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In This Issue: Sound Chemicals Management

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Editors' Note

"As crude a weapon as the cave man's club, the chemical barrage has been hurled against the fabric of life."

– Rachel Carson, *Silent Spring* (1962)

Virtually every manmade product involves the use of manufactured chemicals. The effects of the vast majority of these chemicals on human health are unknown, but numerous studies have begun to link many to cancer, reproductive ailments, developmental impairment, and neurobehavioral disorders. While modern society could not maintain its current standard of living without chemicals, global chemicals production has the capability to impact environmental sustainability and human health in both developed and developing countries. Additionally, there is no way to shield oneself from the hazards of these substances; virtually all children are born into this world having been prenatally exposed to toxic chemicals.

While the chemicals industry is at the center of economic growth worldwide, accounting for seven percent of global income and nine percent of international trade,[1] chemicals production has also caused significant harm across the world. Many chemicals possess transboundary properties, allowing use by one country to poison unsuspecting communities across borders and even oceans. For instance, the breast milk of females in Greenland's Inuit population is so contaminated that it could be classified as hazardous waste.[2] In many cases, no data exist on the dangers of specific chemicals or the dangerous cocktails that they can produce.

Countries have responded to these concerns through domestic legislation, as well as numerous bilateral and multinational environmental agreements. Unfortunately, many of these efforts have failed to manage chemical production in a way that minimizes public health risks. *Sustainable Development Law & Policy* was inspired by the adoption of the Strategic Approach to International Chemicals Management ("SAICM") in February 2006 to explore what sound chemicals management entails. Although SAICM is a significant step towards sound chemicals management, more needs to be done. In particular, the public needs to be educated about the risks that it faces; we hope this issue will contribute to the effort.

Kelly Rain

Kirk Herbertson

Editors-in-Chief

Features:

[1] Organisation for Economic Co-Operation and Development ("OECD"), *Environmental Outlook for the Chemicals Industry*, at 10 (2001) *available at* http://www.oecd.org/dataoecd/7/45/2375538.pdf (last visited Apr. 16, 2006).

[2] Marla Cone, *Pollutants drift north, making Inuits' traditional diet toxic*, Boston Globe, Jan. 18, 2004, *available at* http://www.boston.com/news/world/articles/2004/01/18/pollutants_drift_north_making_inuits_traditional_diet_toxic (last visited Apr. 16, 2006).

Sound Chemicals Management:

An Overview of This Issue

*by Lynn Goldman**

The world in which we live has changed tremendously from that of previous generations. Synthetic chemicals are ubiquitous in our environment worldwide, and traces of these compounds are found in all humans and animals. The U.S. Centers for Disease Control and Prevention's National Human Exposure Report has amply demonstrated that such chemicals are often pervasive, appearing in the vast majority of blood and urine samples taken at random from the general population in the United States. Many chemicals are readily passed across the placenta to the fetus or to the infant via breast milk.

Worldwide, around 15,000 new chemicals are introduced every year. In the United States, at least 75,000 industrial chemicals are currently produced or imported.[1] Public concern has risen due to various studies linking hazardous chemicals to increased occurrences of cancer, respiratory diseases, reproductive disease, impairment in the physical and emotion development of children, neurological disease, and more. New substances are continuously introduced into domestic and global markets, and the impacts of many of these substances are unknown. For example, there is a growing number of nanomaterials that are entering the market with little regulation or data; many of these are likely to have hazardous properties.

Children and their health should be the focus of our domestic and worldwide chemicals policies: children are our future and we need to assign a high value to preserving their potential health and productivity. Pound for pound, children eat more food, drink more water, and breathe more air than adults. Thus, they are likely to be more exposed to substances in their environment than are adults.

In the United States, environmental chemicals are regulated in numerous ways. Pollutants, pesticides, consumer products, and industrial chemicals are each under different statutory and regulatory guidance and frameworks. To properly regulate chemicals, the United States needs to strengthen domestic regulations and build up global interrelationships.

