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Chemical Regulations and the Effect on Manufacturers

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Abstract

This paper examines two major regulatory systems chemists and chemical manufacturers must deal with on a day-to-day basis. There are dozens of different sets of regulations that affect the chemical industry throughout the world. Many countries have their own specific rules that govern the chemicals manufactured or imported inside their borders. Specifically, this paper will examine the rise of the European Union's REACH system, the failure and reform of the United States' TSCA and finally, the effects these two systems have upon each other.

Chemical Regulations and the Effect on Manufacturers

When a person sets out to become a chemist, they could reasonably expect to become well versed with concepts such as hydroxyl numbers, nucleophiles and free radicals over the course of their chemistry careers. Designing, analyzing and evaluating chemical compounds would be typical expectations of a chemist starting work at a manufacturing company once they complete their education. And for the most part, that would be true. But a manufacturing company may expect more from their new employees in areas not covered in a traditional university curriculum. The new employee may be expected to become an expert on the many chemical regulations that govern exactly where and how a chemical manufacturer can legally sell their products.

According to R. Auerbach, who has been working with chemical regulations since 1976, there are multiple different regulatory systems throughout the world. Several of these systems have recently undergone major reform, such as: the European Union's REACH, the United States' TSCA, Korea's new K-REACH, Taiwan's updated TCSCA, and several food contact related regulations. China, Thailand and Turkey were also working to update and revise their regulatory law, which were expected to generate updated requirements in the near future (personal communication, September 11, 2019). Chemical regulatory laws have been and will be an expanding area of emphasis for industrial manufacturing for the foreseeable future.

To understand these regulatory systems may require a person to have assumed a lawyer's mindset rather than a chemist's. These regulations were mostly designed by the various countries and regions to protect their citizens and preserve the natural environment from a wide variety of

dangerous substances. This examination will cover just some of the complex labyrinth of regulations governing chemical manufacturers and the reasons that have made them necessary. The specific regulatory systems this paper will focus on are the European Union's REACH, the United States' TSCA, the effects they have had on one another and their influence throughout the world.

European Chemical Regulatory Systems

According to Mork and Hansson (2007), the European Union established the beginnings of chemical regulation in 1967. A harmonized system for the classification and labeling of chemicals was agreed upon by the member states and was enacted. During the 1970's, European countries had extended discussions over chemical unknowns and the need to find better solutions. In 1981, European countries conducted a chemical inventory, and it was discovered that the global chemical market consisted of an astounding 100,000 plus chemicals (Lewis, Kazantzis, Fishtik & Wilcox, 2006).

This discovery spurred European countries to create their own individual regulatory systems. It was agreed by the European Union member states when a chemical on the market before September 1981, it was considered as pre-existing. The existing chemicals did not necessarily have to be evaluated for health and environmental effects according to the agreement. These pre-existing chemicals were placed on a chemical inventory list known as the European Inventory of Existing Commercial Chemical Substances, or EINECS. The list was only open for a one-time mass addition and then the inventory list was considered closed (Mork & Hansson, 2007).

A separate, more rigorous regulatory listing was created for any chemical that entered the market after the 1981 deadline. These chemicals were considered new for the purposes of inventory listings. These new chemicals were "to be tested for their effects on human health and the environment" (Van Hemmen, 2009, p. 561). Lewis et al. (2006) state that since the introduction of these new regulations, only around 3,000 new chemicals had been fully brought onto the market. The approximately 3,000 chemicals only represent "about 1% of the total production volume" of all of Europe (Mork & Hansson, 2007, p. 23).

New chemicals suffered when compared to the EINECS listed chemicals due to the uncertainty behind the testing and the ensuing risk assessment results. This uncertainty was "not particularly conducive to innovation because of the different rules" (Lahl & Hawxwell, 2006, p. 7116). "Many believed that the lack of regulatory obstacles for the use of existing chemicals had stifled innovation because it was expensive for the chemicals industry to perform research on novel chemical alternatives" (Williams, Panko & Paustenbach, 2009, p. 555). Williams et al. describe that these novel chemical alternatives would have fallen under the far stricter regulations and were not worth the extra effort and cost to chemical companies. The regulatory testing results on new chemicals has not produced "sufficient information or sound chemical risk assessment practices pertaining to the environment. Furthermore, whenever the associated risks of these substances have been identified, the implementation of risk management measures has been unacceptably slow" (Lewis et al., 2006, p. 593).

European Regulatory Reform

During the 1990's, an effort was launched by the European Council to evaluate the risks associated with the high-volume chemicals on the EINECS list. Mork and Hansson (2007) stated

that these risk assessments were to be handled by expert committees from the field of chemistry. From 1993-2005, these committees performed risk assessments for 130 chemicals, 71 of which were completed and 58 required their assessments to be modified to reduce the associated risks. Or put another way, almost 45% of the high-volume chemicals tested from the grandfathered EINECS list needed additional safety measures to be implemented.

Several things were becoming clear to the European governments that "chemical producers know too little about the environmental and human safety of the substances they produce" (Lahl & Hawxwell, 2006, p. 7116). The regulatory systems in place were affecting "patterns of research activity and innovation, causing the European chemical industry to lag behind its main counterparts in the US and Japan" (Lewis et al., 2006, p. 593). With human, environmental, and financial health on the line, the need for reliable chemical data was becoming critical.

As stated by Mork and Hansson (2007), in February 2001, a report titled *Strategy for a Future Chemicals Policy* was released. This report, commonly called the White Paper, outlined the concepts and needs for a new European chemical policy. Mork and Hansson summarize the White Paper's goals as follows:

- Protection of human health and the environment.
- Maintenance and enhancement of the competitiveness of the EU chemical industry.
- Prevent fragmentation of the internal market.
- Increased transparency.
- Integration with international efforts.

- Promotion of non-animal testing.
- Conformity with EU international obligations under the WTO (2007, pp. 23-24).

Another major finding of the White Paper, according to Fisher (2014), was that the society of the world must have chemicals. The everyday reliance on chemically-manufactured products was complete and total. Along with these findings, the White Paper lamented that there were entirely too many unknown chemicals present that were affecting the environment and human health. "The primary focus of the White Paper was thus upon the generation of information" (Fisher, 2014, p. 167).

REACH

When legislation was brought up for debate, "the European Parliament identified REACH as the single most important dossier ever to be discussed within its walls" (Heyvaert, 2009, p. 113). The original bill was toned down and concessions were made. "Industrial lobbying did achieve the alleviation of some of the initially planned regulatory requirements" (Heyvaert, 2009, p. 114). But the lobbying effort did not stop the vast majority of the legislation. So, despite international and industrial complaints and concerns, "the REACH Regulation (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 1999/4, 2006), entered into force in 2007" (Karamertzanis et al., 2019, p. 303).

Lahl and Hawxwell (2006) stated that this revolutionized system consolidated more than forty individual sets of regulatory laws into one legislation. This helped to limit confusion and increase the European Union's ability to focus on enforcing one single system of laws. The old

EINECS system of new and existing chemicals was no more. All chemicals were now considered as new under REACH.

According to Williams et al. (2009), the main goals of REACH were:

1. Compile a suite of physicochemical, toxicological, and ecotoxicological data for each substance.
2. Establish safe usage parameters by conducting chemical safety assessments (CSAs).
3. Allow for regulatory evaluation of substances to determine potential hazards based on the compiled data.
4. Prevent the use of substances of very high concern (SVHCs) without the approval of the European Chemicals Agency.
5. Restrict the use of chemicals for which no safe usage parameters can be established (p. 555).

When REACH legislation was passed, it was around 700 pages long (Lahl & Hawxwell, 2006). As a regulatory system, REACH was "one of the most difficult to understand, and that difficulty is not primarily due to its length" (Lahl & Hawxwell, 2006, p. 7116). Van Hemmen (2009) noted that REACH guidance documents were plentiful and numbered over 6,000 pages at the time. However, the legislation's length was minuscule when compared to the supporting paperwork that has been generated by each registrant.

Tonnage Bands

Forbes (2009) stated “any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of one tonne or more per year, shall submit a registration to the Agency” (p. 35). Forbes continues to describe that different phase-in deadlines were put in place to for these registrations. Imports and manufacturing weights of 100 tonnes or more of a chemical that had previously been listed on the EINECS list had to be registered by May 31, 2013. This was required for each company that intended to manufacture or import the chemical into the European Union. If a chemical fell between one and 100 tonnes, the deadline for registration was delayed until May 31, 2018. The largest quantities of 1,000 tonnes or more had the much shorter registration deadline date set at November 30, 2010.

Exemptions

Of course, there were exemptions to the required REACH registration. Substances manufactured or imported in amounts less than one tonne (1,000 kgs) per year did not have to be registered (Williams et al., 2009). “Substances used in medications for humans or animals, or in foodstuffs or feeds” were exempted primarily because they are regulated by other European Union laws (Lahl & Hawxwell, 2006, p. 7117). And “polymers are exempted as well from the requirement to register since they usually are not very hazardous” (Van Hemmen, 2009, p. 562). Van Hemmen also listed some additional exempted substances, which are commonly found in the environment. Some of these examples are oxygen, cellulose pulp, water, minerals and noble gases.

