U.S. chemical policy under review: how much Europeanisation

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Abstract

The European Union chemical regulation REACH entered into force in 2007. The most ambitious regulations on chemicals in the World will soon become a source of inspiration for other countries to review their own national regulations on chemicals. This is also the case of the USA where the failure of the Toxic Substances Control Act (TSCA) of 1976 to provide a high level of protection for human health and environment contributed to a general consensus for reform. Several reform proposals were considered and discussed in both chambers of Congress, reflecting to various degrees some principles of the European REACH. This article deals with the US chemical policy reform in the context of the European experience with REACH, assessing whether the US chemical policy review is subject to Europeanisation or whether the influence of REACH on the US reform is merely superficial.

Keywords: EU, USA, chemical regulation, REACH, TSCA reform

1. Introduction

The concept of Europeanisation as defined by Robert Ladrech (1994), Tanja Börzel (1999) or Claudio M. Radaeli (2003) has been discussed many times in connection with various national policies. There are now many definitions of Europeanisation varying in terms of generality, workability or specific emphasis. In this article, the main focus is on chemical regulation as a policy which has some institutional and procedural implications. According to Ian Bache (2003), Europeanisation definitions share the view that the EU impacts on domestic politics vary and there are also variations in the domestic actors' response to EU requirements (Bache, 2003). However, this two-way process does not occur only between the EU and its member states' institutions or policies. It could easily spread beyond EU borders at the international community level and influence other actors, including international

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organisations and different countries outside the EU. For example, Frank Schimmelfenning (2012), in his review article, presented several concepts analyzing the Europenisation process beyond the European Union borders, including transnational modes of Europeanisation (Schimelfenning, 2012). Europeanisation may reflect not only the hierarchical process between the EU and its member states (which the author of this study considers as an unnecessary element of Europeanisation) but more indirect transnational logic, as well. In other words, the "EU's conditionality and socialisation can be directed at societal actors - parties, firms, interest groups, NGOs or even regional administrations – rather than central governments" (Schimmelfenning, 2012). As a consequence, states outside the EU may adopt EU-like values, rules and procedures in order to follow EU incentives.

This article deals mainly with analyzing the Europeanisation of the chemical policy in the USA. Europeanisation is not seen as a hierarchical process, where European values, policies and procedures enter the national agenda but rather as a horizontal process of voluntary adaptation to EU regulation. Europeanisation is understood in a similar way as referred to by Simon Bulmer and Martin Burch (1998). In their view, Europeanisation could be seen in two dimensions. The Intrastate dimension refers to the impact of EU policies, rules, practices and values on member state activities in respect of policy making and implementation. It refers to the impact that EC/EU requirements had on the process of setting member states' agendas and goals. Secondly, it refers to the extent to which EU practices, operating procedures and administrative values have impinged on, and become embedded in administrative practices of member states (Bulmer and Burch, 1998, p. 602).

Despite the above mentioned definition, being EU centric and referring to a EU member state, which is influenced by the impact of EU policies, rules, values and practices it could be applied to non-EU member states as well. The considerable EU influence in various areas related to global commerce, notably antitrust laws, privacy regulation or food safety, is well-known. According to Anu Bradford (2012), this is caused by the EU ability to export its influence through legal institutions and standards in areas related to its regulatory policies (Bradford, 2012). In order to comply with European rules, many multinational manufacturers of chemicals or related products applied a single safety standard. As a result, the costs for implementing changes in chemical regulation decreases within other states where companies have already adapted to a higher standard of chemical protection (Uyesato, Weiss, Park, Young, Kazumi, Ferris and Bergkamp, 2013). This indirect impact of European regulation is observable in many countries outside the EU, which initiated changes within chemical regulation as response to REACH, notably the USA, China, Japan, South Korea, Canada and Russia (Naiki, 2010) and others, including Malaysia, Philippines or India, which may follow soon.

Bulmer and Burch focus not only on the top down influence on agendas and goals, but also refer to operating procedures and administrative values (Bulmer and Burch, 1998), which are an inseparable part of regulation and their adoption might be part in the above described process. In the following text, both the determination of member states' policy agendas and goals and administrative practices, values and operating procedures are examined in order to answer the main research question: in what way is chemical regulation review in the USA influenced by the EU regulation[1] REACH? The aim is therefore to explore and analyse the possible causal link and to validate the EU impact on domestic change (Ladrech, 2010). Conducting such an analysis may explore the extent to which US reform proposals are influenced by EU experience and the extent to which US regulation was adapted to fit the REACH regulation. Due to its exploratory nature, the article helps to discover different attitudes towards various regulatory areas (registration, authorisation, substitution etc.) which might be very important in the future because both chemical regulations are likely to be soon assessed due to negotiation of the Transatlantic Trade and Investment Partnership (TTIP)[2]. Once the EU and the USA create a Free trade zone pressure, the harmonisation of chemical regulations will arise. It is now unrealistic to think about merging regulatory systems; however, a certain level of harmonisation will be required. In this sense, further research comparing both regulations in detail will be necessary.

