorities (EU Commission, ECHA, and Member States authorities). Both assessments will be covered below.

4.1.1.1. REACH Hazard assessment

The REACH hazard assessment collects the intrinsic properties of the substance (see Annex III. for a description of the required minimum dataset), the GHS (CLP) classification of the substance (covered later in this chapter), and the calculation of the threshold levels (ECHA 2009). The IUCLID software tool is used for collecting this hazard information in the EU. The primary objective of the hazard assessment is to "identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels of exposure that are considered to be safe" (also known as the DNEL) (ECHA 2009,5). The Derived No-Effect Level or DNEL is "*the level of exposure to the substance above which humans should not be exposed*" (threshold level for potential adverse health effects) (ECHA 2009, 11). This potential will vary depending on the exposure pattern to the substance (population: workers, consumers; route of exposure: dermal, inhalation, oral), as described in the Table 4 below (ECHA 2009).

Table 4. Different DNELs in EU (ECHA 2014 a)

	Workers				Consumers				
Route of exposure	Acute effect local	Acute effects systemic	Chronic effects local	Chronic effects systemic	Acute effects local	Acute effects systemic	Acute effects systemic	Chronic effects local	Chronic effects systemic
Oral	Not required								
Inhalation									
Dermal									
Each of the cells should contain one of the following information: i) DNEL value with unit or ii) hazard identified but no DNEL available or iii) no exposure expected, iv) no hazard identified									

From the matrix one can see that a maximum of 20 kinds of DNELs can be calculated, although usually there is not enough hazard data to calculate 20 DNELs. Calculating a DNEL for workers is different than for the consumers. When appropriate, the DNELs protect potentially exposed subpopulations such as children and pregnant women.

A DNEL is calculated by dividing the value of the health effect dose descriptor by an assessment factor as can be seen from Fig 2.

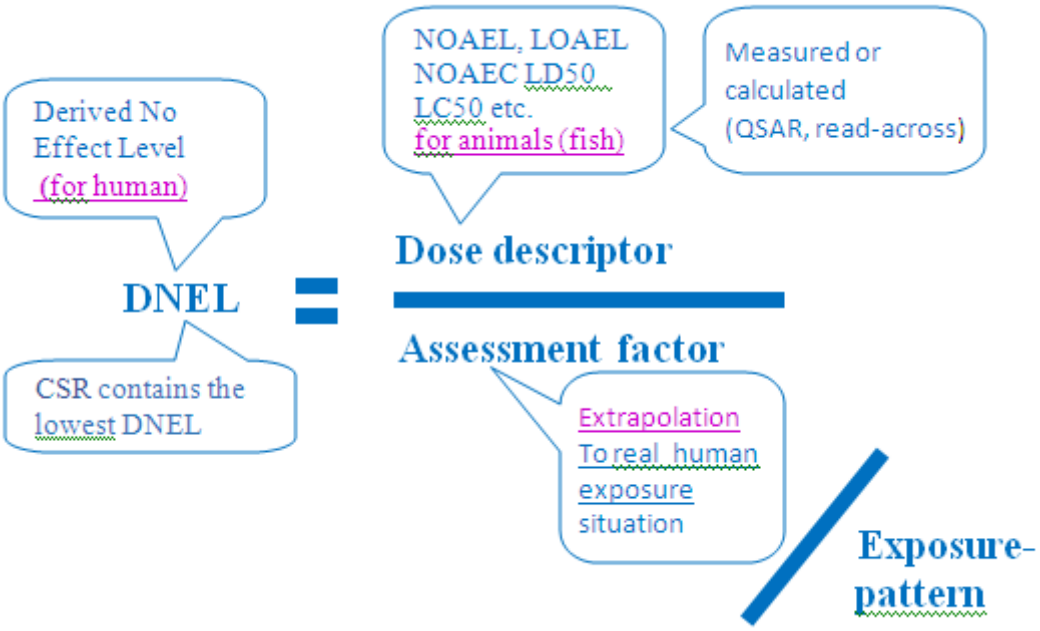


Fig. 2 DNEL calculation

The appropriate measures of dose, called the dose descriptors, are determined in toxicological studies on the hazards. The dose descriptors are usually expressed as NOAEL, NOAEC, LD50, and LC50 (see list of abbreviations for a description of these terms). For example, the most sensitive disease endpoint for a particular chemical may be related to a low-level exposure pattern that occurs over a long period of time (a chronic exposure pattern). The CSR typically focuses on the lowest DNEL, the lowest no-effect level among those that have been determined. Dose descriptor data acquired (primarily) through animal testing must be transposed into the human context through assessment factors.

The Predicted No Effect Concentration, or PNEC, is the "concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short term exposure (i.e., the threshold limit) ” (ECHA 2009,12). See Table 5 below for different types of PNEC.

Table 5. Different PNECs in EU (ECHA 2014 a)

Environmental protection target	PNEC
Fresh water	
Freshwater sediments	
Marine water	
Marine sediments	
Food chain	
Microorganisms in sewage treatment	
Soil (agricultural)	
Air	
Each of the cells should contain one of the following information: i) PNEC value with unit or ii) hazard identified but no PNEC available or iii) no exposure	

Table 5. clearly shows that a maximum of 8 kinds of PNEC can be calculated. Usually there is not enough hazard data to calculate all 8 PNECs.

Each PNEC is calculated by dividing the dose descriptor by the relevant assessment factor for each environmental sphere (ECHA 2009, 12).

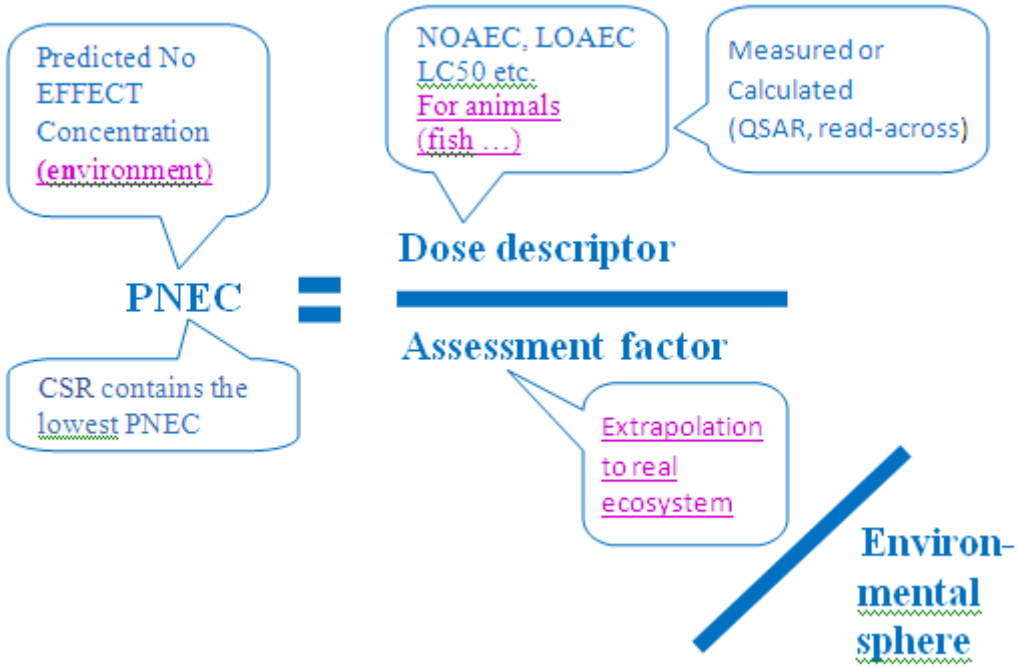


Fig.3. PNEC calculation

Dose descriptor data acquired (primarily) through animal testing must be transposed into the ecosystem through assessment factors (ECHA 2009, 12). The lowest PNEC for each environmental sphere is later used for risk characterization in the CSA (Ibid).

If the result of the hazard assessment concluded that the substance does not meet the criteria for classification as dangerous, or to be considered a PBT/vPvB, the CSA ends here. If

the substance meets any of these criteria, two additional steps are required to complete the process: the exposure assessment and the risk assessment (ECHA 2009).

4.1.1.2. REACH Exposure assessment and risk characterization (risk assessment)

The second step in the Chemical Safety Assessment (CSA) process is the exposure assessment, which is the process of determining the concentration of a substance under which humans and/or the environment may be exposed to (ECHA 2009).

Real-world information about human exposure to chemicals can be measured or estimated. The measurements may be made by companies for consumers or workers. If estimates are used, then ECHA recommends that a modeling tool called Chesar[20] be used, in part because it is synchronized with the IUCLID tool that is used in the EU to collect and report required minimum datasets on the properties of chemicals. The Chesar tool will calculate exposure estimates that can be used in the risk characterization calculation for exposure scenarios that are used in the CSR and for public communications.

Predicted environmental concentrations (PEC) –company's environmental exposure level data - can also be measured or estimated. The measured concentrations may be from fresh waters, waste water systems, and other environmental spheres. If estimates are used, then most lead registrants use the Chesar tool. The Chesar tool calculates a PEC, which can later be used in the risk characterization calculation.

The exposure scenarios cover all identified uses (use groups) of the substance (ECHA 2009). The exposure scenarios are attached to safety data sheets, which the consumers receive with the first supply of the chemical. The content of the exposure scenarios should also be implemented for downstream users of chemicals similar to the safety data sheets' content. Many companies do not attach the exposure scenarios to the safety data sheet or they attach exposure scenarios for all uses of a chemical, and not just the specific uses of their supplier, by creating a safety data book with more than 100 pages instead of safety data sheets. Misinterpreted and poorly implemented exposure scenarios cause many problems in the EU.

After the exposure data are collected, the third step in the CSA process is the risk characterization. For the risk characterization, the levels of exposure (company data) are compared with threshold levels (DNEL and PNEC limits) for each health effect of possible concern, as illustrated below in Fig. 4. (ECHA 2009).

[20] https://chesar.echa.europa.eu/

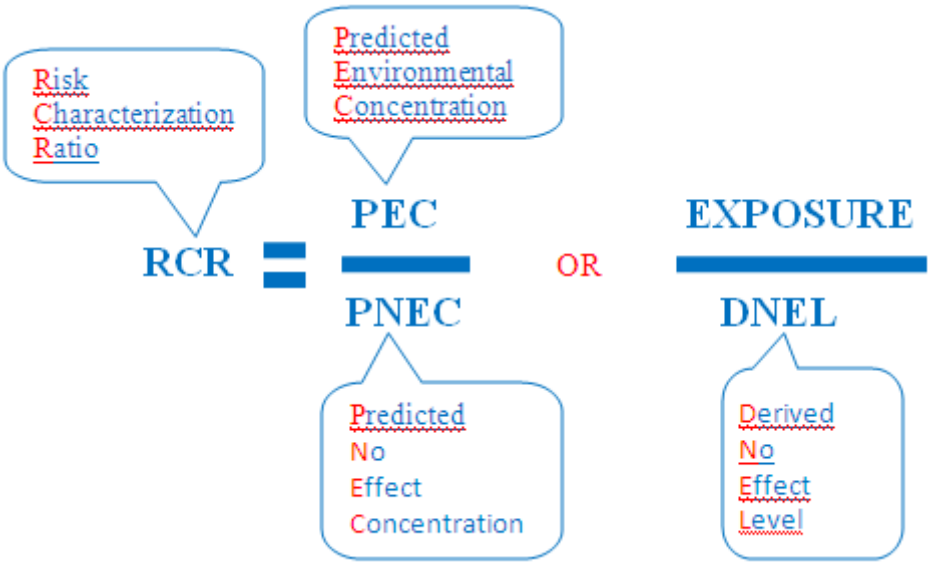


Fig. 4. RCR calculation

"Risks are regarded as controlled under REACH when the exposure levels to the substance are below the threshold levels, both for humans and for the environment" (ECHA 2009,6). This means that, in practice, risk is controlled if RCR is less than 1 (RCR < 1) (ECHA 2009,5). The Chesar tool was specially designed in the EU to provide a user-friendly risk assessment tool, even for relatively inexperienced risk assessors. It is synchronized with the IUCLID tool, so hazard assessment can be completed with a few clicks.

If risks are under control and the risk characterization ratio is less than 1(RCR < 1) for each use, the CSA ends here because safety has been achieved. If risks are not under control (RCR>1), then the CSA must be repeated under different conditions of manufacturing or use, or making more precise exposure estimations. The process is iterative and continues until the risks are under control (RCR < 1) (ECHA 2009, 6). The Chesar tool is recommended for doing these iterations. As illustrated below on Fig. 5, the Chesar tool uses a green check to show that the risk is under control (RCR < 1), and a red sign if it needs more iteration by changing the conditions of use.

Summary of assessments for the contributing scenario

	Assessment	Exposure	RCR
Freshwater	EUSES	17.84 mg/L	178.4
Sediment (freshwater)	EUSES	2.7E4 mg/kg dw	N/A
Marine water	EUSES	1.784 mg/L	178.4
Sediment (marine water)	EUSES	2.7E3 mg/kg dw	2.7E5
Predator (freshwater)	EUSES	1.936E3 mg/kg ww	N/A
Predator (marine water)	EUSES	193.6 mg/kg ww	N/A
Top predator (marine water)	EUSES	78.83 mg/kg ww	N/A
Sewage treatment plant	EUSES	182.4 mg/L	18.24
Air	EUSES	0.012 mg/m³	N/A
Agricultural soil	EUSES	1.241E4 mg/kg dw	1.241E5
Predator (terrestrial)	EUSES	1.166E4 mg/kg ww	N/A
Man via Environment - Inhalation	EUSES	0.012 mg/m³	0.283
Man via Environment - Oral	EUSES	100.7 mg/kg bw/day	4.027E3

Fig. 5. RCR calculation with Chesar tool

If risks are under control and the risk characterization ratio is less than 1 (RCR < 1) for each use, the CSA ends and the registrant should incorporate the results into the safety data sheets and the exposure scenarios used for communications purposes. Manufacturers and downstream users are expected to implement the content of the safety data sheets and the exposure scenarios, since they contain the risk management measures (e.g., changes to health and safety systems and processes) that are sufficient to accomplish safety.

4.2. REACH Restriction

In theory, the REACH registration process should accomplish safety without any need for additional government oversight. However, the REACH regulation provides two avenues for direct "command and control" regulation of chemicals, authorization and restrictions, if the industry-led registration process is not considered adequate by EU authorities (Bergkamp and Herbatschek 2013). If the chemical is classified by the EU as a "substance of very high concern" (SVHC), use of that chemical is permitted only if the industry receives a specific authorization. The authorization process is designed to stimulate industry to substitute SVHCs with safer (replacement) substances or processes. Alternatively, the EU may enact specific restrictions on a chemical that are usually framed on a use-by-use basis. Restrictions

are generally binding requirements that constrain whether a chemical may be manufactured and, if so, for what uses and with specific risk-management measures.

The main difference between restricted chemicals and authorized chemicals in the EU is that the restricted chemicals may be used for every use except for those uses that have been restricted (e.g., the use of some chemicals in children toys has been restricted in the EU), while the authorized chemicals (SVHC) may not be used at all in the EU (banned chemicals) unless industry obtains a specific permit for a special use and develops a plan for chemical substitution.

The EU restriction process focuses on the worrisome uses of chemicals rather than the substances themselves. Any substance, mixture, or articles containing chemicals may be subject to restrictions under REACH, and such restrictions may apply to all manufacturers, importers, downstream users, and distributors of a substance. Currently, there are more than 1,000 restricted substances (cadmium in all jewelry products, plastics, and brazing sticks, asbestos, oil and tar derivatives, CMR) (Abelkop *et al*. 2012).

The burden of proof for restriction lays upon the European Commission and/or EU member states. There are two reasons why the restrictions authority was retained. First, is that REACH authorization procedure does not necessarily protect people in the EU from substances in imported articles. Secondly, the safety measures in individual registration dossiers may not ensure adequate safety from multiple exposures to the same chemical from different uses and exposure to multiple chemicals (Abelkop *et al*. 2012).

4.3. REACH authorization (prohibitions)

The goal of the REACH authorization process is to protect public health and the environment by substituting SVHC (e.g., CMR, a PBT, a vPvB an endocrine disruptor) with suitable, safer alternatives. The European Commission is responsible for posting the SVHC to 'the Authorization List', while the industry must apply for authorization of a SVHC. The European Commission may provide an authorization permit for specific uses. If no permit is granted, the SVHC is phased out of production and the marketplace after a 'sunset date' unless a formal authorization has been sought by a registrant from ECHA and approved by the Commission (Abelkop *et al*. 2012).

The REACH regulation allows the following methods of authorization: The first one is for threshold substances the adequate control route and the second one is for non-threshold substances, or for threshold substances where adequate control cannot be accomplished.

The detailed steps in the authorization process are illustrated below in the Fig. 6. (REACHReady 2014, 4).

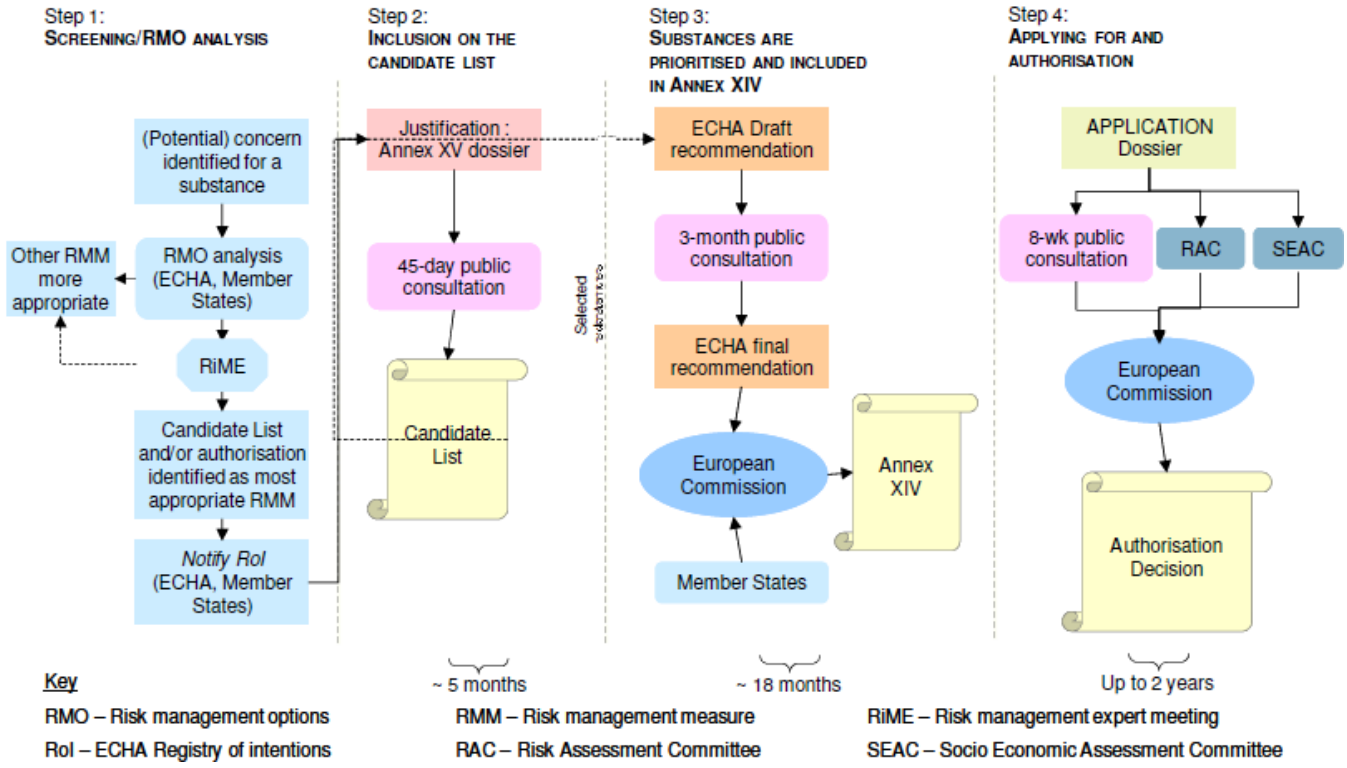


Fig. 6. REACH authorization process (REACHReady 2014, 4)

Currently the candidate list[21] contains 161 substances, which means that the substances are 'candidates' to be placed on the formal Authorization List.[22] First, the ECHA conducts a public consultation and discussion with the Member State Committee, then refers their findings to the European Commission, which makes the final deliberations about the Authorization List (Abelkop *et al.* 2012). ECHA is responsible for drafting a proposed recommendation for the authorization list through the prioritization process (See Table 6). The *Prioritization Score of EU Authorization* is comprised of a quantitative scoring methods in addition to a verbal-argumentative approach (ECHA 2010).