Williams et al. (2009) note the chemical ingredients, also known as monomers, which are reacted to create polymers must be registered. One exemption to this would be if a monomer made up less than two percent of a product’s composition and the monomer’s total weight in that

product was imported in less than one metric tonne per year. Then product containing the monomer could be shipped into REACH regulated countries and the monomer would be exempt from registration filing as related by R. Auerbach (personal communication, September 11, 2019).

R. Auerbach noted that some non-European Union companies were willing to extend their company's REACH registration coverage to customers for certain chemicals. The customers in this case would purchase a registered raw material from the supplier, use the raw material in their manufacture and then would import the finished product into the European Union under the raw material supplier's registration tonnage. Another work around for firsthand registering a chemical would have been when a chemical was purchased from European supplier, then used in manufacturing, and finally imported back into Europe. This process was known as re-import and was REACH covered by the European company's registration (personal communication, September 11, 2019). The benefit of Europe's re-import business was an example of how REACH was used to help promote European businesses.

Chemical Dossier

"REACH regulation requires registrants to submit a registration dossier, which is composed of a technical dossier summarizing the results of a chemical safety assessment" (Karamertzanis et al., 2019, p. 303). Some of the data required in these dossiers, apart from standard registrant and chemical information, included toxicological studies, thermochemical and (thermo)physical properties, as well as risk assessment study results (Lewis et al., 2006). The lack of toxicological data in particular, was one of the primary reasons for REACH to have sprung into existence in the first place (Karamertzanis et al., 2019). Karamertzanis et al.

go on to state that “approximately 40% of the registrations under REACH have been updated at least once after the first submission” (2019, p. 304). This has shown evidence of the European Chemicals Agency’s dedication to ensuring that the most current and complete chemical data was being used for assessing risk for both human and environmental health.

A Chemical Safety Report was also a requirement of the registration dossier for chemicals 10 tonnes and over per year (Williams et al, 2009). The Chemical Safety Report “documents the hazards and classifications of a substance and the assessment as to whether the substance is carcinogenic, mutagenic, reprotoxic, persistent and bioaccumulating toxic, or very persistent and very bioaccumulating” (Van Hemmen, 2009, p. 562). The Chemical Safety Report evaluates how a substance was used by downstream users and outlined risk management steps that would have limited the risk that compromised their health and the environment (Williams et al, 2009).

Van Hemmen (2009) stated that not only did the Chemical Safety Report address downstream users, but the report also considered risk management steps as to how to reduce risk during manufacturing. This assessment was accomplished through an exposure scenario review. This review was another requirement of the Chemical Safety Report.

Van Hemmen (2009) outlined an exposure scenario’s format as follows:

1 - Short title of the exposure scenario

2 - Processes and activities covered

3 - Duration and frequency of use

4.1 - Physical form of substance or preparation; surface to volume ratio of articles

4.2 - Concentration of substance in preparation or article

4.3 - Amount used per time or activity

5 - Other relevant operation conditions of use

6.1 - Risk management measures related to human health (specified for workers or consumers)

6.2 - Risk management measures related to the environment

7 - Waste management measures

8 - Exposure prediction and reference to its source

9 - Guidance to downstream user to evaluate whether work inside the boundaries set by the exposure scenario (p. 563).

Cost on Industry

The cost of REACH registration placed on the chemical industry was extremely high. "Various impact assessment studies undertaken on behalf of the European Commission provide estimates for the associated costs induced by REACH within the range of 3-5 billion Euros" (Lewis et al., 2006, p. 592). A registration dossier that was submitted incurred a cost of over €24,000 each (Benko, 2013). Lewis et al. go on to state that there were provisions put into place to help reduce compliance costs for smaller manufacturers. These were designed to limit the impact REACH would have on their finite resources. If one considered every active chemical company doing business in Europe, and then multiplied that number by every chemical they use to manufacture goods, one could see how the registration fees would have mounted quickly. The registration cost did not even include the cost of the studies required to meet registration.

Some companies were forced to make difficult decisions about which products they would be willing to pay to register because of REACH. T. Pledger related "REACH has had a

significant commercial cost and poses a technical barrier in many cases. It limits the amount of product we can import, dependent on which tonnage band the product has been registered for. Though financial investment has not been the only cost incurred. The effort in manpower resources to get the product imported has also been significant" (personal communication, August 8, 2019). R. Auerbach described one product his company chose to not register because it would have cost over $75,000 in registration fees and testing. The cost of registration was not worth gambling on potential future sales in this case (personal communication, September 11, 2019). According to T. Pledger, some commercially available products that had been previously sold in Europe were sold in such small volumes that they did not justify the cost of continuing the business (personal communication, August 8, 2019).

Chemical Registration

Before December 1, 2008, a pre-registration or phase-in period was opened, which grouped companies that were registering the same substance (Van Hemmen, 2009). As an incentive for the chemical industry's compliance, the registration fees were waived during this pre-registration phase (Williams et al., 2009). The effect was a success. The European Chemicals Agency "announced in early 2009 that over 2.2 million pre-registrations had been filed before the deadline, encompassing over 100,000 chemicals and 66,000 companies" (Williams et al, 2009, p. 557).

In order to participate in pre-registration, manufacturers or importers must have been previously active in the European Union's chemical market (Forbes, 2009). Van Hemmen (2009) stated that the European Chemicals Agency grouped the pre-registering companies that were desiring to register the same substances into groups which were known as Substance Information

Exchange Forums (SIEF). These SIEFs were an information exchange conduit that helped to limited vertebrate animal testing by eliminating multiple duplicate experiments that studied the same chemicals.

The SIEFs were required to choose a Lead Registrant from each grouping. The Lead Registrant was ultimately in charge of preparing the final dossier for the group to the European Chemicals Agency. Each SIEF member was required to provide any existing findings, share the cost of the registration and testing, assist with data and gap analysis, and help generate additional data as needed (Forbes, 2009).

Working with and sharing this much information with companies using the same materials could have led to competitors attempting to take advantage of another company's data. As an additional protection, REACH allowed companies to use a Third-Party Representative to mask their identity from other members of the SIEF. The registering company would still be responsible for their registration duties and fees but would submit the same dossier paperwork as the rest of the SIEF (Forbes, 2009).

Once all the data was collected by the SIEFs, the Lead Registrant prepared the dossier submission (Forbes, 2009). Forbes continued to state that the group members reviewed, discussed, revised and finally submitted the dossier to the European Chemicals Agency. When submitting the registration packet, the registrant would send the information through a secure portal called REACH-IT (Karamertzanis et al., 2019). Karamertzanis et al. describe this system as a "central IT system that supports industry, Member State Competent Authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers" (2019, p. 304).

The Agency then reviewed the submission for the required content and examined the data for quality of testing. Any substance that proved to be of concern would be passed along to the European Union member states for review. The member states would then have used this information for legislation on hazard classification revisions of the substance in question. If no outstanding issues were present, the European Chemicals Agency approved the dossiers within a certain time frame and the registrant would appear on a listing of substances. This list was available to the public for easier evaluation of the known hazards of a product. Some information would be confidential and withheld from the public listing, such as composition details and supplier/downstream user relationships (Lahl & Hawxwell, 2006).

As the SIEF groupings showed, emphasis was placed on the manufacturers and importers under this system. They were responsible for the registration of each substance and testing the dangers of the chemicals they supply to their downstream users (Lahl & Hawxwell, 2006). Registration must have been completed before companies could conduct any marketing in the European Union, this was also known as "no data, no market" (Filipec, 2014, p. 169). When the potential sales of an entire continent were threatened to be cut off, manufacturers were forced into compliance no matter how strongly they objected to the reforms.

Only Representatives

One important business aspect of REACH was that it was focused on positioning European chemical manufacturers for future competitive success (Lewis et al, 2006). Forbes (2009) stated that the European Union manufacturers and importers under REACH were able to become direct registrants themselves. This lessened any trade issues within the European Union

member states. Forbes elaborated that any manufacturers outside of the European Union would not have the same privilege.

In order to import into European Union, manufacturers were required to name an Only Representative. The Only Representative was a company within the European Union that would handle the import duties on their behalf (Forbes, 2009). Essentially, the need for an Only Representative created an entirely new industry in Europe. According to R. Auerbach, REACH was the genesis of the Only Representative business, several existing European companies were able to upgrade and expand their consulting and testing services to move into this line of business because of the legislation (personal communication, October 14, 2019).

The Only Representative would have to agree to a non-disclosure agreement and sign a contract to represent a non-European Union company. The hiring company would then provide their product formulas to the Only Representative. These highly confidential formulas would have contained the composition and exact percentages of each monomer of every product imported to be sold. The Only Representative would then set up a database and track the import quantities of the product. The Only Representative would have to break down the import quantities to the monomer levels that are shipped into the European Union (R. Auerbach, personal communication, September 11, 2019).