TSCA and REACH have been compared in several articles (e.g. Denison, 2009; Applegate, 2008; Brownfield, 2008; Koch and Ashford, 2006); however, they dealt mainly *ex ante* with possible reform proposals. Despite drawing on the REACH experience, no concrete reform proposals were discussed. This lack is addressed in this article which focuses *ex post* on two specific reform proposals: the 2013 Chemical Safety Improvement Act (CSIA) and the 2013 Safe Chemicals Act (SCA) which are assessed in the context of REACH influence.

Based on Yin's types of case studies (descriptive, exploratory and explanatory), the article is considered mainly as an exploratory case study which examines research questions or thesis (Yin, 1994). According to Jonathan Grix, this type of case study is suitable for topic identification for more extensive

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[2] EU chemical sales counted in 2012 for € 558 billion (17.8 % of the World chemical sales) and US (respectively NAFTA) chemical sales counted for € 526 billion. By signing TTIP, EU and USA will create largest economic space for chemical trade, outgrowing China which counted for 952 billion € in 2012 (CEFIC, 2013).

research (Grix, 2004). As noted above, the US chemical regulation reform is not the only one in the world which seems to be influenced by EU REACH. However, in this article, the case of Europeanisation of the US chemical policy is not used for theory assessment or development. The theory is used as a tool for analysis. In this sense, case study is close to the intrinsic study intended to achieve complex understanding of the case (Stake, 2003). This approach is also reflected in the structure of the article.

The second chapter presents developments in the basics of chemical regulation in the USA and Europe. This chapter starts with the adoption of the 1976 *United States Toxic Substances Control Act* (TSCA) and explores the weaknesses of US chemical regulation. The weaknesses identified are compared to the EU chemical regulations prior to REACH. The main aim of this chapter is to display the deeper context of the EU and US regulation. However, it is necessary to identify what Europeanisation should look like. That is why the third chapter briefly introduces REACH in the context of a response to the weaknesses identified in the first chapter. This part also identifies the "European elements" within chemical regulation. The fourth chapter focuses on Europeanisation and deals mainly with several reform proposals, with a special focus on the 2013 Chemical Safety Improvement Act (CSIA) and 2013 Safe Chemicals Act (SCA) which are examined from the European elements perspective. The aim of the chapter is to identify the European elements included in the CSIA and SCA. By identifying the European elements present in REACH, in the US chemical policy proposals, we can measure the scope of Europeanisation. Proposed changes are evaluated in the context of Europeanisation in the last chapter.

2. Failing models of chemical regulation

Chemical regulation in the USA has been based on the *United States Toxic Substances Control Act* (TSCA) since 1976 which is operated by the Environmental Protection Agency. When enacting new regulation, legislators are facing crucial questions about the scope of the regulation. Should new legislation be retrospective and also cover old substances or should it only be created for new ones? The scope of regulation under TSCA presents a compromise, establishing distinct forms of regulation for "existing substances" and "new substances". The key element in this matter is the TSCA Inventory which collects basic information about substances manufactured or processed in the USA (TSCA, p. 218). According to the TSCA's definition, "*new chemical substance means any chemical substance which is not included on the chemical substance list compiled and published under section 8(b)"* (TSCA, p. 192). All substances which are not registered on the TSCA Inventory or are not subject to exemption are not allowed to be manufactured or imported. When TSCA entered into force in 1976 all substances existing at that time were subsequently

grandfathered into the inventory. Thus, the TSCA in effect presumed that all substances marketed before December 1976 were safe to use.[3] To a large extent, this approach undermined the distinction between the two categories. Moreover, it did not improve on the lack of information on the intrinsic properties of registered substances.

According to the TSCA, the producer was obliged to send pre-manufacturing notification for new substances to the Environmental Protection Agency. When the EPA discovered some "unreasonable risk to human health or environment" the regulation was enacted. This could be managed in different forms: recommendations on labelling, recording and monitoring the use, limiting use or production. Total production or a sale ban is also an available solution (TSCA, p. 6). By adopting regulatory decisions, the EPA had to consider the effects of the regulated substance on health, magnitude of exposure, exposure of the environment, benefits for various uses and the availability of substitutes and other economic consequences. In reality, the EPA had only a limited time period of 90 days to object to new chemicals after which the substance was placed on the TSCA Inventory and became an existing substance (Denison, 2009). The limits were much more extensive due to lack of information. The manufacturer's obligation to provide information about intrinsic properties relied mainly on voluntary measures and thus rarely generated new information (Applegate, 2008). Manufacturers were not motivated to test its chemicals because expensive testing might lead to disclosure of toxic properties of chemicals and result in ban (Wagner, 2008). Moreover, the burden of proof was on the side of the EPA with the lack of information which soon led to a paradoxical situation. The EPA did not have enough information to prove the unreasonable risks which led to a regulatory underperformance and to what Wendy Wagner calls "strategic ignorance": manufacturers did not develop toxicity data on their own products (Wagner, 2004).

