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WHY MODERNIZATION OF THE U.S. TOXIC SUBSTANCES LAW IS GOOD FOR PUBLIC HEALTH AND BUSINESS

by Malcolm D. Woolf*

“If we are going to live so intimately with these chemicals – eating and drinking them, taking them into the very marrow of our bones – we had better know something about their nature and their power.”

– Rachel Carson, *Silent Spring* (1962)¹

“EPA has used its authority to require testing for fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979... Only five chemical substances or groups of chemical substances have been regulated...”

– U.S. Government Accountability Office evaluation of the Toxic Substances Control Act (2005)²

INTRODUCTION

When Congress enacted the Toxic Substances Control Act (“TSCA”) in 1976, the Act was considered a “major step forward in providing urgently needed authority to protect human health and the environment from dangerous chemicals.”³ Practitioners, however, have long recognized that TSCA has failed to live up to its promise.

As TSCA reaches its 30-year anniversary, a variety of scientific, economic, and political factors have triggered a renewed dialogue about reforming the U.S. chemicals management framework. This article explains why a modernization of TSCA is not only necessary from a public health perspective, but for business reasons as well.

The public health case for TSCA reform is prompted by undeniable new scientific evidence showing widespread human exposure to industrial chemicals. For example, hundreds of untested industrial chemicals have been detected in the umbilical cord blood of the typical newborn baby in the United States. While medical researchers debate whether this low level chemical exposure is associated with the growing occurrence of cancer, neurodevelopmental disorders, or other diseases, there is no doubt that U.S. Environmental Protection Agency (“EPA” or “Agency”) has little information about the potential health and safety implications of these chemicals. The last three decades have demonstrated that the Agency lacks the tools needed to effectively evaluate or respond to the potential human health

risks unveiled by scientific testing.

The business rationale for modernizing the nation’s toxic chemicals law is equally compelling. New laws in the European Union and in several U.S. states are creating a patchwork of inconsistent chemical regulations that will place many U.S. businesses at a disadvantage. At the same time, businesses are discovering that there is money to be made in producing less toxic products. In addition, the rapid emergence of nanotechnology necessitates a more effective regulatory framework that can encourage innovation and foster acceptance by the public and investors.

The convergence of these factors creates significant pressure to modernize TSCA. Taken together, modernization of the U.S. chemicals management framework is inevitable in the next several years.

THE PUBLIC HEALTH CASE FOR TSCA REFORM

TSCA’s antiquated framework is inadequate to meet the challenges uncovered by modern science. Additionally, biomonitoring studies show widespread human exposure to industrial chemicals, many of which have never been evaluated for potential adverse human health effects.

Recent scientific advances in analytic testing have transformed our understanding of human exposure to manmade chemicals. Through biomonitoring studies, scientists have now detected well over a hundred industrial chemicals in the bodies of most Americans. As discussed below, low concentrations of flame-retardants, plastic softeners, and long banned chemicals such as polychlorinated biphenyls (“PCBs”) are virtually ubiquitous in the blood and fat tissue of most Americans today. As a result, biomonitoring (also known as body burden) studies have created significant pressure to modernize the U.S. chemicals management framework.

The new data gleaned from biomonitoring is defined as “a scientific technique for assessing human exposures to natural and synthetic compounds in the environment.”⁴ Typically, scientists analyze human blood, urine samples, or fat tissue to determine whether a person has been exposed to a particular chemical. Advances in recent years have improved scientists’ ability to detect even small concentrations of chemicals in our bodies. The U.S. Centers for Disease Control and Prevention (“CDC”) explains that “biomonitoring measurements are the most health-relevant assessments of exposure because they

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measure the amount of the chemical that actually gets into people from all environmental sources (e.g., air, soil, water, dust, or food) combined.”⁵ Perfluorooctanoic acid (“PFOA”) is one of countless examples illustrating the gaps created by TSCA’s outdated framework.

While numerous biomonitoring studies have been conducted in the United States, the CDC has conducted the most ambitious effort. In July 2005, the CDC issued the third of its biennial “National Report on Human Exposure to Environmental Chemicals,” evaluating the U.S. population’s exposure to 148 environmental chemicals. Strikingly, they detected all but two of the 148 chemicals in at least some of the samples tested.⁶ In other words, CDC found human exposure to virtually every chemical for which it looked.

For example, CDC found “widespread” exposure to phthalates, an industrial chemical used to soften and increase the flexibility of plastics and vinyl.⁷ According to the CDC, phthalates have been demonstrated to cause adverse reproductive toxicity and other effects in animal studies, though little information is available about the potential human health impacts. Significantly, the CDC also detected continued human exposure to chemicals banned decades ago in the United States, such as PCBs, which were banned from intentional production in 1979.⁸

Another remarkable study focused on industrial chemicals in human umbilical cord blood. Using donated cord blood samples from the United States Red Cross, the Environmental Working Group (“EWG”) found an average of 200 manmade chemicals and pollutants in babies born in the United States in 2004.⁹ Alarming, a total of 287 chemicals were found to have crossed the placental barrier into the baby. Among the chemicals detected were polybrominated diphenyl ethers used as flame retardants in furniture, polychlorinated naphthalene used as wood preservatives, and perfluorochemicals used as stain and oil repellants.

