



**WRITTEN STATEMENT OF  
NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION (NPRA)  
AS SUBMITTED TO THE  
SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH  
Committee on Environment and Public Works  
United States Senate**

**on**

**“Business Perspectives on Reforming U.S. Chemical Safety Laws.”**

**March 9, 2010**

Good morning, Mr. Chairman and Ranking Member Inhofe. My name is Charlie Drevna, and I serve as President of NPRA, the National Petrochemical & Refiners Association. I appreciate the opportunity to testify at today's Subcommittee hearing on "Business Perspectives on Reforming U.S. Chemical Safety Laws." Our association represents more than 450 businesses, including virtually all U.S. refiners and petrochemical manufacturers, their suppliers, and vendors. NPRA members supply consumers with a wide variety of products used daily in their homes and businesses, including fuels, lubricants, and chemicals that serve as building blocks for everything from plastics to clothing, medicine, and computers. As you might imagine, NPRA members have a keen interest in the current legislative efforts to modernize the federal statute governing chemicals management – the Toxic Substances Control Act (TSCA). We appreciate this opportunity to submit our views on TSCA modernization.

## **I. Introduction**

NPRA understands the Subcommittee's desire to examine the implementation of TSCA and, where necessary, consider modifications to the statute to ensure that its important goals and objectives are realized. NPRA supports this objective and looks forward to working with the Subcommittee during its review. We consider the current federal chemicals regulatory framework to be a solid foundation for protecting the health of consumers, our customers and the environment, while simultaneously allowing for the development of products to enhance health, safety and environmental quality. NPRA and our member companies support the responsible modernization of our chemicals risk management regulatory framework. However, NPRA does not believe that a wholesale rewrite of the statute is warranted.

By working together, sharing information, and appropriating the necessary resources, our collective task will be much less cumbersome and much more effective.

## **II. The U.S. Economy Depends on a Reliable Supply of Materials for Manufacturing**

Petrochemicals and their first and second derivatives are the fundamental building blocks that have enabled the United States to maintain its position as a global economic power.

Petrochemicals are used throughout the world of organic chemistry, from fundamental research in universities and government laboratories, to the commercial chemistries of specialty chemical producers. With few exceptions, the products of organic chemistry influence every finished good that is manufactured in the United States or imported into this country – whether as a raw material, processing agent or performance additive. From aspirin to asphalt, cosmetics to computers, seatbelts to soap, and umbrellas to zip-lock bags, these products would not be possible without petrochemical derivatives and performance additives made from petrochemical feedstocks. Without petrochemicals and their uses in other manufacturing sectors, our standard of living and the everyday conveniences we have come to expect in the modern world would simply not be possible. Our manufacturing and distribution infrastructure investments over the past decades have provided the entire U.S. manufacturing community with a consistent and abundant supply of raw materials.

## **III. The Science of Chemistry: Chemicals Are Fundamental**

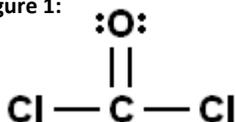
As previously stated, chemistry influences most, if not all, manufacturing in one form or another. Like all manufacturing processes, chemistry is bound by the laws of physics and nature. These physical laws place restrictions on what can and cannot be done when trying to make a chemical compound. For instance, a molecule (i.e., a chemical) is made up of atoms (e.g., sodium, carbon, chlorine, etc.) that are in specific locations or positions on the molecule. In organic chemistry the goal is to take the atoms from one molecule and move them to locations on another, different molecule for the target molecule to assume a specific function or behavior.

The laws of physics and thermodynamics dictate if, how and when those atoms can be moved. To achieve certain critical structural changes, reactive chemicals must be used, and many are by nature hazardous, e.g., toxic, flammable, explosive, etc. In light of these constraints, scientists seeking to achieve certain chemical changes are left with few alternatives. Where hazardous chemicals are used, they are regulated by the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT) and others, and appropriately managed by professional chemists in universities, government and industry.