The TSCA system did not establish effective motivation for data gathering. The EPA had the authority to require testing but the testing requirement was subject to judicial review under which the EPA had to prove that chemicals might present an unreasonable risk. As John Applegate points out, there are more than sixty-two thousand chemical substances within the TSCA Inventory, but the EPA required testing for fewer than two hundred chemicals (Applegate, 2008). Some of the tested chemicals were prioritised. Under section 4 of the TSCA, a special committee was established for the creation of the Priority list. Substances considered for the promulgation of the rules were on the list. However, the committee had to consider relevant factors such as the quantities in which the substance or mixture would be manufactured, the substance quantitites which entered the environment, the number of

[3]It is estimated that existing substances counts for 99 percent by volume of chemicals in commerce (Applegate, 1998).

individuals who were or would be exposed and the extent of exposure (TSCA, p. 197). The toxicity and other substance properties were not mentioned. And this problem still persists.

The "information gap" was not the sole problem of the TSCA system. Michael Wilson and Megan Schwarzman (2009) identified another two gaps under the TSCA. First, the "safety gap" caused by a lack of legal tools possessed by the regulator to identify the potential health and environmental effects of hazardous chemicals, to prioritise them and adopt the appropriate action to mitigate the potential health and environmental hazards (Wilson and Schwarzman, 2009).

While substantial provisions were strong and comprehensive, procedures and judicial review made the whole status useless. This is best demonstrated on the EPA failure to ban asbestos. In the case *Corrosion Proof Fittings v. EPA* (United States Court of Appeals, Fifth Circuit, 1991), asbestos manufacturers sued the flawed EPA decision to ban asbestos arguing that EPA did not use the least burdensome regulation. Appellate Court overturned EPA's ban and required EPA to consider in the socio-economic analysis not only the negative effects of asbestos, but also their positive ones. Due to not having a substitute and to the high costs per life saved, Appellate Court overruled EPA's decision to ban asbestos[4]. This case demonstrated the multiplication effect of the TSCA shortcomings and seriously "crippled" EPA ability to take action (Woolf, 2006).

Due to a lack of appropriate regulation, some states placed priority on the clear objectives for identifying and acted to control chemicals of concern. As a result, the level of control differs in the USA (Denison, 2009). For example, California Proposition 65 of 1986 which was passed by direct voter initiative prohibits businesses from knowingly exposing individuals to listed substances without expressing/giving/ providing a clear and reasonable warning (Office of Environmental Health Hazard Assessment Proposition, 1986).

Secondly, Wilson and Scharzman identify a "technology gap" presented by the lack of initiatives for green chemistry research, development and scientific advances (Wilson and Schwarzman, 2009). For example, under the TSCA, there is no regulation of nonomaterials, which are gradually being placed on the market. Some studies have already proved that exposure of some ultra-small particles could cause harmful effects to the human body, including skin irritation, organ failures and even DNA structure changes (Sharma, Kumar and Dhawan, 2012).

The gaps in chemical regulation were not only the problem of the United States. A similar situation occurred in Europe where chemical regulation was,

[4] Appellate Court ruled that spending $ 200−300 million to save approximately seven lives (approximately $ 30−40 million per life) over thirteen years is not reasonable (Corrosion Proof Fittings v. EPA, § 94).

for decades, based on four acts. In 1967, the Directive 67/548/EEC about the classification, packaging and labelling of dangerous substances, reflecting the commitment of the EC founding member states to harmonise rules for easier trade, was adopted. Another tool was established in the early 1970s by the adoption of Council Directive 76/769/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. The Directive was a response to national restrictions which created obstacles for EC trade. Other cornerstones of chemical regulation were laid down by Council Regulation 793/93 on the evaluation and control of the risks of existing substances. According to this regulation, substances were divided into "existing substances", marketed before 1981 and "new substances", placed on the market beginning in 1981. Producers were obliged to provide information about some chemical properties of substances produced in a quantity of more than 1 000 tons per annum. For the substances produced between 10 to 1000 tons per year, only basic information was required. The last tool was Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations. Despite the above act, the established system of chemical regulation failed in many aspects.

In 1998, the European Commission published a report on the operation of the above four instruments leading to negative conclusions. As of the 110 selected chemical substances labelled as "substances requiring immediate attention because of their potential effect of man on the environment", only 38 have been discussed and 19 risk assessment reports have been completed due to the time consuming process (European Commission, 1998). For example, from the publication of the priority list until the agreement on the risk assessment report, it took, on the average, between 27 and 54 months (European Commission, 1998). Thus, both US and EU systems failed to provide enough information and hindered appropriate risk assessment and risk control. The burden of proof was placed on the Public Authorities rather than on Industry which meant insufficient chemical control. Public authorities and member states did not carry out the necessary activities due to a lack of money or capacities and in reality the burden of proof was placed on public users. In both systems, users had a complicated situation to prove the effects of substances. First, there were too many chemicals. For example, the European Inventory of Existing Commercial Substances (EINECS) collected 100 106 entries. Second, many companies did not understand the complicated regulation and made mistakes. For example, the inspection of 100 companies revealed that 25% of the examined substances were not correctly classified and 40% incorrectly labelled (European Commission, 1998). And third, there was a lack of information about existing substances produced in large quantities: only 3 percent of the high production volume chemicals had a full data set and 86 percent had less than a

base-set level (Schörling, 2004). Only little was known about the influence of chemicals on human health and environment. Moreover, some argued that there was nothing like single substance exposure (Santilo and Johnston, 2006) as an average person is exposed to hundreds of chemicals per day (see for example Thornton, McCally and Houlihan, 2002). The original regulatory systems proved to be ineffective in identifying chemical risks and were slow to act when risks were discovered. The lack of long term real regulatory policy resulted in a system failure which became the impetus for a comprehensive chemicals policy reform in Europe and later also in the US.