Biomonitoring is already having a real world impact on the marketplace. The most recent example involves the perfluorochemical PFOA, widely used in the production of non-stick pans and stain resistant clothes and carpet. Numerous biomonitoring studies found that PFOA has become commonplace in the bodies of most Americans. Researchers at Johns Hopkins Hospital recently confirmed the presence of this industrial chemical in 99 percent of the umbilical cord blood of 300 newborns born at the Hospital.¹⁰ PFOA is known to bio-accumulate in the human body and an EPA Science Advisory Board draft report recently classified PFOA as a “likely carcinogen.”¹¹ As a result of these developments, EPA obtained agreements from DuPont and the other major manufacturers of PFOA to essentially phase-out production voluntarily over the next fifteen years.¹²

This new information on the prevalence of human exposure to industrial chemicals is dramatically different from the scientific understanding of the 1970s. When TSCA was enacted in 1976, chemicals contained within consumer products were generally not believed to be a significant source of potential exposure (except perhaps for chemical or farm workers). Biomonitoring now has proven otherwise. While we still do not understand all of the exposure pathways, it is undeniable that

human exposure to industrial chemicals is far more prevalent than previously understood.¹³

The real question of course is – how safe are we? Some medical researchers estimate that environmental toxins cause up to 35 percent of asthma cases, ten percent of cancer cases, and twenty percent of neurobehavioral disorders in children and contribute to respiratory disorders, cancer, infertility, and heart disease in adults.¹⁴ On the other hand, the chemical industry argues that the extremely low concentrations of chemicals often detected through biomonitoring likely are too minute to cause adverse health impacts.

What is undisputed is that insufficient information is available about the potential human health impacts of many of the chemicals commonly found in our bodies. As such, public concern about biomonitoring results and the rapidly growing body of scientific literature linking industrial chemicals to potentially adverse health impacts is prompting a fundamental reevaluation of TSCA.

TSCA FAILS TO PROVIDE EPA WITH THE TOOLS NEEDED TO EFFECTIVELY EVALUATE CHEMICALS

The discovery of widespread human exposure to industrial chemicals raises the question – is TSCA up to the challenge? Unfortunately, the answer is no. This article evaluates EPA’s record with respect to chemicals on the initial 1979 Inventory (so-called “existing chemicals”), the Agency’s new chemicals program, its authority to take action to reduce chemical risks, and its voluntary initiatives. In each respect, TSCA fails to give EPA the tools needed to effectively evaluate and manage the risks posed by industrial chemicals.

FEW CHEMICALS IN COMMERCE SINCE 1979 HAVE UNDERGONE EPA REVIEW

By any measure, EPA’s record with respect to reviewing the safety of existing chemicals is unacceptable. A recent report by the U.S. Government Accountability Office (“GAO”) concluded that “EPA does not routinely assess existing chemicals, has limited information on their health and environmental risks, and has issued few regulations controlling such substances.”¹⁵

The data speaks for itself: of the 62,000 chemicals in commerce in 1979 when the EPA program began, EPA has used its authority to require testing for fewer than 200.¹⁶ Further, EPA has performed internal reviews of only an estimated two percent of the chemicals on EPA’s original TSCA inventory.¹⁷ No wonder that little information exists on so many of the chemicals now being detected in human bodies through biomonitoring studies.

EPA cannot fairly be blamed for this intolerable record. Rather, the program was doomed from the start. Congress declared that it should be the “responsibility of those who manufacture and those who process” chemical substances to develop “adequate data” about their effects on health and the environment.¹⁸ While the purpose is clear, the statute fails to require chemical companies to submit basic toxicity information to EPA.

Instead, EPA was forced to gather this information itself. The Agency’s primary statutory tool for data collection, however, has proven ineffectual. Under TSCA section 4(a)(1), EPA can require chemical manufacturers to conduct testing if the EPA

Administrator finds that the chemical or mixture “may present an unreasonable risk of injury to health or the environment.”¹⁹

This creates a classic “Catch-22” situation. The Agency must already have sufficient data to demonstrate that a chemical poses an unreasonable risk of injury to human health or the environment before it can start a data collection rulemaking. Based on the circular logic of this provision, EPA must already have the data needed to evaluate a chemical’s risk in order to compel companies to submit the missing data.²⁰

Another crippling gap in EPA’s ability to evaluate the human health risks posed by existing chemicals is TSCA’s failure to require companies to develop and submit essential information on chemical uses and potential human exposure. Risk is often described as a function of hazard plus exposure. The absence of a requirement in TSCA that manufacturers disclose basic information on chemical uses and potential exposure pathways makes it impossible for the Agency to develop an effective, risk-based program.

To partially address this concern, EPA issued a TSCA Inventory Update rule in 2003, requiring among other things, that chemical companies provide readily obtainable exposure-related use and processing information at sites with production volumes at 300,000 pounds or above. While a good first step, the limited information required under this rule is woefully insufficient to allow EPA to properly assess actual, real-world human exposure. Without more comprehensive exposure information, EPA is left without a meaningful way to calculate risk.