Simply stated, scientists cannot produce the materials that make our standard of living possible without relying on specific chemicals. The production of medicine illustrates this point. Producing medicine often requires multiple steps. Each step in the process carefully moves atoms from one molecule to locations on another molecule. Eventually, the scientist will obtain the desired chemical that performs a precise medicinal function. The movement of these atoms, from one molecule to another, is a chemical reaction and can only take place using certain materials and conditions. The chlorine atom, for instance, when located on a specific part of a molecule, allows these steps (reactions) to take place. One common misconception, though, is that any chlorine atom will do. That is not the case. Chlorine atoms take on different behaviors, or physical properties, depending on the specific atoms to which they are attached.

For instance, common table salt consists of the sodium (Na) and chlorine (Cl) atoms, which make up the chemical sodium chloride (NaCl). The chlorine atom used to make medicine, however, often comes from phosgene (COCl<sub>2</sub>) or phosphorous trichloride (PCl<sub>3</sub>). Phosgene, for

Figure 1:



example, has one carbon atom bonded to one oxygen atom and two chlorine atoms (see Figure 1), giving the chlorine atoms in phosgene very

specific characteristics that are quite different from the chlorine found in table salt. The very specific nature of the chlorine atom in phosgene is critical to its fundamental role in pharmaceutical manufacturing, and minimizes the formation of unwanted, potentially toxic by-products that would otherwise contaminate the medicine. The complex chemistry associated with making medicine has well-defined physical boundaries and requires the use of reactive and toxic chemicals.

#### **IV. Chemical Risk Management Is an Essential Part of Doing Business**

Recognizing that some chemicals can be reactive and toxic, vigorous protection of human health and the environment is imperative and requires appropriate chemical risk management. Even though most chemicals in commerce are used in industrial applications and never come in contact with the general public, there is a fundamental need for the federal government to *appropriately* manage the risks of all chemicals in commerce from production to disposal.

Like manufacturing, chemical risk management has also evolved over time. Shortly after the creation of the EPA in 1970, Congress realized the need to give the Agency broad authority to protect human health and the environment. Congress enacted specific statutes focused on specific environmental media (air, land and water), and crafted TSCA to focus on the production and distribution of chemicals introduced in commerce.

To assure compliance with the wide range of environmental and occupational safety laws and regulations, many chemical manufacturing companies, including NPRA members, have created and maintained environmental, health and safety (EH&S) departments to help fulfill their obligations under the law. EH&S departments of petrochemical manufacturers quickly concluded that, if approached in a well-organized, systematic manner, compliance with these statutory and regulatory requirements would be less difficult. The collective experience of

EH&S professionals world-wide has led to the current evolution in industrial chemical risk management. This approach has expanded beyond the petrochemical industry as the practice has been adopted by most other major manufacturing sectors, such as electronics, aerospace, automotive and consumer products.

#### **V. Chemical Risk Management Must Be Appropriate for the Situation and Based on Sound Science**

Effective chemical risk management strives for the balance between doing nothing – which is unacceptable – and zero risk tolerance – which is neither feasible, sustainable, nor desirable. Prior to the 1970s, society had little concern about industrial chemicals, primarily because it was assumed that the general public would never come into contact with these types of materials. Over time we have learned that certain industrial chemicals can be released during manufacture, use or disposal. Thus began a more comprehensive approach to chemical risk assessment and risk management.

When Congress enacted TSCA, its intent was to provide EPA with broad authority to regulate chemicals in commerce. While some believe TSCA does not provide EPA with the tools to effectively regulate chemicals on the market, it was the intent of Congress to provide a series of checks and balances so that regulatory decisions made under TSCA are scientifically and economically sound. TSCA charges EPA with the collection of existing health and hazard characterization information on all chemicals in commerce today; authorizes EPA to require chemical manufacturers to generate new information on these chemicals; requires manufacturers to report to EPA accounts of previously undetected hazards and risks; and requires both EPA and the manufacturers to manage known risks posed by certain chemicals. The statute also provides the Agency with an opportunity to review new chemicals prior to their introduction into commerce.