3. REACH: Paradigm shift in EU chemical regulation?

The architects of the new chemical regulation in the EU built a new regulatory system with three decades of experience with the TSCA and the insufficient European chemical regulation based on four acts. There were four main challenges: first, to encourage producers to provide data, second, to close the information gap on the existing substances' properties, third, to establish an effective system of risk assessment and risk control with a special focus on substances of very high concern and fourth, to reduce animal testing and promote alternative testing methods. After extensive negotiations and permanent lobbying (Selin, 2007 or Contiero, 2006), a new system of chemical regulation was created.

REACH (Registration, Evaluation and Administration of Chemicals) addressed all the above mentioned challenges. Under the registration part, new legislation requires producers and importers to register their substances produced or imported in a quantity up to one ton per year to the newly created European Chemicals Agency. This part of REACH reflects the urgent need for information on chemical properties as the registrant is obliged to provide a data set (dossier) including technical information (substance identification, information on the manufacture and use, the classification and labelling, intrinsic properties etc.) in all cases and a chemical safety report for substances produced or imported in quantities of ten tons or more per year. Moreover, substances produced or imported in quantities of more than 1000 tons have to undertake extensive toxicity tests). The Registration dossier must be prepared in the IUCLID 5 (International Uniform ChemicaL Information Database) software which has been developed in cooperation with the Organisation for Economic Cooperation and Development and could be used for OECD High Production Volume (HPV) Chemical Programme (ECHA, 2014).There are three deadlines set out for the registration based on production volume. Until November 2010, there was phase 1 registration for CMRs produced in quantities of more than one ton/year, very toxic substances to aquatic organisms produced in quantities above 100 tones/year and other substances produced in volumes of more than 1000 tones/year. Phase 2 registration deals with chemicals produced in quantities

between 100 and 1000 tones/Year which had to be registered by May 2013. By May 2018, all remaining substances produced in quantities of more than one tone/year should be registered.

The incentive for producers to register and provide information about marketed substances is set high. Without registration, they are not allowed to enter the EU market. The "No data, no market" principle thus becomes the main motivation for registrants. Once the registration dossier is sent to the ECHA, it conducts an evaluation of the submitted information (compliance check). The ECHA also examines proposed tests. In order to gather more data for risk assessment, the substance is evaluated by the member states' competent authority. In order to prevent test duplication, registrants are forced to share tests where animals were used and are allowed to share the costs of testing. The ECHA solves possible data sharing disputes among concerned parties. Information sharing is an important element of REACH in order to ease the registration process and provide data to consumers. Registrants can fully cooperate in the preparation of the registration dossiers and even in the testing stage. For example, the ECHA also runs the Substance Information Exchange Fora (SEIF) where all information about registered chemicals is available. Contrary to the SCA, there is no similar provision. Moreover, the exchange of information has also become a source of criticism. European companies complain that they had to pay expensive tests and registration costs to provide the required information while companies outside the EU can use them for free.

The availability of scientific data about intrinsic properties, extrapolation methods and toxicological effects is a necessary prerequisite for risk assessment and later effective risk management. Under the authorisation procedure, REACH focuses on managing chemical risks passed by Substances of Very High Concern, covering carcinogenic, mutagenic or substances toxic for reproduction, substances which are persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (V/vB) according to REACH Annex XIII, and also substances identified on a case basis with relevant evidence about their effects. Those substances cannot be placed on the market unless exemption is granted for their specific use. Before a dangerous substance appears on the Authorisation List (REACH Annex XIV), it is placed on a Candidate List by a Member State or the ECHA.

Very similar to the authorisation process is the restriction procedure which could be initiated by the ECHA or a member state in order to limit the use of a certain substance which poses a great risk to human health or the environment. The Risk Assessment Committee within the ECHA provides information on whether the suggested restriction is appropriate. The committee for socio-economic analysis inform about the socio-economic impact of the proposed restriction. The substance can be used only when the socio-economic contribution outweighs risks posed by its use. This procedure includes a six-

month-long public consultation period and advice on enforceability by Forum. It is important to note that permission is granted when the producer or importer proves that the risks are adequately controlled or when there is no alternative substitution available. In other words, a safer alternative must be used where possible (or risk is under appropriate control) which places the burden of proof on chemical industry.

The above designed system represents a paradigm shift. The burden of proof is removed from the consumer to the producer who is forced to prove that the marketed substance is safe. REACH works with the precautionary principle (Sachs, 2011) suspecting the dangerous effects of substances of Very High Concern. Those substances are exempted from the market unless socio-economic benefits outweigh the potential risks which must be adequately controlled and, at the same time, no safer alternative exists. The "No data, no market principle" together with the ongoing evaluation of chemicals ensures a high level of information for the ECHA which might adopt effective regulatory measures to protect human health and the environment.