As a result, EPA officials acknowledge that TSCA’s authorities are not an effective means of testing large numbers of chemicals. In 30 years, EPA has issued rules requiring testing for only 185 of the approximately 82,000 chemicals currently on the TSCA Inventory.²¹ As GAO concluded, “EPA has made little progress in reviewing existing chemicals since EPA began reviewing chemicals under TSCA in 1979.”²²

EPA LACKS SUFFICIENT INFORMATION TO ADEQUATELY EVALUATE NEW CHEMICALS

Without question, TSCA’s new chemicals review program is much superior to that for existing chemicals. Nevertheless, EPA remains hamstrung by TSCA’s limitations that prevent the Agency from obtaining the toxicity and exposure information necessary to protect public health. As a result, GAO found that “EPA lacks sufficient data to ensure that potential health and environmental risks of new chemicals are identified.”²³

Under TSCA section 5, chemical companies are required to submit a pre-manufacture notice to EPA of their intention to produce a new chemical. But companies are not required to submit test data regarding the chemical’s toxicity and, not surprisingly,

most companies do not voluntarily provide such data. GAO found that only about fifteen percent of pre-manufacture notices included health or safety test data.²⁴

Faced with the lack of actual data, EPA scientists have little choice but to evaluate a chemical’s toxicity through reliance on modeling techniques, such as structure activity relationship analysis. Using this approach, a new chemical is compared to chemicals with similar molecular structures with known health and safety effects. However, these models have never been validated for regulatory purposes. In fact, GAO highlighted a joint EPA and European Union study in 1993 showing that the accuracy of EPA’s predictions varied depending upon the effect or property being compared.²⁵ A 2001 study conducted by PPG Industries found a 25 percent error rate when comparing the model’s results to actual test data for certain environmental end points.²⁶

The uncertainty surrounding the toxicity and health effects of new chemicals is compounded by the inadequate data available on potential exposure. Under TSCA section 5, companies are required to include basic exposure data as part of the pre-manufacture notice, including information on categories of uses, anticipated production volume, and potential exposure levels and releases. While valuable, this data quickly becomes obsolete as production and market conditions change.

TSCA, unfortunately, does not require companies to update their pre-manufacture notices. As a result, EPA must rely on exposure data that often is outdated soon after production commences.

Notwithstanding these limitations, EPA’s new chemical review program plays an important role in screening out industrial chemicals that may pose a threat to human health. Over the

30-year program, EPA’s reviews have resulted in some form of Agency action to address potential risks to human health for over ten percent of new chemicals submitted for review.²⁷ Nevertheless, more complete and up-to-date toxicity and exposure data about new chemicals is needed to enhance EPA’s ability to respond to the challenges uncovered by modern medical science.

TSCA’S STANDARD FOR RESTRICTING CHEMICALS HAS PROVEN UNWORKABLE

While most chemicals do not pose potential human health risks, public health agencies must be empowered to take action when appropriate. TSCA practitioners have learned, however, that the statute’s standard is simply impracticable. EPA officials acknowledge that “even when EPA has toxicity and exposure information on existing chemicals, ... [the Agency] has difficulty demonstrating that harmful chemicals pose an unreasonable risk and that they should be banned or have limits put on their production or use.”²⁸

Again, the data speaks for itself. Over the course of 30

[U]ncertainty surrounding the toxicity and health effects of new chemicals is compounded by ... inadequate data.

years, EPA has issued regulations to ban or limit the production or restrict the use of only five chemicals. The Agency has not even initiated such a rulemaking since 1989.

The landmark case illustrating the practical difficulties of implementing TSCA's safety standard concerned asbestos. After scrutinizing the issue for a decade and evaluating over one hundred studies, EPA determined that asbestos was a potential carcinogen at all levels of exposure and posed an unreasonable risk to health and the environment.²⁹ A federal court invalidated EPA's asbestos ban in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). The court found that EPA "basically ignored the cost side of the TSCA equation"³⁰ and failed to adequately consider less burdensome alternatives.³¹

The burden of proof imposed on EPA under TSCA section 6 is overwhelming and unrealistic. To limit use or ban production of a chemical, the Agency must meet two tests. First, EPA must have substantial evidence to prove that the chemical presents "an unreasonable risk of injury to health or the environment." This requires EPA to make an array of technically arduous findings, including an evaluation of (1) the effects of the chemical on human health or the environment; (2) the extent of potential exposure; (3) the chemical's benefits; (4) the availability of substitutes for each known use; and (5) the reasonably ascertainable economic consequences of the rule.

If EPA is able to clear these hurdles, the Agency must then determine that its proposed course of action is "the least burdensome alternative." In other words, EPA must establish that restrictions such as warning labels or use limitations would not be sufficient to address the risks before imposing a more restrictive limitation.

The asbestos decision has cast a long shadow, with many TSCA practitioners believing that EPA could never meet the statutory standard as interpreted by the court. EPA apparently agrees since the Agency has not started a single rulemaking to limit production or ban the use of a chemical since this court decision over fifteen years ago.

EPA'S VOLUNTARY HIGH PRODUCTION VOLUME CHALLENGE IS INADEQUATE TO PROTECT HUMAN HEALTH

Tacitly recognizing TSCA's ineffectiveness, many chemical manufacturers have worked with the Agency to develop the High Production Volume ("HPV") chemical challenge, essentially to fill the data gaps left by TSCA's unworkable regulatory framework. Despite considerable progress, this voluntary initiative was not intended and cannot substitute for an effective risk based chemical management system.