[21] Candidate list: http://echa.europa.eu/hu/candidate-list-table

[22] Authorization list: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

Table 6. Prioritization Score of EU Authorization

Inherent properties		Volume		Wide dispersive use	
57(a) or/and 57(b) or/and 57(c) or/and 57(f) [13,14]	1	no volume	0	no use	0
57(f) (ED)	7	< 10 t/y	3	IND	5
57(d) or 57(e)	13	10 – <100 t/y	6	PROF	10
57(d) and (at least) one other SVHC property or 57(e) and (at least) one other SVHC property	15	100 – <1,000 t/y	9	CONS	15
		1,000 – <10,000 t/y	12		
		≥ 10,000 t/y	15		

Score Total = Score Inherent properties[23] + Score Volume + Score Wide dispersive use

Prioritization is performed by ECHA on a substance-specific basis and is normally given to substances with wide dispersive use or high volumes, or substances with the following properties: CLP carcinogenicity category 1A or 1B, CLP germ cell mutagenicity category 1A or 1B, CLP reproductive toxicity category 1A or 1B, endocrine disrupter, PBT persistent, bioaccumulative and toxic, and vPvB very persistent and very bioaccumulative. The higher the total score, the higher the chance the candidate will be put on the authorization list (ECHA 2010).

The information used in the priority setting process is drawn mainly from the Annex XV registration dossiers from industry, comments from the public consultation process, suggestions from experts in the Member States, and data collected by ECHA staff and ECHA consultants. Data contained in the registration dossiers prepared by the industry is also considered. If a candidate list substance is not recommended for the authorization list in one year, it is reassessed the next year along with the other substances on the Candidate List, and may be included as a high priority substance for authorization in future years. The public is available to give comments to the draft recommendations (ECHA 2010).

[23] 57 (a) CLP carcinogenicity category 1A or 1B
57 (b) CLP germ cell mutagenicity category 1A or 1B
57 (c) CLP reproductive toxicity category 1A or 1B
57 (f) endocrine disrupter
57 (d) PBT persistent, bioaccumulative and toxic
57 (e) vPvB very persistent and very bioaccumulative

The Authorization List currently contains a total of 31 substances.[24] The REACH authorization process facilitates the introduction of acceptable substitutes without disrupting the use of SVHCs when risks are adequately controlled or when the benefits outweigh the risks. Since a stigma exists on chemicals listed under the REACH authorization process, companies are unlikely to seek authorization in lieu of substitution. Even if the benefit of the chemical is greater than the risk, most companies will choose to eliminate the substance from the EU market. This is the result of either of their own volition, or due to customer aversion to SVHC substances. Removing risky substances from the market is of great benefit to safety if higher-risk substances are replaced by lower-risk substances (Abelkop *et al* 2012).

[24] European Chemicals Agency, Authorization List, available at http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp.

4.4. Safety standards, restrictions, and prohibitions in the USA

Safety assessments, safety standards, risk threshold, risk assessments, and risk characterization describe the conditions under which the manufacturing and use of a substance is considered to be safe. The safety assessment should be prepared after the EPA has chosen which chemicals have a high priority for completing a safety assessment. The safety assessment can be risk based or hazard based. The USA have chosen a risk-based determination. Risk is determined as a function of a chemical's intrinsic hazard, its use, and expected levels of exposure (CIEL 2014). This chapter will show how the USA determines whether a chemical is safe from a manufacturing and use point of view.

4.4.1. Safety standards, restrictions, and prohibitions in TSCA

TSCA allows chemicals to remain in US commerce and use until the EPA promulgates a rule and publishes findings that a chemical presents or will present an 'unreasonable risk' of injury to human health or the environment (CRS 2013). An 'unreasonable risk' determination requires consideration of both risks and benefits (positive and negative benefits) (Uyesato et al. 2013). If the EPA demonstrates that a risk associated with a chemical is unreasonable, the Agency is required to initiate rulemaking. However, rulemaking is required only to the extent necessary to reduce that risk to a 'reasonable' level and EPA must take the regulatory approach that is 'least burdensome' to industry.

EPA officials believe that demonstrating an unreasonable risk is a more stringent requirement than demonstrating, for example, a significant risk, and that a finding of an unreasonable risk requires an extensive cost-benefit analysis (GAO 2009). The EPA must also demonstrate unreasonable risk from each use they seek to ban in order to withstand judicial review, given the Corrosion Proof Fittings case.

In the Corrosion Proof Fittings case, the EPA collected some data in an attempt to ban asbestos industry-wide, but the asbestos manufacturers (represented by Corrosion Proof), sued the EPA on the grounds their rulemaking procedure was flawed, and that they did not use the least burdensome regulatory approach. The EPA wanted to ban all asbestos, not just banning it for dangerous use or simply labeling asbestos products. The EPA argued that asbestos presents an unreasonable risk, and that they chose the least burdensome regulations required to adequately protect against the risk. The Court found that the EPA was required to collect data not only on the negative effect of asbestos (tiny fibers of asbestos can become trapped in

the lungs and stay there for many years causing difficulty breathing and lung cancer (Webmed n.d.), but also on the positive effects (lives would be saved by using fire-retardant asbestos as an insulator). Hence, the Court overturned the EPA's ban (Corrosion n.d.). The Court found that the EPA did not quantifiably calculate the long term health benefits of banning asbestos. So, the burden on proof was on EPA to find the least burdensome alternative for potential substitutes (Lynn 2015). The Court also ruled that the EPA must analyze asbestos on a use-by-use basis, rather than simply ban all uses of asbestos because the substance is hazardous.

From this Corrosion Proof Fittings example it can be seen that the current TSCA 'safety standard' or 'risk threshold' for chemical regulation is too stringent (Uyesato *et al.* 2013). In order to regulate alchemical the EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment, which is too cumbersome for the EPA to implement. "Public confidence in TSCA has weakened since 1976, EPA has issued regulations to control only five existing chemicals determined to present an unreasonable risk" (GAO 2009, 2). This is too few, and was one of the primary concerns for TSCA reform.

Two interviewees mentioned that the weakest point of TSCA is risk management and risk assessment, since "it is really difficult to require testing in the current law, and difficult to manage risks," and "the quantitative risk assessment concept is missing from TSCA, and very much limited for the government to define what are the acceptable levels. (pers. comm)" Some interviewees said that the weakest point of REACH is that "the burden of proving safety shifted from government to industry" since ECHA found in the compliance check that chemical industry quite often submitted very low quality data (CIEL 2014). Another said just the opposite that "the weakest point of TSCA is that the burden of proof to prove safety is on the government. (pers. comm)"

Now, I consider how the different stakeholders believe that new safety assessment rules should be incorporated into the TSCA reform bills.

The EPA issued a TSCA reform principle where the first and third points cover safety standards. They state that the EPA should have clear authority to establish safety standards that are based on scientific risk assessments and to take risk management actions when chemicals do not meet the safety standard. Sound science and risk-based criteria should be the basis for the assessment of chemical risks (EPA 2015 a).

The EPA deputy director of the Office of Pollution Prevention and Toxics, Jeff Morris, said that, given current resources at EPA, seven risk assessments are possible in one year (EPA n.d.). In the S. 697 TSCA reform bill, the goal is to complete safety assessments for at least 25 high-priority substances in five years, which is perhaps calculated based on EPA effectiveness' numbers (7/y). In the previous chapter, it was shown that in the EU the industry made risk assessments for thousands of chemicals in the REACH registration dossiers over a five-year period. The question is why there is such a large difference between the risk assessment production in the EU and US.

As stated in the introduction, before REACH came into effect the burden of preparing risk assessment was on the EU authority. The EU authority was able to produce comprehensive risk assessments for nine chemicals per year[25] (Hansen and Penman 2013, 377). The low rate of production was seen to reflect a lack of commitment as well as a lack of resources.

REACH shifted the burden of producing risk assessments from government to industry, hoping that industry would be more productive than government. It has proven to be a good solution in the EU from an environmental health and safety point of view because the industry has made more progress than EU authorities were making prior to REACH.

Another possible explanation, which I explore below, is that the content of a risk assessment in the US is more complex than the content of a risk assessment in the EU. Later in the dissertation, I provide evidence to support this hypothesis, and suggest ways that risk assessment in the US might be simplified.

Through TSCA reform, the industry favors enactment of a new or revised safety standard that gives the public more confidence that public health and the environment are being protected (SOCMA 2014). The industry also favors shorter deadlines (maximum 18-24 months) for completion of chemical assessments. In the USA, 400 chemicals were waiting at least ten years for initial or updated risk assessments. Trichloroethylene's risk assessment alone was not completed for 22 years (CIEL 2014). Industry associations advocate for a clear separate between risk assessment and risk management. They also emphasize the use good science, since the quality of the risk assessment will depend on the quality of the science supporting it (SOCMA 2014).

Companies do not support a ban of a chemical when there are no technically and economically feasible alternatives that are safer than the existing chemical. During cost-benefit analysis the EPA should not identify economically feasible alternatives, rather EPA

[25] 138 comprehensive risk assessment report was prepared in 15 years

should choose from those alternatives recommended by commentators. The most important industry recommendation is that the TSCA reform bill should be fundamentally risk-based: it should require the EPA, before making a regulatory decision, to look at a chemical's inherent properties along with its potential uses and exposures.

Environmentalists in the US are not satisfied with typical risk assessments for three main reasons. First, quite often the risk assessment uses unreliable exposure information (e.g., due to inadequate data on production volume, chemical uses, exposure scenarios, and measurements of actual exposure). Secondly, typical risk assessments do not take into account cumulative or synergistic effects of chemicals, or their adverse impacts on highly vulnerable subpopulations (CIEL 2014). Third, risk assessments are prepared based on limited toxicity data. In the USA two-thirds of industry submissions for approval of new chemicals do not include test data on chemical hazards; 85% of submissions do not include data on human health effects. U.S. environmentalists are more sympathetic with REACH than industry is, as they see the European system as stricter, more precautionary, more realistic, and more protective of human health and the environment.

4.4.2. Safety standards, restrictions, and prohibitions in TSCA bipartisan reform bills

S. 1009 proposed that the TSCA establish safety standard, safety assessment, and safety determination definitions, which are new concepts compared TSCA. Safety standard contains "unreasonable risk of harm to human health or the environment" term. The safety assessment means a risk-based assessment and mention margin of exposure (MOE) as a reference parameter.

S. 1009 would allow the continued manufacture and use of a chemical until the EPA identified it as high priority, determined that it did not meet the safety standard for the intended conditions of use, and established restrictions or a ban. The EPA conducts a risk-based safety assessment of each high-priority substance by a scheduled deadline, which is subject to public comments. Low-risk substances are not subject to safety assessment. The safety assessment is conducted with a science-based methodology and evaluates hazards, use, and exposure information including an evaluation of possible adverse impacts on vulnerable subpopulations (e.g., children). The safety assessment is focused solely on risk to human health and the environment. After the safety assessment, the Administrator prepares the safety determination using the best available science, as to whether a chemical substance meets the safety standard under the intended conditions of use or, alternatively, informs the industry that

additional information is necessary to make a safety determination. The public can also comment at this stage of the determination process. If the results of the safety determination indicate that a problem exists, requirements for risk management of the high-priority substance can be established.

To ban or phase out a chemical, the EPA would first have to consider and publish a statement discussing the feasible alternatives and their relative risks, and the economic and social costs and benefits. The safety determination, as a final agency action, is subject to judicial review, including review of the associated safety assessment. However, the company suing the EPA would have to prove that the EPA was acting in violation of the statute or in violation of some procedure from the new statute or the administrative procedure act. EPA is no longer required to adopt the least burdensome approach.

S. 697 proposed that TSCA establish safety standard, safety assessment, and safety determination definitions similar to S. 1009, but two terms are slightly modified. The term susceptible population is added to the safety standard, whereas in S.1009 it is mentioned only with regard to safety assessment. And technical parameters such as "margin of exposure" (MOE) are deleted. I explain later in the dissertation why MOE is important in the U.S. risk assessment process.

There is substantial opposition to the "unreasonable risk" standard, especially among experts with a progressive, pro-regulation point of view. For example, 25 legal experts expressed serious reservations about the safety standard term in S. 697 (Ashford et al. 2015).According to these experts, the main issue is that this new safety standard term still uses the 'unreasonable risk' term, without defining the precise meaning of 'unreasonable risk.' In the current TSCA, 'unreasonable risk' is connected to cost-benefit analysis (according to Corrosion Proof Fittings). "The ambiguity in this definition will likely result in costly and extensive litigation, delaying further EPA action to protect people and the environment from hazardous chemicals. (…) Using a 'reasonable certainty of no harm' health-protective safety standard would better protect the public health and eliminate any confusion as to whether EPA must weigh the health benefits of determining that a chemical is unsafe against the costs" (Ashford *et al.* 2015, 2). Instead of unreasonable risk, some experts favor use of the narrative standard 'reasonable certainty of no harm,' which is used to some extent in US law governing pesticides. This stance is common among U.S. environmentalists (Cook 2015) and some states (Boxer-Markey bill).

Other experts oppose use of the standard "reasonable certainty of no harm" because it does not allow for consideration of the benefits of chemicals. For example, this standard

might not permit continues use of dichlorodiphenyltrichloroethane **(**DDT) to combat malaria, since the benefits of DDT use in this application are much greater than the risks.

S.697 requires that the EPA restrict any high-priority chemical that does not meet the safety standard. It would replace the requirement for the identification of the 'least burdensome' approach in the evaluation of alternatives that are deemed relevant and feasible (Lynn 2015).[).]

States have also expressed a deep concern regarding the safety assessments' long timeline and evaluating process: "S. 697 would provide EPA with up to three years to conduct its safety assessment, with two more years allowed to promulgate a final regulation, and up to an additional two years to extend the rulemaking process before it is final, the bill allows for up to seven years, plus an additional period of time allowed for the regulated entity to come into compliance (Massachusetts 2015)"

House bill-2015 does not establish a safety standard, safety assessment, and safety determination term. Instead, it contains a risk evaluation term: "The Administrator shall conduct risk evaluations… to determine whether or not a chemical substance presents or will present…, an unreasonable risk of injury to health or the environment" This term is very similar to current TSCA, but the bill changes that definition by excluding 'cost' considerations from risk evaluation and deleting the 'least burdensome' language from the restrictions power. Those changes focus the evaluation entirely on risks to environment, health, and safety. In this House bill, the risk evaluation can be initiated in two ways for existing chemicals. Firstly, the EPA conducts the risk evaluation based on justified findings and, secondly, the chemical manufacturer requests the EPA to conduct a risk evaluation for a particular chemical substance without any current findings. In this second case, a manufacturer can offer to pay the cost of an evaluation, which should help with EPA resource constraints, provide additional data, and increase the throughput of chemical evaluations. (SOCMA 2015) According to the EPA (Jones 2015), this second case "likely lead EPA focusing the majority of its limited risk evaluation resources on completing evaluations for chemical substances requested by industry", rather than for the chemicals with the most potential for risk.

Environmentalists do not oppose the idea of industry-initiated risk assessments, since the chemicals are held to the same standard of safety" (Igrejas 2015) However, limits are advocated on the number of industry-initiated assessments, and a minimum schedule for EPA-initiated evaluations is recommended.

Californian Senator Barbara Boxer released stricter health and environmental recommendations for S.1009 not just about the state preemption part, but about other issues as

well (CW 2014). The first recommendation was that to control chemical risks takes too much time. As a solution, Boxer suggested having a specific time limit for conducting safety assessments and to have additional funding provided. The second change she recommended was to tighten the safety standard definition of S.1009. She suggests deleting the ‘unreasonable risk’ term and instead recommends 'reasonable certainty' that a substance will do no harm. What is the problem with the ‘unreasonable risk’ definition from an environment health and safety point of view? As previously mentioned, an 'unreasonable risk' determination requires consideration of both risks and benefits (Uyesato *et al.* 2013) in the current US understanding. If the EPA demonstrates that a risk associated with a chemical is unreasonable the Agency is required to initiate rulemaking, but only to the extent necessary to reduce that risk to a 'reasonable' level, and they must take 'the least burdensome' regulatory approach. “EPA officials believe that demonstrating an unreasonable risk is a more stringent requirement than demonstrating a significant risk” (GAO 2009, 9). Specifically, the process of establishing a significant risk, versus that of finding an unreasonable risk, requires an extensive cost-benefit analysis. The EPA must also demonstrate significant risk from each use they sought to ban in the rulemaking record in order to withstand judicial review, similar to the Corrosion Proof Fittings case.

In S. 1009, safety standard means “a standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance.” Boxer’s safety standard definition means “a standard that ensures with reasonable certainty, without taking into consideration cost or other non-risk factors, that no harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably foreseeable conditions of use, including no harm to general population or to any potentially exposed or susceptible subpopulation that the Administrator has identified as relevant to the safety assessment and determination for a chemical substance” Boxer not only took out the unreasonable risk term which was so hard for the EPA to demonstrate, but she also took out the cost-benefit part. Instead of no risk needed to demonstrate that no harm, and not just for the general population but for the susceptible subpopulation as well. Basically, she recommends a risk and hazard-based assessment over a risk based assessment. Boxer would like to lead TSCA to Californian stricter direction.

California Senator Barbara Boxer (D-CA) released a counter-proposal bill to S. 697, together with Ed Markey (D-MA) on the 12th of March, 2015. This bill is called S.725 - Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, or shortly the Boxer-Markey -

2015 bill. It is not a bipartisan bill and hence it has a small chance of becoming law, but it has a chance to influence the wording of the final TSCA bill. The Boxer-Markey-2015 bill declares there will be no preemption of state chemical laws, which means it would allow states to enforce federal restrictions on chemicals, and does not allow the EPA to preempt state authority.

According to Barbara Boxer's summary report, the S. 725 bill better protects public health than S. 697 in 11 points. One of the differences is that the Boxer-Markey-2015 bill requires the EPA to review more chemicals more quickly. She suggested to start evaluating 75 chemicals (instead of 25 in S. 697) within five years, and S. 725 will require expedited safety reviews of asbestos and chemicals that persist in the environment and build up in human bodies (Boxer 2015 a).

The second change she recommended was the tightening of the safety standard definition of S. 697. She suggested deleting the 'unreasonable risk' term, and instead of it recommended 'reasonable certainty' that a substance will do no harm to human health and the environment. The safety standard term of S. 725 is exactly the same as what she recommended in the Boxer bill in 2013 (See above). Since it is not a bipartisan bill it will not be analyzed more thoroughly in this dissertation. However, it is clear from this bill that she would like to lead TSCA to Californian stricter direction.

In conclusion, the proposed TSCA reform bills try to solve many requests of the industry, the environmentalists, and the authority related to safety determination issues (cost-benefit and least burdensome issues), but there are many unresolved topics in TSCA reform. It is also interesting to see that, in 2015, an industry-initiated risk assessment process is included in order to increase productivity of risk assessment. Industry and environmentalists both support this idea, so the burden on the authority can be decreased. Although this reform is modest, one can argue that it draws from the favorable experiences with industry-led risk assessment under REACH.

Crucial differences between US and EU safety-determination processes have been documented. For example, in REACH the Chemical Safety Assessment is not made available for the public; only the industry and the ECHA can see it. In the USA the safety assessment and the safety determination can be commented on by the public, which makes the whole process very transparent.

While in REACH the industry prepares CSR for all hazardous substances over 10 t/y in a very effective way (thousands of risk assessments were prepared in the last few years), TSCA reform bills require a safety assessment just for about 25 high-priority existing substances, which are prepared by the authority. In the USA the restriction and ban are part of safety determination, while in REACH it is in two steps. The first step is completed by the industry through CSR in the REACH registration, and the second step is conducted by the authority through the restriction and authorization processes. Through this process ECHA/Commission will prepare their own risk assessments or rather call it risk prioritisation to support restrictions/listings, and the industry prepared – registration dossiers / risk assessments are only one source of this information, public consultation and dialogue with Member State Committee is part of the restriction and ban process as well.

The open question is the same whether the EPA will require or collect enough good quality input data for safety assessments, or whether they would make the same mistake as REACH, where the industry tried to prepare numerous dossiers with poor quality data and the authority had to ask the industry to up-date many dossiers.

5. SAFETY ASSESSMENTS IN THE USA CURRENT PRACTICE

5.1. Overview

Throughout this chapter, the terms risk assessment and safety assessment are used interchangeably, the former often used in the EU and the latter often used in the USA. This chapter covers current risk assessment practices used by US EPA for new and existing chemicals. The US practices will be compared to REACH risk assessment practices to establish similarities and differences. The question of why the pace of US risk assessment preparation is so slow will be explored, including steps that might accelerate the throughput.