The Only Representative would monitor and report the annual import levels of products and monomers levels. These levels would be compared versus the REACH registration tonnage levels for which the non-European Union company they represented had been approved. The Only Representative would also have compared their import data against the export records provided by the hiring company. Additionally, the Only Representative would have compared

the product purchases reported by downstream users, such as customers and distributors, to the registered tonnage levels for which their client had been registered (R. Auerbach, personal communication, September 11, 2019). If a company exceeded their import tonnage registration, the European Chemicals Agency could have issued fines to the importer or even up to restricting a company from conducting business in the European Union ever again (R. Auerbach, personal communication, October 14, 2019).

Safer Chemicals

Through registration, REACH gathered massive amounts of new data on chemicals and grew their database. The European Chemicals Agency and its partner countries began "working more and more on groups of substances rather than individual ones" (European Chemicals Agency, 2018, p. 9). "Such information makes a significant contribution towards the safe use of chemicals given the high number of substances that are classified because of the presence of known hazardous constituents or impurities" (Karamertzanis et al., 2019, p. 314). They discovered additional information on the unknowns that only served to enhance their knowledge on how to classify dangerous chemicals.

"REACH has dual aims: a high level of protection, and the enhancing of competitiveness and innovation" (Fischer, 2014, p. 167). One such way that REACH performed these goals was to promote the replacement of hazardous chemicals with safer alternatives. "Substitution contributes to the overarching EU objectives for a non-toxic environment and a circular economy, wherein innovation and sustainable production and consumption are key elements" (European Chemicals Agency, 2018, p. 4).

To help facilitate this substitution initiative, the European Chemicals Agency (2018) listed the following for its 2019-2023 Strategic Pan:

- Promoting best practice examples of increased substitution of hazardous substances, green chemistry, and sustainability in the supply chain;
- Promoting a mindset and behavioral change within industry towards sustainable and safer chemicals;
- Collaborating with industry associations in raising awareness in developing and providing tools for sustainability assessments of chemical supplies (p. 5).

The European Chemicals Agency planned to hold numerous supply chain workshops with assistance from the member states of the European Union. At these workshops, the goal was to increase communication for more targeted substitutions on chemicals of concern or of very high concern. This helped suppliers focus on what research services they could provide for the purchasers and clarified what the purchasers were looking for from the suppliers. These workshops were also a valuable tool for gauging what the most pressing concerns were for research that may require additional government funding (European Chemicals Agency, 2018). These supply chain workshops were very European Union focused. This helped to pursue the goal of promoting the future success of the European chemical industry as world leaders in safe chemical substitution innovation.

"Sustainable substitution requires a proper understanding of the hazards and risks associated with the substances to be substituted and, when a chemical is substituted by another, of the hazards and risks of the alternatives" (European Chemicals Agency, 2018, p. 9). "REACH

may/will lead to many substitutions of chemicals, either forced or on a voluntary basis. In the end we may expect a less hazardous exposure to chemicals" (Van Hemmen, 2009, p. 568).

Trade Influence

"REACH not only represents a comprehensive regulatory policy framework for the management of chemicals in the European Union but is also compatible with World Trade Organization rules and directives" (Lewis et al., 2006 p. 592). Not all World Trade Organization countries fully agreed with the assessment of full compatibility, however the European Union had been dismissive of these concerns (Heyvaert, 2009). These opposing countries have pointed out the "unnecessary barrier to international trade" that REACH generated, particularly the 'no data, no market' rules (Forbes, 2009, p. 49).

However, the World Trade Organization agreements have allowed for members to adopt rules for "protecting human, animal, or plant life and health, and the environment" that they have felt were necessary (Forbes, 2009, p. 49). Forbes also stated that "REACH falls within at least one of these provisions and, importantly, it is possible that it cannot be challenged" through the World Trade Organization because of the emphasis REACH placed on human and environmental health (2009, p. 49).

BREXIT

One benefit of consolidating the multiple regulations that were in place before REACH was the ability to have one consistent set of rules for the entire European Union. REACH had intended to stop the "fragmentation of the internal market" (Van Hemmen, 2009, p.

562). However, the internal market has been on the verge of fragmenting with the oncoming of United Kingdom's Brexit push.

In 1973, the United Kingdom joined the European Union (formerly known as the European Economic Community) and had been a willing partner for over 40 years. But the United Kingdom decided to leave after a referendum was held June 23, 2016. The votes were tallied with the results of 52-48 percent in favor of leaving. The United Kingdom will become the first member ever to do so. ("Brexit: All you need…", 2019). How both parties have handled this breakup has been uncharted territory and the outcome was still unclear as of October 2019.

Several Brexit deals have been agreed upon by negotiators and leaders from both sides, only to be voted down by Parliament. These failed negotiations have led to the resignation of two Prime Ministers thus far. So, how would this affect chemical regulation? If no deal can be agreed upon, the plan would be to adapt the entire REACH regulation as UK REACH per the *European Union (Withdrawal) Act 2018*. There would be minor changes made to adopt the wording specific for the United Kingdom, but otherwise the whole legislation will be put in place as was on the date of withdraw (Health and Safety Executive, n.d.).

If no deal was reached, then the UK REACH and REACH "regulatory agencies would operate independently from each other" (Health and Safety Executive, n.d., para. 2). The Health and Safety Executive went on to state that this would mean that the United Kingdom and European Union each would be separate entities but require the same rules. All manufacturing and importers worldwide would be required to submit all the same registration once again to UK REACH.

If manufacturers and importers did not comply, then those companies would be cut out of conducting business in the United Kingdom the same manner in which they would have been in the European Union with the "fundamental principle of 'no data, no market'" (Health and Safety Executive, n.d., para. 1). "Without a Withdrawal Agreement, the UK simply exits the EU two years after notice is given - this is now known as 'no-deal'" (Smith, 2018, p. 36). Smith continued to state that without a deal, the United Kingdom would lose access to the over 750 trade agreements the European Union already had in place. The governments of the United Kingdom and European Union were hoping for a deal as a best-case scenario. The reality would be that companies should have been planning contingencies for a no-deal scenario.

However, Parliament has attempted to ease the transition as much as they could for United Kingdom companies in a no-deal scenario. "While qualifying registrations held by UK companies will be automatically transferred to the new system, the registrants will still be required to resubmit data" (No-deal Brexit REACH…, 2019, p. 15). "A survey of 38 UK companies by the Chemical Business Association (CBA) has found that 75 percent of them don't own the data that would be required for them to register chemicals under UK REACH" (No-deal Brexit REACH…, 2019, p. 15). Many companies, domestic and abroad, have relied on data sharing throughout REACH registration via SIEFs or other negotiated agreements (Broadwith, 2019). Broadwith also stated that data sharing between companies may not be as cooperative this time when all the registration paperwork must be re-registered. Companies that owned the REACH data may see a financial incentive to charge other companies for data.

Another issue that had emerged for companies in the European Union, United Kingdom and the world in a no-deal scenario would be concerning Only Representatives. The 27 countries in the European Union constituted the United Kingdom's "largest trading partner, representing

around 44.5% of UK trade goods and services in 2017" (Smith, 2018, p. 34). United Kingdom companies may be forced to hire an Only Representative to represent them in the European Union, and vice versa for European Union companies to be able to continue the large amount (of now international) trade with each other (Broadwith, 2019). Countries on the outside of the current European Union, would have to find a new Only Representative to represent their import business in either the United Kingdom or European Union, dependent on which area their current Only Representative resided.

The entire manufacturing industry should be very concerned with the uncertainty that Brexit has brought to international trade. According to Smith (2018), one large company had estimated that Brexit may cost them between €40 to 60 million a year in extra costs. Some companies were just not sure what to plan for. "Large companies have already been planning for Brexit and have assembled teams to deal with it, but surveys show that only one in seven small to medium enterprises in their supply chain have started planning" (Smith, 2018, p. 39). This would result in a huge effect on the large companies if they could not be assured of receiving raw materials from portions their supply chains.

A Managing Director that spoke on behalf of BASF, a large enterprise, expressed concern because of the sheer amount of chemical substances they had to register during REACH registration. BASF was unsure of the cost of re-registration, and they were extremely concerned when the unknown cost was multiplied by 1,000 registrations (No-deal Brexit REACH…, 2019). A European Business Development Manager for Estron Chemical, a small to medium sized enterprise, expressed concern as well when it came to be time to register new products. For each new product brought to market, the registration costs would be double what they have been previously (T. Pledger, personal communication, August 8, 2019). "The call from industry is that

the best outcome would be for the UK to remain within the jurisdiction of REACH, and somehow associated with the European Chemicals Agency that oversees it" (Broadwith, 2019, para. 7).