The HPV Challenge program was prompted by a 1997 report by Environment Defense entitled "Toxic Ignorance," finding that EPA lacked basic toxicity information about the great majority of the most heavily used industrial chemicals.³² EPA subsequently confirmed that 93 percent of chemicals produced in volumes exceeding one million pounds annually lacked complete toxicity screening data.³³ Forty-three percent of these HPV chemicals had no health or safety data available.

Many chemical manufacturers stepped up to the challenge in 1998 and pledged to develop basic screening level information for roughly 2,200 of the 2,800 HPV chemicals.³⁴ Health and safety data is beginning to pour in for EPA and public review. In addition, the industry announced plans in 2005 to expand the program to include additional chemicals that have reached HPV status since the program was initially launched.

While the success of this voluntary program is considerable, the program's limitations should not be ignored. First, hundreds of HPV chemicals lack industry sponsors, which means no one has voluntarily agreed to provide the screening level test data that EPA needs.³⁵ It is unclear whether EPA has the political will or statutory authority to require the generation of this data for these so-called "orphan chemicals."

Second, EPA pledged last year to evaluate this initial screening data and identify approximately five to ten percent of the HPV chemicals that merit additional scrutiny.³⁶ President Bush's budget for next fiscal year, however, proposes a \$2.2 million dollar cut for EPA's HPV program.³⁷ Without adequate resources, the data on these chemicals – produced annually at over a million pounds – will sit at EPA collecting dust.

Finally, even if EPA can overcome the obstacles involving orphan chemicals and the annual congressional funding battle for this voluntary initiative, the ultimate question remains – can the Agency act to address the risks posed by a dangerous chemical? As discussed earlier, the legal hurdles imposed by TSCA – as interpreted by the courts – seriously cripple the Agency's ability to take action. A voluntary program does not change EPA's statutory limitations. While the HPV challenge is a laudable effort, it is insufficient to fill the gaps created by TSCA.

In sum, recent scientific advances in biomonitoring have revealed that all of us – even newborns – have industrial chemicals in our bodies. Adequate data does not exist to determine whether such exposure causes cancer, neurodevelopmental disorders, or other ailments. As such, renewed concern about the public health impacts of chemical exposure is prompting the need to modernize TSCA.

THE BUSINESS CASE FOR TSCA REFORM: THE NEED FOR GLOBAL HARMONIZATION

TSCA MODERNIZATION NEEDED TO PREVENT PLACING U.S.-BASED GLOBAL COMPANIES AT A COMPETITIVE DISADVANTAGE

A comprehensive new chemicals law in Europe known as REACH (for the Registration, Evaluation and Authorization of Chemicals) is expected to be enacted later this year. REACH will have a significant impact on U.S. businesses as the chemical trade across the Atlantic is estimated at \$600 billion every year, and U.S. companies reportedly have \$2.5 trillion invested in Europe.³⁸ As a result, many predict that REACH will alter the chemical industry worldwide.

In short, REACH will compel U.S. companies that do business in the European Union to develop and make public basic

health and safety data on the chemicals used in production. The increased scrutiny imposed on chemicals by REACH may put global chemical companies at a competitive disadvantage compared to their domestic U.S. competitors and creates new pressure for global harmonization.

REACH is intended to reverse the existing burden of proof by requiring manufacturers or importers of chemicals in Europe to make publicly available basic screening level toxicity and exposure information.³⁹ It is based on the principle of “no data, no market.” Each chemical manufactured or imported in Europe over a minimum threshold will need to register by, among other things, submitting a human health and environmental safety assessment. Chemicals will be prioritized for evaluation and authorization based on production volume and risk (*e.g.* priority is given to chemicals known to have persistent and bio-accumulative toxic properties or have endocrine disrupting properties). Chemicals of concern will require authorization to continue in use in the EU if the risk to human health or the environment is “adequately controlled” or if the “socio-economic benefits outweigh the risk to human health or the environment . . . and if there are no suitable alternatives.”⁴⁰ The scale of potential health benefits is enormous, with an EU Commission study illustrating that the total health benefits of REACH could be in the order of magnitude of 50 billion euros over the next 30 years.⁴¹

In the United States, REACH may have the perverse impact of penalizing companies that develop health data to demonstrate the safety of their products. Because REACH will apply to U.S. companies that manufacture or export into the European Union, those companies will need to develop – or join consortia to develop – the health and safety data needed for EU authorization. In comparison, a U.S. company that domestically manufactures an alternative chemical will not be required by TSCA to conduct similar tests and thus will avoid a potentially significant expense.

The result will be an unfair playing field. One can readily foresee the day when a company that has conducted the studies necessary to receive EU authorization seeks to level the playing field by compelling a competitor’s products to undergo similar reviews.⁴² Put differently, once a number of leading U.S. companies have brought their operations into compliance with REACH, it is hard to see why they would want their U.S. competitors to continue operating without conducting a similar safety review.

At the very least, REACH will transform the U.S. political dynamic on chemical policy. Once U.S. chemical companies exporting to Europe have made basic health and safety screening data on their products publicly available, the industry’s traditional reluctance towards similar transparency in the United States will likely change. Inevitably, therefore, REACH will bolster TSCA modernization efforts.

NEW AND EMERGING STATE LAWS ARE CREATING A PATCHWORK OF CONFLICTING CHEMICAL REGULATIONS

Recent scientific developments, along with the lack of federal leadership on chemical issues, have led to increased activity by the states. In recent years, the number of individual states

enacting laws banning or restricting the use of certain chemicals has escalated sharply. The emerging patchwork of potentially inconsistent state laws creates a very difficult and unpredictable business climate. Modernization of TSCA would help prevent the confusion and needless duplication associated with 50 different state chemical policies.