In the US the regulatory programs for new and existing chemicals differ in important ways. EPA's new chemicals program, as outlined in the Pollution Prevention (P2) Framework manual (P2 2012), has very specific boundaries placed on it by the TSCA statute, such as the limited time frame for EPA assessments and no upfront testing requirements. Over 1000 new chemicals are submitted each year to the EPA under the new chemicals program, although many of them are often dropped before going to full manufacture. In almost all cases, the risk-related deliberations about new chemicals are treated as confidential business information, since information in a risk assessment can allow one manufacturer or processor to learn about the innovative plans of a competitor. As a result, the public rarely sees the results of the new chemicals screening risk assessments based on P2 framework (pers. comm). EPA typically has to make a decision on new chemicals in less than 90 days. Thus, the EPA has a significant workload that must be prioritized using the screening level risk assessment methods. A screening-level assessment is defined as one that is performed at an early stage, where information on the chemical is limited and the assessment is completed by making plausible (yet unverified) assumptions based on information about similar chemicals.

The EPA also manages the 'existing' chemicals program, which focuses on a relatively small number of chemicals selected by EPA management (e.g., the 83 chemicals highlight in EPA's TSCA Work Plan for existing chemicals). An EPA risk assessment for an existing chemical does not proceed without extensive problem formulation steps, and then a comprehensive approach is typically taken with respect to all hazard and risk scenarios using combinations of measured data, modeling exercises, and toxicological assumptions. In some cases, existing risk assessments are complicated with findings from epidemiological findings that need to be reconciled with toxicological studies. There may also be complex studies of the chemical's pharmacokinetics (behavior in the body) and pharmacodynamics (biological mechanisms of disease causation) that are available that need to be incorporated into dose-

response relationships and risk characterizations. These assessments take years to complete, are very extensive, and employ more complicated risk assessment approaches than are used for new chemicals. EPA's risk assessment document for trichloroethylene (TCE), reviewed below, illustrates some of the complexities of risk assessments undertaken for EPA's existing chemicals program (pers. comm).

5.2. New chemicals quantitative risk assessment calculation in the USA

The EPA's Pollution Prevention (P2) Framework Manual (P2-2012) contains the methods used to screen new chemicals in the absence of data, including details about the risk assessment calculations. This screening method has not been formally released by the EPA, but the method was suggested to me by US risk assessors.

There are two kinds of risk assessments in both the USA and the EU: the human health risk assessment[26] and the environmental/aquatic risk assessment. Both risk assessments contain three major steps: hazard (toxicity) identification, exposure assessment, and risk characterization (RA n.d). Each step is defined and described below.

5.2.1. Non-cancer human health quantitative risk assessment calculation in the USA

Toxicologists in both the US and Europe generally believe that there are safe doses to industrial chemicals that are defined by thresholds in the dose-response function, the curve relating magnitude of dose to probability and severity of disease. The threshold dose is sufficiently small that it is assumed that no adverse effects will occur, even among sensitive subpopulations. In the USA, the concept of threshold dose is used to inform a Margin of Exposure (MOE) calculation. S. 1009 bill-2013 mentioned the MOE in the safety assessment definition, while the other two bills from 2015 were silent about it, which means that EPA has discretion to use it in the future. REACH risk assessments, as we shall see, use the concept of threshold dose but do not present results of MOE calculations.

The first step is the hazard (toxicity) identification, which entails identifying potential toxicity/hazard and the corresponding dose levels that trigger adverse effects (NOAEL or

[26] I do not address human health risk assessment for chemical carcinogens because they represent a small fraction of the total chemicals of interest and they may require consideration of advanced, nonthreshold models of risk assessment that are beyond the scope of this dissertation.

LOAEL[27]). Quantitative hazard assessment can be performed if toxicity studies (mainly from animal studies or read-across, QSAR data) provide NOAEL (preferred) or LOAEL values for the chemical of concern (the target chemical). If there is no data for the target chemical, data are used from similar, analog chemicals. Thus, the case of no data is not treated as equivalent to the case of negative data, which indicates low toxicity (P2-2012). Hazard determinations are always based on scientific judgment, at least to some degree. For instance, if conflicting data exist, a weight-of-evidence approach is used by scientists to support conclusions about hazard identification.

The general conclusion of an EPA assessment regarding hazard/toxicity levels, as indicated below, is assignment to one of three concern levels: low, medium, and high.

Table 7. EPA hazard concerns at human health screening risk assessment (P2-2012)

Hazard Concern	Definition Based on Experimental Data
Low	No basis for concern identified or systemic toxicity with NOAEL > 1000 mg/kg/day; only minor clinical signs of toxicity; liver and/or kidney weight increase or clinical chemistry changes with LOAEL ≥ 500 mg/kg/day
Moderate	Suggestive animal studies for chemical or analog(s) or chemical class known to produce toxicity or organ pathology (gross and/or microscopic) with LOAEL < 500 mg/kg/day; clinical chemistry changes and organ weight changes at < 500 mg/kg/day; NOAEL < 1000 mg/kg/day
High	Evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies. Death, organ pathology (microscopic) at LOAEL ≤ 100 mg/kg/day; multiple organ toxicity; NOAEL ≤ 10 mg/kg/day.

REACH does not employ a three-level hazard class (low, moderate, high) and instead proceeds directly to a concrete DNEL,[28] a threshold limit value for human health hazard risk assessment (see Chapter 3). The more nuanced approach to toxicity concern in the US may reflect the fact that the risk-management process is more discretionary in the US than in Europe. If risk management is highly prescriptive as it is under REACH, there may be less utility in producing a nuanced toxicity assessment with several levels of toxicity concern.

The second step of risk assessment is the exposure assessment. The EPA determines exposure doses for workers (occupational exposure) with ChemSTEER software and for consumers with E-FAST software (p2-2012). REACH recommends using Chesar software to

[27] NOAEL: No-observed-adverse –effect-level (animal tests) LOAEL: Lowest-observed-adverse-effect-level (animal tests)

[28] Derived no effect level (extrapolated to humans) threshold limit

determine both workers and consumer exposure doses (see Chapter 3). In both the US and Europe, the amount and quality of exposure information is highly variable and a source of significant scientific and regulatory concern.

The third step of risk assessment is the risk characterization which compares hazard/toxicity levels with exposure doses. In the USA a quantitative analysis is based on a Margin of Exposure (MOE) calculation (P2 2012); in the EU Risk Characterization (RCR) calculations are performed (see Chapter 3).

Margin of exposure (MOE) is "a ratio of the toxicity effect level to the estimated exposure dose" (P2 2012, 13-8). "The lower the MOE (margin between the toxicity effect level and the exposure dose), the more likely a chemical is to pose an unreasonable risk" (Ibid). In the EU, the RCR is the opposite. The lower the RCR, the less likely a chemical is to pose an unreasonable risk. Generally, MOE is toxicity/exposure while RCR is exposure/toxicity, which is why they are reversed, but both methods compare toxicity levels with exposure doses. The toxicological theory is the same but, since the US and EU use different conventions and software, the numerical results differ. S. 1009 suggests a MOE calculation in the definition of safety assessment, presumably because EPA has used MOEs in its risk assessments for many years.

5.2.2. Environmental risk assessment calculation in the USA

This part will show that the environmental quantitative risk assessment method of the US EPA is almost the same as what the EU is doing during REACH registration. This risk assessment contains three major steps similar to the EU: the first is hazard (toxicity) identification, which contains the development of a Standard Aquatic Toxicity Profile and Concentration of Concern (COC); the second is Exposure assessment, which calculates predicted (potential) environmental (surface water) exposure concentrations (PEC); and the third is risk characterization, which compares potential environmental concentrations to adverse-effect levels.

The first step is to collect data for a standard aquatic toxicity profile that includes acute and chronic endpoints for three species that are representative of the aquatic food chain: fish, crustacean (Daphnia spp. Invertebrates), and algae or other aquatic plants (green algae). In the USA analysts collect this information with ECOSAR software. (P2 2012) When there are no data available for an endpoint, ECOSAR can be used to fill data gaps. The EPA also

defines three concern levels for aquatic toxicity (low, moderate and high), as described below in Table 8.

Table 8. EPA hazard concerns at environmental screening risk assessment (P2-2012)

	Low concern	Moderate concern	High concern
Acute	> 100 mg/l	1 - 100 mg/l	< 1 mg/l
Chronic	> 10 mg/l	0.1 - 10 mg/l	< 0.1 mg/l

In the USA, exposure assessments are not done for chemicals with low hazard concern as they are assumed to have low potential for risk. The EU concern level for aquatic toxicity, based on CLP regulation,[29] is actually less strict for both aquatic acute and chronic toxicity (1 mg/l.) than the USA limits. Thus, it should not be assumed that REACH methods of safety assessment are always more protective than EPA methods.

The next part of the hazard assessment is to determine the Concentration of Concern (COC) value: the value at which harm to the aquatic environment is likely to occur if that concentration is exceeded. Usually an acute and a chronic COC are developed. The EPA uses an E-FAST model or ECOSAR model to calculate COC. In the EU, the Concentration of Concern (COC) value is named the PNEC[30] threshold limit. The USA calculates COCs in the same way the EU calculates PNEC: dividing the aquatic toxicity endpoints by assessment factors (Acute COC for fish = LC50/ Assessment factor).

The second step is to determine exposure concentration. In the USA EPA uses the E-FAST model, which calculates a Predicted Environmental Concentration (PEC) or 'Surface Water Concentration.' The PEC is the concentration of the chemical calculated to be in receiving waters and is determined using a simple stream flow dilution model (E-FAST). In the EU, the Chesar tool is used for calculating PEC, or it can be directly measured by a company.

The third step is risk characterization, which compares potential environmental concentrations to effect levels. The USA and EU have the same process for acute aquatic risk. The USA compares COC to the PEC, while the EU compares PNEC to the PEC.

In the EU a risk is adequately controlled if RCR is less than 1 (RCR<1), which means that the PEC data are less than PNEC, the threshold limit. In the USA, they use the same logic for acute aquatic risk, that is PEC should be smaller than the COC (limit value), or

[29] CLP regulation (amending) 286/2011/EU regulation Table 4.1.0

[30] PNEC: Predicted No Effect Concentration PNEC is the concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short term exposure

alternatively, a potential risk exists if the PEC is greater than the acute COC. However, in the USA they do not use the same logic for chronic aquatic risk as in the EU.

Chronic aquatic risk is evaluated through the E-FAST program by "determining the number of days per year the COC is exceeded" if the "COC is exceeded less than 20 days per year, the potential for chronic risk is low because organisms will not be exposed long enough for chronic effects to occur" (P2 2012, 13-5). It means in practice that if a PEC is greater than a chronic COC, but the COC is exceeded for only 1-19 day/year the exposure will not occur long enough to induce chronic aquatic risk and the use of the chemical is determined as safe (Ibid).

Overall, there is a high degree of similarity between the risk assessment practices employed in the US and Europe. In a sense, the differences in law and policy seem to be greater than the differences in technical practices of safety assessment.

5.3 TSCA Work Plan prioritization for existing substances

In bill S. 697, the initial list of high-priority substances is required to contain at least 10 high-priority substances, at least five of which are drawn from the list of substances identified by EPA in the agency's October 2014 TSCA Work Plan. The EPA may use this prioritization process or may modify it later on, which is why it is important to examine in the context of TSCA reform. Perhaps more importantly, the theory behind the scoring system in the 2014 Work Plan is somewhat similar to what ECHA used for prioritization of the candidate list of chemicals in REACH authorization, which was described in subchapter 3.2.1.

In March 2012, the EPA identified a work plan of 83 existing chemicals out of 1235for further assessment. Selection was based on "TSCA Work Plan Chemicals: Methods Document," which described a two-step process to identify and prioritize potential candidate chemicals for risk assessment (EPA 2012). The Step 1 selection was based on criteria such as use in children's products, detected in biomonitoring programs, potential for acting as a PBT, probable or known carcinogen, reproductive or developmental toxin, and neurotoxin. The data were obtained from both US and international databases.[31] After the first screening step,

[31] ***Carcinogenicity:*** IRIS: 1986 Class A, B1; 1996 Known or Probable; 1999 or 2005 Carcinogenic, IARC Carcinogens, Group 1, 2A, NTP Known Carcinogens ***PBT:*** TRI PBT Rule, Great Lakes Binational PBT, Canadian P, B, and T (all three criteria met), LRTAP POPS, Stockholm POPs ***Children's Health:*** IRIS: Repro/Dev (RfD or RfC for repro or dev), NTP CERHR: Infants Any Effect or Pregnant Women Any Effect , Cal Prop 65 Reproductive ***Neurotoxicity:*** IRIS , ***Children's Product Use:*** Reported in products intended for use by children in 2006 IUR, Washington State

345 chemicals remained as potential candidates and entered into the Step 2 scoring system, as illustrated in Fig. 7.

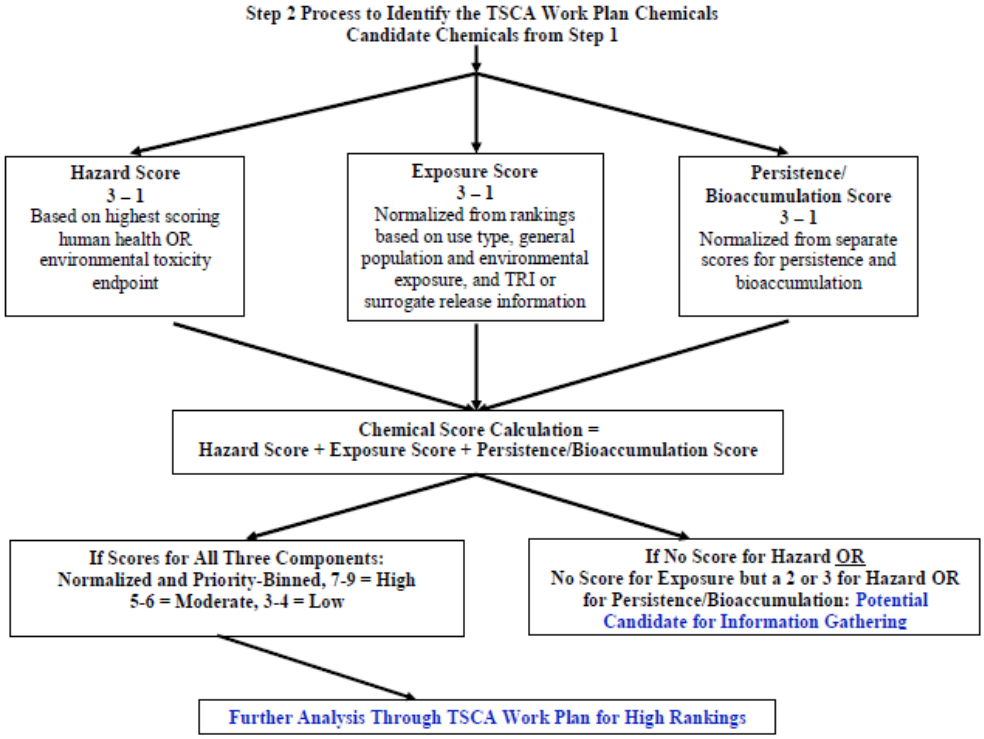


Fig. 7. TSCA Work Plan Chemicals: Scoring system to identify and prioritize potential candidate chemicals for risk assessment (EPA 2012)

The Hazard Score encompasses both human health and environmental toxicity concerns. The hazard criteria depend on acute mammalian toxicity, carcinogenity, mutagenicity/genotoxicity, reproductive toxicity, developmental toxicity, neurotoxicity, chronic toxicity, respiratory sensitization, acute aquatic toxicity, and chronic aquatic toxicity. The Hazard Score was determined based on three hazard levels, as each hazard level was assigned a corresponding hazard rating (High-3, Moderate-2, and Low-1). If no hazard data were available on a chemical to provide a hazard score, the chemical was placed in a 'Potential Candidates for Information Gathering' group (EPA 2012).

The Exposure Score normalized from the rankings based on use type, general population, environmental exposure, and Toxic Release Inventory data (TRI) or surrogate release information. The industrial use, consumer use, and commercial use are combined to develop a Use Type score for exposure evaluation (EPA 2012). If exposure data is not available on a chemical, thus no exposure score is established, the chemical is registered on a "'Potential Candidates for Information Gathering" list (EPA 2012).

Persistence scoring is calculated based upon the evaluation of the potential half-life data in air, water, soil, and sediment. Bioaccumulation scoring is calculated from the bioaccumulation / bioconcentration (BAF/BCF) data. If there is no persistence or bioaccumulation data, the EPA calculates it through a predictive model (EPA 2012).

The three scores were summed to obtain the Total Score. The overall ranking was determined by the Total Score. The high ranking chemicals (83) became potential candidate chemicals for risk assessment (EPA 2012, 29).

Identification of some chemicals as TSCA Work Plan Chemicals does not mean that the EPA would not consider other chemicals for risk assessment and potential risk management action under TSCA and other statutes. The risk assessment will contribute to the final decision as to whether the chemical presents an unreasonable risk to human health or the environment. The identification of these 83 chemicals early in the risk assessment review process would afford all interested parties the opportunity to bring additional relevant information on those chemicals to the Agency's attention.

The resulting risk assessments are resource-intensive analytic projects that require multiple EPA staff, contractors, and peer reviewers. Jeff Morris (EPA deputy director Office of Pollution Prevention and Toxics) has stated that seven risk assessments are possible in a year (EPA n.d.). Thus, in the USA, this prioritization process is the first step in the process that identifies and describes the conditions under which the manufacturing and use of an existing substance is considered to be safe. The second step is risk assessment, which will be covered in the next subchapter.

In the EU, similar steps are taken but the sequence is reversed and the industry takes the lead with risk assessment. First, the industry collects the necessary data and prepares a risk assessment (calculate, PNEC, DNEL, and RCR) and, based on those results and other information, the authority use a scoring system for determining which substances require regulation (authorization or restriction) as can be seen from Table 6. in subchapter 3.2.1.

5.4. Existing chemicals quantitative risk assessment calculation in the USA

After prioritization, those existing chemicals that were assigned a high score are scheduled for further risk assessment. The risk assessment identifies and describes the conditions under which the manufacturing and use of a substance is considered to be safe.

Why has EPA estimated that are only seven risk assessments are possible in one year? In the EU, the industry prepared thousands of risk assessments over several years as part of the REACH registration process. In this chapter it was shown that the EPA uses similar theories to the EU for risk assessments of new substances, and that they are able to make this screening level risk assessment, written in the P2 framework, for about one thousand of new chemicals per year. The human health and environmental risk assessment method for the US Work Plan prioritization method and US Pollution Prevention framework is very similar to the European one, sometimes even the same. So why is there such a large difference in the effectiveness of preparing a risk assessment for existing chemicals between the EU and USA? To answer this question, a completed real risk assessment prepared by the EPA, available on their homepage, was analyzed.

The TSCA Work Plan 2014 Chemical Risk Assessment of trichloroethylene (TCE) was examined (EPA 2014). TCE is the first chemical to complete the work plan risk assessment process under TSCA. It is 212 pages long and was prepared by 13 experts. The TCE risk assessment uses the hazard and dose response information published in the final toxicological review (EPA TCE 2011) that the US EPA's Integrated Risk Information System (IRIS) published in 2011. This Toxicological Review of TCE is 1200 pages (+ 1269 pages appendices), was prepared by 21 experts, and reviewed by 26 experts. Only very experienced and educated toxicologists are able to understand its details. One of the results of the risk assessment was that TCE is carcinogenic to humans by all routes of exposure, and has other hazardous properties as well.

What happened once the TCE risk assessment was completed? If risks are found in the risk assessment, the information is supposed to inform risk management strategies to reduce identified risks. However, it is impossible to find risk management strategies to reduce identified risks in the TCE risk assessment report, as risk management is a separate process at EPA. On the EPA homepage one can see that "A number of different options exist for mitigating risks from TCE, including transition to safer chemicals and greener processes/technologies, promotion of best practices, and phase out of uses. Implementing these approaches could involve regulatory action, voluntary approaches, or a mixture of both" (EPA TCE n.d., 1). It may take several years to prepare a risk management process for TCE, restrict it in some uses or phase it out entirely.

The Center for Progressive Reform found roughly 500 chemicals in the public IRIS database, with as many as 400 waiting for at least ten years for initial or updated chemical risk assessment. Environmentalists say that inevitable scientific uncertainties can be, and have

routinely been, manipulated to delay needed regulatory action, even in the face of substantial evidence of public harm (CIEL 2014). In the EU the TCE was registered in 2010 by five legal entities. It is also on the authorization list with a sunset date of April 21st, 2016, which means that the TCE may not be marketed in the European Union after this date, unless authorization for specific uses is granted by the European Commission. TCE is on the CLP harmonization list as a carcinogenic chemical, and it also has other hazards similar to what was found in the USA. Hence, the EU can regulate TCE quite quickly, in a few years, under the REACH process.