The uncertainty that surrounded the possible no-deal scenario could be alleviated with an actual deal that was approved by both the European Union and the United Kingdom's Parliament. A potential new deal was agreed upon between Boris Johnson, Prime Minister for the United Kingdom, and Jean-Claude Juncker, European Union Commission President, on October 17, 2019. Johnson had threatened to leave the European Union on October 31, 2019 with or without a deal. In response, Parliament had responded by passing a law that made a negotiated extension request a requirement if no deal was in place by October 19, 2019 (Smith, 2019).

United States Chemical Regulatory Systems

Federal government regulations over certain types of chemicals have dated back to 1906. This first regulation that concerned business transactions between states affected the "misbranded and adulterated foods, drinks and drugs" (Krimsky, 2017, p. 2). According to Krimsky, after 107 people were killed by a contaminated batch of Elixir Sulfanilamide, the Federal Food Drug and Cosmetic Act was passed through Congress. This law ensured that drug manufacturers were responsible for proving that their products were safe for use before they could be sold to consumers.

Industrial chemical manufacturing had a major increase in production as World War II was ending. The area of chemical commerce was still unregulated, as it did not fall under any of the previous laws enacted in the United States. The federal government took a hands-off

approach during this post-war boom and refrained from acting unless public health was at risk (Krimsky, 2017). However, their time for inaction was rapidly drawing to a close.

As explained by the United States Environmental Protection Agency, "the American conversation about protecting the environment began in the 1960s" (2018, para. 1). The book *Silent Spring* was released, which addressed the overuse of pesticides. Then an oil rig off California's coast spilled millions of gallons of oil, which contaminated the water and beaches. And finally, the Cuyahoga River running past Cleveland, Ohio once again caught on fire, fueled by the water's chemical contamination (United States Environmental Protection Agency, 2018).

Because of these reasons, in addition to more instances of industrial negligence, the American public was growing restless for government intervention. President Richard Nixon seized on the public support and led the way (United States Environmental Protection Agency, 2018). President Nixon formed the President's Council on Environmental Quality, which produced the 1971 report called *Toxic Substances* (Eichenberger, 2015). The committee's report on the risks toxic chemicals had found: "(1) toxic substances were entering the environment; (2) the effects of these substances were largely unknown and potentially severe; (3) existing legal mechanisms were not suited to address these effects; and (4) new legal authority was required" (Eichenberger, 2015, pp. 125-126). The council's recommendations on proposed legal authority were drawn up, sent to Congress and recommend the creation of a new federal agency. (United States Environmental Protection Agency, 2018).

According to the United States Environmental Protection Agency (2018), these recommendations included:

- The EPA would have the capacity to do research on important pollutants irrespective of the media in which they appear, and on the impact of these pollutants on the total environment.
- Both by itself and together with other agencies, the EPA would monitor the condition of the environment - biological as well as physical.
- With this data, the EPA would be able to establish quantitative "environmental baselines" - critical for efforts to measure adequately the success or failure of pollution abatement efforts.
- The EPA would be able - in concert with the states - to set and enforce standards for air and water quality and for individual pollutants.
- Industries seeking to minimize the adverse impact of their activities on the environment would be assured of consistent standards covering the full range of their waste disposal systems.
- As states developed and expanded their own pollution control programs, they would be able to look to one agency to support their efforts with financial and technical assistance and training (para 4.)

TSCA Implementation

The need for oversight on the chemical manufacturing industry was becoming increasingly clear. As the public outcry grew louder, there was "a realization that the chemical industry was not effectively policing itself in the absence of effective regulation" (Eichenberger, 2015, p. 126). Eichenberger stated that witnesses came forward to Congressional committees and testified "that certain chemical manufacturers and processors knew about the carcinogenic effects of chemicals used in the processes, but intentionally withheld the information from the

public, their employees and the government in an effort to avoid liability and regulation" (2015, p. 126).

According to Eichenberger (2015), Congress intended to put the burden of any regulatory compliance and chemical hazards directly on the chemical industry in the form of required information. The industry would be forced to share the information they already knew and address the gaps about what they did not know. While their intentions to address the public's safety was noble, the final product that emerged was influenced by the chemical industry. Ultimately "Congress sought to balance concerns over toxic exposure and our information deficit with assurance that our burgeoning chemical industry would maintain its ability to operate and innovate" (Eichenberger, 2015, p. 127).

"Although both the Senate and House of Representatives agreed that the proposal should be enacted as law, the two houses could not come to a consensus on the exact language of the provisions" (Behnke, 2017, p. 461). But the Congressional disagreements were soon to be resolved. "In 1976, the urgency of passing the bill received an unanticipated and tragic increase due to an outbreak of severe neurological disorders in workers at a company that manufactured pesticides" (Eichenberger, 2015, p. 127). Eichenberger continued to state that as the national news picked up on the story, the increased coverage put additional pressure on Congress to finally act.

Congressional action took the form of the *Toxic Substances Control Act* (TSCA). After these events, chemical regulation in the United States was finally born. The need for the bill was justified based on President Nixon's committee recommendations and had the legal backing of the clause in the United States Constitution that charges the government with the responsibility

to ensure the general welfare of the country's citizens (Krimsky, 2017). Behnke reported that "President Ford signed TSCA into law on October 11, 1976" (2017, p. 461).

TSCA's Content

When TSCA was enacted, the EPA was placed in charge of the enforcement of the laws governing manufacturing and the chemicals used by the industry (Behnke, 2017). According to Eichenberger (2015), the original structure of TSCA was limited to one section, also known as Title I. Under Title I, the EPA was "authorized to gather information, regulate chemical substances, and disseminate the information it collects to interested parties" (Eichenberger, 2015, p. 127).

One example of gathering information was that the EPA compiled a list of all chemicals in use at the time. When the list was compiled, it reached over 62,000 chemicals. These chemicals were immediately considered grandfathered and safe to use commercially, unless they were eventually proven as unsafe. (Krimsky, 2017).

Another method under which the EPA could gather information was through cooperation with a chemical's manufacturer, Eichenberger stated that the EPA could:

> Require manufacturer testing of existing chemicals under certain circumstances, require pre-market screening and regulatory tracking for new chemicals, control unreasonable risks through regulation, gather information about production, use, and adverse effects of existing chemicals, and protect certain business information it receives. (2015, pp. 127-128)

As maintained by Behnke (2017), even with the ability to require testing, TSCA legislation came up short with respect to information sharing. Manufacturers did not have to "disclose the hazardous traits of chemicals to the public, private, or government entities that used these substances" (Behnke, 2017, p. 462). This shortcoming would eventually become one of the major failings of TSCA.

When a chemical was found to be a danger to either to health or to the environment, then the EPA was allowed to issue rules to regulate the chemical. Some of options for an issued rule could range from a notice to distributors on the chemical hazards, all the way up to a total ban on a chemical. However, there were certain considerations the EPA had to address before they could regulate a chemical through these rules (Eichenberger, 2015).

As stated by Krimsky, for the EPA to regulate a chemical:

> In addition, under the act, EPA had to demonstrate that the benefits of regulation a chemical were greater than the costs – to the manufacturer, to companies utilizing the chemical, and to the economy – and that its regulation offered greater benefit than the social value of the products it was used to create. (2017, p. 3)

When a chemical was to be regulated, a new rule would be issued. This was a lengthy process that could take at least three to five years. Due to the difficult nature, costs and time involved with issuing a rule, the EPA found that negotiating voluntary agreements with chemical manufacturers was far easier, cheaper and faster (Eichenberger, 2015).

As the EPA collected data from manufacturers and testing, there were certain rules in place under TSCA that restricted with whom they could share those findings. Companies could

claim to the EPA that the data they provided was confidential and not to be shared. When a confidentiality claim was made, the information was protected. If the information was leaked or disclosed, the offending party could have been fined and imprisoned (Eichenberger, 2015).

Banning Asbestos

According to Behnke (2017), the wording of the TSCA legislation allowed for many loopholes and exclusions that chemical manufacturers could exploit and defeat the EPA's rulings. The "EPA could, in theory, take an existing chemical off the market but it would have to meet a formidable burden, namely produce substantial evidence that the chemical presents or will present an unreasonable risk to health and the environment" (Krimsky, 2017, p. 3). Behnke goes on to state that TSCA "put the government in a position in which it lacked the legal tools it needed to prevent or substantially limit possible environmental and health hazards" (2017, p. 461). One example of TSCA's failure was the EPA's attempt to ban asbestos, which had been proven to be a known carcinogen (Rosner & Markowitz, 2017).

"By 1970, asbestos was used in some 3,000 products, such as roof shingles, floor tiles, house siding, ironing boards, and particularly in brakes, among other consumer items" (Rosner & Markowitz, 2017, p. 1395). According to Rosner and Markowitz, asbestos was still able to be used in brakes and construction materials even in current times. The material can still be found in homes and businesses anywhere in the United States.

Rosner and Markowitz (2017) state that as far back as the 1930s, asbestos was suspected of being dangerous to workers. When materials that contained asbestos were cut or ground down, it was noted that the dust produced would slowly strangle the workers. Around 30 years later, asbestos was suspected as being a cause of the lung cancer, mesothelioma. The British Ford

Motor Company held “conference in 1969 on the possible dangers presented to brake mechanics and those installing or replacing brake linings” (Rosner & Markowitz, 2017, p. 1395).