State regulation of brominated flame-retardants illustrates this point. These chemicals, which have been detected in everything from human breast milk to house dust, are linked in animal studies to thyroid, liver, and neurological developmental disorders. Seven states have enacted bans on the manufacturing, processing, or distribution of products containing certain brominated flame-retardants and legislation is pending in at least three other states.⁴³ Most of these laws limit the use of two specific flame-retardants (pentaBDE and octaBDE), but a pending bill in Washington State would also cover yet a third compound (decaBDE).⁴⁴ Similarly, most of these laws apply to concentrations over 0.1 percent, but Maine’s prohibition applies only to concentrations over one percent.

A similar patchwork of state laws is emerging with respect to mercury. Some states have banned mercury thermometers and novelty items containing mercury (Rhode Island, New Hampshire, Connecticut, Oregon, Michigan, Maine), others regulate auto switches (Oregon, Maine), and some focus on the use of products containing mercury in schools (Maine) or hospitals (Michigan). California has banned mercury from landfills and restricted the mercury content of vaccines to pregnant women and babies.

Trying to navigate the maze of differing state laws consumes significant corporate resources. Unfortunately, business will continue to shoulder the financial and human resource burden until the federal government reasserts leadership on chemical policy. Until TSCA is modernized, a growing number of chemicals are likely to be subject to conflicting State regulation.

BUSINESSES ARE INCREASINGLY REALIZING THAT THERE ARE PROFITS IN LESS TOXIC PRODUCTS

Even prior to final enactment of REACH or the adoption of additional state-specific chemical restrictions, a growing number of businesses are discovering that the production and use of less toxic products is profitable. Testing a chemical to obtain more complete health and safety information prior to distribution in commerce helps validate a company’s product, enhances a company’s reputation, and minimizes potential tort liability. In addition, products that can be advertised as environmentally safer alternatives increasingly have a marketing advantage over competitor’s products.

One reason for the growing profitability of less toxic chemicals is the increasing demand by downstream business customers. For example, the major computer manufacturers, including Intel and Dell, are demanding that their suppliers avoid polybrominated flame-retardants.⁴⁵ Similarly, the multi-billion dollar health care group Consorta established an environmentally preferable purchasing program and discovered that non-polyvinyl chloride (“PVC”) based hospital feeding tubes actually cost less than PVC based ones.⁴⁶

Some companies are going even further. SC Johnson and

Son, Inc., the manufacturers of products such as Windex, Glade, and Pledge, established a “Greenlist process,” whereby the company evaluates each and every ingredient according to their human health and environmental impacts.⁴⁷ In the process, SC Johnson has removed over ten million pounds of volatile organic compounds, reduced its overall environmental footprint, and made the company among the most recognized and awarded environmental leaders in the United States.⁴⁸

The costs of ignoring a product’s potential impacts on human health are staggering. A 2002 RAND study estimated that the asbestos industry’s liability cost alone could reach \$210 billion, with more than 600,000 individual claims for compensation.⁴⁹ Lest one think that WR Grace’s asbestos liability is a unique case, consider the experience of RJ Reynolds with tobacco or Merck after VIOXX.

Fortunately, the chemical industry seems to be learning this lesson. In May 2000 for example, 3M phased out its use of PFOS from Scotchgard and other products⁵⁰ as a result of widespread human exposure and concerns that the chemical was persistent, bioaccumulative, and toxic. Wall Street rewarded 3M for its responsible corporate leadership and the company’s stock price rose.⁵¹ Based on similar concerns, DuPont and eight other manufacturers of PFOA recently volunteered to eliminate all sources of exposure by 2015.⁵²

In short, the traditional profit motive and liability concerns are accelerating the shift to less toxic substances. More and more businesses are adopting environmentally preferable purchasing programs and chemical manufacturers are already working to satisfy this growing demand. As a result, this trend is likely to reduce the chemical industry’s reluctance to modernize TSCA and builds support for chemical reform from the industry’s influential downstream business customers.

THE NEED TO PROMOTE PUBLIC AND INVESTOR CONFIDENCE IN NANOTECHNOLOGY CREATES A NEW DRIVER FOR MODERNIZING TSCA

In 2001, *Science* magazine described nanotechnology as the “breakthrough of the year.”⁵³ Nanotechnology – the term used to describe the intentional engineering of materials at the atomic or molecular level with novel properties – has the potential to revolutionize fields as diverse as healthcare, energy, and manufacturing. Nanotechnology has already been incorporated into experimental treatments for cancerous tumors, self-cleaning windows, wrinkle-free fabrics, and pollution-reducing fuel additives. Over 200 nanotechnology based consumer products are already on the market,⁵⁴ and over 600 raw materials, intermediate components, and industrial equipment reportedly employ nanotechnology.⁵⁵ The National Science Foundation predicts that nano-related goods and services could be a \$1 trillion market by 2015.⁵⁶

One of the greatest challenges for this nascent industry is public acceptance. The fear of nanotechnology run amok, as exemplified in Michael Crichton’s best selling thriller, *Prey*, has the potential to permanently shape the public’s perception of nanotechnology and stifle it in its infancy. Europe’s experience with genetically modified foods provides a cautionary tale about the need for public acceptance of new scientific approaches. As

J. Clarence Davies, a senior advisor to the Project on Emerging Nanotechnologies, warns, “past experience, as well as surveys and focus groups, show that if the public does not think that the government is exercising adequate regulatory oversight of a potentially hazardous new technology, then it will mistrust and likely reject that technology.”⁵⁷

Many nanotech applications are subject to TSCA, which broadly covers “any organic or inorganic substance of a particular molecular identity.”⁵⁸ Unfortunately, the gaps in TSCA become gorges when considered in the context of nanotechnology.