While TSCA imposes on EPA the duty to protect workers and consumers as well as the environment, there are provisions in the statute that reduce the likelihood of arbitrary or counter-productive decisions. For example, before EPA can require a company to conduct a costly and intensive toxicity test using laboratory animals, it must first have a sound basis for requiring the production of this information. The Agency must find that the substance in question is used in such a way that there may be a potential for substantial exposure to the chemical to workers or the public. Requiring these findings prior to issuing an order to conduct testing ensures that the information collected by EPA is necessary for the protection of the public and the environment. It also sets the framework for a scientifically and economically sound approach to chemicals management that is tiered, targeted and risk-based.

When EPA does find that a chemical presents, or will present, an unreasonable risk, TSCA provides the Agency with very broad authority to take action to reduce the risk. EPA can require a company to communicate the risk in a specific manner; place restrictions on how a chemical is used; ban certain uses of the substance; and even ban the chemical from the marketplace altogether. Some may argue that there are too many legal hurdles preventing EPA from taking quick and effective regulatory action. In reality, and because it gave the Agency such broad authority, Congress felt the need to ensure that the Executive Branch fully understood the potential consequences of its actions. TSCA requires that EPA fully explore various options to manage the risk, from scientific, economic and social perspectives, because restrictions and bans can cause far-reaching disruptions in the marketplace, including decreasing the availability of essential goods.

Congress took great care in writing TSCA to assure the protection of individuals and the environment, while simultaneously preventing the stifling of innovation and the vast benefits that come with economic prosperity.

## **VI. Regulatory Chemical Risk Management Has Evolved in the United States**

To fully appreciate the evolution of regulatory chemical risk management in the United States, it is important to look at how the various sections of TSCA interact with each other in their entirety and resist isolating and focusing on individual sections. The first question that could be asked is: Why was a distinction made between existing and new chemicals? (This distinction was not made solely in the United States; in fact, it was made by all nations and regions that established chemical regulation laws in the 1970s.)

As enacted, Section 8 of TSCA required EPA to establish an inventory of chemicals that were already in commerce, and to promulgate regulations that required companies to update the health and safety information on those chemicals periodically. This was to provide a baseline of information that enabled the Agency to know what chemicals were in the marketplace and in what amounts. In reality, the approximately 62,000 chemicals originally reported to the TSCA Inventory were never reflective of the chemicals actually in commerce. EPA approached the creation of the Inventory by allowing industry to add whatever chemicals they were currently making – *or were going to make in the future*. This approach led to the addition of many chemicals that were never actually introduced into commerce, as well as the addition of some substances that are physically impossible to produce.

Requiring EPA to conduct risk assessments on all existing chemicals at the same time was simply not feasible or cost-effective because many of the chemicals on the TSCA Inventory were industrial intermediates used only to make other chemicals in closed systems and under tightly

controlled industrial environments (i.e., there was no risk of public exposure to those chemicals). Furthermore, some chemicals on the TSCA inventory have never even been produced; rather, they were simply added to the inventory in the event a company might decide to produce them in the future. Instead, Congress added provisions to Section 8 that required companies to keep records of alleged significant adverse reactions to any chemical and to report any known substantial risk immediately to the Agency. Congress provided EPA with additional authority under Section 8 to collect existing information related to hazards and exposures, even if the risks were not fully characterized.

If EPA determined that the existing hazard and exposure information was insufficient to adequately determine a chemical's risk, then Congress intended for the information collected under Section 8 actions to be used by the Agency to justify requiring companies to conduct additional testing and submit those studies to EPA under TSCA Section 4. Section 4 of TSCA gives EPA authority to require companies to conduct specific laboratory tests to augment the Agency's risk assessment and risk management activities. Once EPA had sufficient information, if it determined that the chemical posed an unreasonable risk, the Agency could take action under TSCA Section 6, which gives EPA very broad authority to take risk management actions. These actions include restricting the use of a substance, requiring specific protective measures, or even imposing an outright ban of a material. The caveat, however, is that EPA would have to fully consider the consequences of its proposed actions, such as a potential lack of available alternatives or a dramatic rise in the cost of goods due to potential disruption in the marketplace.