Committees were established by industry to look at the effects. Some examples of these committees were the Asbestos Study Committee and the Asbestos Information Association of North America. These committees were aware and accepted that asbestos was a danger to workers who were handling items such as brakes. These industrial committees also understood why the government was issuing new regulations to protect workers, even if they were not in complete agreement (Rosner & Markowitz, 2017).

One such regulation was that companies must warn their employees of the dangers asbestos posed to them. After this regulation was issued, the brake industry decided they would not warn their workers. The industry executives acted in defiance instead. “They publicly pronounced that asbestos, when ‘locked in’ to fabrics, lacquers, plastics or other finished products, was not a danger as it could not be released into the air” (Rosner & Markowitz, 2017, p. 1396). The committee members did privately acknowledge that brakes functioned through friction, and used brakes exposed workers. Warnings were again considered, but ultimately disregarded because of the damage it would have brought to their products (Rosner & Markowitz, 2017).

More and more studies were released over the next few years that linked asbestos to cancer. In light of these, the government, OSHA in particular, attempted to regulate the amount of asbestos fibers that could be free in the air. In 1975, the plan was to reduce the regulation from 5 fibers/cc to 2 fibers/cc. There was a push to reduce the regulation further to 0 fibers/cc, as that would be the only truly safe level of exposure. The industry called the 2 fibers/cc limit

impossible to meet by the deadline that was in place. Additionally, the industry definitely could not ever meet a zero-level threshold. A year later, OSHA altered the recommendation to push the limit to 0.5 fibers/cc. The industry opposed yet again, and the standard held at 2 fibers/cc till the 1980's (Rosner & Markowitz, 2017).

The industry was well aware of the effects of using asbestos and the toll it was having on their employees. Eventually industry executives agreed to post warning signs in auto workshops and garages, but would not use the wording the government suggested, which mentioned asbestosis and cancer. Instead, they posted that asbestos might be hazardous to a person's health (Rosner & Markowitz, 2017).

Eventually the EPA took over the fight from OSHA and outright banned asbestos in the United States. The ban was challenged in the judicial system and eventually came to a head in the case of *Corrosion Proof Fittings v. EPA* that was heard in the 5th Circuit of the United States Federal Court of Appeals. The court ruled against and overturned "the EPA regulation that banned asbestos products on a number of grounds, including that the EPA had failed to give adequate weight to statutory language requiring it to promulgate the least burdensome, reasonable regulation required to protect the environment adequately" (Fisher, 2014, pp. 166-167). Behnke (2017) stated that the main factor that went against the EPA in the case was the 'least burdensome' statement in TSCA. In this case, the court ruled that least burdensome meant the EPA had to consider the cost on industry and evaluate if there was another way to regulate asbestos rather than an outright ban. After this ruling went against the EPA, their perceived power was significantly damaged. "The EPA did not attempt to regulate any other existing chemicals under TSCA" (Behnke, 2017, p. 461).

Premanufacturing Notification

The EPA was left near powerless to regulate existing chemicals after losing the asbestos court battle. But regulating new chemicals which were being introduced into the market, and not previously listed on TSCA's chemical inventory, was covered by a whole different set of undamaged rules (Krimsky, 2017). DeVito and Farris (1997) state that this review process began in 1979. According to Eichenberger, "TSCA's premanufacture notification requirement has been reasonably successful at requiring companies to notify the EPA when a new chemical is manufactured or an existing chemical is put to a new use" (2015, p. 134).

When a chemical company designed a new product and a customer became interested after evaluating experimental samples, the chemical company was not allowed to make the product on an industrial scale right away. The manufacturer was required to first notify the EPA of their intentions to produce a new chemical. This notification was called a premanufacturing notice (Krimsky, 2017).

Eichenberger (2015) stated that once the EPA was notified, they had 90 days to review the premanufacturing data submitted by the manufacturer. Eichenberger also stated that the notice "shall include health, safety and test data, the manufacturer is only required to provide what is known to them or reasonably ascertainable" (2015, p. 135). "There were no penalties associated with lack of data" (Krimsky, 2017, p. 4).

R. Auerbach stated that when filing a premanufacturing notification, quite a lot of information could be part of the submission if the manufacturer wished (personal communication, October 6, 2019). R. Auerbach offered some examples of EPA requested information such as composition, structure, residual monomers, manufacturing process,

treatment of waste, employee and end user exposure, spectral data, and any available toxicity data. But only some information was required by TSCA and the rest was voluntarily provided by manufacturer, if they desired.

"In general, these notifications contain no testing data and only an estimated fifteen percent contain any health and safety information" (Eichenberger, 2015, p. 135). Krimsky (2017) reported that as of 2003, 85 percent of the premanufacturing notifications submitted to the EPA did not contain data concerning human health. Eichenberger goes on to state that this created a system that rewarded chemical companies to know very little about the products that they were attempting to take to market. While the more responsible companies that generated the proper amount of test data for the EPA would be at a regulatory disadvantage.

DeVito and Farris (1997) summarize the EPA's approval process:

> The PMN Review Process consists of four distinct, successive technical phases: the chemistry review phase, the hazard (toxicity) evaluation phase, the exposure evaluation phase and the risk assessment/risk management phase. These phases are structured to "drop" substances of low-risk from review and to focus more sharply on, and explore more deeply, those substances of greater risk as the review progresses.

Certain types of polymers could have been an example of a drop substance. The EPA established that these polymers were not suspected of being dangerous to the environment or to humans. Certain criteria was required to be met by these polymers in order to qualify to be dropped from review. Some examples of these requirements were the type of polymer, measured oligomer levels below certain thresholds (10% <500 Daltons and 25% <1,000 Daltons), and that the polymer could not swell when exposed to water. These were just a few of the rules that

applied for drop requirements, although the 90 day wait period was still enforced even if the application was dropped from review (DeVito & Farris, 1997).

Eichenberger (2015) stated that the EPA could extend the 90-day window due to limited data. DeVito and Farris (1997) state that the window for extension could only be a maximum of 180 days. However, Eichenberger stated that the criteria for extensions were typically hard to justify. If the EPA wanted to delay a premanufacturing notice "which they feel lacks sufficient health and safety information, the agency has the burden to show that the manufacture, processing, or distribution of the chemical may present an unreasonable risk or will result in substantial exposure" (Eichenberger, 2015, p. 135).

R. Auerbach related that of all the premanufacturing notices that he had been a part of, only once had the EPA requested additional information that would have delayed the 90-day window (personal communication, October 6, 2019). R. Auerbach stated that the test data the EPA had requested was additional toxicity data, which would have cost his company approximately $100,000 to pay for the testing. Ultimately, the premanufacturing notification was withdrawn.

"On average the EPA receives between 600 and 2,000 premanufacture notifications per calendar year" (Eichenberger, 2015, p. 135). With all the new chemicals that entered the market through the premanufacturing notifications, it was expected that there would be "approximately 85,000 chemicals on the TSCA inventory by 2017" (Krimsky, 2017, p. 4). However, according to Eichenberger, the EPA's chemical inventory was viewed as flawed and not correct. Chemicals that were no longer manufactured were supposed to be removed from the list. But chemical manufacturers were not required by TSCA to report to the EPA if they had discontinued making

products. And so, most do not bother with notifying the EPA. “Current industry estimates place the actual number of chemicals in commerce at about 25,000” (Eichenberger, 2015, p. 136).

The combination of such a short amount of time for review and the overwhelming amount of new chemicals applications submitting to enter the market was not a recipe for success. “Lack of agency resources and inability to move quickly makes it nearly impossible for the EPA to conduct an adequate premarket review based on the notification” (Eichenberger, 2015, p. 135). In short, the EPA’s regulation of new chemicals under the limitations of TSCA was set up for failure from the very beginning.

State Preemption

Under the original TSCA, states were authorized to develop their own legislation to govern the use of chemicals inside their borders. These laws were required to go above and beyond the federal regulations in place from Congress and the EPA. In this case, the federal laws were essentially a minimum set of regulations. For example, no state could pass laws to have laws that were less stringent than federal regulation to attract industry interest. However, if a federal law was in conflict with the state’s law, the federal law would always preempt the state through the Supremacy Clause in the United States Constitution (Behnke, 2017).

According to Behnke, “numerous states have spent a decade or more developing their own regulatory systems on chemical substances. Over time, several states- including California, Washington, Maine, Maryland, and Minnesota – have become leaders on executing increasingly stringent laws” (2017, p. 473). The unquestioned regulatory leader amongst these states was California with their 1986 legislation named *Safe Drinking Water and Toxic Enforcement Act* or as the chemical industry knew it, Proposition 65 (Lovett, 1997).

Proposition 65 "requires businesses to publish warnings when exposing consumers to significant amounts of chemicals identified by the state to cause cancer or reproductive toxicity" (Lovett, 1997, p. 368). Lovett reported that Proposition 65 placed the responsibility of regulatory labeling onto the manufacturer. The Californian government was only responsible for assembling the list of chemicals which were suspected to be cancer causing or posed reproductive hazards.