Some nanomaterials likely meet this definition and thereby will evade government review (unless EPA chooses to issue significant new use rules). The criteria for being considered an existing chemical is having “the same molecular identity” as a chemical already on EPA’s Inventory. Some nanomaterials likely meet this definition and thereby will evade government review. Nevertheless, nano-sized versions of existing chemicals may pose unique human health risks due to their minute size and increased surface area.

For those nanotech applications that clearly are subject to TSCA’s new chemical program, the statute still is not an effective means to foster the safe development of nanotechnology. Rather, TSCA discourages innovation of new nanomaterial by failing to recognize the distinction between pre-manufacture notification and pre-market notification. While some review may be appropriate prior to manufacture for worker protection, an in-depth EPA evaluation may be unnecessary for nanotechnologies that are years away from commercialization.

Furthermore, EPA lacks authority under TSCA to require that a company provide health or safety data unless it has enough information to show that a substance “may present an unreasonable risk.” As a practical matter, EPA traditionally turns to its structure activity relationship models as a screen for potential risk. Such models do not yet exist for nanotechnology, so EPA is left without meaningful tools to evaluate nanomaterials. Perhaps equally important, EPA’s review is entirely dependent on the manufacturer’s intended use of the material and exposure estimates, which are likely to change as new applications are rapidly discovered without any notice to EPA (unless the Agency by rule expressly requires such notice).

Industry groups are beginning to recognize the need for a more effective legal framework for nanotechnology. For example, Chad Holliday, the CEO of DuPont, wrote in a Wall Street Journal op-ed with Fred Krupp of Environmental Defense that:

[B]oth public and business interests will inevitably compel regulatory protection to ensure product safety and to create a level playing field for business. Current regulations, designed for a world before nanotechnology, should be reassessed and changed as needed to account for the novel properties of nanomaterials. Business and government may need new approaches to make sure workers, consumers, the public and the environment are adequately protected.⁵⁹

In short, the exploding field of nanotechnology is creating yet another new challenge to the 30-year old U.S. toxic sub-

stances law. Businesses (and their investors) are seeking to reassure an uncertain public that nanotechnologies are safe and are increasingly adding their voices to the growing chorus supporting modernization of TSCA's antiquated framework.

CONCLUSION

Scientific advances in biomonitoring have revealed that industrial chemicals are in all Americans, even in newborn babies. While medical researchers continue to debate whether such chemicals are the cause of the growing occurrence of cancer, neurodevelopmental disorders, or other diseases, it is undisputed that insufficient information is available about the potential human health impacts of many of these chemicals. Unfortunately, EPA lacks adequate authority under TSCA to require that manufacturers provide the data needed to review existing chemicals or sufficient information to evaluate new chemicals prior to manufacture.

Businesses are quietly beginning to recognize the need to modernize TSCA with an approach that better responds to the needs of the global marketplace. The European Union and individual States are adopting different approaches to chemical regulations. This emerging patchwork of duplicative and sometimes inconsistent approaches, together with the growing business demand for less toxic products and the emerging need to safeguard and establish the credibility of nanotechnology, is creating new pressures for TSCA reform from the business community.

As a result, the discussion in U.S. chemicals policy is shift-

ing from whether to reform TSCA to how best update the 30-year old statute. The first comprehensive overhaul legislation, the Kids Safe Chemicals bill, was introduced by Senators Lautenberg (D-NJ) and Jeffords (I-VT) on June 25, 2005, to jump start this debate.⁶⁰ The bill would reverse the burden of proof by requiring manufacturers to provide basic health and safety information prior to distributing a chemical in consumer products. It would also create a risk-based prioritization for chemical review and a bright line safety standard that accounts for children's increased sensitivity to toxic exposures.

While the bill is not expected to be enacted this year, the increased congressional interest reflects growing public health concerns along with business pressure for global harmonization, the increased profitability of producing less toxic products and the desire to promote the safe use of nanotechnology. The convergence of these trends makes modernization of the U.S. toxic substances law inevitable during the next several years.



ENDNOTES: U.S. Toxic Substances Law

¹ RACHEL CARSON, *SILENT SPRING* 17 (1962).

² U.S. Government Accountability Office ("GAO"), *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, June 2005, GAO-05-458, at 18, available at <http://www.mindfully.org/Pesticide/2005/EPA-Chemical-GAO-05-45813jul2005.htm> (last visited Mar. 18, 2006).

³ Toxic Substances Control Act ("TSCA"), Report by the House of Representatives Committee on Interstate and Foreign Commerce, Report No. 94-1341, July 14, 1976, 94th Cong., 2d Sess. at 1. See also *Statement on Signing the Toxic Substances Control Act, October, 12 1976*, Public Papers of the Presidents, Gerald R. Ford, at 881 ("Only a few chemicals have been tested for their long-term effects on human health or the environment. Through the testing and reporting requirements of the law, our understanding of these chemicals should be greatly enhanced.")