This approach to chemical risk management is straightforward and effective. However, the implementation phase has not always been so easy. Over the years, EPA has faced conflicting pressures – from activists on the one hand, who have wanted EPA to quickly determine the risks

of all chemicals in commerce and take immediate action on those that are found to present risks, and from the regulated community on the other, which has expressed concerns about the aggregate costs and cost-efficiency of an overzealous regulatory testing program. To find a balance between the two interests and maintain a workable and scientifically sound regulatory scheme, EPA has pursued a tiered, targeted and risk-based approach to chemicals management. Resources and testing are focused on those chemicals with the greatest potential to cause harm to the most people. The Agency first implemented this regulatory concept, in the late 1970s and early 1980s, in the area of new chemicals, which EPA is required to review before they enter into commerce.

TSCA responsibly addresses the issue of new hazard data for chemicals that companies wish to sell into commerce for good reason.<sup>1</sup> In the absence of measured data, EPA devised a more efficient and effective way to quickly review a chemical and decide whether or not the chemical could pose an unreasonable risk, or if the Agency needed more information to make a sound judgment. Due to the broad authority given to EPA, the Agency proposed that companies would submit processing and use-related information on a form, the pre-manufacture notification (PMN), which would allow agency technical staff to estimate the concentrations to which individuals could be exposed. If the estimates indicate a potential for significant exposures, EPA then has the authority to restrict certain processes and uses until more hazard information is developed to allow for a more adequate risk characterization. Over time and with the advent of computers, the Agency has been able to develop software models to assist in conservatively estimating concentrations of chemicals to which people could be exposed.

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<sup>1</sup> The intent of Congress was to preserve the high degree of innovation in this country and not significantly raise barriers of entry into the marketplace, especially for small businesses. It can be readily observed that regions requiring overly burdensome or unnecessary testing before a chemical can be sold into commerce do not have nearly as many new chemicals introduced into their regional markets, including new and often safer chemicals that enhance human health and environmental protection, as do those regions that do not require testing.

In addition to new ways of obtaining potential exposure information, EPA determined that it was able to enter into enforceable consent agreements with companies, through which the manufacturer and the Agency would agree to an appropriate battery of tests to further characterize a chemical's hazards. This hazard information would provide greater clarity regarding the chemical's risk to the general public and the environment. EPA has been quite successful in securing the cooperation of companies for the submission of hazard information because it was not cost-effective for a company, under a threat of processing or use restrictions, to adjudicate the matter in court. In addition, companies that wanted to submit more new chemicals did not want to create a negative impression on the Agency that would be reviewing those new chemicals. Also, EPA chose the reasonable and workable approach to ask for testing in a tiered and targeted manner, which used exposure information to help determine which tests would be appropriate.

EPA has been successful in obtaining hazard and exposure information for new chemicals. Under the threat of regulatory action under Section 5, the Agency successfully entered into enforceable consent agreements with many companies, whereby companies submitted toxicity and other studies requested by EPA. Additionally, EPA collected extensive information related to use and exposure on the form used for pre-manufacture notices. These important and clarifying facts are often not mentioned in the TSCA reform debate.

During the nearly three decades of chemical reviews, Agency technical staff noticed that the hazard information under review revealed patterns that could be associated with certain chemicals' molecular structures. Scientists in the field of chemistry already knew that certain physical and chemical properties could be ascertained according to a chemical's molecular structure. Predicting the way that molecules behave is, in fact, the essence of the science of

chemistry. It was reasonable for Agency scientists to assume that structure-activity relationships (SAR) would hold true for chemical reactions taking place inside the human body. However, even today, the chemical reactions taking place inside the body are not nearly as well-understood as reactions taking place in a test tube, where most variables can be recognized and controlled.

EPA technical reviewers understood that predicting chemical reactions inside the body – the basis upon which the field of toxicology is based – was in its infancy (and still is when compared to other natural sciences). The question then became: To achieve protection of consumers and the environment, how accurate does EPA have to be when characterizing the hazards of chemicals? If the Agency took a conservative approach and overestimated potential impacts, it would limit the need for an extensive array of specific tests and still maintain protection of human health and the environment. Conservative approaches use default assumptions, which usually overestimate conditions and employ protective safety factors. This led EPA to begin estimating ranges of toxicity, rather than trying to characterize certain endpoints with exactitude.