Worldwide, around 15,000 new chemicals are introduced every year.

A number of international, global, and regional agreements have been developed to assist with chemicals management. The enormity and complexity of this issue has led many nations to accept the idea that harmonization is necessary to properly manage chemicals. Chemicals do not acknowledge political boundaries; thus, regulation must occur at the global level.

Chemical regulation needs to occur in the context of cooperation on an international scale to protect children's health. In some ways, a high degree of worldwide cooperation on chemical assessment and safety already exists. For example, the Organisation for Economic Co-operation and Development Chemicals Forum has developed an internationally harmonized

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set of guidelines for chemicals testing, an agreement on good laboratory practices, and an agreement on mutual acceptance of data that allows all nations to adopt these agreements.

This issue of *Sustainable Development Law & Policy* examines efforts to promote sound chemicals management at the domestic and global scale. Contributors to this issue discuss the next steps for chemicals regulation within the United States. Articles encourage assessing and tackling the new risk posed by nanotechnology. The establishment and implications of the Strategic Approach to International Chemicals Management is analyzed, and the status of the Basel Convention is explored. Chemical regulation in the European Union is examined, along with a proposal for an independent entity to manage global chemicals agreements and protocols.

As a whole, these articles address the broad range of issues and possible solutions in chemicals management. The concerns, ideas, and possible solutions identified in this issue highlight the obstacles that many individuals in the global community feel are of the utmost importance to protect environmental public health. In the end, it is important to remember that chemicals policies should be action-oriented and employ approaches that are sufficiently protective to provide assurances that we are acting cautiously to protect our children, future generations, and the environment.

[1] U.S. EPA Web site, http://www.epa.gov/region5/defs/html/tsca.htm.

The Uncertain Future of MTBE Production:

Effects of the U.S. Energy Policy Act of 2005

*by Cari Shiffman**

Fuel industry analysts project that the production of methyl tertiary butyl ether ("MTBE"),[1] an oxygenated fuel additive used to help reduce air pollution from automobiles,[2] will decrease in the United States over the next two years, due in part to the government's support of ethanol over MTBE in last year's U.S. Energy Policy Act ("Energy Act") and domestic concerns over groundwater contamination.[3] In recent years, controversy has surrounded MTBE due to assertions that the additive contaminates groundwater when leaked from underground storage tanks.[4] The U.S. Environmental Protection Agency and the World Health Organization labeled it as a possible carcinogen when consumed in high doses.[5] Additionally, 26 states banned MTBE usage because of water contamination concerns.[6]

The future of MTBE production in the United States is even more uncertain due to the exclusion of limited liability protection for MTBE producers in last year's Energy Act.[7] The House of Representatives ("House") proposed to give limited liability protection to MTBE manufacturers in product defect suits filed after September 5, 2003, in exchange for MTBE producers' contributions toward a trust fund for cleaning sites contaminated by MTBE.[8] Domestic cleanup costs range from $2 billion to $25 billion.[9] Following debates between the House and the Senate over limited liability protection for MTBE producers in the Energy Act, Congress redacted the limited liability provision from the Act.[10] Additionally, Congress substituted the Clean Air Act's oxygenated gasoline requirement with a renewable fuels plan that supports the gasoline additive ethanol over MTBE.[11]

Valero, the second largest U.S. producer of MTBE, announced that it will stop MTBE production due to the elimination of limited liability protection in the Energy Act.[12] If other producers follow suit, then the U.S. gas supply may face supply disruptions, resulting in a rise in gas prices.[13] Domestic MTBE production is expected to further decline as ethanol is increasingly substituted for MTBE.[14]

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Endnotes:

[1] *MTBE*, Chemical Wk., Nov. 9, 2005, at 59.

[2] Chris Woodyard, *Refiner's Change Could Raise Gas Prices*, USA Today, Aug. 5, 2005, at B1.

[3] *MTBE*, *supra* note 1.