⁴ Michael A. Kamrin, *Biomonitoring Basics*, Environmental Health Research Foundation, June 2004, at 1, available at http://biomonitoringinfo.org/images/What_is_Biomonitoring.pdf (last visited Mar. 18, 2006).

⁵ U.S. Dept. of Health and Human Services and Center for Disease Control and Prevention ("CDC"), *Third National Report on Human Exposure to Environmental Chemicals: 2005 Executive Summary*, at i, available at http://www.calasthma.org/uploads/resources/thirdreport_summary.pdf (last visited Mar. 18, 2006). [hereinafter *Executive Summary*].

⁶ CDC, *Third National Report on Human Exposure to Environmental Chemicals: 2005*, <http://www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf> (last visited Apr. 20, 2006) [hereinafter *Third Report*].

⁷ *Executive Summary*, *supra*, note 5 at 2.

⁸ According to the CDC, the human health effects observed after exposure to PCBs include liver disorders, elevated blood lipids and gastrointestinal cancers. *Third Report*, *supra*, note 6 at 202.

⁹ J. Houlihan, et al., *Body Burden - The Pollution in Newborns: A benchmark investigation of industrial chemicals, pollutants and pesticides in human umbilical cord blood*, Environmental Working Group, July 14, 2005, available at <http://www.ewg.org/reports/bodyburden2/execsumm.php> (last visited Mar. 17, 2006).

¹⁰ *Teflon Chemical Found in Infants; Hopkins Researchers are Studying Toxin's Effects on Newborns*, BALTIMORE SUN, Feb. 6, 2006 at A1.

¹¹ U.S. Environmental Protection Agency ("EPA"), Office of Pollution Prevention and Toxics, Risk Assessment Division, *Draft Risk Assessment of the Potential Human Health Effects Associated with Exposure to Perfluorooctanoic Acid and its Salts*, Jan. 4, 2005.

¹² Press Release, EPA, 100% Participation and Commitment in EPA's PFOA Stewardship Program (Mar. 2, 2006).

¹³ Research on the human health effects of industrial chemicals has prompted the development of epigenetics, a new branch of science focused on the study of chemical exposures in the womb. Such exposure has been found to alter gene functioning. See e.g., B. Weinhold, *Epigenetics: The Science of Change*, ENVTL. HEALTH PERSPECTIVES, Vol. 114, No. 3, Mar. 2006, available at <http://www.ehponline.org/members/2006/114-3/ehp0114-a00160.pdf> (last visited Mar. 18, 2006); T. Fujimoto, K. Kubo, S. Aou, *Prenatal exposure to bisphenol A impairs sexual differentiation of exploratory behavior and increases depression-like behavior in rats*, BRAIN RES., Jan. 12, 2006, 1068(1):49-55.

¹⁴ P. Landrigan, C. Schechter, et al., *Environmental Pollutants and Disease in American Children: Estimates of Morbidity, Mortality, and Costs for Lead Poisoning, Asthma, Cancer, and Developmental Disability*, ENVTL. HEALTH PERSPECTIVES, Vol. 110, No. 7, July 2002, at 721, available at <http://www.ehponline.org/members/2002/110p721-728landrigan/EHP110p721PDF.PDF> (last visited Mar. 18, 2006).

¹⁵ GAO, *supra* note 2, at 18.