Both a June 2005 and January 2009 GAO report to Congress on TSCA questioned the accuracy of the long-standing models used by EPA to review new chemicals. The reports failed to note, however, that the conservative nature and protectiveness of the models is sufficient to achieve their risk assessment and risk management objectives. With an ever-increasing amount of data from testing programs and consent agreements under both the new and existing chemicals programs, EPA has more than sufficient data to refine its models.<sup>2</sup> Patience is needed, however, because this is not and cannot be an overnight process.

The field of toxicology is still evolving, and the discipline should be afforded the same time needed by other natural sciences to develop. The constant demand by some that EPA be

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<sup>2</sup> Data collected under consent agreements and the voluntary HPV Challenge are typically not included in discussions concerning the effectiveness of TSCA Section 4. Including these sources of information, EPA has data on several thousand chemicals.

required to do everything at an unreasonably rapid pace, as is the case under the new European chemicals policy, is ill-advised and may inhibit the natural evolution of toxicology as a science, and ultimately lead to errant decision-making.

## **VII. EPA Has Faced Challenges When Implementing TSCA, but Has Met Those Challenges**

While proponents of a dramatic overhaul to domestic chemicals policy have argued that TSCA prevents EPA from carrying out its duties, NPRA believes that the challenges with TSCA implementation are more due to grossly inadequate funding, outside pressure that results in hasty regulation, and the sequence in which the TSCA tools have been implemented. A thorough and careful review of the Federal Register and associated dockets reveals that in some early risk management actions, EPA did not, or was not able to, do as thorough a job as was necessary. A review of opinions from related court cases over the years readily affirms this.

That is not to say NPRA believes that EPA has not been doing its job well. On the contrary, when TSCA was passed, chemical risk management was in its infancy, as were certain aspects of the fields of toxicology, exposure assessment, and chemical risk assessment. EPA has been able to successfully develop ways to achieve the objectives and goals of TSCA, while allowing innovation to foster in the marketplace. The main factors contributing to EPA's difficulties in implementing TSCA are due more to its choices in the timing and sequence of Section 4 test rules, and over-reaching bans of uses in Section 6 risk management actions, versus challenges posed by the statute.

Many proponents of TSCA reform point to one specific case (*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991)), where EPA attempted to ban asbestos using its authority under Section 6, as proof that TSCA does not provide EPA sufficient authority to manage risks. EPA was challenged in court because there was a critical need for asbestos in this particular use

(brake linings), no suitable alternatives for asbestos existed in this application, and the Agency did not explore other ways to manage the risk. The clearly written opinion of the Court of Appeals for the Fifth Circuit demonstrates that EPA could have maximized its chances for success in regulating only certain uses of asbestos. If EPA had taken the appropriate approach towards the risk management of asbestos – concentrating resources first on those uses that could result in the highest concentrations of airborne particles and where alternatives could be used – the Agency would have been in a significantly better position to prevail in the case. Instead, the Agency tried to ban a critical use of the substance for which there were no readily available substitutes. Further, EPA did not evaluate other risk management approaches short of a ban. NPRA believes that this, and not some inherent TSCA shortcoming, is the primary reason the rule was successfully challenged in court. After EPA lost this case, the Agency basically stopped trying to issue Section 6 actions. An agency that has rarely used its authority cannot simply blame the statute that grants it that authority for lack of action. Attempts to ban most uses of a substance with readily demonstrable benefits, especially public health or life-saving benefits, must meet a very high burden of proof.

The Agency's difficulties in promulgating test rules have been due less to TSCA statutory problems than to decisions made by EPA on timing and sequence. In most cases, if the Agency had chosen to collect use and exposure information under Section 8 first, and then reviewed the available information, especially pertaining to uses and potential exposures, the Agency would not have faced the challenges that it had faced early on when attempting to promulgate Section 4 test rules. Because EPA will now be collecting use and exposure information as part of the Inventory updates from industry, in addition to its use of information collections under other

parts of Section 8, issues surrounding the promulgation of Section 4 test rules should begin to diminish.