The EU has created a complex system of chemical regulation which addressed the main gaps similar in both the EU and US regulatory systems. REACH was adopted six years before the TSCA was updated by extensive reform. Due to the similar shortcomings of the two regulatory systems before REACH, it could be expected that the US lawmakers reflected on the EU experience with REACH. The next chapter will explore the TSCA reform and identify the REACH common elements. It focuses on the question: to what extent are the two systems similar in terms of rules, procedures and values?

4. Alternatives in chemical reform

After 30 years of experience with the TSCA, there was a general consensus that chemical law was in need of crucial reform. Some authors argue that the REACH model for regulation was considered a costly alternative and anticipated that none of the "core elements" would be used in the US chemical reform (Uyesato et al., 2013). However, there was reflection of REACH provisions in the US since REACH was debated and several states looked at Europe for regulatory models (Sachs 2009: 1860-1861). Several reforming proposals were submitted to Congress which, in some parts, reflected REACH to various degrees. In 2010, there were two bills considered before both the House and Senate: The Toxic Chemicals Safety Act of 2010 (HR 5820) and the Safe Chemicals Act of 2010 (S 3209), which was later revised and reintroduced as the Safe Chemicals Act (SCA) of 2011 (S 847). Despite considerable discussion, none of these bills came to enactment due to other priorities in the 2012 election year. Attempts to find the best solution for complex reform continued in 2013 when New Jersey democratic senator Frank Lautenberg and Los Angeles republican senator David Vitter introduced a bipartisan bill to modernise

the TSCA. The so called Chemical Safety Improvement Act (CSIA) became the alternative to the Safe Chemical Act which was considered as more protective than the industry-backed CSIA (Shapiro, 2013). However, the Safe Chemical Act of 2011 was also updated and re-introduced as the Safe Chemical Act (SCA) of 2013 (S. 696) by democratic senators Frank R. Lautenberg and Kirsten Gellibrand. The main differences could be seen in several areas (for detailed comparison see Yen, 2013). The following text is divided into three areas covering registration, evaluation and authorisation of chemicals, reflecting the structure of REACH.

Registration

The main purpose of registration under REACH is data gathering which was the main aspect of the TSCA reform. The modern regulatory systems based on risk assessment require scientific information about chemical properties. Toxicity and exposure information are necessary for effective decisions by the regulatory authority to ensure a high protection of human health and environment. The CSIA as well as the SCA of 2013 address the lack of information about chemicals and require, like REACH, a review of existing chemicals. Under the SCA, manufacturers and processors will be required to submit a minimum information set (there is no basic data set required under the CSIA which is contrary to previous reform proposals). The EPA will use submitted information for screening purposes to determine risk assessments. If there still is a lack of information, the EPA can require additional information or require testing. Where a lack of information remains or the manufacturers fail to submit the information needed, the EPA may adopt regulatory action and not allow the substance to enter the market. Similar provisions are also under the CSIA, where the EPA can demand more information and the failure of a manufacturer in complying could mean they will be subject to penalties. Contrary to REACH, the information provisions under the CSIA do not require data on aggregate and cumulative exposure. However, the EPA can demand testing for bio-accumulation and persistence.

Both proposals continue the practice of the TSCA pre-manufacturing notice for new substances. However, under the reforming bills, the EPA received more power and information requirements for producers increased. Under the CSIA, manufacturers and processors have to report new significant use of chemicals and, under the SCA, even changes in production volumes. Based on the provided information, the EPA will put the substance within an appropriate category. Under the SCA, the EPA will determine whether the substance belongs to Substances of Very High Concern, is unlikely to meet the Safety Standard, Substances with insufficient information or substances likely to meet the safety standard. The CSIA reflects only two categories and recognises substances not

likely to meet safety standards and substances where additional information is needed.

Under the CSIA, not all chemicals on the market are subject to review as the EPA will update its inventory and divide chemicals according to their active use. Chemicals notified by manufacturers or processors five years before the CSIA entered into force are listed on Active Inventory while chemicals notified more than five years before CSIA entered into force are considered inactive.

Another failure is a lack of deadlines under the CSIA. Contrary to the SCA, where deadlines were explicitly mentioned, there are no deadlines set for the EPA's inventory review, prioritisation of chemicals or regulatory actions which might be considered as one of the greatest shortcomings. Again, under REACH, deadlines are applied to data gathering provisions. Producers are required to deliver data under a registration procedure according to the quantity produced per annum. Failing to meet deadlines means the application of the "no data, no market" rule.

Evaluation

Not all substances are subject to evaluation under both proposals as some substances are not considered as active and there is the prioritisation of safety Assessments. Under the SCA, all substances are prioritised for safety assessment and divided into four categories: Substances of very high concern, substances with insufficient information, substances of very low concern and substances to undergo safety determinations. Once a substance is placed among substances to undergo safety determinations it is further prioritised, ranked from priority 1 to priority 3. This system remained from previous proposals of the SCA. For example, under the SCA of 2011, there were three classes established. For example, Priority Class 1 was supposed to contain chemical substances requiring immediate risk management like substances which are persistent, bio-accumulative or have the potential for widespread exposure to humans or other organisms. Under Priority Class 2, chemicals which require a safety standard were placed and Priority Class 3 chemicals did not require immediate action and were considered safe at any stage of the chemical substance lifecycle (SCA, p. 55).