- ¹⁶ GAO, *supra* note 2, at 18.
- ¹⁷ GAO, *supra* note 2, at 18
- ¹⁸ TSCA § 2(b)(1).
- ¹⁹ EPA may also require testing if “there may be substantial potential for human exposure to the chemical.” Without information on how the chemical is used, it is difficult for EPA to make this finding. Biomonitoring could show actual exposure, but it is impractical and cost prohibitive as a technique to evaluate tens of thousands of chemicals at this time.
- ²⁰ In addition, EPA faces a number of other hurdles in using section 4. For example, a finding of “unreasonable risk” or “substantial potential for human exposure” falsely assumes that EPA has a robust collection of exposure information, including how much of a chemical may be released and its long term fate and transport. According to EPA officials, the process of issuing a proposed rule, considering all comments, and promulgating a final rule often takes two to ten years and significant Agency resources. GAO, *supra* note2, at 26.
- ²¹ GAO, *supra* note 2, at 26.
- ²² GAO, *supra* note 2, at 19.
- ²³ GAO, *supra* note 2, at 10.
- ²⁴ GAO, *supra* note 2, at 11.
- ²⁵ GAO, *supra* note 2, at 11.
- ²⁶ GAO, *supra* note 2, at 11.
- ²⁷ GAO, *supra* note 2, at 16.
- ²⁸ GAO, *supra* note 2, at 27.
- ²⁹ 54 Fed. Reg. 29,459 (July 12, 1989).
- ³⁰ Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1223 (5th Cir. 1991).
- ³¹ Corrosion Proof Fittings, 947 F.2d at 1217.
- ³² ENVTL. DEFENSE FUND, TOXIC IGNORANCE: THE CONTINUED ABSENCE OF BASIC HEALTH TESTING FOR TOP-SELLING CHEMICALS IN THE UNITED STATES (1997), available at http://www.environmentaldefense.org/documents/243_toxicignorance.pdf (last visited Mar. 18, 2006).
- ³³ EPA, Office of Pollution Prevention and Toxics, *Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals*, Apr. 1998, available at www.epa.gov/opptintr/chemtest/hazchem.htm (last visited Mar. 18, 2006)
- ³⁴ EPA, Office of Pollution Prevention and Toxics, *Status and Future Directions of the High Production Volume Challenge Program*, 2004, at 1.
- ³⁵ GAO, *supra* note 2, at 25.
- ³⁶ President’s Proposed Budget of the United States for Fiscal Year 2007, EPA Budget Justification, at EPM-220.
- ³⁷ Proposed Budget, *id.*
- ³⁸ Paul D. Thacker, *US Companies Get Nervous About EU’s REACH*, ENVTL. SCI. & TECH., Jan. 5, 2005, available at http://pubs.acs.org/subscribe/journals/esthag-w/2005/jan/policy/pt_nervous.html (last visited Mar. 18, 2006).
- ³⁹ At the time of this article, the EU Parliament and the EU Council of Ministers have each enacted slightly differing versions of the law. They are expected to reconcile these competing drafts into a final law before the end of 2006.
- ⁴⁰ REACH, Article 57, Authorization.
- ⁴¹ Commission of the European Communities, Extended Impact Assessment, SEC(2003) 1171, Oct. 29, 2003, at 31.
- ⁴² Some have suggested that U.S. companies will be able to “mine” their own files for pre-existing health and safety data that they can sell to European producers.
- ⁴³ States with enacted legislation include California, Hawaii, Illinois, Maryland, Michigan, New York, and Maine. States with pending legislation include Connecticut (Senate bill 785), Minnesota (HF 1299), and Oregon (Senate bill 962).
- ⁴⁴ Warren Cornwall, *Lawmakers consider banning potentially toxic flame retardant*, SEATTLE TIMES, Mar. 3, 2006, at B3, available at http://seattletimes.nwsources.com/html/localnews/2002840862_pbde03m.html (last visited Mar. 18, 2006).
- ⁴⁵ *Intel moves towards greener chips*, BBC NEWS, April 8, 2004, available at <http://news.bbc.co.uk/go/pr/fr/-/2/hi/technology/3610499.stm> (last visited Mar. 18, 2006); see also, Michael Singer, *Dell does new eco-friendly desktops*, CNET, June 2, 2005, http://news.com.com/Dell+does+new+eco-friendly+desktops/2100-1042_3-5729588.html (last visited Mar. 18, 2006).
- ⁴⁶ R. Liroff, *Cleaning Up: Toxic Chemicals in Consumer Products – A Strategic Challenge to Business*, Businesses for Social Responsibility’s LEADING PERSPECTIVES, Fall 2005, at 12.
- ⁴⁷ Press Release, SC Johnson Exceeds Goal to Use More Earth-Responsible Raw Materials, SJ Johnson News Web Page, Mar. 8, 2006, available at http://www.scjohnson.com/family/fam_pre_pre_news.asp?art_id=136 (last visited Mar. 18, 2006).
- ⁴⁸ Press Release, *id.*
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- ⁵⁰ 3M website, What You Should Know About 3M’s Next Generation Scotchgard Protector Products, http://www.3m.com/us/home_leisure/scotchgard/environmental.jhtml (last visited Mar. 18, 2006).
- ⁵¹ *3M and Scotchgard: Heroes of Chemistry or 20 Year Coverup?*, Chemical Industry Archives – a Project of the Environmental Working Group, available at <http://www.chemicalindustryarchives.org/dirtysecrets/scotchgard/1.asp> (last visited Mar. 18, 2006).
- ⁵² Press Release, 100% Participation and Commitment in EPA’s PFOA Stewardship Program, U.S. EPA, Press Release, Mar. 2, 2006 (on file with the author).
- ⁵³ R. Service, *Molecules Get Wired*, SCIENCE, Dec. 21, 2001, at 2443, <http://www.sciencemag.org/cgi/content/summary/294/5551/2442> (subscription required).
- ⁵⁴ “A Nanotechnology Consumer Products Inventory,” Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Mar. 2006, available at <http://www.nanotechproject.org> (last visited Mar. 18, 2006).
- ⁵⁵ EPA, *Draft Nanotechnology White Paper*, Science Policy Council, External Review Draft, Dec. 2, 2005, at 3.
- ⁵⁶ J. Clarence Davies, *Managing the Effects of Nanotechnology*, Woodrow Wilson International Center for Scholars, Jan. 2006, at 8, available at <http://www.innovationsgesellschaft.ch/images/publikationen/manangingef-fects.pdf> (last visited Mar. 18, 2006).
- ⁵⁷ Statement of J. Clarence Davies, US Senate Commerce, Science and Transportation Committee hearing on nanotechnology, Feb. 15, 2006.
- ⁵⁸ TSCA section 3(2)(A).
- ⁵⁹ F. Krupp and C. Holliday, *Let’s Get Nanotech Right*, WALL ST. J., June 14, 2005, at B2.
- ⁶⁰ The Kids Safe Chemicals bill was introduced on July 13, 2005, by Senators Lautenberg and Jeffords and co-sponsored by Senators Kerry, Corzine, Clinton, Boxer, & Kennedy. A companion bill was subsequently introduced in