After these early experiences in court, EPA has been reluctant to attempt Section 6 and Section 4 actions. The Agency has stated that the findings for actions under these particular sections are difficult to make. EPA has recently used its Section 8 authority, however, to successfully collect the necessary use and exposure information to justify more Section 4 test rules on the remainder of the high production volume chemicals that have not been voluntarily tested by industry. The first Section 4 test rule was successfully promulgated several years ago, and the Agency plans to finalize another test rule within the next several months.<sup>3</sup> Additionally, EPA has stated that it will continue issuing test rules until all HPV chemicals are either volunteered or covered under a rule.

Regarding Section 6, EPA has used collaborative partnerships and stewardship programs to provide manufacturers along the supply chain with opportunities to voluntarily discontinue certain products. All cases where the Agency has taken a collaborative approach have resulted in demonstrable success (e.g., withdrawal of the substance from commerce or establishment of a specific timeframe for withdrawal). In addition, EPA typically follows up with a Section 5 Significant New Use Rule, which authorizes the Agency to require companies to submit notifications (similar to PMNs) when a company wants to reintroduce the existing chemical back into the marketplace. During public meetings of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), EPA and other stakeholders repeatedly expressed that Section 5 was an effective risk management tool for new uses of existing chemicals as well as new chemicals. NPRA is puzzled and somewhat perplexed that EPA and others appear to have

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<sup>3</sup> The first HPV test rule was not challenged in court by any chemical company, primarily because EPA worked together with industry and collected sufficient information to make the appropriate exposure findings.

recently altered their views about the effectiveness of Section 5 and, in general, the new chemicals program within OPPT.

In addition to the authorities provided under TSCA, EPA collaboration with multiple stakeholders is probably the most workable and efficient use of its resources when assessing and managing the risks of chemicals. The collaborative approach was put to the test in a dramatic manner in the late 1990s, when the High Production Volume Chemical Challenge (HPV Challenge) was created. EPA asked chemical companies to voluntarily provide a base set of hazard and environmental fate information for all chemicals manufactured or imported at greater than 1 million pounds per year in aggregate. The chemical industry willingly complied and sponsored over 2,150 chemicals, either in the U.S. HPV Challenge program or the Organization for Economic Cooperation and Development (OECD) HPV Programme. The HPV Challenge has resulted in more publicly available hazard data, generated in a timelier manner, than any other program in the world, regulatory or otherwise.

Building upon the success of the HPV Challenge and coordinating with its counterpart in Canada, in 2008 EPA committed to conducting hazard and risk characterizations on all HPVs and moderate volume chemicals (MPVs) in commerce as part of the U.S. government commitment to the Security & Prosperity Partnership of North America.<sup>4</sup> The name for this initiative was the Chemical Assessment and Management Program (ChAMP). Under ChAMP, EPA would have been able to prioritize risk assessment and risk management activities for chemicals in a more transparent and expeditious manner than ever before. Unfortunately, those commitments and plans have been abandoned. The decision to abandon that ground-breaking

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<sup>4</sup> MPVs are described as chemicals manufactured or imported at quantities between 25,000 pounds and 1,000,000 pounds per year in aggregate. Most chemicals below the 25,000 pound-per-year threshold are primarily either research and development chemicals or certain fine chemicals, both of which are typically used in tightly controlled industrial environments.

program had nothing whatsoever to do with the TSCA statute. In fact, EPA stated that it abandoned ChAMP in favor of using more of its authorities under TSCA, which seems contradictory to its calls for TSCA reform.

There have been calls from some groups to completely overhaul domestic chemicals policy and follow the European approach to chemicals management. The European Union has just started to implement new legislation – Registration, Evaluation and Authorization of Chemicals (REACH) – which dramatically overhauls its chemicals policy. It calls for extensive animal and other testing of chemicals, based primarily on the quantities at which they are manufactured or imported. There are many misconceptions about REACH that must be examined and resolved, such as:

- Assertion: REACH relieves the government of the burden of chemical safety and places it on industry.