The effects of Proposition 65 have led to positive effects in California through the threat of economic loss. As explained by Lovett (1997), sales have been severely affected by the required warning of birth defects and cancer on product labels. "Even the threat of having to give Proposition 65 warnings can prompt immediate reformulation of a product" (Lovett, 1997, p. 369).

Lovett listed some examples of these product formula changes:

- Eliminating trichloroethylene from typewriters correction fluid;
- The discovery that lead was leaching into wine from foil caps, spurring the now-universal use of plastic or aluminum caps; and
- A series of failure-to-warn cases in the mid-1990s that caused industry to redesign plumbing fixtures and water pumps so that lead would not be leached into the water through brass parts (1997, p. 369).

Lautenberg Reform

In Charleston, West Virginia on January 9, 2014, a bulk tank filled with 4-methylcyclohexane methanol (MCHM) had leaked. The 10,000-gallon spill flowed into a nearby river that was the main supply of drinking water for 300,000 people. The properties and health

effects of MCHM were incomplete at best. The people of the area were still using bottled water for drinking, bathing and cooking for months after the incident. Public outrage pushed for renewed calls for chemical reform following the spill (Eichenberger, 2015).

According to Krimsky (2017), an example of TSCA's failings was that under the original TSCA, the EPA had to ensure that in eliminating chemicals they had chosen the least burdensome process to achieve their goal. The wording of least burdensome had caused the judicial system to rule against the EPA as was seen in the attempt to ban asbestos. As a result, "since 1976, the EPA has used its authority under TSCA to limit or ban only 5 existing chemicals: fully halogenated chlorofluororoalkanes, polychlorinated biphenyls (PCBs), dioxin, asbestos (later overturned by the courts), and hexavalent chromium" (Krimsky, 2017, p.4).

The manufacturing industry and environmental groups both added themselves to the growing list of those eager for TSCA reform. The chemical industry was looking to increase the public's confidence after years of decreasing trust, open avenues for increased innovative ideas, and establish uniform nationwide regulations, rather than differing rules state to state. Environmental groups were pushing for regulation that was more effective in the judicial system and reduce the ever-increasing number of hazardous chemicals and their effect on environmental and human health (Eichenberger, 2015).

As TSCA continued to flounder, Senator Frank Lautenberg, a Democrat from the state of New Jersey, stepped up to become a champion for chemical safety reform. According to Plautz and National Journal (2015), Lautenberg had earlier in his career led bills through the Senate to stop airlines from allowing smoking on planes and to toughen punishment for drunk drivers. But

his dream was to cap off his legacy by shepherding legislation on chemical safety reform through Congress.

Guc (2018) stated that Lautenberg introduced the Kid Safe Chemicals Act of 2005 to indicate the need for regulation reform. He never expected this bill to pass though. In 2010, Lautenberg introduced the Safe Chemicals Act of 2010 and then updated, refined and reintroduced the Safe Chemicals Act of 2011. Neither bill made any progress through the Senate (Filipec, 2014).

In 2013, Lautenberg partnered with two very different Senators on chemical reform bills. The Safe Chemical Act of 2013 was co-sponsored with Senator Kristen Gillibrand, and ultimately met the same fate as the previous versions of the bill (Filipec, 2014). Per Plautz and National Journal (2015), Lautenberg then invited Senator Joe Manchin to co-sponsor another reform legislation attempt, but Manchin declined. Instead Manchin encouraged Lautenberg to meet with Senator David Vitter. Vitter was a Republican from Louisiana and the two had never really worked together before.

Vitter had been working on a competing reform bill that would have been more industry friendly than Lautenberg's. The two Senators sat down, got to know each other, and agreed they could work together. They merged their bills, each removed certain aspects the other disliked. And shortly after, a bipartisan bill was introduced to Congress by the unlikely pair. The bipartisan effort initially scared off some of each Senator's previous supporters due to widespread distrust of the other party (Plautz & National Journal, 2015).

Then, "just six weeks after the bill came out, Lautenberg passed away at age 89" (Plautz & National Journal, 2015, para. 13). Plautz and National Journal stated that despite the death of

his across-the-aisle partner, Vitter continued to press their bill after receiving the encouragement of Lautenberg's widow. Vitter sought out a new Democratic partner in Tom Udall from New Mexico. The two decided to make some changes including renaming the bill after their fallen comrade, grandfathering several state laws, and adding more provisions protecting populations most vulnerable to the effects of chemical toxicity, such as elderly, children, and pregnant women.

According to Plautz and National Journal (2015), Vitter and Udall worked their way through the Senate looking for co-sponsors. Plautz and National Journal stated that the goal was to reach 60 senators to avoid the Senatorial tactic of blocking a bill known as a filibuster. Another goal was to keep the co-sponsor count as a one-for-one deal, to truly be bipartisan. When they signed on a Republican co-sponsor, they made sure to also find another Democrat sponsor. The bill was ultimately passed and delivered to the Oval Office. "On June 22, 2016, President Barack Obama signed the 'Frank R. Lautenberg Chemical Safety for the 21st Century Act' into law" (Behnke, 2017, p. 464).

The New Lautenberg TSCA

The Lautenberg Act increased the authority of the EPA to enforce the regulatory laws that had long been ignored. The EPA was now allowed to require information from manufacturers. This data had previously been only rarely provided to the EPA on a voluntary basis (Krimsky, 2017).

Guc (2018) described the EPA's testing ability as such:

> EPA no longer must compel testing through rule promulgation. Instead, EPA may require testing through an order or consent agreement, and even then, EPA can require testing merely for the purposes of developing more information about the chemical in question, or its manufacturing process or role in commerce. (p. 470)

According to Krimsky (2017), the EPA was now able to judge if an unreasonable risk to health existed from a chemical. Krimsky continued to state that if a chemical did pose such a risk, then the EPA would no longer subject to their biggest loophole. The least burdensome method of regulation was mercifully eliminated, which as was seen in the asbestos case, usually fell back to a cost – benefit analysis.

Although certain state chemical programs were grandfathered, such as California's Prop 65, the federal government established a much more dominate role in the regulation of chemicals. Behnke (2017) stated that "if the EPA has determined a chemical does not pose an unreasonable risk, then the states cannot enact new legislation or continue to enforce previous legislation" (p. 467). Krimsky (2017) reported that any regulations a state had in place on a chemical would be preempted if the EPA was conducting a safety assessment.

"In an effort to triage what has become a forty-year backlog of chemicals that need testing, the new TSCA mandated a prioritization scheme which had to be developed within a year of the Act's enactment" (Guc, 2018, p. 471). Guc continued to describe the prioritization of chemicals, which was broken down in two categories; high-priority and low-priority. Ten of the chemicals designated as high-priority for risk evaluations were required to be pulled from an official document named TSCA Work Plan for Chemical Assessments.

The high-priority list was required to be composed of 20 chemicals, plus an additional 20 placed on the low-priority list (Guc, 2018). Guc continued to state that after one of the 20 high-priority chemicals had completed its safety assessment, then a new chemical must be added to the high-priority list. According to the United States Environmental Protection Agency (2019a), with the known data that had existed on a chemical, certain criteria would have to be reviewed each time before an addition could be made to the high-priority list:

- The hazard and exposure potential of the chemical substance;
- Persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of drinking water;
- The conditions of use or significant changes in the conditions of use of the chemical substance; and
- The volume or significant changes in the volume of the chemical substance manufactured or processed (para. 4).

Once a chemical has been labeled as high-priority, it would undergo a risk evaluation. The risk evaluation examined how the chemicals were used, who was exposed, and any hazards the material presented to humans and the environment. The EPA would have to assess the likely exposure routes a chemical presented. The EPA would also be required to list all hazards that the chemical may cause, such as cancer, neurological issues, or mutations. After these steps were complete, a risk determination would identify if the chemical posed an unreasonable risk. If the chemical was a hazard, then it would be subject to additional risk management steps (United States Environmental Protection Agency, 2019b).

The first 10 chemicals selected in December 2016 by the United States Environmental Protection Agency for risk evaluations were:

- Asbestos
- 1-Bromopropane
- Carbon Tetrachloride
- 1,4 Dioxane
- Cyclic Aliphatic Bromide Cluster (HBCD)
- Methylene Chloride
- N-Methylpyrrolidone
- Perchloroethylene
- Pigment Violet 29
- Trichloroethylene (2019b, para. 23).

When a company decided to manufacture a new chemical under the old TSCA, all the company was required to do was wait 90 days after notifying the EPA. Under the Lautenberg TSCA, an acknowledgment from the EPA was now required that stated that they believe the chemical posed no unreasonable risk. The EPA also updated its new chemical notification system, which was now handled through submission of registration data through a manufacturer specific secure portal (R. Auerbach, personal communication, September 11, 2019).