Looking at the process of TCE risk assessment and risk management, two issues become apparent from a policy convergence point of view. The first one is that risk assessment in the USA is deeply science-based. Consequently, a minimum of 60 very high-qualified and experienced experts participated in the preparation of the TCE risk assessment. The second one is that preparing a risk assessment takes years, yet the risk management part of the process is not completed and a ban or restriction has not yet been proposed or implemented.

Policy diffusion theories suggest that environmental policies are continuously evolving. According to Denison (2007), "it is evident that a strong government capability dedicated to chemical risk assessment and management is an essential element of any sound chemicals policy." The US industry would like the USA to demonstrate that a risk and science-based approach to chemicals management is a better alternative than REACH. The US industry would like to create, through TSCA reform, a gold standard in effective chemical management systems that would be a model for the rest of the world (ACC 2014).

The TCE risk assessment, prepared by 60 US scientists under current TSCA and multiple administrations of EPA, may be more scientific than the EU process. But, to train government officials to a level where they are able to produce such detailed risk assessments and toxicological reviews (more than 2000 pages) takes substantial time and money. Hence, the US system is a model for small, or even medium-sized, countries only if those countries train more scientists in the disciplines relevant to risk assessment (e.g., toxicology and environmental science/engineering), and only if countries find a way to accelerate the risk assessment preparation time.

Currently, REACH is much easier to be copied and implemented than TSCA and a reformed TSCA is still a somewhat unknown and untested system. In Europe, the industry collects the data and prepares the risk assessment with a Chesar tool, which is designed so that inexperienced risk assessors are able to learn it in one to two days. Then, the authority simply

has to evaluate the dossiers and set up requirements. The REACH guidance is clear and understandable, and practitioners can learn it by themselves. There is no need to train experts for years; in one or two weeks they are able to learn the basics; the rest of it is written in very detailed guidelines.

Until the US EPA is finished simplifying the existing chemicals risk assessment and risk management processes and is able to effectively restrict or phase out chemicals, their new legislation is unlikely to serve as a gold standard for other nations. Countries which lack deep toxicological expertise are more likely to adopt a REACH-like system, since it can be copied easier. None of the bipartisan TSCA reform bills are likely to solve these issues because they do not address the complexity of EPA's risk assessment processes. The TSCA reform processes of risk assessment are very similar to what the EPA is currently doing.

So why does the EPA insist on doing such a detailed risk assessment? Several interviewees mentioned that the EPA does not want to give up the responsibility by transferring it to the industry, as has occurred under the REACH registration process. Another possibility is that the findings of EPA risk assessments have ramifications in the US tort liability system, which causes EPA and industry to seek a high degree of confidence in the findings. The litigation process under common law is less of a concern in Europe than it is in the US.

Professor Lynn R. Goldman, in her March 18th written testimony, mentioned that Congress could set a faster pace for EPA to prioritize chemicals, to complete assessments and to manage chemical risks: "It is of critical importance that Congress make it clear that these assessments are not intended to be an academic exercise" (Lynn 2015, 7). Edward R.B. McCabe, Senior Vice President and Chief Medical Officer for the March of Dimes Foundation, mentions the same principle in his written testimony: "given that over 80,000 chemicals are currently in commerce across our nation, reform legislation must establish a sensible, practical framework for the appropriate prioritization and assessment of chemicals in a timely fashion. A system that allows for indefinite timeframes and evaluation of only small numbers of chemicals will fail to protect the health of pregnant woman and children" (McCabe 2015, 4). So a simplified risk assessment process for existing chemicals - perhaps in ways that are already being implemented by EPA for new chemicals- would be sufficient to accomplish a faster pace in the USA.

6. FEDERAL PREEMPTION OF STATE REGULATORY PROGRAMS

This chapter examines how another issue, the preemption question, is slowing the pace of TSCA reform. The question is whether, and in what ways, federal regulation of chemicals should take precedence over state and local regulations. The chapter has a focus on California's stricter regulatory system since California is one of the most active states in chemical regulation and has much at stake in the preemption debate.

6.1. State preemption debates in TSCA reform

In both the EU and in the USA, legislation has a legal hierarchical order. Usually lower level legislation cannot be written in opposition to upper level legislation. In Europe, the legal hierarchy between the EU's chemical legislation and the chemical legislation of member states are clearly established. However, in TSCA reform debate this topic has not been resolved, since there is controversy about whether EPA regulation should preempt the regulatory powers of the fifty states.

In the EU a 'regulation' is a legal act of the European Union that becomes immediately enforceable as law in all member states simultaneously. A 'regulation' does not need to be passed into national law by the Member States, although national laws may need to be changed to avoid conflicting with the regulation. A regulation is translated into all EU languages word for word at the moment it is issued. Regulations should be distinguished from 'directives,' which need to be transposed into national law to become effective. Significantly, a 'directive' specifies the result to be achieved: it is up to the Member States individually to decide how this is done (EC 2012). REACH is issued as a 'regulation' and not as a 'directive,' which is why the preemption issue is resolved.

According to the US Constitution, there are certain areas the state has the right to regulate and certain areas the state does not have the right to regulate. One of the areas where the states have the right to regulate is the environment, unless the U.S. Congress enacts legislation that explicitly restricts the right of the state to regulate. Federal environmental laws vary in how this issue is resolved (pers. comm.).

TSCA Section 18 does not completely preempt state law regarding chemicals (CRS 2013), which means TSCA does not fully restrict the right of states or local governments to regulate chemical risks governed by TSCA (Uyesato et al. 2013). There are two important exceptions as to when the EPA actions may restrict the right of states to regulate. The first is

if the EPA issues a rule requiring testing of a chemical. In that case, no state may require testing of the same substance for similar purposes. The second exception is if the EPA issues a rule or order regulating the manufacture or use of a chemical. In the case, state and local rules are also prohibited unless they are the same as the EPA's regulation, carry out another Federal law, or ban the use of that chemical entirely. The EPA may allow any state or local regulation if it is consistent with TSCA actions, affords a higher degree of protection than EPA actions, and does not unduly burden interstate commerce. Due to these two broad and important exceptions, EPA does have some authority under current TSCA to preempt state laws and regulations that conflict with federal regulations, although this provision has not been widely applied (EPW n.d.). It is not widely applied in part because EPA has issued few chemical regulations under TSCA.

Most states do not enact their own chemical regulatory programs and instead defer to the regulatory leadership of the EPA under TSCA and other federal environmental laws. In recent years, however, four out of 50 states (California, Maine, Minnesota, and Washington) have enacted and begun to implement their own chemical regulatory programs (EPW n.d.). Industry fears the growing state regulatory activism, in part because companies doing business in multiple states may confront a variety of conflicting regulatory requirements. Thus, one of industry's policy objectives in TSCA reform is to restrain or fully preempt the regulatory power of the states with regard to existing industrial chemicals.

Under S. 1009, states would have access to the chemical safety information that the EPA has collected. But, the bill does not necessarily allow the states to use that information to enact its own regulatory programs.

The S.1009 bill would not preempt the traditional state roles of regulating water, air, and waste. Nor would S. 1009 fully preempt new state chemical regulatory programs (e.g. as in the four states mentioned above). The bill would preempt state laws in two situations, both connected to when EPA makes a safety determination on a specific chemical. In the first case, "when EPA classifies a chemical as a low priority, all existing state regulations of that chemical will be left in place, but the development of any new regulations related to that specific chemical would be preempted following an EPA finding that the chemical is 'likely to meet the safety standard'. If information is submitted to the Agency by state, company, or NGO, EPA has the authority to immediately reclassify the chemical as high priority and assess if to the entire country, rather than waiting for states to act one-by one, or individually" (EPW n.d., 2). In the second case, "when EPA completes a final safety determination of a high priority chemical, any existing or new state regulation of that specific chemical would be

preempted to the degree that is in conflict with the scope of the federal determination or risk management regulations. State laws and regulations related to a specific chemical are left in place until the safety determination is complete and if they are not addressed in the scope of the determination they are not preempted" (EPW n.d., 2).

The S.1009 bill also allows states to apply for a waiver of the preemptive effect of an EPA decision in two cases: when compelling local conditions dictate a state response or when EPA's assessment and determination are unreasonably delayed. As long as the waiver criteria are met, the state can implement its regulation. S. 1009's state preemption approach could minimize the burdens on states and minimize undue burdens on commerce (B&D 2013), since it is promoting uniform protections for all Americans and not just those living in states with the resources to develop their own stricter chemical regulatory programs.

The S.697 bill contains a different preemption provision compared to S. 1009. It leaves in effect all regulatory actions that states have taken prior to January 1st, 2015. It requires states to refrain from imposing new restrictions on high priority chemicals while the EPA is reviewing those chemicals. That restriction on state power has triggered significant resistance from Vermont, California, Massachusetts, and Minnesota for the following reason (Lynn 2015): "In S. 697 bill all new state restrictions on high-priority chemicals would be preempted once EPA start its safety assessments. The S. 697 bill allows EPA to take up to three years to complete such a safety assessment, to take two more years to promulgate a final regulation, and to extend the rulemaking process by an additional two years. This process creates nearly a decade during which states cannot restrict a high- priority chemical in order to protect the public and the environment" (Vermont 2015, 2). The S. 697 bill allows states to take action to control chemicals that EPA has determined to be low priority (Lynn 2015), but states should notify EPA about proposed restrictions of chemicals and the EPA will prioritize the chemical if it is expected to have a national impact (Denison 2015).

"Waivers can be obtained both before and after final safety determination and risk management rule" (Denison 2015) but, according to Californian Senator Barbara Boxer, the S. 697 bill "would make it effectively impossible for states get waiver to set more protective standards than EPA's" (Boxer 2015 a, 1). State regulatory actions taken after January 1st, 2015 are preempted if the EPA determines that chemical meets the safety standard under the reformed TSCA. Preemption is limited to the specific uses and conditions of use that are included in the scope of the EPA's safety assessment and determination (Denison 2015). The S. 697 bill would not preempt State actions requiring reporting, monitoring, or other forms of information collection, including California's Proposition 65 program.

House Bill-2015 maintains the ability of state governments to act when the EPA has not regulated (ACC 2015). Under House draft bill – 2015, preemption would start only after the EPA makes a final decision on a chemical, either in a rule managing the risk or in a decision that the chemical poses no unreasonable risk (CW 2015 a). Here the state resistance to the S. 697 approach is solved, since the preemption starts not at the beginning of the risk assessment but after the risk assessment is finished and a rule or determination is final. However, the Alliance of Automobile Manufacturers would prefer a provision where preemption operates earlier, once EPA begins the risk assessment process. The Alliance of Automobile Manufacturers "cannot support a situation in which a state regulates a chemical substance while EPA is considering whether to regulate the same substance, and may regulate in a different manner that the state does. In such cases, the most stringent regulation quickly becomes the default standard for the industry" (Auto Alliance 2015, 7).

An environmentalist has expressed concern that "the (House) draft does not contain a grandfather clause to preserve the stricter state laws enacted since 1976." (Igrejas 2015) The scope of preemption in the House draft is also not entirely clear. EPA action might prohibit a state from taking action on a chemical used in a toy, for example, if EPA had examined the use of that chemical in furniture. (Igrejas 2015). The draft House bill was modified in the H.R.2576 bill in order to "explicitly preserve existing state laws not in conflict with TSCA, including California's Proposition 65 and other chemical laws passed before August 1, 2015" and "limit the effectiveness of federal preemption of state chemical laws until after EPA makes a final assessment decision" (Verdant 2015).

6.2. 'California Effect' by California State

The preemption provision of S. 1009, Section 15, has caused significant resistance in nine states. California Senator Barbara Boxer has led the opposition with the following argument: "National standards must allow states to strengthen safeguards for their citizens. State laws often lead to benefits nationwide as consumers and industry react to standards and information generated at the state levels" (CW 2014). The California effect is so named because this US state is famous for its stricter environmental health and safety regulations, somewhat similar to the reputation of the Scandinavian countries in the EU. California quite often promotes its stricter environmental health and safety standards, encouraging other states

to enact similar higher standards. We can see the California effect in the TSCA debate through the positions of Senator Boxer.

As stated earlier, there are three factors (legal, economic, and political) that contribute to the success of one jurisdiction exporting a strict standard to other jurisdictions. Out of these three factors, economic power is perhaps the most salient. California is the world's eighth largest economy[32] and has the largest GDP among the 50 US states. Since companies want to do business in California, they will seek to comply with California standards and then see value in other states adopting standards similar to California. Industry may try to defeat or weaken regulatory authority in the California legislature but the environmental movement in California may be stronger than industry.

Industry may seek to restrain California's regulatory power through legislation enacted by the U.S. Congress. Since California is the most populous state, it has the largest delegation of representatives to the US House of Representatives. California has 53 out of the 435 congresspersons while, for example, Alaska has one and Texas, the second most populous state, has 36 (House 2015). On the other hand, each state has exactly two out of the 100 Senators, meaning that California has no more Senators than any other state. Thus we should expect that the influence of California in the U.S. Senate will be quite limited. An interesting question is whether industry has the political power in the U.S. Congress to enact legislation that preempts or restricts California's power to regulate chemicals.

In 2013 the General Assembly (legislature) of California created a new regulatory program called 'Safer Consumer Products'.[33] The program focuses on product design, and on the lifecycle environmental impact of the manufacture, transport, use, and disposal of a product. The California 'Safer Consumer Products' regulations have considerable impact on which chemicals are permitted to be used by manufacturers in the design and construction of products sold in California (Uyesato *et al.* 2013). Responsible entities must remove the candidate (listed) chemicals from their product supply chain, and/or submit an Alternatives Analysis containing detailed toxicological and exposure data related to alternative chemicals that will substitute the listed chemical (Cowan *et al.* 2014).

California's official lists of chemicals and products list contain selected candidate chemicals and products that are slated for reduction or elimination. Those lists will not simply have an effect in California, since the lists may affect the import and export of

[32] http://www.ccsce.com/PDF/Numbers-July-2014-CA-Economy-Rankings-2013.pdf California once again the world's 8th largest economy based on GDP July 2014

[33] OFFICE OF ADMINISTRATIVE LAW NOTICE FILE NUMBER: Z-2012-0717-04 and OFFICE OF ADMINISTRATIVE LAW NOTICE FILE NUMBER: Z-2012-0717-04 Effective October 1, 2013

products in the United States, since manufacturers cannot always control where their products end up. Manufacturers must make sure to be in compliance with the strict California 'Safer Consumer Products' regulations (Uyesato *et al.* 2013). If it is beneficial to make one unique product design that is accepted in all states, the stricter rules in California may influence how a product is designed for the rest of the United States.

Some organizations believe California's 'Safer Consumer Products' regulation could bring much more accountability and safety to the use of chemicals in products. Other organizations believe the California program may imposes overly burdensome regulations on industry, including restrictions on international trade. Specifically, trade agreements like the North American Free Trade Agreement (NAFTA) and the World Trade Organization's Agreement on Technical Barriers to Trade (TBT) are designed to prevent regulatory (nontariff) barriers to international trade (Cowan et al 2014).Given the controversy around California's new regulatory program, it should be expected that preemption provisions in TSCA reform bills will be aimed at blocking the California program.

Boxer's efforts in the Senate have been somewhat successful in changing the federal preemption provisions in the TSCA reform bills. For example, on April 29th, 2015 the US Senate Environment and Public Works Committee passed a modified version of the S. 697 bipartisan bill. The biggest change was in the preemption part of the bill, but Boxer voted against it because she believes the changes are still not sufficient enough to preserve states' rights. The key changes to the preemption provision are the following.

In the revised S. 697 bill all new state restrictions on high-priority chemicals would be preempted once the EPA defined the 'scope of uses of the chemical.' Preemption would not take effect when agency designates the chemical as high-priority. If the deadline for EPA's safety determination is missed, states are automatically granted a waiver from preemption. The EPA would also be required to approve a state application for waiver of preemption if the state regulation does not violate federal law or unduly burden interstate commerce, and is based on peer-reviewed science (E&E 2015). All state laws enacted before August 1st, 2015 are exempt from preemption, which means states can continue to enforce chemical bans and restrictions enacted before August 1st, 2015. States will be allowed to co-enforce the federal law, which means that states can enforce laws identical to federal laws, but state and federal authorities cannot collect penalties from violators for the same offence. All state laws on chemical disclosures are not subject to preemption.

In this chapter, it has been shown that the relationship of EPA's regulatory power to the power of the states (especially California) is a major unresolved issue in TSCA reform. The preemption provisions in the TSCA reform bills continue to be negotiated and refined, so it is not clear what the final TSCA reform legislation will say about federal preemption of state regulation. Throughout this US debate, the status of REACH as a regulation in the EU has not exerted much influence on the design of the TSCA reform bills.

7. HARMONIZATION OF CHEMICAL LEGISLATIONS

The previous chapter outlined the similarities and differences between REACH and the proposed TSCA reform bills, and the policy diffusion of chemical legislation. This chapter will demonstrate examples of cases in which the EU and USA have started working on possible future interactions for the harmonization of chemical legislation. This will especially focus on TTIP discussions, GHS harmonization, and what other nations who are in the process of revising their chemical policies can learn from TSCA reform debates, or from REACH, in order to improve their chemical legislation.

7.1 Trans-Atlantic Trade and Investment Partnership (TTIP) debate

As seen in the previous chapter on theory, Sebastian Princen (1999) states that legal, economic, and political factors contribute to the success and failure of exporting a strict standard. Out of these three factors, economic size and economic power are the most salient. In economic factors he suggested that a large and wealthy country that has an attractive market has more opportunities to impose its strict standard. However, the market size of a country with less strict standards is also important. An economically more powerful country can use its market power to withstand the pressure to adapt a greener standard. Political factors refer to the strength of pressure groups of a country that has to accept a stricter standard, as countries are more likely to introduce stricter standards if they have strong public interest groups (e.g. environmental groups or trade unions) who lobby for strict standards. Legal factors refer to how a country regulates its trade rules. Today, both the EU and USA want to change their trade rules through the Trans-Atlantic Trade and Investment Partnership (TTIP), which will be a new trade agreement between the EU and USA. The negotiations have started between the two blocs, but have not yet finished.

The aim of the TTIP is to increase trade between the EU and USA through the minimization of technical barriers of trade (CIEL 2014).One of the technical barriers of trade is the differences in regulations. When the objectives of the regulations are not the same, these differences are unavoidable. However, for environmental health and safety regulations the objectives of the regulations are the same in both areas: to protect people's health and the environment. In these cases, regulatory cooperation can avoid unnecessary divergences and make it easier to trade products and services (EC 2015).

Both the EU and US health and safety regulations are among the most advanced systems in the world, and are both models for other nations. As seen in previous chapters, both of them try to protect people's health and the environment in a similar extent, but in different ways. A regulatory cooperation could create new economic opportunities, greater consumer choices, better quality, more thoroughly enforced regulation, and increase the EU and USA's ability to influence the quality of global rules. Both the USA and EU would like to export stricter environmental, health, and safety standards to other nations. They have a much bigger chance if they work together, since together they are an even bigger economic and legal power, as based on the theory described previously by Princen (1999). TTIP could boost the EU and US' influence in the world by setting high standards in global trade and projecting the EU and US' environmental health and safety values (EC 2015 a). TTIP could open the US market to EU firms and the EU market to US firms, especially for smaller ones (SMEs).

„The general objectives of the TTIP are (EC 2015 b, 2):

a) To reinforce regulatory cooperation thereby facilitating trade and investment in a way that supports EU and USA's efforts to stimulate growth and jobs, while pursuing a high level of protection of inter alia :the environment; consumers; working conditions; human, animal and plant life, health and safety; personal data; cybersecurity; cultural diversity; or preserving financial stability;

b) To reduce unnecessarily burdensome, duplicative or divergent regulatory requirements affecting trade or investment, particularly given their impact on small and medium sized enterprises, by promoting the compatibility of envisaged and existing EU and US regulatory acts;

c) To promote an effective, pro-competitive regulatory environment, which is transparent and predictable for citizens and economic operators;

d) To further the development, adoption and strengthening of international instruments, and their timely implementation and application, as a means to work together more effectively with each other and with third countries to strive toward consistent regulatory outcomes."(EC 2015 b, 2)

Public interest advocates have long criticized the bias and secrecy of how the TTIP trade agreements are negotiated. One of the issues was that the chemical industry's proposal was not disclosed publicly, and came to the public's attention only as a leaked document. The Center for International Environmental Law (CIEL) analyzed and strongly criticized the TTIP

proposal from the chemical industry in 2014 (CIEL 2014). Member States also criticized the transparency of the TTIP negotiations, since EU member states' representatives could not have access to the details of the negotiations (pers. comm.)

The European Commission reacted to this public fear, that the negotiations are not transparent enough, and prepared a website about TTIP negotiations (EC 2015 c). This website states that the European Commission is publishing every proposal that the EU gives to American negotiators and they collected the top ten myths about the TTIP (EC 2015 a), according to the EU Trade Commissioner. Out of these ten myths, two of them are really related to environmental health and safety topics.