[4] Darren Goode, *Barton Announces Deal on MTBE Liability, Trust Fund…*, Cong. Daily, July 22, 2005, at 1 [hereinafter *Barton Deal*].

[5] Environmental Protection Agency, Methyl Tertiary Butyl Ether, Drinking Water, http://www.epa.gov/mtbe/water.htm (last visited Mar. 12, 2006). The World Health Organization released a document reporting that MTBE is a potential carcinogen in rats, but cautioned against over applying these results to humans. *See* World Health Organization, Background Document for Development of WHO Guidelines for Drinking-water Quality: Methyl Tertiary-Butyl Ether (MTBE) in Drinking-water (2005), a*vailable at* http://www.who.int/water_sanitation_health/dwq/chemicals/MTBE200605.pdf (last visited Mar. 12, 2006).

[6] *MTBE*, *supra* note 1.

[7] Kara Sissell, *MTBE Liability Relief Dropped from Energy Bill*, Chemical Wk., Aug. 3, 2005, at 11.

[8] Darren Goode, *Energy Bill Flash Points*, 37(30) Nat'l J. 2380, 2381 (2005) [hereinafter *Energy Bill*]; *Barton Deal*, *supra* note 4; Sissell, *supra* note 7.

[9] ENSR International, a group supported by MTBE lobbyists, estimate cleanup costs to be only $2 billion, while the American Water Works Associations estimates cleanup costs to be closer to USD twenty-five billion. *See Energy Bill*, *supra* note 8, at 2381.

[10] Sissell, *supra* note 7.

[11] *MTBE*, *supra* note 1; Peck Hwee Sim, *Valero to Quit MTBE Production*, Chemical Wk., Aug. 10, 2005, at 12.

[12] Sim, *supra* note 11.

[13] Woodyard, *supra* note 2.

[14] *MTBE*, *supra* note 1.

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] Perflurooctanoic 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] Alarmingly, 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]

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

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

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 products[50] 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 shifting 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 Summery, 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 Perfluoroctanic 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.

Endnotes: U.S. Toxic Substances Law *Continued on page 76*

NANOTECHNOLOGIES: THE PROMISE AND THE PERIL

*by Jennifer Sass, Patrice Simms, and Elliott Negin**

INTRODUCTION

Despite the incredible potential of engineered nanomaterials to advance cleaner, safer technology, emerging data continue to indicate serious potential for harm to human health and ecological systems. Nanoscale materials, engineered to be one to one hundred nanometers ("nm"), currently have a number of commercial applications, from high-capacity computer drives to food packaging, shampoos, sunscreens, and cosmetics. The word "nanos," from the Greek word for "dwarf," indicates 10^{-9}, or one-billionth. Nanometer-sized materials are one-billionth of a meter in size; larger than atoms, but much smaller than a cell. As a comparison, there are as many nanometers in an inch as there are inches in four hundred miles (25,344,000). The width of a human hair is 80,000 nm.

Scientists predict that these submicroscopic nanoparticles, or ultra-fine particles, will give rise to new cancer therapies, pollution-neutralizing compounds, more durable consumer products, advanced detectors for such biohazards as anthrax, and higher-efficiency fuel cells, among other things. These predictions are due to the unique properties of nanoscale materials compared with their normal-size counterparts.[1] However, laboratory studies already warn that nanoparticles can cause inflammation, damage brain cells, and cause pre-cancerous lesions. Early research also has found that nanoparticles easily pass through body tissues from one area of the body to another. Responsible regulation and oversight will be needed to prevent harmful exposures.

Beyond some basic experimental data on cells and in animals, there is very little known about the toxicity of nanomaterials.

Beyond some basic experimental data on cells and in animals, there is very little known about the toxicity of nanomaterials. For example, we know nothing about whether nanomaterials in products such as cosmetics and shampoos penetrate the skin, or vaporize or off-gas from consumer products. When considering the potential for harmful effects from nanomaterials, there are two lines of evidence that are helpful: first, what is known from well-conducted scientific tests published in the peer-reviewed journals; and second, what can be extrapolated from the substantial data on the harmful effects of ultrafine particulate air pollution.