New and existing chemicals that would require testing were now subject to fees to be paid by the applying manufacturer. The fees that were collected were now deposited into a TSCA specific fund that supported regulatory compliance efforts. This fund had not existed

under the original TSCA. Previously, any fees that were collected had gone directly into the United States Treasury general fund (Guc, 2018).

Polymer Exemption

One exception to new chemical registration was to be qualified for polymer exemption. In accordance with the United States Environmental Protection Agency (2017), polymer exemptions were "to encourage the manufacture of safer polymers by reducing industry's reporting burden for this category of chemical substances and concentrate the Agency's review resources on substances expected to pose higher risk" (para. 1). The United States Environmental Protection Agency stated that any polymer that met the exemption rules was allowed to be manufactured without filing of a premanufacturing notification.

The manufacturer of a polymer-exempt material would be required to retain records that were subject to inspection by the EPA. Reports were also required to be submitted annually by January 31st on the pounds produced and number of polymer exempt materials that were manufactured or distributed. This method was expected to free up EPA resources to be able to focus on higher risk chemicals (United States Environmental Protection Agency, 2017).

Criteria for exemptions include:

- Polymers with molecular weight (MW) of 1,000 Daltons or greater and less than 10,000 Daltons are eligible, with restrictions on low MW species and reactive functional groups;
- Polymers with MW of 10,000 Daltons or greater, with restrictions on low MW species (United States Environmental Protection Agency, 2017, para. 5).

> The list of allowable elements has been expanded to include chlorine, bromine, iodine as monatomic counterions; and fluorine, chlorine, bromine and iodine if covalently bound to carbon; biopolymer which meet the polymer definition are no longer excluded; polymers that are cationic or anticipated to become cationic in aquatic environments are now eligible for exemption if the polymer is solid, not soluble or dispersible in water and will be used only in solid phase, or equivalent weight is equal or greater than 5,000; and there is an expanded list of specified reactants for polyesters. (United States Environmental Agency, 2017, para. 6)

There were exclusions that prevented some polymers from being listed as polymer exempt. Polymers that break down or decompose were not eligible. All raw materials that were included in the synthesis of a polymer must be included on TSCA's chemical inventory list. If a polymer absorbed water, then it was also prevented from being listed as polymer exempt (United States Environmental Agency, 2017).

Non-Compliance with TSCA

Under the new TSCA, the punishments for non-compliance could be severe. For example, if a company was discovered to be selling a non-TSCA listed or a non-polymer exempted product in the United States, the monetary fines would be severe. The offending company's regulatory specialist and ownership would be held as the responsible parties and could be subject to possible imprisonment (R. Auerbach, personal communication, September 11, 2019).

State of Lautenberg's TSCA

The new legislation has had a great effect by expanding the EPA's authority and restored their presence in the chemical regulatory world. But criticism still existed from environmental and the industry. On one hand, some think the legislation was not enough and tramples state's rights to self regulate and enforce stricter laws. As previously stated, a state cannot legally pass a law that goes beyond the federal law, barring a judicial challenge (Behnke, 2017). But, on the other side of the argument, the Lautenberg reform had gone too far. Some feel that the EPA had been given too much authority and was using it to overregulate. That side has been fighting overregulation by attempting to reduce the EPA's financial resources.

Effects of Changing Administrations on TSCA

The push to regulate and limit industrial damage to the environment was first put into law on January 1, 1970. The first of many laws to come was the National Environmental Policy Act (NEPA), which was approved by President Nixon (Pelley, 2008). "The idea behind the NEPA, also known as the Magna Carta of U.S. environmental policy, is simple: federal agencies should evaluate and disclose the environmental impacts of major projects before they are launched" (Pelley, 2008, p. 7).

Since Nixon's administration there have been eight administrations to hold the office of President of the United States. Those administrations have had vastly different beliefs, be it personal or through outside influence, on how the Environmental Protection Agency should be ran. "Wealthy donors, think tanks, and fossil fuel and chemical industries have become more influential in fighting regulation. In the broader public, political polarization has increased, the environment has become a partisan issue, and science and the mainstream media are distrusted" (Fredrickson et al., 2018, p. 96).

During the Nixon administration, the Environmental Protection Agency was created and the *Clear Air* (1970) and *Clean Water Acts* (1972) were signed into law (Fredrickson et al, 2018). And in 1976, with President Ford's signature, the *Toxic Substances Control Act* became law (Guc, 2018). It wasn't until the 1980's that the environmental policies of the previous decade were first threatened.

"Reagan abandoned the practice of previous administrations of appointing agency heads with federal government experience and sympathy for the agency's mission. Instead he chose people from industry who shared his anti-regulatory views" (Fredrickson et al, 2018, p. 96). According to Fredrickson et al., Anne Gorsuch was named Administrator of the Environmental Protection Agency. Gorsuch had been a harsh critic and vocal opponent against the Clean Air Act and other environmentally friendly regulations. Gorsuch slashed the EPA's staff by 21 percent and cut civil cases against industry by 75 percent in her first two years on the job. Under Gorsuch's watch the agency "resisted classifying formaldehyde as a human carcinogen," "neglected to warn about dioxin levels in the Great Lakes fish" and was slow "on a clean-up of heavily leaded soil around a Dallas, Texas smelter" (Fredrickson et al, 2018, p. 97).

Gorsuch was eventually forced out of office mainly due to leaks from within the EPA that highlighted the neglect her department had fostered. Reagan, under public pressure re-appointed William Ruckelshaus, the Agency's first administration to the post. For the remainder of Reagan's Administration, Ruckelshaus ran the department with transparency and independently from politics (Fredrickson et al., 2018).

The next time the Environmental Protection Agency was threatened came during the administration of President George W. Bush. The threats were not as overt, but relied "on

delaying decisions and undermining science, rather than cutting budgets" (Frederickson et al., 2018, p. 98). According to Pelley, under the Bush 43 administration, the NEPA was sidestepped as needed. A portion of border fence that was to be constructed would run through "the San Pedro Riparian National Conservation Area in Arizona, plugging up season streams and wildlife corridors" (Pelley, 2008, p. 7). Because the environmental impact studies were skipped, these side effect of blocked streams and wildlife migration were not anticipated.

Pelley (2008) related that other laws that were passed during the Bush 43 years that attempted to ignore the environmental impact studies. These studies were required through the NEPA and could take up to three and a half years to complete, or essentially a Presidential term. The Bush 43 administration was after seeking results.

The harshest Presidential administration that has affected the Environmental Protection Agency's mission thus far has been Donald Trump's. A traditional Republican administration would typically attempt to encourage a healthy economy through less government intervention in private commerce. However, Trump's administration has hardly been a traditional administration. The current mission has seemed to be to undo the previous administration's environmental efforts en masse, with or without cause or consideration for the long-term damage caused to the planet, wildlife, or even the human race. "Trump has made eliminating federal regulations a priority" (Popovich, Albeck-Ripka & Pierre-Louis, 2019, para. 1). According to Popovich et al., the Trump administration has targeted over 80 regulations to scale back or eliminate all together.

Fredrickson et al. (2018) stated that Scott Pruitt, who made his reputation on being a hostile opponent of the Environmental Protection Agency, was appointed to be Trump's first

Administrator. In 2018, the proposed budget for the Agency was to be cut by 31 percent, a higher percentage than Reagan ever achieved. The Administration has "removed or obscured information about climate change from web sites, dismissed scientific advisory panels" and blocked scientific grants given out by the Agency (Fredrickson et al., 2018, p. 100).

After several controversies, Pruitt moved on, but the mission remained to be the same. A former coal lobbyist, Andrew Wheeler was next to take over as Acting Administrator (Trump administration…, 2019). Under Wheeler, one standard the Agency was attempting to roll back was the Mercury and Air Toxics Standards (MATS) which came into effect in 2012 and primarily affected coal plants. The MATS legislation "required plants to reduce mercury and other pollutants by over 90% in five years and since the rule was created, mercury emissions have dropped by 80-90%" (Trump administration…, 2019, p. 16). Inside the utilities industry, not everyone was on board with rolling back the standard.

> The majority of utilities companies have already made the changes required by MATS by investing in equipment such as scrubbers. An open letter by trade groups and unions to the EPA in July 2018 stated that any change in the rules would be of no benefit because they have already spent an estimated US $18bn to comply since 2012. (Trump administration…, 2019, p. 17)

The utilities companies were not the only ones opposed to deregulation. "More than 20 states are suing the Trump administration over its rollback of climate-change regulations for power plants in what could be a landmark case deciding what the federal government's responsibility is for fighting global warming" (Puko, 2019, para. 1). Puko stated that the states were accusing the federal government of abandoning the Clean Air Act. The Trump

administration had stopped enforcing the Obama era Clean Power Plan and replaced it with less strict Affordable Clean Energy rules.