The first of these two myths is that the TTIP will weaken strict EU standards that protect people and the planet. The fact is that EU standards simply are not up for negotiation. TTIP will uphold all EU standards. The TTIP wants to cut the costs that EU exporters face when standards are the same in the EU and US, but the EU and US rules differ. The EU committed to protect their high standards, safeguard EU regulators' independence, uphold the precautionary principle, and ensure government's right to pass new laws in the future to protect people.

The second myth is that the TTIP will mean a 'race to the bottom' for the environment and worker's rights. The fact is that TTIP will contain a dedicated chapter to foster sustainable development. The EU is determined to uphold the highest environmental health and safety standards in the world and promote them. TTIP will encourage the EU countries to decide its own levels of protection for people at work and for the environment, and commit the EU and US to enforcing them.

The aim of the TTIP negotiations about chemicals is to improve the way the EU and US regulators work together using existing bodies, avoid unnecessary costs caused by different regulations in the EU and US, and respect the EU's strict standards that protect people and the environment (EC 2015 d). The EU Commission issued a position papers on chemicals (EC 2015 e).In that paper, based on a REACH review, they concluded that REACH is not going to be amended. The EU Commission is following TSCA reform bills, especially the S. 1009 which has bipartisan support. However, since S.1009 does not contain a registration part, nor elements comparable to REACH authorization, the regulatory co-operation/convergence is limited.

The EU Commission identified four main areas in which a higher degree of convergence may be sought to increase efficiency and reduce costs. These four areas would not require any change in the regulatory systems of each side.

The first area is “Co-operation in prioritizing chemicals for assessment and assessment methodologies.” As shown in the previous chapter, after a prioritization the EPA does a very detailed full risk assessment for high-ranked chemicals (83 TSCA Work Plan Chemicals). While in the EU, mainly the industry collects the data and makes a risk assessment through REACH registration dossiers. The authority then makes a limited and targeted assessment through the evaluation of those dossiers and if needed through restriction, authorization, or harmonized classification. The TTIP will not change the prioritization or assessment processes of the two sides, but the EU and US could cooperation more intensively on the integration of new scientific developments related to risk assessment and risk evaluation. The EU would like to get more information about the activities of US states (e.g. California) related to prioritization and risk assessment. The analysis of the method of risk assessment in the EU and US shown in the previous chapter verifies this possible cooperation area.

The second area of cooperation between the EU and US is promoting alignment in the classification and labeling of chemicals, for which the international standard is the UN GHS (Globally Harmonized System for the classification and labeling of chemicals).[34] Both the EU and US follows the UN GHS standard. In the EU the UN GHS was comprehensively implemented into the CLP Regulation[35], specifically the physical, health, and environmental danger parts of the standard. In the USA just the physical and health danger parts were implemented by the OSHA (Occupational Safety and Health Administration) authority.[36] The EPA would have to also implement the environmental danger part of UN GHS later on in the USA. The EU maintains a list of binding harmonized classification and an inventory of all existing industry self-classifications which are not yet harmonized, while the USA does not have any list or inventory. If the EU and US could agree on a classifications for chemicals, it could be a good basis for a global list of agreed GHS classification. The next chapter will show the differences and similarities between the EU GHS, called CLP, and the US GHS in more detail, and whether a proposed convergence is possible or not.

The third area is 'cooperation on new and emerging issues' like endocrine disruptors, nanomaterials, and mixture toxicity. The EU Commission recommends mutual consultation before any blocs start preparing new criteria or legislation about these topics.

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34 UN GHS link:http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

35 CLP regulation 1272/2008/EC Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

36 OHSA GHS regulation 29 CFR Parts 1910, 1915, 1917, 1918, and 1926 RIN 1218-AC20 URL: http://www.osha.gov/dsg/hazcom/ghs.html

An endocrine disruptor is a chemical (EDC), or mixture of chemicals, that interfere with any aspect of hormone action causing concern for human health like hormone related cancers, reproductive problems, genital birth defects, effects on brain development, and effects on metabolism (ChemTrust 2014). About 800 chemicals have been identified as having potential, suspected, or confirmed endocrine disrupting properties (CIEL 2013). When interviewees were asked if TSCA reform needs a special provision on endocrine disruptors, a few of them strongly agreed and a few of them strongly disagreed with this statement. Those who did not agree explained that the endocrine disruptors are just a mechanism of toxicity, and it would be more sensible to focus on developmental or reproductive toxins rather than on a specific mechanism. Others agreed to have special control since it is very hard to safely manage these chemicals. At the Helsinki Chemicals Forum, according to the presentation of the CHEM Trust NGO, the most crucial tasks for endocrine disruptors are the following: improve tests for better identification, apply existing laws to minimize exposures, and use existing tools for substitution and innovation (ChemTrust 2014).

Besides endocrine disruptors, mixture toxicity is another new or emerging issue which could mean possible cooperation for the EU and USA. In the chemical databases the effect or the feature of the chemical is based on studies of one chemical at a time. Mixing different chemicals might alter their effects to additive, synergistic, or even antagonistic directions (CIEL 2013). Humans and wildlife are exposed to chemical mixtures and not just to individual chemicals. This cocktail effect of chemicals can cause doses previously considered safe to suddenly become unsafe. For example, it has been shown that mixtures of low levels of environmental toxins in fish can double the toxic effect on human cells compared with the effects of those chemicals separately (Hedlund 2013).

Nanomaterials[37] are another area where cooperation is possible. Nanomaterials are different from bulk chemicals in physico-chemical properties, which can cause differences in toxicological and eco-toxicological hazards. These differences imply new risks to the environment and health and safety. The development of internationally applicable technical,

[37] According to the EU Commission's recommendation "the nanomaterials consist of natural, incidental or manufactured particles in an unbound state as an aggregate or agglomerate with one or more external dimensions in the size range 1 nm-100 nm for more than 50% of their number size distribution, in specific cases beteen 1-50%. Fullerens, grapheme flakes and SWCNT with one or more external dimensions below 1 nm are nanomaterials. Has a specific surface area by volume greater than 60 cm2/cm3, but number size distribution prevails"
Link: http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm

legal guidance, and training materials could be a good area for cooperation for the EU and USA (SSNC 2014).

The fourth area of cooperation between the EU and US is enhanced information sharing and protection of confidential business information (CBI). Both the US and the EU authority, animal welfare organizations, and even the US industry (SOCMA 2012) expressed interest in increasing data exchange between regulators to avoid duplication of tests involving animals. On both sides more and more data is available to the public. The full tests are owned by the industry, and the EU and US authorities usually just receive robust study summaries. Hence the TSCA reform bill's interpretation of CBI would be a crucial question for TTIP negotiation, if the new TSCA would let the US authorities provide confidential information to third-country authorities. The possible cooperation can be achieved through electronic formats and tools used to store data (EC 2014).

The Center for International Environmental Law (CIEL) analyzed and strongly criticized, in detail, the proposal from the chemical industry and the whole TTIP process in 2014. CIEL's opinion is that TTIP will freeze progress in regulating toxic chemicals, create an industry bypass around democracy, give commercial interests and trade precedences over the protection of human health and the environment, stifle innovation in safer chemicals, and impede global action on toxic chemicals (CIEL 2014).

According to CIEL, creating additional committees like the Regulatory Cooperation Council would cause new barriers in the law-making process in both blocs, would reduce the regulatory efficiency, and would remove or decrease civil society participation to influence the direction of regulatory policy (CIEL 2014). TTIP would stifle the potential of stricter rules, which help bring safer chemicals to the market. The OECD conducts numerous methods for determining hazardous properties of chemicals and mutual acceptance of data. Any debate from additional scientific advisory committees would likely delay implementation of more protective laws and fail to resolve disagreements between different scientific communities. CIEL is really concerned that the European system, which is stricter, more precautionary, more realistic, and more protective of EHS values, would be undermined if TTIP discussions are not open and transparent enough, and if the main focus of discussion is not serving a broader public good but serving the benefit of the chemical industry.

This subchapter showed the four key TTIP areas where cooperation between the two blocs, the EU and US, is possible: prioritizing chemicals for assessment and assessment methodologies, classification and labeling of chemicals, new and emerging issues like endocrine disruptors, nanomaterials, mixture toxicity, information sharing, and protection of

confidential business information (CBI). The next subchapter will present a detailed analysis of possible cooperation in classification and labeling of chemicals (GHS /CLP).

7.2 GHS harmonisation

The most promising area for cooperation between the EU and US is promoting alignment in classification and labeling of chemicals. In this area there is an international standard called the UN GHS (Globally Harmonized System of classification and labeling of chemicals).[38]The UN GHS was agreed on by the UN Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labeling of Chemicals. It was published in 2003 after a decade of negotiations. The GHS was developed worldwide to minimize differences between different systems of jurisdiction for the classification and labeling of substances and mixtures. The GHS aims to contribute towards global efforts to provide protection from the hazardous effects of chemicals and to facilitate trade. It provides harmonized criteria for classification. It follows a 'building block' approach in order to enable jurisdictions to adopt systems according to the needs of their law (ECHA 2015 a).

The aim of classification is to identify the hazardous properties of a substance or mixture through standard tests or chemical modeling, and based on these properties make a decision of whether the chemical fulfills the hazardous criteria or not. If it fulfills the criteria, then it is called a hazardous substance or mixture. Hazardous chemicals get an appropriate hazard label. The classification is based on intrinsic hazards (hazard-based) and does not take exposure into consideration (not exposure or risk based).

The UN GHS provisions are implemented in the EU through the CLP regulation.[39] The CLP regulation's implementation is completed in two steps with two deadlines. December 1st, 2015 was the deadline for substance classification and labeling and June 1st, 2015 was the deadline for mixture classification and labeling.

The UN GHS provisions were implemented in the USA in 2012, in one step with one deadline, through an OSHA legislation[40] called revised Hazard Communication Standard. The 1st of June, 2015 was the deadline for both chemical substances and chemical mixtures.

[38] UN GHS link: http://www.unece.org/trans/danger/publi/ghs/ghs_rev05/05files_e.html

[39] Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

[40] 29 CFR Parts 1910, 1915, 1917, 1918, and 1926 RIN 1218-AC20 **http://www.osha.gov/dsg/hazcom/ghs.html**

The UN GHS was comprehensively implemented, at least the physical, health, and environmental danger part, into the CLP Regulation in the EU, while in the USA just the physical and health hazard parts were implemented by the OSHA (Occupational Safety and Health Administration) authority. The EPA would also have to implement the environmental hazards part of UN GHS later on in the USA. The EU maintains a list of binding harmonized classification and an inventory of all existing industry self-classifications[41] which are not yet harmonized, while the USA does not have any list or inventory.

Vogel (1995, 55) states that the "removal of nontariff barriers and the strengthening of health and safety regulations requires a strong international authority". His thesis is that the stronger the international authority, the more likely a California effect is to take place. In this context the United Nations is the international authority who can facilitate the spread of strict GHS standards worldwide. Genschel and Plümper (1997) state that strict standards are more likely to spread if the benefits relative to the costs of adopting them increase. What would a benefit be for the EU and US using UN GHS classification? How could GHS really facilitate trade? The answer is very simple: full harmonization could be a plausible scenario for a real benefit and could also facilitate trade.

Currently a chemical label prepared by US requirements does not fulfill the EU's requirements, so before bringing it into the EU relabeling must be organized. Even though the UN GHS is implemented in both blocs, currently the US chemical classification criteria are different than the EU classification criteria, so the same chemical can easily be more hazardous or less hazardous in the EU than in the US.

Even if the classification and the labeling could be the same in the EU and USA, there is still a difference between how the two blocs think about the labeling of hazardous chemicals. The trend of US companies is to overclassify a chemical (to be stricter) while in the EU the trend of companies is to underclassify a chemical. Why the difference? In the USA a chemical company that produces hazardous chemicals is subject to lawsuits under the common laws of the 50 states, where injured people can demand monetary compensation for damages and can request that the court impose punitive damages on companies that harm people or the environment (pers. comm.).While it might seem that common law litigation occurs only 'after the harm occurs,' the threat of litigation is intended to persuade companies to engage in proper risk management of chemicals. Due to this reason some US companies think that if they overclassify and overlabel the chemicals (classify and label stricter than necessary), they are safer from a customer's lawsuit.

[41] http://echa.europa.eu/information-on-chemicals/cl-inventory-database

In the EU the trend is to substitute the more hazardous chemicals for less hazardous chemicals, so that the customers want to buy from suppliers who sell less hazardous substances or mixtures. Because of this, if a company overclassifies a chemical in the EU it could cause a disadvantage for them compared to their competitors who classify correctly.

The UN GHS follows a 'building block' approach to enable jurisdictions to adopt the system according to the needs of their law, which means each country or region is allowed to choose which hazard classes and categories, called building blocks, they would like to implement into their local legislation. The UN GHS is updated regularly, currently the fifth version is available on the UN website.[42] The countries are allowed to choose which version of the UN GHS they want to implement into their legislation. The free choice of the building block approach and the free choice of the different versions automatically leads to differences in classification for a given substance/mixture between countries, even if the classification criteria used are the same.

GHS was developed worldwide for a globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols for chemicals, and to minimize differences between systems of different jurisdictions for classification and labeling of substances and mixtures. Fig. 8 shows an overall picture of which countries are implementing GHS worldwide. However, the official GHS implementation status by country is available from on the UN website[43].

[42] UN GHS versions: http://www.unece.org/trans/danger/publi/ghs/ghs_rev05/05files_e.html

[43] UN GHS impelemntation worldwide: http://www.unece.org/trans/danger/publi/ghs/implementation_e.html

■ : Countries/regions that have already implemented GHS.

■ : Countries/regions where GHS is voluntary.

■ : Countries/regions that are in the process of implementing GHS.

■ : Countries/regions where GHS is not implemented or not available.

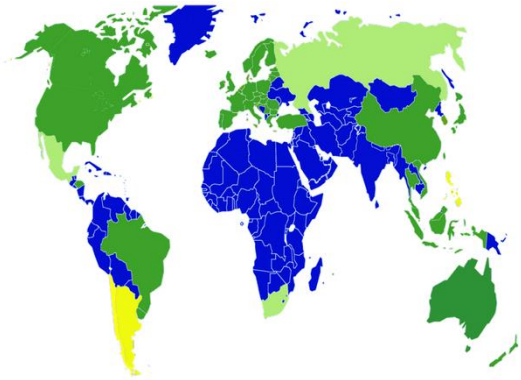

Fig. 8. GHS implementation worldwide

This thesis, however, just focuses on the differences between the EU GHS (called CLP) and US GHS, which cause a trading barrier between the two blocks due to labeling differences and classification differences. The UN GHS was comprehensively implemented, at least the physical, health, and environmental hazards parts, into the CLP Regulation in the EU, while in the USA just the physical and health danger parts were implemented by the OSHA (Occupational Safety and Health Administration) authority. So, one of the biggest differences is that the environmental danger part is missing from US GHS, but this is not the only one. A detailed analysis was made for each hazard class, and the differences were categorized.

Classification means a decision if the chemical substance or mixture is hazardous or non-hazardous based on the criteria of the hazard classes. There are 29 hazard classes in the EU and 26 in the US. There are hazard categories that belong to each hazard class,[44] which make a prioritization of hazard severity. If a substance or mixture is in compliance with any

[44] **Physical hazard classes in EU and in USA:** 1. Explosives, 2.Flammable gases, 3.Aerosols, 4.Oxidising gases, 5.Gases under pressure 6. Flammable Liquids, 7.Flammable solids, 7.Self-reactive substances and mixtures, 9. Pyrophoric liquids, 10. Pyrophoric solids, 11. Self-heating substances and mixtures, 12. Substances and mixtures which in contact with water emit flammable gases, 13. Oxidising liquids 14. Oxidising solids 15. Organic peroxides, 16. Corrosive to metals

Health hazard classes in EU and in USA:1.Acute toxicity, 2. Skin corrosion/irritation, 3. Serious eye damage/eye irritation, 4. Respiratory or skin sensitization, 5. Germ cell mutagenicity, 6. Carcinogenicity, 7. Reproductive toxicity 8. Specific target organ toxicity (STOT) – single exposure, 9. Specific target organ toxicity (STOT) – repeated exposure, 10. Aspiration hazard

Environmental hazard classes in EU:1. Hazardous to the aquatic environment, 2. Hazardous to the ozone layer

hazard criteria of any hazard classes, then it will get a hazard statement (H statement). The hazard statement indicates if the chemical is classified as hazardous. After choosing the correct hazard statement, the chemical automatically gets a precautionary statement (P statement), a signal word (Warning or Danger), and a GHS pictogram which belongs to that hazard statement (see Fig 9.).

Fig. 9. GHS pictograms

The main differences between the EU and U.S. hazard classes and categories due to the building block approach are summarized in Table 9. The red color indicates a difference.

Table 9. Differences between the EU and U.S. GHS hazard classes and categories

EU CLP		US OSHA HCS	
Hazard class	Category	Hazard class	Category
Physical hazards			
Explosives	1.1, 1.2, 1.3, 1.4, 1.5, 1,6	Explosives	1.1, 1.2, 1.3, 1.4, 1.5, 1,6
Flammable gases	1, 2	Flammable gases	1, 2
Flammable aerosols	1,2	Flammable aerosols	1,2
Oxidising gases	1	Oxidising gases	1
Gases under pressure	1-4	Gases under pressure	1-4
Flammable Liquids	1-3	Flammable Liquids	1-4
Flammable solids	1,2	Flammable solids	1,2
Self-reactive substances and mixtures	A-G	Self-reactive substances and mixtures	A-G
Pyrophoric liquids	1	Pyrophoric liquids	1
Pyrophoric solids	1	Pyrophoric solids	1
Self-heating substances and mixtures	1,2	Self-heating substances and mixtures	1,2
Substances and mixtures which in contact with water emit flammable gases	1-3	Substances and mixtures which in contact with water emit flammable gases	1-3
Oxidising liquids	1-3	Oxidising liquids	1-3
Oxidising solids	1-3	Oxidising solids	1-3
Organic peroxides	A-G	Organic peroxides	A-G
Corrosive to metals	1	Corrosive to metals	1
Health hazards			
Acute toxicity	1-4	Acute toxicity	1-4
Skin corrosion/irritation	1, 1A,1B,1C, 2	Skin corrosion/irritation	1A,1B,1C, 2
Serious eye damage/eye irritation	1,2	Serious eye damage/eye irritation	1,2
Respiratory or skin sensitisation	1,1A,1B	Respiratory or skin sensitisation	1,1A,1B
Germ cell mutagenicity	1A,1B,2	Germ cell mutagenicity	1A,1B
Carcinogenicity	1A,1B,2	Carcinogenicity	1A,1B,2
Reproductive toxicity	1A,1B,2	Reproductive toxicity	1A,1B,2
Specific target organ toxicity (STOT) – single exposure	1,2,3	Specific target organ toxicity (STOT) – single exposure	1,2,3
Specific target organ toxicity (STOT) – repeated exposure	1,2	Specific target organ toxicity (STOT) – repeated exposure	1,2
Aspiration hazard	1	Aspiration hazard	1
Environmental hazards			
Hazardous to the aquatic environment (Acute)	1	Hazardous to the aquatic environment (Acute)	Not required
Hazardous to the aquatic environment (Chronic)	1-4	Hazardous to the aquatic environment (Chronic)	Not required
Hazardous to the ozone layer	1	Hazardous to the ozone layer	Not required

Based on Table 9., one could think that there is not much difference in classification, just mainly in the environmental hazard part, that the USA has not yet implemented.

However, due to legislation modifications, the US and EU's precautionary statements can easily be different depending on which version of CLP is implemented at the EU company. It is obligatory to write P statements word by word, as it is written in the legislation, on labels and safety data sheets. If, due to the version change, the legislators modify a P statement the industry should modify all labels and safety data sheets. In this table

a good example of a typical bureaucratic change in a P statement can be seen, which makes the EU industry's life a little bit more complicated without actually giving any additional value. P 340 statement version 1: "Remove *victim* to fresh air and keep at rest in a position comfortable for breathing" from a content point of view is the same as the P 340 version 3: "Remove *person* to fresh air and keep comfortable for breathing." As can be seen from Table 10. the different version of P statements causes an extra burden to the industry, since they need to modify all MSDS' and all labels in all EU languages.