Under CISA, all active chemicals will be subject of the EPA's review which will rate them as "high" or "low" priority according to the hazard and/or high exposure they present to human health and the environment and the ability of the EPA to schedule and complete the risk assessment. Once a chemical substance is evaluated as "high priority", the EPA must conduct further safety evaluations (CSIA, p. 17). Under the CSIA, the EPA fails, contrary to REACH, to prioritise chemicals explicitly in umbilical cord blood or PBTs. However, it could be expected that the EPA is aware of the existence of these chemicals and they will be under special scrutiny. Similarly to REACH, in the case of any information

deficit, the SCA EPA can ask for more information and require testing for evaluation purposes. Under both proposals, the EPA can newly require testing by issuing orders which could be considered as a slight improvement to the TSCA, where the only way was to accept a time consuming rulemaking process placing the burden of proof on the EPA. Removing the burden to prove "unreasonable risk" from the EPA is unlocking the possibility to act in this matter. Similarly to REACH, the burden of proof will be placed on producers to demonstrate that the chemicals they use are safe. Reforming bills are moving TSCA closer to the European "precautionary principle" and shifting regulation to a more risk-based safety standard becomes the basis for the US reform and presented shift to more risk-based[5] safety standard (Uyesato et al., 2013).

However, contrary to the REACH, the requirement to test is mainly (with more exceptions under the SCA) based on the EPA decision and thus requires the EPA to act. Under REACH, manufacturers are required by law to test chemical substances which are prioritised for testing. A similar situation is in the area of new chemicals intended to enter the market. Under the TSCA before the new chemical substance enters the market, the EPA has to act and express that the new chemical is "likely safe". This could be evaluated as a "security switch" contrary to the pre-manufactory notice under the TSCA. However, contrary to the REACH, the burden to act is on the EPA as European manufacturers under the notion "no data, no market" are required to prove that their chemicals are safe. Similarly to REACH also, under the CSIA or the SCA, all costs of testing required by the EPA are to be borne by companies. It is important to note that US companies have a slightly better position in data availability as their counterparts in Europe are undertaking complex testing of marketed substances.

Authorisation and Restriction

The CSIA improves the regulatory performance of the EPA as the restriction process (risk management) was also the subject of the review. Like under the TSCA, the EPA can use many tools including labelling requirements, monitoring use or total ban. However, the EPA had to consider the availability of technically and economically feasible alternatives, risk posed by those alternatives or the economic and social costs and benefits of the proposed regulatory action and options considered (CSIA, p. 71). Contrary to the TSCA, there is no explicit requirement to adopt the "least burdensome alternative";

[5]There is a distinction between risk-based and hazard-based regulation, representing a qualitative shift in the protection of human health of environment. While hazard deals with the potential source of harm or adverse health effect, risk-based regulation tries to decrease the likelihood that a person or environment may be hurt due to hazard exposure. For example, exposure to Benzene (hazard) may lead to Leukemia (harm caused by hazard). The risk depends on how long a person is exposed to Benzene. With increasing exposure increases the likelihood and risk of Leukemia is higher.

however, rules for considering regulatory action result in a similar outcome and the revised regulatory process under the CSIA might be much easier than under the TSCA. Considering the available options is a similar aspect to the European REACH, where socio-economic analysis and alternative options (substitution) are considered prior to restriction. While a substation is a compulsory element within REACH for all hazardous chemicals where a safer alternative exists, under the CSIA, there are similar provisions for "green chemistry".

In general, a producer may, under the CSIA, continue production of a chemical since the EPA identifies the substance as "high priority" and does not determine that the substance does not comply with the safety standard for its use. The safety standard ensures that the risk of harm to human health or to the environment will not result from exposure to the chemical. However, safety assessment under CSIA is not suitable for judicial review (CSIA, p. 29) but subject to public notice and an opportunity for comment. However, safety assessment might be part of the judicial review[6] as a part of the final agency action (CSIA, p. 73). Regulation under the SCA is much more restrictive. Only the EPA can make affirmative safety determination for the chemical and determine that there is a reasonable certainty that no harm can be brought against human health or the environment from the aggregate exposure to the chemical substance. This determination will be not subject of judicial review (CSA, section 6). For the EPA's conclusion, the EPA may ask the manufacturer to provide scientific data. When deciding whether a substance meets safety standards the EPA has to consider the consequences on the health of vulnerable populations, including children. The above mentioned procedure is compulsory for Substances of Very High Concern, Substances unlikely to meet safety standards or for substances where there is insufficient information. All other substances may be marketed.

Under REACH, the use of a substance may be authorised if the manufacturer proves that the risks connected with use are adequately controlled. This is similar to the SCA, where the producer has, by scientific information, to drive the EPA to the conclusion that there is reasonable certainty of no harm concerning the substance. The CSIA may only grant an exception in authorisation when

> a) the exemption is in national security; b) the lack of availability of the chemical substance would cause significant disruption in the national economy; c) the use for which the exemption is sought is a critical or essential use for which no feasible alternative for the use would materially reduce the risk to health or the environment or no feasible alternative for the use is economically, technically or efficiently available; or d) the use

[6] As evident in *Corrosion Proof Fittings v. EPA* case options for judicial review may in the end undermine regulatory performance of an agency and make procedures flawed.