SMALL SIZE, BIG RISKS

Carbon-based nanomaterials, such as miniscule carbon cylinders called nanotubes and tiny carbon spheres called buckyballs, have desirable electrical, mechanical, and thermal properties, useful for such applications as developing strong, lightweight building and packing materials, computers, and aerospace engineering. However, the data thus far indicate that exposure to various carbon nanomaterials may be harmful to the brain, lung, cardiovascular, and immune systems. Carbon nanotubes tend to cluster into "ropes," acting more like fibers than particles when inhaled, giving rise to lung inflammation and granulomas (clusters of cells with injury or inflammation) that may form scar tissue (fibrosis). Nanotubes are also insoluble and cannot be broken down by the body's natural processes.

Single-walled carbon nanotubes ("SWCNTs") have been reported by five different research groups to be associated with lung toxicity.[2] Government researchers from the National Institute of Occupational Safety and Health ("NIOSH") reported rapid lung inflammation, rapid progressive fibrosis, and granulomas within seven days after a single dose of SWCNTs into the lungs of mice.[3] Cell damage increased in a dose-dependent manner by one day after exposure. One year earlier, DuPont researchers had reported acute lung toxicity and transient inflammation in rats associated with a single dose of SWCNTs of either 1 or 5 mg/kg administered into the upper lung.[4] That same year, a collaboration between the National Air and Space Administration ("NASA") and the University of Texas reported dose-dependent granulomas and inflammation in mice that were administered a single dose of either 0.1 or 0.5 mg of single-walled carbon nanotubes into the lungs, roughly equivalent to a mouse inhaling nanotubes for about three and a half workdays (low dose) or seventeen workdays (high dose) at the workplace standard for graphite dust. [5]

Despite these data, and the lack of complete safety testing, a major supplier of carbon nanotubes, Carbon Nanotechnologies, Inc., has registered its product under the Toxic Substances Control Act ("TSCA") as a synthetic graphite. Workplace haz-

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ard labels or material safety data sheets reference the workplace permissible exposure limits for graphite (15 mg/m^3 of total dust, and 5 mg/m^3 for the breathable fraction).[6] Scientists have warned that workers breathing nanotube dust at a fraction of the workplace allowable level "would likely develop serious lung lesions."[7]

Nanomaterials can also be composed of metal atoms. Examples include nanogold, nanosilver, silicon nanowires, reactive metal oxides such as nanotitanium dioxide, and quantum dots – a closely packed semiconductor crystal with unique optical and light-emitting properties. Evidence suggests that metal-based nanomaterials can cause damage to humans and the environment. In 2005, researchers from the New Jersey Institute of Technology reported that the root growth of corn, cucumbers, cabbage, carrots, and soybeans was stunted after a 24-hour exposure to high doses (2 mg/mL) of alumina nanoparticles in water.[8] Alumina nanoparticles currently are used in scratch- and abrasion-resistant coatings on commercial products such as safety glasses, car finishes, and flooring. Researchers from the University of California at San Diego reported that cadmium-selenium core semiconductor (quantum) dots used in biological imaging were acutely toxic to liver cells in a Petri dish at doses typically used for imaging.[9] The dots are replacing traditional imaging with fluorescent dyes, due to their enhanced and longer-lasting brightness.