Table 10. Precautionary statements modifications due to GHS version change

	P 340	P341	Effective substance	Effective mixture
UN GHS version 3	Remove *victim* to fresh air and keep at rest in a position comfortable for breathing.	If breathing is difficult, remove *victim* to fresh air and keep *at rest in a position* comfortable for breathing.		
UN GHS version 4	Remove *person* to fresh air and keep comfortable for breathing.	deleted		
UN GHS version 5	Remove *person* to fresh air and keep comfortable for breathing.	deleted		
US OSHA HCS	Remove *person* to fresh air and keep *comfortable* for breathing	If breathing is difficult, remove *person* to fresh air and keep *comfortable* for breathing.	1 June 2015	1 June 2015
EU CLP (1272/2008/EC)	Remove *victim* to fresh air and keep at rest in a position comfortable for breathing.	If breathing is difficult, remove *victim* to fresh air and keep *at rest in a position* comfortable for breathing.	1 Dec 2010	1 June 2015
EU CLP (286/2011/EU)	Remove *victim* to fresh air and keep at rest in *a position comfortable* for breathing.	If breathing is difficult, remove *victim* to fresh air and keep *at rest in a position* comfortable for breathing.	1 Dec 2012	1 June 2015
EU CLP (487/2013/EU)	Remove *person* to fresh air and keep *comfortable* for breathing.	deleted	1 Dec 2014	1 June 2015

Mixture classification is another area where there can easily be differences. In mixture classification, when the individual ingredient has data, at certain classes the classification is based on concentration thresholds. The EU implemented specific concentration thresholds (SCL) (it can be stricter or lighter than the general concentration limits) while the USA has not implemented any SCL. The generic concentration threshold (cut-off value) is implemented in both blocs, but they are also different in certain classes, which can again cause classification differences.

The EU maintains a list of binding harmonized classification (CLP Annex VI) while the USA do not have those kinds of lists. The companies can do self-classification in both areas (except for harmonized list in EU), which means almost all substances have different classifications depending on the company's available test data. In the REACH registration the lead registrant can harmonize the classification, and there is a platform in REACH-IT for SIEF members to discuss the harmonization of the classification, but companies are not eager to participate in these discussions. If the EU and US could agree on a classification for chemicals, it could be a good basis for a global list of agreed GHS classification. There is likely a very small chance to do a full harmonization for all substances in the near future. However, one thing the USA could do is implement the EU harmonization list; this list can then be a first version of a global list. To do this, the EPA should first implement the environmental hazard classification in the USA.

Together with an IT firm, IQS Intelligent Solutions Service company, we prepared a web-based GHS-expert software called AGATE2[45] aiming to help perform the GHS classification both for EU and US companies.[46] To better demonstrate the differences between the GHS classification of the EU and USA, a mixture called "Test material PhD" was classified based on EU GHS (CLP) and based on US GHS criteria. The "Test material PhD" mixture contains the same components with the same w/w % in both cases (See Table 11.).

Table 11. "Test material Phd" mixture components%

Non-hazardous component	74.8%
Acute toxicity category 1 material	20%
STOT SE category 2 material	5%
Reproductive toxicity category 1 material	0.2 %

[45] Agate2 link: www.agate2.com or http://clp.iqs.hu:8080/ (Need Java to use it) Youtube link which shows how it works: https://www.youtube.com/watch?v=ZJk7JMyZTEo

[46] I was the GHS expert who prepared the specification of the AGATE2 software.

Those hazard classes were chosen which were known to have different cut-off values in the two blocs. In the following pages it will be apparent that this resulted in different H statements, different P statements, different pictograms, and different labels, even though the chemical mixtures are the same.

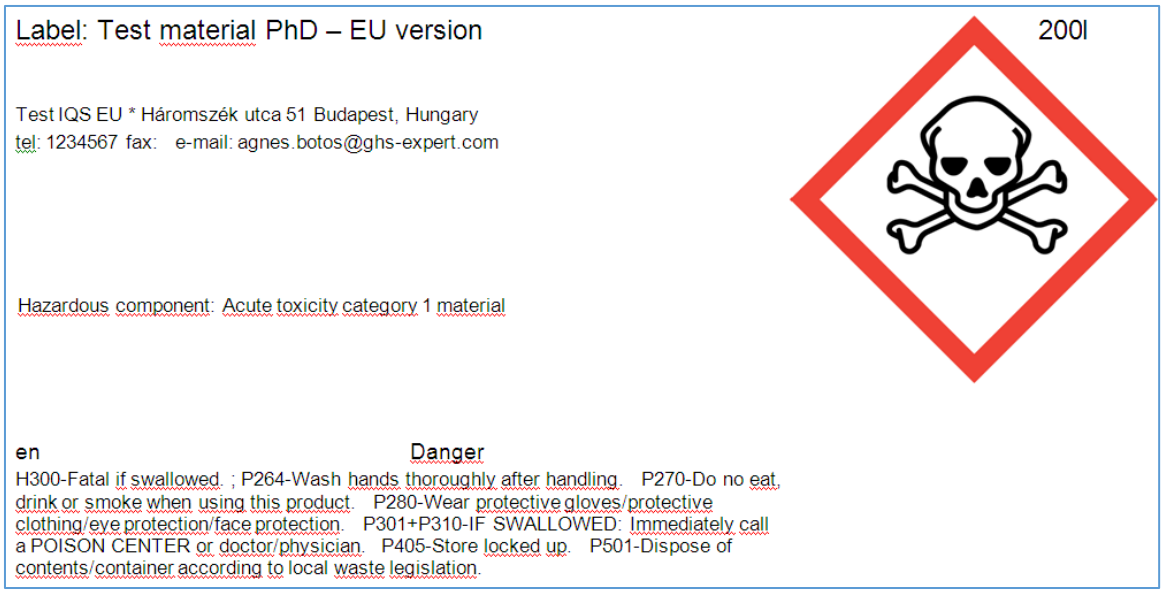

Fig. 10. "Test material PhD" mixture EU label

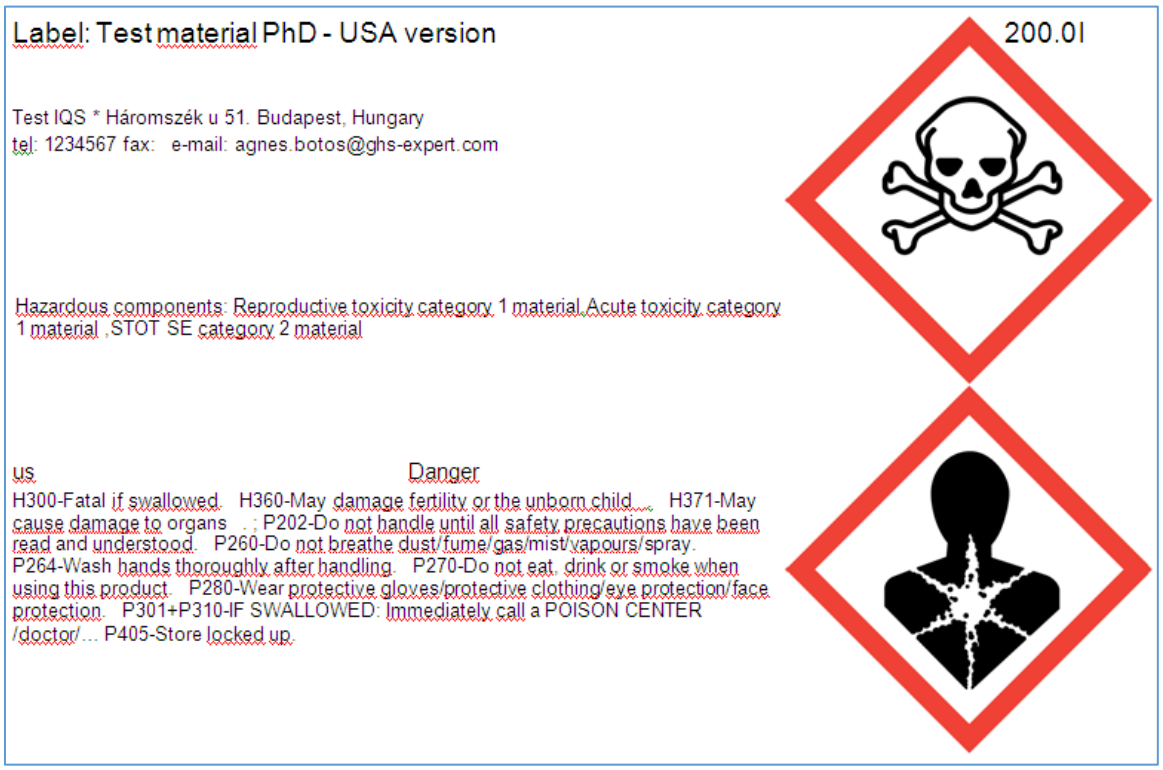

Fig. 11. "Test material Phd" mixture U.S. label

Both chemical legislations require that the chemical manufacturer, distributor, or importer provide Safety Data Sheets (SDSs) (formerly MSDSs or Material Safety Data Sheets) for each hazardous chemical to downstream users in order to communicate information on the hazards of the chemical. UN GHS contains the format of the 16-section safety data sheet (SDS) including the following sections. Both blocs use this format.

Section 1. Identification
Section 2. Hazard(s) identification
Section 3. Composition/information on ingredients
Section 4. First-Aid measures
Section 5. Fire-fighting measures
Section 6. Accidental release measures
Section 7. Handling and storage
Section 8. Exposure controls/personal protection
Section 9. Physical and chemical properties
Section 10. Stability and reactivity
Section 11. Toxicological information
Section 12. Ecological information
Section 13. Disposal considerations
Section 14. Transport information
Section 15. Regulatory information
Section 16. Other information, including date of preparation or last revision

Sections 12-15 may be included in the US SDS, but are not required by OSHA. This means a US SDS may not be used in the EU as it is, and this can make extra work for the industry. In the EU there are really detailed guidance documents[47] (138 pages) on how to complete the 16 points of the SDS, while on the OSHA website only a short guidance document can be found[48] (3 pages). If the USA could implement the EU's MSDS guidance document, it would make harmonization in the case of SDS' possible, since this is an area which could have a very easy solution.

This subchapter presented one of the key TTIP areas, the GHS harmonization (classification, labeling, and packing of hazardous substances and mixtures), where cooperation between the two blocs is possible. In GHS harmonization, the United Nations is the international authority who can facilitate the spread of a strict GHS standard worldwide. The United Nations did its job, and now the question is whether or not the EU and US really want full harmonization of their GHS systems. |It was shown in the analysis that full harmonization really is possible, only a new and similar version of GHS legislation should be

[47] EU SDS guidance: http://echa.europa.eu/documents/10162/13643/sds_en.pdf

[48] U.S. SDS guidance: https://www.osha.gov/Publications/OSHA3514.html

issued in both countries. Only a full harmonization could be a plausible scenario for a real benefit, and a full harmonization could facilitate trade. If there is a difference between the EU and US versions of GHS, then GHS will stay a trade barrier like it is today.

8. CONCLUSION

This chapter will summarize how this analysis has resolved the research problem, highlighting practical and theoretical contributions and suggesting future areas for research.

8.1. Comparison of REACH and the bipartisan TSCA reform bills

Primarily, this research aims to address the two research problems: "What are the similarities and differences between REACH and the proposed reforms of TSCA, and are there some promising areas for harmonization?" and "How and why do environment health and safety values and technical practices of REACH influence the technical practices of EPA and the TSCA reform debate in the USA?"

During the TSCA reform debate, since 2008, ten US bills have been issued, but only the bipartisan bills have had the chance to become law. Thus, this dissertation compared REACH with the three bipartisan TSCA reform bills, S.1009 (2013), S.697 (2015), and H.R. 2576 (2015), in order to determine similarities and differences. The comparison was structured around those categories which the TSCA debate focuses on most: data development, priorities for safety assessments, safety standards, restrictions, and preemptions. The possible future interactions for harmonization of chemical legislations was examined, which was particularly focused on TTIP discussions and especially on GHS. Based on a review of the literature, there have been no previous rigorous comparisons of the bipartisan TSCA reform bills and REACH regulations, which is why this study is a unique intellectual contribution.

I have obtained information about REACH and TSCA through multiple methods: personal interviews in the US and EU, focus groups with practitioners, questionnaires, document reviews, and case studies of specific chemicals. The methods are employed to help learn how the EU's chemical policy is – and is not -- diffusing in the USA. My trips to the US, along with interviews with US and EU stakeholders and government officials, helped me better understand US experts' views on REACH and TSCA reform.

Table 12. (See it in Annex IV.) Summarizes the comparison of REACH, TSCA and TSCA reform bills according to the following issues: data development, priorities for safety assessments, safety standards, restrictions on chemical use, and preemption of regulatory activity by lower levels of government.

8.1.1. Data development requirements

Physical chemistry, toxicological, ecotoxicological, and environmental fate data development is a key requirement in each chemical policy, as without good data it is difficult to analyze and evaluate a chemical substance and its safe use. REACH compels manufacturers and importers of substances to supply regulators with a minimum safety-related data set for existing and new chemical substances. Under current TSCA, the EPA must demonstrate the need for data through a "may present an unreasonable risk" finding requirement, which makes their task difficult since they cannot compel manufactures to generate the health and safety data needed to demonstrate that unreasonable risk is shown (catch-22). The three bipartisan TSCA bills are not a fundamental change from a data development point of view. Compared to current TSCA, none of them put the burden on the industry. The US Environmental Protection Agency still collects the data and none of them require minimum datasets. However, all of the three bipartisan TSCA reform bills try to solve the catch-22 issue, and the EPA can more easily and quickly collect test data from the US industry.

8.1.2. Prioritization for safety assessments

Through the prioritization process, the EPA makes a decision for which chemicals should be subject to detailed safety assessments, which are of lesser concern and can wait for safety assessments until a later time, and which should be eliminated from the TSCA inventory list. In contrast with the US, EU prioritization for risk assessment is not crucial to consider due to the fact that REACH requires a simple risk assessment for all existing and new hazardous substances over 10 tonnes /y.

However, ECHA conducts a prioritization of the candidate list chemicals in REACH Authorization. I, compared with the prioritization score of EU Authorization to the current US prioritization process described in the TSCA Work Plan Chemicals: Methods Document. I conclude that the current US prioritization process for safety assessment uses a scoring system that is very similar to the scoring system used by the ECHA for prioritization of candidate list chemicals in REACH authorization. The final scores, of course, are different in the EU and in the US, however the theory of prioritization scoring is quite similar.

No part of the TSCA reform bill contains a concrete technical prioritization procedure. Therefore, the EPA may use the current TSCA Work Plan prioritization process, or may

modify it in the revised TSCA. However, without seeing the concrete procedure, we can conclude that the prioritization of existing substances for risk assessment is not solved in any TSCA reform bills from an environmental health and safety point of view, since US environmentalists say there are more than 1000 chemicals which present significant public health impacts and require priority attention (Boxer 2015 b). However, the TSCA reform bills only contain a maximum of a few dozen high priority chemicals that should undergo safety assessment over several years. The burden on collecting and prioritizing information stayed on the US-EPA in all TSCA reform bills, and the US will not make a fundamental change, like in the EU, where no prioritization is needed, since all hazardous substances over 10 tonnes /y will have a safety assessment prepared by the industry in REACH registration dossiers.

8.1.3. Safety standards

Safety standards / risk assessments describe the conditions under which manufacturing and use of a substance is considered to be safe. In Europe, the industry collects the data and prepares the risk assessment with a Chesar tool, which is designed so that inexperienced risk assessors are able to quickly master it. Then, the authority simply has to evaluate the dossiers and set up requirements. The REACH guidance is clear and understandable, and practitioners can learn it by themselves. There is no need to train experts for years; in one or two weeks they are able to learn the basics; the rest of it is written in very detailed guidelines.

Upon analyzing the US' *new chemicals risk assessment* calculation, written in US Pollution Prevention Framework Manual, it became clear that the EPA's process for environmental and health quantitative risk assessment is theoretically the same risk assessment that the industry uses in the EU; with the Chesar tool for both new and existing chemicals. The EPA completes a risk assessment for over 1000 new chemicals per year, and REACH registrants make a similarly large number with this simple risk assessment.

Upon analyzing the US' *existing chemicals risk assessment* calculation – through a case example of trichloroethylene (TCE) substance - it became clear why the EPA asserts that just seven risk assessments are feasible per year. The preparation of the TCE risk assessment took years, and is more than 2000 pages. 60 very high-qualified and experienced experts participated in the preparation of the TCE risk assessment. Until the US EPA is finished simplifying the existing chemicals risk assessment and risk management processes and is able to effectively restrict or phase out chemicals, their new legislation is unlikely to serve as a

gold standard for other nations. Countries which lack deep toxicological expertise are more likely to adopt a REACH-like system, since it can be copied easier.

"Public confidence in TSCA has weakened since 1976, EPA has issued regulations to control only five existing chemicals determined to present an unreasonable risk" (GAO 2009, 2). This is too few, and was one of the primary concerns for TSCA reform. There are no bipartisan TSCA reform bills that would solve these issues, to effectively restrict or phase out chemicals from an environmental health and safety point of view, since US environmentalists say there are more than 1000 chemicals which present significant public health impacts and require priority attention (Boxer 2015 b). Bill S. 697 requires that, within five years, 25 high priority chemicals must undergo safety assessment and any high priority chemicals that do not meet the safety standard be restricted. H.R. 2576 requires the EPA to complete at least 10 chemical assessments per year for existing substances. The burden on collecting information and prioritizing them has stayed on the US EPA in all TSCA reform bills; the USA will not follow the EU in making the fundamental change to put the burden on the industry, in order to accelerate the process. In US hearings it was voiced that these existing chemical risk assessments should not be an academic exercise and that the system should be changed to increase the number of risk assessments which can be conducted and evaluated, in order to better protect health of people and the environment. Unfortunately, none of the TSCA reform bills implemented this concern. So the implementation of a simplified risk assessment process for existing chemicals - perhaps in ways that are already being implemented by EPA for new chemicals- would be sufficient to accomplish a faster pace to control existing chemicals and to get back public confidence in TSCA.

During my analysis of technical procedures, I concluded that the simplified screening level of risk assessment prepared in the EU by using the Chesar tool is theoretically the same risk assessment that the EPA uses with new chemicals risk assessment. The EPA conducts a risk assessment for over 1000 new chemicals per year, while the REACH registrant makes a similarly large number with this simple risk assessment model. These facts show that it is possible to dramatically accelerate the number of existing chemicals subject to risk assessment, and it is even possible that the harmonization of technical practices of risk assessments in the two sides of the Atlantic Ocean can be achieved.

8.1.4. Restriction of chemicals

If a chemical does not meet the safety standard (risk characterization), the next process is to restrict or phase out the use of the chemical. In the USA the restriction and ban are part of safety determination / risk assessment and risk management, while in REACH it is a two-step process.

In the EU the first step is completed by the industry through collecting test data and preparing a CSR in the REACH registration. The second step is conducted by the authority through the restriction and authorization processes, both made on a use-by use basis.

TSCA allows chemicals to remain in US commerce and use until the EPA promulgates a rule and publishes findings that a chemical presents, or will present, an 'unreasonable risk' of injury to human health or the environment (CRS 2013). In this case the risk should be reduced to a ‘reasonable’ level and EPA must take the regulatory approach that is ‘least burdensome’ to industry. So in the USA, in order to regulate alchemical, the EPA must find that there is a reasonable basis to conclude that the chemical presents, or will present, an unreasonable risk of injury to health or the environment. This is too cumbersome for the EPA to implement, since it is really difficult for the EPA to require testing in current TSCA. If risks are found during the risk assessment, the next step is to prepare risk management strategies to reduce the identified risks, including transition to safer chemicals and greener processes/technologies, promotion of best practices, and the phasing out of uses.

Since 1976 EPA has only been able to require testing on little bit more than 200 existing chemicals and EPA has regulated or banned only five of these chemicals (Jones 2015). This is too few, according to many experts and was one of the primary concerns for TSCA reform.

Since TSCA reform bills contain a maximum of a few dozen high priority chemicals that should undergo safety assessment within the period of a few years, only these chemicals have a chance to be regulated. US environmentalists say there are more than 1000 chemicals which present significant public health impacts and require priority attention.

However, all the three bipartisan TSCA reform bills are, in some aspects, better than the current TSCA. Particularly, the EPA can more easily collect information and make decisions to implement bans than in current TSCA, since the EPA is no longer required to adopt the least burdensome approach at risk reduction. This may result in better protection of human health and the environment.

8.1.5. State preemption

In the EU the REACH regulation preempts the chemical legislation of Member States, simply because it is an EU regulation and not an EU directive. Hence, it is immediately enforceable as law in all EU member states simultaneously, which is why the preemption issue is not a real issue in EU. In contrast, in the USA the preemption debate is a significant setback for the pace of TSCA reform. In this debate, the crucial question is: How will federal regulation, and revised TSCA, take precedence over state chemical regulations?

The industry‘s objective is to restrain, or fully preempt, the regulatory power of the states in order to avoid a variety of conflicting regulatory requirements. Those member states who enacted their own stricter chemical regulatory programs would like to keep their right to implement more rigorous chemical regulations than TSCA to better protect their residents. The EPA would like uniform protection for all Americans, not just those living in states with the resources to develop their own more stringent chemical regulatory programs.