> as compared to reasonably available alternatives, provides a net benefit to human health, the environment, or public safety" (CSIA, p. 72).

Thus, the CSIA, contrary to REACH, offers more ways to grant exceptions which are economically reasonable and does not establish zero risk safety standards.

Another element which differs to the European REACH is the principle of "pre-emption" under the CSIA. When state requirements restrict or prohibit chemical use, they remain valid within the state until the EPA takes final action. Moreover, state requirements to mandate monitoring or special labelling would not be affected by the EPA decisions. Contrary to the USA, in the European Union, member states can act as intermediary and provide data for the ECHA to take appropriate regulatory action which is legally binding within all member states.

Comparing REACH and the US regulatory proposals, we can identify several aspects that all regulations share. Table 1 identifies common and uncommon elements of both regulations.

5. Europeanisation of US chemical policy?

The above mentioned table shows a considerable shift in three areas: scope of regulation, approach to new chemical substances and evaluation. Regarding the scope or regulation, the TSCA made the distinction between existing chemical substances and new chemical substances, which were not listed in the TSCA inventory. The scope of registration was *de-facto* limited due to the lack of information about existing substances which were grandfathered into the TSCA inventory (Kvinge, 2011). Grandfathering diminished the formal distinction between new and existing substances and contributed to the information gap, as existing chemical substances were considered safe. The CSIA is closing this gap by reviewing the TSCA inventory, however making a new distinction between "active" and "passive" substances. As active substances are those marketed, it could be claimed that this change would shift the registration part closer to the European REACH as the scope is widened. A similar approach in the scope of data gathering is under the SCA. However, both proposed regulations represent a qualitative shift in data gathering compared to the TSCA.

The second approach to new chemicals changed. Under the TSCA, the manufacturer was obliged to send a pre-manufacturing notice containing basic information about the substance intended for market sale. The EPA had a 90-day period to object the substance and find the "unreasonable risk". This was extremely hard due to the lack of information and the voluntary basis of data gathering tools. The CSIA is shifting more power to the EPA which is required to declare chemicals as "likely safe" before allowed to enter the market.

Table 1: Elements of chemical regulation

Regulation element	REACH (2007)	TSCA (1979)	SCIA (2013)	SCA (2013)
1. Overall approach to regulation	Scientific risk assessment	Scientific risk assessment	Scientific risk assessment	Scientific risk assessment
REGISTRATION				
2. Scope of registration	All chemical substances intended for market use	All substances since 1976	All substances intended for market use	All substances in commerce
3. Distinction between old and existing chemical substances	No	Yes, but existing substances grandfathered into TSCA inventory	Distinction between "active" and "passive" substances	Yes, but EPA may demand data on existing substances
4. Prioritization based on properties	Yes, explicitly mentioned	No	No	Yes
5. Clear deadlines for registration	Yes, based on REACH directive	No	No, only internal	Yes
6. Regulation of new chemical substances	Yes, "no data, no market"	Pre-manufacturing notice	Yes, approval by EPA "likely safe"	Yes, according to category
7. Registration data compliance check	Yes, ECHA can demand information	No, mostly on voluntary measures	Yes, EPA can demand information	Yes
EVALUATION				
8. Scope of evaluation	Compulsory to all substances	Rare due to administrative obstacles and burden of proof on EPA side	EPA can demand testing	All substances in inventory
9. Prioritization for testing	Yes, based on properties	Yes, based mainly on expected exposure level	Yes, "high priority substances" based on hazard and exposure	Yes, 3 categories
10. Data sharing obligation	Yes	No, mainly on voluntary basis	No specific provision	Yes, by administrator + Risk information for forkers
11. Who pays testing	Companies	Companies	Companies	Companies
AUTHORIZATION (regulation)				
12. Special focus on PBT, vPvB, carcinogenous, mutagenous or reproductive toxic	Priority for authorization	Generally focuses on "hazardous chemicals"	Generally focuses on "hazardous chemicals"	Yes, explicitly SVHC
13. Adequate risk control exemption	Yes	After showing that substance for certain purpose will not present unreasonable risk of injury to health or the environment	No	Yes, but EPA decides
14. Socio-economic analysis prior authorization (regulation)	Yes	Yes	Yes	Yes
15. Substitution considered	Yes, supreme rule	Yes, one of recommendations considered	Yes, supports green chemistry and safer alternatives	Yes, one of recommendations considered
RESTRICTION				
16. Judicial review	Yes	Extensive, burden of proof on EPA	Maintaining the standard of evidence from TSCA	Limited compared to TSCA, review of safety determinations; burden of proof on manufacturer
17. Public consultation / public access to information	Yes, obligatory	No provisions	Slightly better than under TSCA	Better access to information than SCIA
18. Socio-economic analysis prior restriction	Yes, conducted by ECHA Committees	Yes	Yes	Not in all cases

Source: Author, based on mentioned regulations.