The Environmental Protection Agency has had its share of ups and downs over the years since its inception. The Agency was given a near unenforceable mandate by the original TSCA, and then receiving broad new powers under the revised bill. But these new powers will always be at the mercy of the administration in the White House at the time. Nixon, Ford, Carter, Bush 41, Clinton, Obama seem to have given the Agency varying degrees of support, while Reagan, Bush 43, and Trump have attempted to pull the rug out from underneath it.

United States vs. Europe

According to Negev et al, "chemical regulations in individual countries are known to influence regulatory practices in other countries through trade" (2018, p. 463). Negev et al also stated that the two largest and most influential markets in the world were the United States and the European Union. The two regulatory systems act as informational role models to other countries that have attempted to avoid international trade barriers with the two large trading blocs (2018).

Response of the United States

That does not necessarily mean that the United States and European Union were in lock step with each other in their regulatory beliefs. The United States attempted to influence the world market by attempting to limit the growing influence of European Union since before REACH's implementation. In reality, there was quite an underground resistance to the REACH legislation from the United States industry and the government.

According to Brown (2003):

> Industry groups such as the European Chemical Industry Council and the American Chemistry Council, as well as the U.S. Chamber of Commerce have mounted major lobbying campaigns to ease REACH's impact on business, asserting that REACH would cause widespread unemployment, deal a body blow to the U.S. economy and "deindustrialize" Europe by forcing manufacturers into the developing world. (p. 769)

In the United States at the time of REACH's implementation, when the chemical industry claimed information that was submitted to the EPA was a confidential trade secret, generally the EPA accepted as fact. If the submitted data revealed hazardous information, then the claim could have been challenged. If that information was found to not be confidential, then the EPA would be able to share the hazardous chemical data it had obtained (Sissell, 2007). "TSCA and REACH both protect confidential business information, but REACH requires greater public disclosure" (Sissell, 2007, p. 21). The amount of information that REACH would be able to share with the public was one of the unknowns that terrified the United States chemical industry.

Even within the United States' own borders, the concept of REACH was having an effect on certain states with a desire to have strong regulatory laws, much to the industry's dismay (Black, 2008). Black offered the example that Maine was searching for a better way to regulate chemicals. An effort by the Governor of Maine in 2006 was heavily influenced by REACH's effort to develop safer chemical alternatives. The Governor issued an executive order to create a "task force to come up with an overall policy requiring and offering incentives to develop safe chemicals in consumer products" (Black, 2008, p. 127).

While the ideas of the proposed REACH were spreading, as reported by Black (2008), the United States government appeared to be willing to help small to medium-sized companies with the rigors of REACH registration, at least in the public eye. Black stated that the U.S. Department of Commerce stated that their goal was to help prepare the small to medium sized companies with training on what data would be required of them, and when they would be required to submit it. However, the government's effort may not have been completely wholehearted. According to R. Auerbach, who was responsible for REACH registration of his small to medium sized United States chemical company, "to my knowledge, the US Government did not do anything to help companies with REACH registration" (personal communication, September 11, 2019).

The United States government was also actively attempting to interfere and undermine the REACH legislation before it was passed into law. Brown (2003) stated that a memo titled the *United States Nonpaper on EU Chemicals Policy* was circulated to United States embassies in the European Union in March 2002. Brown continued to state that Secretary of State Colin Powell was responsible for this distribution and encouraged the United States ambassadors to distribute the memo to trade and environmental groups in their assigned European countries. The memo "was unsigned and printed on plain paper without any U.S. government letterhead. It said REACH could distort global markets and violate World Trade Organization principles" (Brown, 2003, p. 769). According to Brown, the language used in the memo matched other reports being prepared by United States industrial groups that were falsely claiming that the United States products would be banned by political pressure in Europe.

Black (2008) described yet another United States effort to stave off REACH inspired influence in the western hemisphere:

> In August 2007, in what could be thought of as the North American response to REACH, the United States, Canada, and Mexico signed an agreement in Montebello, Quebec, to assess 9,000 chemicals produced or imported in volumes of 25,000 pounds or more. The countries are required to complete risk characterization on these chemicals by 2012. By 2020 the countries must have inventoried all chemicals currently in commerce. The agreement is aimed at sharing information and coordinating risk management of the chemicals. (p. 127)

Response of the European Union

The European Union was not entirely innocent with their attempts at world influence either, although their efforts appear to have better intentions. In the opinion of Heyvaert, Europe wanted to push their regulations as "an attempt to reel other regions into the European sphere of influence" (2009, p. 116). Lewis et al. (2006) state that REACH's influence "will eventually have a much broader impact on chemicals policy and regulation initiatives as they begin to be implemented on a worldwide scale" (p. 592). The European Union was looking to export their chemical policy in an effort to build common ground and rapport "by opening scope for cooperation and exchange, in which process the EU, as the original architect of the regulatory format, is poised to take a central role" (Heyvaert, 2009, p. 117).

With REACH's implementation, Europe was using their newly-enhanced influence to supplant the United States as the world's leader on chemical regulation. But their aspirations may have been much higher than just that. The European Union's push for additional global influence coincided with a wide range of issues that Europe was making efforts to push toward their ideal solutions. Issues such as the "the meteoric rise of India and China on the global

market, the ascendance of complex and transboundary risks such as climate change on the global political agenda, to the waning intellectual and moral leadership of the United States" (Heyvaert, 2009, p. 116).

Worldwide Influence

Some smaller countries, Israel for example, implemented their chemical regulatory rules based off of both the United States' TSCA and Europe's REACH (Negev et al., 2018). For example, "in 2016, Israel adopted the latest revision of the EU standard, which now regulates 18 trace metals" (Negev et al, 2018, p. 465). According to Negev et al., their old standard had been limited to just eight trace metals, which matched the United States and the old European Union's standard. With the potential effect on human health and restricted trade with the European Union, Israel chose to enact the tighter restriction.

Heyvaert (2009) maintained that if regulatory conditions were to become more alike worldwide, then the required registration information will become much easier to prepare for submission. Small markets have always looked to the larger markets for guidance in regard to regulatory legislation. "Large regulated markets have both the expertise and resources to conduct comprehensive risk assessments, upon which a small market can rely. From a trade perspective, adopting standards of large markets reduces international trade barriers, both import and export" (Negev et al., 2018, p. 468).

Conclusion

This examination has touched on just two of the dozens of different regulatory systems across the world. The European Union's REACH has been widely considered the toughest set of

regulations throughout the world, while the United States' TSCA was one of the first major sets of regulations to attempt to govern industrial chemical manufacturing. However, it has taken major bipartisan reform to allow the EPA to have had a chance to become effective.

A large portion of the chemical industry rallied against REACH from the start. The industry felt "the financial burden created by the new and extended data reporting, the testing and assessment provisions, and the authorization requirement would blight the chemical industry's competitiveness on the world market" (Heyvaert, 2009, p. 114). Perhaps the chemical industry was scoffing at the notion that the burden of proof of chemical safety was shifted away from government and onto the manufacturers themselves. Or, it could have been that so many companies had to pay what could be construed as a tax, just for the privilege of potentially selling their products into the European Union. Or, it might have been the effect of increased scrutiny on the chemical market and the manufacturers occasional careless handling of their chemicals had caused harm to human and environmental health. It may have been all these reasons, a combination of them, or even another unnamed reason altogether that the chemical industry was anti-REACH.

On the other hand, the United States had an unenforceable and ineffective program under the original TSCA which was in place for over 40 years. Reform legislation with support from the chemical industry, who had hoped for a more streamlined nationalized set of rules, was passed in order to increase the strength of the EPA's ability to enforce TSCA. The EPA was now able to regulate new, and more importantly, existing chemicals equally, without the phrase of 'least burdensome' being held against them in judicial rulings. The EPA had a clear path to save lives and make better efforts to protect the environment from industrial contamination. Until,

only a few years later, the EPA's funding was once again slashed by the whims of a new Presidential administration.

REACH came into being despite efforts of the chemical industry and the leadership in place at the time of the United States to thwart it. TSCA reform sprung out of a combination of public outrage, a form of peer pressure that was felt coming from Europe, and an elder politician's crusade for reform. Both regulatory systems have merit and were created with the best of intentions to protect human health and attempt to better protect the world in which the human race exists.

Effective chemical regulation has been seemingly gaining momentum throughout the world. More countries have begun to adopt REACH or TSCA regulations as their own in an effort to reduce trade barriers and make chemical registration easier on importers and manufacturers. Streamlining the required data may be the best way to appease the chemical industry as a whole.

Will one set of these two regulations take precedence and become the worldwide standard? Heyvaert stated that "the globalization of regulation may limit opportunities for comparative learning and exchange, which narrows the basis for review and reform" (2009, p. 121). Or in other words, the chemical regulatory world could settle on one method and accept that the findings discovered from a round of REACH or TSCA testing and apply the same data worldwide. While these findings may be true, there still will be other chemical unknowns that should be discovered. The scientific method teaches that results should be questioned, tests should be re-ran and verified, and very rarely does an answer stay the same forever. Vigilance

should continue to be practiced with an eye on future reform and refined test methods within the world of chemical regulations for the sake of the environment and our future generations.

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