All three bipartisan TSCA reform bills try to solve the preemption issue, yet there is still no consensus. The California effect theory states: an economically powerful US state will strive to export its stricter environmental standards to its trading partners through the use of market access. Such behavior is visible within the TSCA reform debate: California Senator Barbara Boxer released a counter-proposal to S.1009 called Boxer-TSCA and a counter-proposal to S. 697 called the Boxer-Markey - 2015 bill for short. She released stricter health and environmental recommendations not just about the state preemption part but also about other issues such as accelerated safety assessments, more EPA funding for safety assessments, and a stricter safety standard. Boxer's effort was somewhat successful in achieving modification of the S. 697 bipartisan bill, but Barbara Boxer voted against it as she thought the changes were still not sufficient enough to preserve the rights of states. An interesting question is whether industry has the political power in the U.S. Congress to enact legislation that preempts or restricts California’s power to regulate chemicals.

If no radical change is expected at the federal level in the TSCA bills, then it is expected that the U.S. states will continue to take actions on chemicals to better protect their residents. This reality helps explain why some industry leaders favor a strong national regulatory program, since it will discourage the proliferation of conflicting state programs (even without preemption).

8.2. Harmonization of chemical legislations

Although policy convergence of REACH to TSCA reform bills has not happened, the EU and the US have started working on limited harmonization of chemical legislation through the Trans-Atlantic Trade and Investment Partnership (TTIP), which will be a new trade agreement between the EU and US.

The EU Commission issued a position paper on chemicals (EC 2015 e). In that paper, they concluded that REACH is not going to be amended and TTIP will not weaken strict EU standards that protect people and the planet. The EU Commission identified four main areas in which a higher degree of convergence may be sought to increase efficiency and reduce costs. Out of these four areas, two are examined in this dissertation.

The first area is "Co-operation in prioritizing chemicals for assessment and assessment methodologies." During my analysis of technical procedures, I concluded that the simplified screening level risk assessment prepared in the EU by utilizing the Chesar tool is theoretically the same risk assessment that the EPA uses for new chemicals risk assessment. I also concluded that the current US TSCA Work Plan prioritization process for safety assessment uses a scoring system which is very similar to the scoring system used by the ECHA for prioritization of the candidate list chemicals in REACH authorization. The final scores, of course, are different in the EU and in US, but the theory of prioritization scoring is quite similar. My analysis verifies what the EU Commission identified. Specifically, it is possible for the cooperation of technical practices of risk assessments methodologies and prioritization of chemicals for assessment on both sides of the Atlantic.

The second area of cooperation between the EU and US is promoting alignment in the classification and labeling of chemicals. In this area there is an international standard called the UN GHS. The UN GHS provisions were implemented in the EU through the CLP regulation and in the US through an OSHA rulemaking, called revised Hazard Communication Standard (June, 1, 2015).

Even though the UN GHS is implemented in both blocs, currently the US chemical classification criteria are different than the EU classification criteria, so the same chemical can easily be more hazardous or less hazardous in the EU than in the US. It was shown in my analysis that full harmonization really is possible only if a new and similar version of GHS legislation with the same cut-off values and with the same general and specific concentration limits were to be issued in both countries. Only a full harmonization could be a plausible scenario for a real benefit, and a full harmonization could facilitate trade. If there is a

difference between the EU and US versions of GHS, then GHS will remain a trade barrier like it is today.

8.3. Theoretical differences between REACH and TSCA

There were several main drivers of REACH legislation development. The first was lack of data on existing chemicals, which resulted in a lack of trust from the public that the chemicals were being used safely. The second driver was that the prioritization of existing substances, and the process of making a full risk assessment and management by the authority, was very slow. The third driver was that the polluter pays principle was not implemented, as the data and safety assessments were not generated by the manufacturer and users of chemicals. EU has chosen a radical solution to solve all these issues in the REACH regulation by putting the burden of data generation and risk assessment and management preparation on the industry, and leaving the evaluation, restriction, and authorization to the authority.

TSCA reform has the same main drivers as REACH, which is why TSCA reform was expected to reflect, to some degree, REACH reform. The policy diffusion literature predicts that policy makers can learn from the experiences of other governments, which depends on many factors. Based on literature reviews and topics of conferences we can see that American academics, industry leaders, the authority, and environmental advocacy groups carefully follow not only European chemical legislation, but Canadian and other nations' chemical legislation as well in order to observe all available information. Not just the facts count when it comes to learning about other nation’s chemicals policies but also the beliefs of politicians. In the USA some politicians and stakeholders believe the European way is not as good as the American way. Different stakeholders have different interests in TSCA reform, and depending on their interest sometimes see REACH as a negative or as a positive model. Prior belief that the European way is not good enough is strong in the USA, which is why REACH's radical solution to put the burden of data generation, risk assessment, and risk management preparation on the industry carried less weight at the final TSCA discussion. In the end none of the bipartisan TSCA reform bills implemented this concept to shift the burden to the industry, even though TSCA reform debate referred to this EU solution several times, and some stakeholders referred to it as a good and effective model.

REACH was expected to be more precautionary in its design, including more prescriptive about the generation of data (no data, no market), since the US government is sometimes tolerant of risky decisions/technologies that are supported by only limited safety data. This expectation seems true, since none of the bipartisan TSCA reform bills radically changed the current TSCA 'weak' precautionary principle; the US interpretation that an existing chemical is safe until proven unsafe has stayed unchanged in all TSCA bipartisan bills. The 'stronger' precautionary principle that the EU uses, that the chemical is unsafe until it is proven safe through risk characterization, is not going to be implemented in the USA for existing chemicals. However, the USA will not change the new chemical process which uses this stronger precautionary concept at Premanufacture Notice's (PMN) risk assessment, even though the EPA collects data mainly through models for new chemicals and without the required additional testing in the EU. It can be concluded that both the existing and new chemicals processes of the EU are more precautionary than in the USA, due to the 'no data no market' principle implementation in the EU.

TSCA reform bills were expected to be less strict than REACH, since the relative balance of power between industry and environmental groups is more strongly tilted toward the industry in US political culture. The EU is actively spreading the knowledge of REACH around the globe to contemplate the adoption of REACH and the globalization of REACH's environmental health and safety values. The "California effect" theory, which describes the case when a country exports its stricter environmental standards to its trading partners through the use of market access, can be seen in US TSCA reform debates but not in the bipartisan TSCA reform bills. The success and failure of exporting strict standards is influenced by *legal*, *economic*, and *political* factors. Countries are more likely to introduce stricter standards if they have strong public interest groups (e.g. environmental groups or trade unions) that lobby for a strict standard. As already mentioned, prior belief that the European way is not good enough is strong in the USA. Two powerful American industry associations, the American Chemistry Council and SOCMA, both declared that REACH should not be a model for chemical management in the USA since a risk- and science-based approach would be a better alternative. The US industry does not want any additional testing and risk management costs, since this would raise the cost of producing chemicals and would put US plants and products at an economic disadvantage. If we check the three bipartisan bills, the industry and EPA's desires are more often implemented into the TSCA reform bills than the environmental groups' stricter principles. So, the balance of power between the industry and environmental groups is more strongly tilted toward industry in TSCA reform discussions, resulting in the

TSCA reform bills being less strict than REACH from an environmental health and safety point of view.

8.4. Overview

The EU is determined to uphold and promote the highest global environmental health and safety standards. After reviewing the similarities and differences between REACH and the proposed bipartisan TSCA reform bills, it can be concluded that, throughout the US debate, the status of REACH as a regulation in the EU has not exerted much influence on the design of TSCA reform bills. REACH merely accelerated the TSCA modification, as it was referred many times in TSCA debate, both as a negative and positive example. However, the fact remains that none of the REACH elements (registration, evaluation, restriction, and authorization) were implemented in any TSCA reform bills.

In the case studies, I sought to understand how the technical aspects of risk assessment, prioritizing chemicals for assessment, and the classification and labeling of chemicals, are conducted in the US and the EU. The case study analysis found that the technical practices of risk assessment for new chemicals in the US are theoretically similar to what the EU industry prepares for REACH registration of new and existing substances. Based on this case study, I conclude that to effectively accelerate the number of existing chemicals subject to risk assessment, the EPA should simplify the risk assessment process. Perhaps this can occur in ways that are already being implemented by the EPA for new chemicals. It was also found that the current US TSCA Work Plan prioritization processes for safety assessment utilizes a scoring system that is very similar to the scoring system used by the ECHA for prioritization of the candidate list chemicals in REACH authorization. In another case study, it was also evident in the analysis that the full harmonization for classification and labeling of industrial chemicals is truly possible. Thus, the potential for harmonization of technical practices is much greater than the potential for harmonization of policy frameworks within the EU- US context.

The findings in this dissertation support the notion that there is some degree of policy diffusion between chemical legislation in Europe and the US. Indeed, the focus on improved regulation of existing chemicals in the US is followed by roughly ten years of emphasis on this topic in the EU, with similar arguments for reform made in the US and the EU. Nonetheless, the attempt to export stricter EHS values in REACH failed in the case of the US, and American decision makers are unlikely to reform TSCA based on the REACH model. In

other words, I can conclude that REACH's key environmental health elements and safety principles were not adopted in any of the bipartisan TSCA reform bills in the US.

Soon, it is expected that US decision makers will come to a consensus, and will be able to issue the revised TSCA. In the summer of 2015, the House of Representatives voted on the H.R. 2576 TSCA reform bill and the Senate voted on the S.697 TSCA reform bill on the 18th of December, 2015, which is a big step towards issuing the final bill. I am excited to read the final TSCA reform bill, compare it to REACH and to previous TSCA reform bills, and see how the principles of the industry, EPA, states, and the environmentalists were implemented into the final version. I encourage scholars and practitioners interested in TSCA reform to critique my dissertation and tackle some of the difficult issues that I have not addressed.

ANNEXES

Annex I. Names and Affiliation of Interviewees 2014

	Name	Affiliation	Stakeholders	Expertise
1	Marta Venier	Indiana University	academics	scientific
2	Mark Greenwood	Greenwood Environmental Counsel	consultant	legal & policy
3	E. Donald Elliott	Yale Law School	academics	legal & policy
4	Charles Auer	Charles Auer & Associates, LLC	consultant	scientific & policy
5	Lynn Bergeson	Bergeson & Campbell	consultant	legal
6	Phil Howard	Syracuse Research Corporation	academics	scientific
7	Dennis Devlin	ExxonMobil	industry	scientific
8	Jeff Morris	U.S. Environmental Protection Agency	authority	policy
9	John Applegate	Indiana University	academics	legal
10	Tina Bahadoori	U.S. Environmental Protection Agency	authority	scientific & policy
11	Pat Casano	General Electric	industry	legal
12	Michael Walls	American Chemistry Council	industry	legal & policy
13	Maria Doa	U.S. Environmental Protection Agency	authority	policy
14	Adam Finkel	Rutgers School of Public Health	academics	scientific & policy
15	Baskut Tuncak	CIEL Center for International Law	environmentalist	policy

Annex II. Interview questionnaire

Bloomington IU SPEA, USA 10 Feb - 7 March 2014

The questionnaire was prepared by Agnes Botos

Strictly Confidential

Introduction:

My name is Agnes Botos. I am a part-time doctoral student* at the Environmental Sciences and Policy Department, Central European University (CEU) in Budapest, and a REACH consultant in Hungary. (Phone: +36-20-2205737 e-mail: agnes.botos@GHS-expert.com, address: 1194 Budapest Haromszek u. 51. Hungary Homepage: www.GHS-expert.com)

I am writing a doctoral dissertation on industrial chemicals policy with funding from my university. **The specific subject of my dissertation is the influence of REACH in Europe on the TSCA reform debate in the United States.** Your name has been given to me as a specialist who might be able to guide me on my investigation.

The aim of the research:

During my research I would like to undertake a qualitative study of the interactions between the EU and U.S. chemical policy debates.

The answers and the contact details of the filled questionnaires will be handled strictly confidentially.

I would like to ask some open-ended questions and then some closed-ended questions that allow comparison of your responses with the responses of other specialists. When I publish my dissertation, I will disclose your name as one of the specialists that I interviewed but I will not - without your permission - attribute any of your specific responses to your name. Do you have any questions before I began to ask you some questions?

*Members of my dissertation committee: Dr. Anna Gergely (Steptoe and Johnson LLP), Dr.John Graham (Indiana University SPEA), Dr. Zoltan Illes (CEU), Dr. Alan Watt - chairman (CEU),

GENERAL

- Place and date of the interview:

  ……..

- Name of the person who was interviewed:…….

- Educational background…….

- Organizational affiliation……

- Title……
  ……

1. How long have you been working on TSCA related issues in the USA?

   A, I have never worked on TSCA issues
   B, less than 1 year
   C, 1-4 years
   D, 5-10 years
   E, more than 10 years

2. What is your role?

   A, I am deeply involved in the TSCA reform issues as a scientific expert.
   B, I am deeply involved in the TSCA reform issues as a policy expert.
   C, I am deeply involved in the TSCA reform issues as a legal expert.
   D, NA

Questions

3. In general terms, what would you say has been an impact of REACH – the legislation itself and the implementation process – on the TSCA reform debate in the United States?……

4. Here are some statements that are sometimes made about TSCA reform. Please indicate the degree to which you agree with the following statements:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1. The "unreasonable risk" standard of safety in TSCA needs to be changed.	6	2	5	1	1
2. The burden of proving safety under TSCA needs to be more strongly shifted from government to industry.	7	3	3	1	1
3. A better priority-setting procedure for regulating existing chemicals under TSCA needs to be established.	8	3	4		
4. The precautionary principle needs to be incorporated into TSCA reform.	4		5	3	3
5. TSCA reform needs to be designed on a use-by-use basis, not simply a chemical-by-chemical basis.	2	3	8	1	1
6. TSCA reform needs to have a strong emphasis on sound science and risk assessment.	10	2	3		
7. TSCA reform needs to have a special provision on endocrine disruptors.	3		5	5	2
8. TSCA reform needs to have a special provision on PBTs.	5	2	3	4	1
9. TSCA reform needs to include a provision to encourage data sharing between ECHA/REACH and EPA/TSCA.	8	3	3	1	
10. TSCA reform needs a provision to encourage data sharing between companies.	3	4	6	2	
11. TSCA reform needs to restrict the application of confidential business information to situations where it is really applicable.	6	4	3		2

5. Please indicate the degree to which you agree with the following statements:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
12. The precautionary principle is having an impact on the TSCA reform debate.	1	2	5	7	

13. REACH legislation is too complex and burdensome to serve as a model for TSCA reform.	3	3	6	3	
14. Policy makers in the United States typically have a solid understanding of REACH.		3	3	8	1
15. REACH is imposing barriers to trade between the USA and Europe.	1	2	8	3	1
16. The technical definition of safety in REACH (RCR<1) is a model for TSCA reform.		1	11	3	
17. The cross-Atlantic recognition of REACH registration dossiers is feasible.	5	4	5	1	
18. The required toxicity, ecotoxicity. and environmental fate tests should be harmonized in USA and in EU.	5	4	3	3	
19. If REACH never been enacted, the momentum behind TSCA reform would be weaker.	3	8	3	1	
20. The notion in REACH that PBTs do not have a safe level of exposure is not well grounded in science.	3	2	4	6	

21. Do you see any part of REACH that should be followed in TSCA reform?

    A, Yes, Please explain……...
    B, No, Please explain……
22. Do you see any part of REACH that should not be followed in TSCA reform?

    A, Yes, Please explain……...
    B, No, Please explain……
23. According to your opinion what is the weakest point of REACH legislation?

24. According to your opinion what is the weakest point of current TSCA legislation?

25. What is the impact of the concern that 'REACH has too much complexity' on the TSCA reform debate in the USA?

26. What is the impact of REACH 'location of burden of proving safety (industry versus government)' on the TSCA reform debate in the USA?

27. What is the impact of REACH 'publicly available test data' on the TSCA reform debate in the USA?

28. What is the impact of 'cross-Atlantic recognition of registration dossiers' on TSCA reform debate in the USA?

29. What is the impact of REACH 'precautionary principle' on the TSCA reform debate in the USA?

30. What is the impact of REACH 'Transatlantic Trade and Investment Partnership (TTIP)' on the TSCA reform debate in the USA?

31. What is the impact of REACH 'no distinction between new and existing substances' on the TSCA reform debate in the USA?

32. What is the impact of REACH ‘one substance one registration’ on the TSCA reform debate in the USA?

33. What is the impact of REACH ‘publicly available data like PNEC and DNEL’ on the TSCA reform debate in the USA?

34. What is the impact of REACH ‘use-specific registration’ on the TSCA reform debate in the USA?

35. What is the impact of REACH ‘exposure scenarios’ on the TSCA reform debate in the USA?

36. What is the impact of REACH ‘authorisation and restriction’ on the TSCA reform debate in the USA?

The questionnaire is finished. Thank you very much!

Annex III. Minimal dataset in EU and US

(Reference: Denison 2007)

Comparison of Required Hazard Information Elements for All Chemicals under REACH, Optional Elements for New Chemicals under TSCA, and VoluntaryElements under US HPV/OECD SIDS[a]

NOTES FOR REACH: Most information requirements are caveated and made conditional on many factors, such as chemical type or properties, or results of preceding tests or availability of higher tests specified in the production volume-based hierarchy. Some of the most important ones are described in the notes accompanying certain entries to this table. At Registration, all relevant data required under Annexes VII-VIII are to be submitted, but only test proposals for any additional tests (based on production volume) under Annexes IX-X. Determination by Agency or a member state as to which Annex IX-X tests are to be done is made as part of Evaluation. In addition, numerous alternatives to direct testing are allowed, including use of estimation techniques, category-based extrapolation, etc. (see REACH Annex XI).								
Grey highlights indicate tests that can be waived if exposure potential is demonstrated to be low.								
REACH section ID	**Called for under HPV/ SIDS**	**Endpoint**	**REACH Annex VII 1 to 10 t/yr**		**REACH Annex VIII**	**REACH Annex IX**	**REACH Annex X**	**TSCA new chem >100,000 kg/yr and sign. env. release or human exposure**
			phase -in chem	**new chem or phase-in chem + SVHC or dang. w/ disp. use**	**10 to 100 t/yr**	**100 to 1000 t/yr**	**> 1000 t/yr**	
8.		**Mammalian Toxicological Data**						
8.1		Skin Irritation and Skin Corrosion in Vitro		+	NA	NA	NA	
8.1.1		Skin Irritation in vivo			+	+	+	
8.2		Eye Irritation in vitro		+	NA	NA	NA	

REACH section ID	Called for under HPV/ SIDS	Endpoint	REACH Annex VII 1 to 10 t/yr		REACH Annex VIII 10 to 100 t/yr	REACH Annex IX 100 to 1000 t/yr	REACH Annex X > 1000 t/yr	TSCA new chem >100,000 kg/yr and sign. env. release or human exposure
			phase -in chem	new chem or phase-in chem + SVHC or dang. w/ disp. use				
8.		**Mammalian Toxicological Data**						
8.2.1		Eye Irritation in vivo			+	+	+	
8.3		Skin Sensitization in vivo		+	+	+	+	
8.4		Genetic Toxicity						
8.4.1	+	In vitro Gene Mutation in Bacteria		+	+	+	+	+
8.4.2	+	In vitro Cytogenicity/Chromosomal Aberrations in Mammalian Cells or Micronucleus Study			+	+	+	+
8.4.3		In vitro (Gene Mutation) in			(+)[c]	(+)[c]	(+)[c]	
8.4.X		Further in vivo Mutagenicity Studies			(+)[d]	(+)[d]	(+)[d]	
8.5	+	Acute Toxicity						
8.5.1		By Oral Route		+	+	+	+	+
8.5.2/3		By Inhalation Route and/or by Dermal Route			+	+	+	
8.6		Repeated Dose Toxicity						
8.6.1	+	Short-Term (28 days)			+	+	+	+
8.6.2		Sub-Chronic (90 days)			(+)[g]	+	+	
8.6.3		Long-Term (≥ 12 months)			(+)[h]	(+)[h]	(+)[i]	
8.6.4		Further Studies			(+)[h]	(+)[h]	(+)[j]	