The third evaluation of chemicals was highly ineffective under the TSCA due to the burden of proof being on the EPA which had to find the "unreasonable risk". Under the CSIA, the EPA may demand testing which will most likely be held according to the priority risk and by taking into account the production volume, expected level of exposure and the hazardous properties of chemicals. While under the TSCA the testing priority was based mainly on the expected exposure level, under the CSIA, the category of "high priority substances" was established. This category mainly refers to hazard and exposure and thus shifting criteria more to the REACH regulation where evaluation priority is based mainly on chemical properties. A similar situation is under the SCA, where three priority categories were established according to substance properties.

Many elements are similar to both regulations, as for example, the socio-economic impact is considered before regulation (restriction) takes place or alternatives are considered prior to the substance ban. However, safer alternatives and green chemistry provisions are much more extensive under the SCA and thus, closer to REACH. There are three activities mentioned to support green chemistry: first, to establish a network of green chemistry and engineering centres. Second, to make grants to promote and support research, development and adoption of safer alternatives and third, to create a program to facilitate the development of a workforce that produces safer alternatives. Similarly, public consultation and access to information provisions are better under the SCA.

The above mentioned examples present the three most visible changes and raise the question of possible European influences on US chemical regulation. As shown above, both regulatory systems faced serious deficiencies before REACH was adopted in the EU and thus could have served as a good example or at least, source of inspiration for the US law makers. Both the SCIA and the SCA address the main deficiencies of the TSCA. While addressing similar areas to REACH in the case of European regulation, in many ways, they are taking a different direction. Due to the more protective nature of the SCA, this regulation is slightly closer to REACH than the CSIA.

Simon Bulmer and Martin Burch (1998) presented two dimensions where the European influence on US policy can be examined. First, regarding the extent of the impact of EU requirements or policies on the US policy, we may acknowledge that the influence was minimal as the US focused mainly on revision to increase the functionality of the TSCA. Despite the fact that both regulatory systems shared deficiencies, US purposes seem to be aimed at overcoming the TSCA regulation obstacles and adopted reforming measures thus could be seen as functional in nature Second, regarding the extent to which the EU practices, operating procedures and administrative values have impinged on, and become embedded in the administrative practices of the US, we can

claim that the vast majority of practices remained untouched. It could be noticed that a slight shift occurred in three areas of the scope of registration, new chemical substances pre-market procedures and testing. The REACH model could serve as a source of inspiration, but not as a normative example. We can distinguish some structural similarities between the two regulatory systems. Both the SCIA and the SCA are thus clearly a US response to common deficiencies in former chemical regulations and the labelling "US REACH" is far from an appropriate comparison. REACH represents a new paradigm with chemical regulation while the CSIA and the SCA are just a functional shift within an old paradigm, which has been softened due to the incorporation of the "precautionary principle" and support for green chemistry under the SCA. The burden of proof has changed to the "burden to act" on the side of the regulating authority and reminding the agency that rights belong to the vigilant. With new tools addressed under both bills, the active EPA approach to regulation could work better than under the TSCA. The Corrosion Proof Fittings case showed that judicial review could be a huge obstacle for agencies. The shifting of the burden of proof and new statutory allocation are good prerequisites for effective regulation.

6. Conclusion

Both the CSIA and the SCA represent a qualitative shift in US chemical regulation. Three of the eighteen aspects are bringing the US regulatory model closer to the European chemical regulation based on REACH. However, it is hard to determine the extent to which those changes are influenced directly by the attractiveness of REACH and to which they could be seen as a functional and gradual development within a single regulatory system without any foreign influence. The CSIA is enabling the EPA to demand more information and issue order testing. However, contrary to REACH, the burden of action is on the EPA rather than on the chemical industry. The information gap has been softened due to the TSCA inventory review and attention has been placed on the active inventory substances. Regarding the nature of the TSCA, the CSIA and the SCA reform could be seen as an evolutionary attempt to fulfil purposes and activate "rusty" tools of previous regulation rather than a revolutionary step to a shifting paradigm of chemical regulation. If there was any influence of REACH, it was only in terms of principles.

Currently, both bills are frozen. TSCA was assigned to a congressional committee for consideration on May 22, 2013. According to prognosis of Civic Impulse, LLC server www.govtrack.us, there is just 20 % chance of getting past the committee and 7 % chance of being enacted (Civic Impulse, 2014a), compared to the SCA which has 71% chances 71 % of getting past the committee and 10 % chances of being enacted (Civic Impulse, 2014b). However, after the death of Senator Frank Lautenberg in May 2013, the fate of

CSA remains uncertain, opening new space for reshaping reform proposals which might better reflect European REACH. This attitude will be necessary in the context of ongoing TTIP negotiations where a different paradigm of chemical regulation may cause serious problems. Europeans will unlikely decrease high safety standard guaranteed by the long negotiated and painfully implemented REACH. Next to the TSCA failures, US decision makers should reflect REACH by shifting reform proposals towards REACH like provisions which will at least increase the safety standard in the US, ease entry to € 558 billion EU chemical market for US companies and make TTIP negotiations more likely to succeed.

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