Reality: REACH only increases the burden on industry. It does not reduce the burden on government. No government authority is going to receive a chemical dossier from industry and take it at face value. Rather, the government authority will conduct its own risk assessment, based on available information, and render its own decisions, risk-based or not. This will be just at least as time-consuming and resource-intensive under REACH as it is under TSCA. In fact, it will likely be more time-consuming because EU authorities will have to sift through a plethora of data that it collected, whether that data was needed or not. A careful reading of the REACH statute shows that the authorities must fully evaluate socio-economic considerations before proposing a restriction or ban, much like what EPA is required to do under Section 6 of TSCA. Furthermore, REACH places so much burden on industry that small- and medium-sized chemical manufacturers are facing significant difficulties complying with the program. For example, the French government recently announced a plan to provide over €600,000 in assistance to help French companies meet the November 2010 REACH registration deadline<sup>5</sup>. It is mostly in the risk management decision-making criteria that the two approaches diverge. Decisions in the U.S. must be based on sound science and weight of the evidence, while decisions in the EU can be based on partial science (i.e., only hazard) and current political disposition.

- Assertion: REACH will spur innovation in safer chemicals.

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<sup>5</sup> Chemical Watch. “French Government and Industry Join Forces to Meet REACH Deadline. 16 Feb 2010.

Reality: Innovation is a function of spending on research and development and ease of entry into the marketplace. Little more than a decade ago, the EU decided to require companies to conduct overly burdensome toxicity and environmental fate testing, disregarding whether or not there were any actual exposures to the substances, before a particular chemical could enter the marketplace. This approach has inhibited the development of products in Europe that could enhance health and the environment. This fact can be verified through the number of new, and usually safer, chemicals introduced into the European marketplace (around 2,000 over the past ten years), versus the number of new chemicals that companies have at least attempted to introduce in the U.S. (between 1,200 and 1,500 *per year*). Another compounding factor is that in business, toxicity and other laboratory testing is considered part of research and development and typically comes out of R&D budgets. That leaves much less money for new, and often safer, product development.

- Assertion: REACH fully considers animal welfare.

Reality: No matter what the statutory language reads, REACH will have a devastating impact on animals. It is disingenuous for the European Commission to require testing for thousands of chemicals, based solely on volume, and claim that it has fully considered animal welfare.

- Assertion: REACH is the wave of the future for chemicals policy.

Reality: REACH is a regulatory concept that has never been attempted anywhere in the world, at any time. It is entirely premature to draw any conclusions about REACH and it is equally untimely to attempt any comparison between REACH and regulatory programs that have been in effect for decades. In fact, authorities in Europe have already been inundated with so much information that they simply cannot keep up.

Pursuit of a program like REACH, taken on with the best of intentions for human health and safety, could very well impair health and safety by denying critical products entry into the marketplace. Such a program will place unnecessary burdens on industry that will result a significantly higher cost of doing business, inhibiting the development of products to enhance our way of life. The United States should resist adopting or moving towards this type of program as it explores modernizing TSCA.

## **VIII. Due to Current Economic Uncertainty, Care Must Be Taken When Reforming Chemicals Policy**

This Subcommittee will examine TSCA's implementation and, where necessary, make the appropriate modifications to the statute to ensure that its goals and objectives are realized. In the same vein, however, we live in an era where global competition and rapid technological change – now unfortunately coupled with a debilitating financial crisis – are calling into question the economic constructs on which our prosperity has rested for decades. Care must be taken to ensure that the overarching goals of TSCA – protecting human health and the environment – are achieved while at the same time promoting innovation, economic growth and U.S. competitiveness in the global marketplace.

NPRA is confident that these goals are complementary, not mutually exclusive, and NPRA pledges to work with Congress and all stakeholders to ensure the desired outcome.

## **IX. Conclusion**

Chemical risk management has evolved and is continuing to evolve in the United States. EPA is recognized as a world leader in chemicals policy, and the Agency's opinion is highly valued in the international community. A thorough study of the TSCA statute clearly reflects that Congress has given EPA broad authority to regulate chemicals in commerce. The intent of Congress – protection of human health and the environment while maintaining an appropriate system of checks and balances – is also clear in both the statute and the Record.

Our nation's current chemicals policy has allowed American businesses to survive in an increasingly competitive marketplace. Reform of domestic chemicals policy will necessarily take time and careful deliberation. NPRA therefore urges Congress to consider an inclusive, transparent process when crafting language to modernize the Toxic Substances Control Act.