8.7		Reproductive Toxicity							
REACH section ID	**Called for under HPV/ SIDS**	**Endpoint**	**REACH Annex VII 1 to 10 t/yr**		**REACH Annex VIII 10 to 100 t/yr**	**REACH Annex IX 100 to 1000 t/yr**	**REACH Annex X > 1000 t/yr**	**TSCA new chem >100,000 kg/yr and sign. env. release or human exposure**
			phase -in chem	**new chem or phase-in chem + SVHC or dang. w/ disp. use**				
8.7.1	+	Screening Reproductive/ Development Toxicity			+	NA	NA	(+)[k]
8.7.2	+	Developmental Toxicity (Pre-Natal)				+[l]	+[m]	(+)[k]
8.7.3		Two-Generation Reproductive Toxicity				+[l]	+[m]	
8.8		Toxicokinetics						
8.8.1		Toxicokinetic Behavior, if Information is available			+	+	+	
8.9		Carcinogenicity					(+)[n]	
9.		**Ecotoxicological Data**						
9.1		Aquatic Toxicity						
9.1.1	+	Aquatic Invertebrates (Daphnia) Acute Toxicity		+	+	+	+	+
9.1.2	+	Aquatic Plants (Algae) Toxicity (Growth Inhibition)		+	+	+	+	+
9.1.3	+	Fish Acute Toxicity			+	+	+	+
9.1.4		Activated Sludge Respiration Inhibition			+	+	+	
9.1.5	(+)[q]	Aquatic Invertebrates (Daphnia) Chronic Toxicity		(+)[p]	(+)[p]	+[p]	+[p]	(+)[q]

9.1.6		Fish Chronic Toxicity			(+)[r]	+[r]	+[r]	(+)[q]
REACH section ID	**Called for under HPV/ SIDS**	**Endpoint**	**REACH Annex VII 1 to 10 t/yr**		**REACH Annex VIII 10 to 100 t/yr**	**REACH Annex IX 100 to 1000 t/yr**	**REACH Annex X > 1000 t/yr**	**TSCA new chem >100,000 kg/yr and sign. env. release or human exposure**
			phase -in chem	**new chem or phase-in chem + SVHC or dang. w/ disp. use**				
9.1.6.1		Fish Early-Life Stage Toxicity			(+)[s]	(+)[s]	(+)[s]	
9.1.6.2		Fish Short-term Embryo/Sac-Fry Stage Toxicity						
9.1.6.3		Fish Juvenile Growth						
9.2		Degradation						
9.2.1		Biotic Degradation						
9.2.1.1	+	Ready Biodegradability		+	+	+	+	+
9.2.1.2		Surface Water Simulation				(+)[t]	(+)[t]	
9.2.1.3		Soil Simulation						
9.2.1.4		Sediment Simulation						
9.2.1.5		Further Studies					+	
–		Soil Biodegradation						+
–		Anaerobic Biodegradation						+
9.2.2		Abiotic Degradation						
9.2.2.1	+	Stability in Water/Hydrolysis as Function of pH			+	+	+	+
9.2.3		Identification of Degradation Products				+	+	

9.3		**Fate and Behavior in the Environment**						
9.3.1		Adsorption/Desorption Screening			+	+	+	
REACH section ID	**Called for under HPV/ SIDS**	**Endpoint**	**REACH Annex VII 1 to 10 t/yr**		**REACH Annex VIII**	**REACH Annex IX**	**REACH Annex X**	**TSCA new chem >100,000 kg/yr and sign. env. release or human exposure**
			phase -in chem	**new chem or phase-in chem + SVHC or dang. w/ disp. use**	**10 to 100 t/yr**	**100 to 1000 t/yr**	**> 1000 t/yr**	
9.3.2		Bioaccumulation in Aquatic Species				+	+	
9.3.3		Further Information on Adsorption/Desorption				+	+	
9.3.4		Further Environmental Fate and Behavior Studies					(+)[u]	
–		Fate in Wastewater Treatment						+
9.4		Terrestrial Organisms						
9.4.1		Invertebrates Short-Term Toxicity				+	+	
9.4.2		Soil Micro-Organisms Effects				+	+	
9.4.3		Plants Short-Term Toxicity				+	+	
9.4.4		Invertebrates Long-Term Toxicity				(+)[v]	(+)[w]	
9.4.6		Plants Long-Term Toxicity						
9.5		Sediment Organisms						
9.5.1		Sediment Organisms Long-Term Toxicity					(+)[x]	
9.6		Birds						
9.6.1		Birds Long-Term or Reproductive Toxicity					(+)[y]	

–	+	Photodegradation						+
–	+	Transport/Distribution between Compartments (Fugacity)						
REACH section ID	**Called for under HPV/ SIDS**	**Endpoint**	**REACH Annex VII 1 to 10 t/yr**		**REACH Annex VIII 10 to 100 t/yr**	**REACH Annex IX 100 to 1000 t/yr**	**REACH Annex X > 1000 t/yr**	**TSCA new chem >100,000 kg/yr and sign. env. release or human exposure**
			phase -in chem	**new chem or phase-in chem + SVHC or dang. w/ disp. use**				
10.		**Methods of Detection and Analysis**			+[z]	+[z]		
7.		**Physical-Chemical Data**						
7.1		State of the Substance at Standard Temperature and Pressure	+	+	+	+	+	
7.2	+	Melting/Freezing Point	+	+	+	+	+	
7.3	+	Boiling Point	+	+	+	+	+	
7.4		Relative Density	+	+	+	+	+	
7.5	+	Vapor Pressure	+	+	+	+	+	
7.6		Surface Tension	+	+	+	+	+	
7.7	+	Water Solubility	+	+	+	+	+	+
7.8	+	Partition Coefficient (n-octanol/water)	+	+	+	+	+	
7.9		Flash Point	+	+	+	+	+	
7.10		Flammability	+	+	+	+	+	
7.11		Explosive Properties	+	+	+	+	+	
7.12		Self-ignition Temperature	+	+	+	+	+	
7.13		Oxidizing Properties	+	+	+	+	+	

7.14		Granulometry	+	+	+	+	+	
7.15		Stability in Organic Solvents / Identification of Breakdown Products				+	+	
7.16		Dissociation Constant				+	+	
7.17		Viscosity				+	+	

Source: Environmental Defense, based on:

HPV/SIDS: Identification of SIDS elements called for under U.S. HPV and OECD SIDS Programs: See: (1) EPA's formal announcement of the U.S. HPV Challenge Program, FederalRegister, 26 December 2000, Vol. 65, No. 248, pp. 81694-5, available at www.epa.gov/chemrtk/pubs/update/ts42213.pdf . (2) EPA's program guidance document, "Determining the Adequacyof Existing Data," Appendix A, available at www.epa.gov/chemrtk/pubs/general/datadfin.htm. Note that the list of the SIDS elements omits those applicable to inorganic substances, as theyare not included among HPV chemicals identified by EPA under the HPV Challenge Program.

REACH: Final text of REACH, published in the European Union's Official Journal, Volume 49, 30 December 2006, Annexes VII-X, available at http://eurlex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf.

TSCA New High-Volume Chemicals: The criteria EPA uses to define substantial production, exposure and release are specified in its Exposure-based Policy, available atwww.epa.gov/oppt/newchems/pubs/expbased.htm, and the testing elements of the data sets are available at www.epa.gov/oppt/newchems/pubs/expbasedtesting.htm.

NOTES

[a]	Requirements listed in the following sets of columns are **cumulative**, i.e., they carry over requirements applicable at lower tiers as well as new requirements at that tier: REACH Annexes VII, VIII, IX and X; and CEPA Sch. 5, NSNR §7(2), NSNR §7(3). Explanation of terms/abbreviations: "HPV" = high production volume; "SIDS" = Screening Information Data Set; "phase-in chem" = a chemical already on the market, to which REACH's requirements will apply on a phased scheduled based on tonnage or certain properties; "t/yr" = metric tons per year per producer or importer; "SVHC" = substance of very high concern; "dang. w/ disp. use" = substance classified as dangerous, with a dispersive use; "Sch." = Schedule; "NDSL" = Non-Domestic Substances List; "Non-NDSL" = substance not on the NDSL; "NSNR" = New Substances Notification Regulations; "(C&P)" = chemicals and polymers; "kg/yr" = kilograms per year per producer or importer; "sign. env. release or human exposure" = significant environmental release or human exposure.
[c]	To be conducted only if negative results found in Annex VII 8.4.1 and Annex VIII 8.4.2.
[d]	To be conducted if positive results found in any of the other genotoxicity studies in Annexes VII and VIII.
[g]	To be proposed by the sponsor if frequency and duration of human exposure and nature of potential effect indicate a longer-term study is appropriate, or there is evidence of accumulation of the substance or its metabolites
[h]	Further studies shall be proposed or may be required if shorter-term studies do not detect an expected effect, there is a more specific expected serious effect, the route of exposure used in shorter-term studies was inappropriate or there is particular concern about exposure.
[i]	May be proposed by the sponsor or required if frequency and duration of human exposure and nature of potential effect indicate a longer-term study is appropriate.
[j]	Shall be proposed by the sponsor or may be required where there is evidence of toxicity of particular concern or of a specific type (e.g., neurotoxicity), or particular concerning over exposure.
[k]	This element may be required for chemicals anticipated to be produced at or above HPV levels (1 million pounds/year, or 455 metric tons/year), for which high worker exposure or exposure to consumers or the general population is expected.
[l]	To be performed initially on one species, with the decision as to whether to perform on a second species at this tonnage level or the next highest based on the results of the first test and other available information.
[m]	To be performed initially on one species, with the decision as to whether to perform on a second species based on the results of the first test and other available information.
[n]	May be proposed or required if the substance has wide dispersive use or frequent or long-term exposure is expected, and the substance is classified as a category 3 mutagen or there is evidence of induction of hyperplasia and/or preneoplastic lesions; if the substance is already classified as a category 1 or 2 mutagen, it is presumed to be a genotoxic carcinogen, so testing would not be required.

p	A chronic test shall be considered if the substance is poorly water soluble.
q	May be required if the substance is expected to be chronically toxic.
r	A chronic test shall be considered if the substance is poorly water soluble or the safety assessment indicates the need to further investigate aquatic toxicity.
s	These longer-term studies shall be considered if the chemical safety assessment indicates concern for effects on aquatic organisms. If a decision is made to conduct such tests, only one of the tests specified in 9.1.6.1, 9.1.6.2 and 9.1.6.3 need be provided.
t	These studies shall be considered if the chemical safety assessment indicates concern for effects on aquatic organisms. Which tests to conduct depends on the results of the chemical safety assessment.
u	Further testing shall be proposed or may be required if the chemical safety assessment indicates the need to further investigate environmental fate and behavior. Which tests to conduct depends on the results of the chemical safety assessment.
v	In particular for substances with a high potential for soil adsorption or that are very persistent, long-term testing shall be considered instead of short-term.
w	Further testing shall be proposed or may be required if the chemical safety assessment indicates the need to further investigate effects on terrestrial organisms. Which tests to conduct depends on the results of the chemical safety assessment.
x	Further testing shall be proposed or may be required if the chemical safety assessment indicates the need to further investigate effects on sediment organisms. Which tests to conduct depends on the results of the chemical safety assessment.
y	Any proposal or requirement to test for these endpoints should first carefully consider the large mammalian database that is usually available at this tonnage level.
z	To be provided upon request for the relevant compartments for which studies were performed that used the method(s).

Annex IV. Table 12. Comparison of REACH, TSCA & the bipartisan TSCA reform bills

Criteria for comparision	Data development: Minimum safety related dataset	Data development: Unreasonable risk finding (Catch 22)	Prioritization for safety assessments	Safety standards for existing chemicals	Safety standards for new chemicals	Restrictions on chemical use	Preemption of regulatory activity by lower levels of government
How is this factor addressed in REACH?	Minimum safety related dataset varies on the tonnage range. "No data, no market" principle is implemented. One substance, one registration principle is implemented. No difference between existing and new substances.	Industry collects the data. Minimum safety-related dataset is obligatory. No difference between new and existing substance dataset.	All chemicals has minimum safety related dataset. All chemicals has hazard assessment above 1 t/y. Hazardous chemicals above 10 t/y has exposure assessment and risk charachterization. Pre-registration provides a delayed compliance dates. ECHA conducts a prioritization of the candidate list chemicals in REACH authorization.	Chemical Safety Assessment is prepared by IUCLID and Chesar tool by the industry: 1. step: Hazard assessment (GHS, DNEL, PNEC) 2.step: Exposure assessment (Exposure , PEC) 3. step Risk characterisation (Risks are under control if RCR <1)	Chemical Safety Assessment is prepared by IUCLID and Chesar tool by the industry: 1. step: Hazard assessment (GHS, DNEL, PNEC) 2.step: Exposure assessment (Exposure , PEC) 3. step Risk characterisation (Risks are under control if RCR <1)	Authorisation part of REACH is designed to stimulate industry to substitute Substances of Very High Concern (SVHC). Candidate list contains 161 substances. The candidate list chemicals are prioritized with a numerical scoring system and recommended to the authorisation list. Authorisation list contains 31 substances. Restricition is focus on the restriction of worrisome uses of chemicals.	REACH is a regulation and becomes immediately enforceable as a law in all EU member states. No preemption issue in EU. REACH completly preempts EU member state law regarding chemicals.
How was this factor addressed in TSCA?	No minimum safety related dataset.	EPA can require data submission for chemicals which presents an unreasonable risk , but cannot compel manufacturers to generate EHS data needed to demonstrate unreasonable risk.	Current TSCA is the lack of a mandate for EPA to screen existing chemicals for potential data needs and to do so in a timely manner (though the current TSCA does give EPA this authority). **TSCA Work Plan prioritization:** 83 substances out of 1235: Scoring system to identify and prioritize potential candidate chemicals for risk assessment.	No safety standard term in current TSCA. TSCA allows chemicals to remain in US commerce and use until the EPA promulgates a rule and publishes findings that a chemical presents or will present an 'unreasonable risk' of injury to human health or the environment. In this case the risk should be reduced to a 'reasonable' level and EPA must take the regulatory approach that is 'least burdensome' to industry. Trichloroethylene **(TCE)** risk assessment took years and 60 experts were involved. Risk management strategies to reduce identified risk is not yet prepared by EPA for TCE. Only 5 existing chemicals determined to present an unreasonable risk since 1976.	No safety standard term in current TSCA. Manufacurers must notify EPA when they intend to manufacuter a new chemical. After a 90 day review period companies are free to begin marketing the chemical unless the agency determines that the substance 'may present and unreasonable risk.' EPA can require companies to conduct safety testing if it finds that a new chemical may pose a risk, but it must take the determination without safety data. **New chemicals screening level risk assessment:** First step is hazard assessment (low, moderate, high, COC), Second step is exposure assessment (exposure, PEC). Third step is risk assessment (MOE, PEC/COC)	In order to regulate a chemical EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment, which is too cumbersome for the EPA to impelement. EPA has issued regulations to control only five existing chemicals determined to present unreasonable risk since 1976. Corrosion Proof Fittings Case: The EPA wanted to ban all asbestos, not just banning it for dangerous use or simply labeling asbestos products, but they could not ban it.	TSCA does not completly preempt state law regarding chemicals. TSCA does not fully restrict the right of states to regulate chemical risks governed by TSCA.
Industry, Authority, Environmentalist, Member states desire	**Industry:** against minimum dataset, needed tiered and targeted dataset with a screening level analysis. **Environmentalist:** want to have minimum dataset for all chemicals.	**EPA** want to avoid Catch 22 situation: EPA should have authority to gather data from manufacturers and downstream users quickly and efficiently both for new and existing chemicals	**EPA:** Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner.	**EPA**:Chemicals should be reviewed against Safety Standards that are based on sound science and reflect risk-based criteria protective of human health and the environment. 7 risk assessment /y is possible to do for EPA. **Industry:** Industry favors enactment of new or revised safety standard that gives the public more confidence that the public health and the environment are being protected. Industry support just a risk-based safety standard. **Environmentalists** see REACH as a better model for safety assessment.	**Industry:** No need change at current TSCA new chemicals screening level risk assessment, since New Chemicals program helped achieve a balance between innovation and regulation. **Environmentalist:** Half of all premanufacturing notices (PMN) are submitted without any test data. Need to collect more real test data not just using alternative analysis. Minimum dataset would be good for New Chemicals Program.	NA	**Industry**'s objective is to restrain or fully preempt the regulatory power of the states with regard to existing substances. **Member States** like California would like to keep their right to implement stricter chemical regulations than TSCA. **EPA** would like uniform protection for all Americans, not just those living in states with the resources to develop their own stricter chemical regulatory programs.
How was this factor addressed in S.1009?	No minimum safety related dataset. Industry give data voluntary to EPA. EPA need to demonstrate the need for extra data.	EPA can require data from industry through an 'order' and not 'rules'. EPA need to demonstrate the need for extra data.	Risk-based screening process should be completed for identifying active existing substances into two groups: high priority or low priority. It should be completed by the EPA in timely manner, but no concrete number for high priority substances. EPA can require additional test using a two-tiered testing framework.	Safety standard, safety assessment and safety determination definitions are implemented. EPA conducts a risk-based safety assessment for high-priority substances. No concrete number how many high priority substances should have safety assessments. EPA is no longer required to adopt the least burdensome approach.	Require current TSCA new chemicals screening level risk assessment. Leave in place existing TSCA New Chemicals program. S. 1009 would categorize new substances and uses as not likely / likely to meet the safety standard or additional information needed.	The restriction and ban of chemicals are part of the safety determination.	S. 1009 would preempt states law in 2 situations.
Does S.1009 represent progress as compared to the TSCA?	No	Yes	Yes	Yes	No	NA	NA

Criteria for comparision	Data development: Minimum safety related dataset	Data development: Unreasonable risk finding (Catch 22)	Prioritization for safety assessments	Safety standards for existing chemicals	Safety standards for new chemicals	Restrictions on chemical use	Preemption of regulatory activity by lower levels of government
Does S.1009 offer a response solving this problem from EHS point of view?	No	Yes	No	No (The problem is the low number of the safety assessments and not the quality)	No (Test is not conducted just alternative analysis at 50 %)	NA	NA
Values or process of REACH implemented? (California effect happened?)	No	NA	No	No	No, since no minimal dataset (The process is theoretically similar what EU industry prepares for REACH registration for new and existing substances	No	NA
How was this factor addressed in S.697?	Prohibit minimum safety related dataset.	Unreasonable risk finding is eliminated. EPA can require data from industry through an 'order' and not 'rules'.	Risk-based screening process should be completed for identifying active existing substances into two groups: high priority or low priority. 25 high-priority substance should be on the list in 5 years.	Safety standard, safety assessment and safety determination definitions are implemented. Safety standard term uses 'unreasonable risk' term without defining it. EPA conducts the safety assessment. EPA is no longer required to adopt the least burdensome approach. 25 high-priority substance should be on the list in 5 years.	It would force EPA to determine that a new chemical is safe before it is allowed to enter the market.	The restriction and ban of chemicals are part of the safety determination.	It leaves in effect all regulatory actions that states have taken prior to January 1st, 2015. It requires states to refrain from imposing new restrictions on high priority chemicals while the EPA is reviewing those chemicals. State regulatory actions taken after January 1st, 2015 are preempted if the EPA determines that chemical meets the safety standard under the reformed TSCA.
Does S.697 represent progress as compared to the TSCA ?	No	Yes	Yes	Yes	Yes	NA	NA
Does S.697 offer a response solving this problem from EHS point of view?	No	Yes	No	No (The problem is the low number of the safety assessments and the long timeline and evaluating process.)	No (Test is not conducted just alternative analysis at 50 %)	NA	NA
Stricter REACH values implemented? (California effect happened?)	No	NA	No	No	No, since no minimal dataset (The process is theoretically similar what EU industry prepares for REACH registration for new and existing substances	No	NA
How was this factor addressed in H.R.2576?	No minimum safety related dataset.	Unreasonable risk finding is eliminated. EPA can require data from industry through an 'order' and not 'rules'.	H.R. 2576 does not contain a prioritisation provision for existing chemicals. Revised H.R.2576 requires EPA to complete 10 chemical assessments / y for existing substances but no explicit prioritization provisions in it.	Safety standard, safety assessment and safety determination definitions are not established. Risk evaluation term is implemented. EPA is no longer required to adopt the least burdensome approach. Industry can request EPA to conduct risk evaluation for a particular chemical and pay for it. Revised H.R.2576 requires EPA to complete 10 chemical assessments / y for existing substances.	Require current TSCA new chemicals screening level risk assessment. Leave in place existing TSCA New Chemicals program.	The restriction and ban of chemicals are part of the safety determination.	It maintains the ability of state governments to act when the EPA has not regulated. The preemption would start only after the EPA makes a final decision on a chemical, either in a rule managing the risk or in a decision that the chemical poses no unreasonable risk.
Does H.R. 2576 represent progress as compared to the TSCA?	No	Yes	No	Yes	No	NA	NA
Does H.R. 2576 offer a response solving this problem from EHS point of view?	No	Yes	No	No (The problem is the low number of the safety assessments and not the quality.)	No (Test is not conducted just alternative analysis at 50 %)	NA	NA
ANNEX IV. Table 12. Comparison of REACH, TSCA & the bipartisan TSCA reform bills							
Stricter REACH values implemented? (California effect happened?)	No	NA	No	No	No, since no minimal dataset (The process is theoretically similar what EU industry prepares for REACH registration for new and existing substances	No	NA

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