University of Rochester investigators reported in 2000 that nano-teflon fumes (about 16 nm) were much more acutely toxic than Teflon, the popular brand name for polytetrafluoroethylene, when inhaled for only fifteen minutes by rodents, and rapidly passed through epithelial tissues to other parts of the body, inducing severe inflammation, edema, and hemorrhage of lungs within hours after exposure.[10] In 1992, University of Rochester investigators examined the effects of exposure to nano titanium dioxide (TiO_2; 20 nm), a material in sunscreen. The study showed that rodents that inhaled ultra-fine TiO_2 for three months, under conditions simulating occupational exposures (six hours/day, five days/week), had significantly more lung inflammation and scar tissue compared with those that inhaled larger TiO_2 particles (250 nm).[11]

Heeding the Red Flags

Although there is a paucity of toxicity data on nanomaterials *per se*, the hazards of nano-sized (ultra-fine) air pollution are well-documented. Particulate matter less than 10 micrometers (PM_{10}; 10,000 nm) is linked to increased disease and death from lung cancer and cardiopulmonary disease.[12] These diseases are more closely linked with exposure to smaller particles than to larger-sized ones.[13] The risks are especially high among sensitive individuals, such as those with pre-existing conditions of the heart and lungs, including asthma and chronic obstructive pulmonary disease.[14]

Some of the acute toxicity of ultra-fine particles is likely due to their larger surface-area–to-mass ratio, ability to penetrate biological tissues, and their increased biopersistance compared with larger particles of the same composition.[15] Given these characteristics and the results of targeted studies such as those mentioned above, the potential for harmful effects from widespread use of nanomaterials must be taken seriously.

Misallocation of Federal Spending

Despite these early warnings, government response thus far to the potential risks has been woefully inadequate. In spring 2005, the President's Council of Advisors on Science and Technology issued its five year review of the interagency National Nanotechnology Initiative, established in 1991 to direct federal research activities on nanotechnology.[16] Although the text of the report is 46 pages long, the section addressing "Environmental, Health and Safety" does not appear until page 35 and is less than one page long. According to the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars, only four percent of the fiscal year ("FY") 2006 federal nanotechnology funding was earmarked for research on health and environmental effects, and another four percent on social implications and education.[17] Meanwhile, federal funding for nanotechnology research and development has soared from $464 million in 2001 to $1.2 billion in FY 2007.[18] Of this investment, the National Science Foundation will get $373 million. More than $600 million is earmarked for the U.S. Departments of Defense ($345 million) and Energy ($258 million). By comparison, only $142 million is slated for the human health and environment protection branches of the federal government, the U.S. Environmental Protection Agency ("EPA") ($9 million), and the U.S. Department of Health and Human Services ($133 million), which includes the National Institutes of Health. With this disparity in funding priorities, it is hard to imagine how safety testing could ever catch up with research and development.

Some federal agencies are addressing the potential downside of nanotechnology. The Department of Health and Human Services' National Toxicology Program is researching potential health risks. In addition, NIOSH is developing a "best practices" document on handling nanoparticles in the workplace to reduce risks. In FY 2005 the EPA awarded $4 million for research on nanotechnology impacts on human health and the environment. However, much more needs to be done to better understand the potential risks of nanotechnologies.

Response by Industry and its Financiers

The private sector response to potential health and environment threats has been mixed. Some corporations seem concerned only about public perception and hope to disavow actual risk by avoiding safety testing, keeping safety data confidential, and providing empty reassurances to the public. Fearing actual or perceived risks, insurance companies such as Swiss Re,[19] and financial investment advisers such as Innovest[20] and Allianz,[21] have called for safety testing and regulatory oversight of nanomaterials. Other large corporations and many small start-up companies also would welcome safety testing and regulations if they were not overly costly or burdensome, because they would contribute to market stability by reducing future risks of liabilities and consumer rejection.

Regulatory Blind Spot

Unfortunately, existing environmental laws render federal agencies ill-equipped to regulate the nanotech industry.[22] TSCA, enacted by Congress in 1976 to gather information about chemical substances and control those deemed dangerous to the public or the environment, is the most obvious candidate for regulating nanomaterials. But TSCA lacks an effective means of requiring companies to provide risk data, and it places the burden on the government to demonstrate unacceptable risk before it can adopt regulatory restrictions of any kind.

In response to a proposal by the EPA for a voluntary program to "regulate" nanomaterials,[23] in June 2005, Natural Resources Defense Council ("NRDC") and other public interest groups urged the EPA to identify all engineered nanomaterials as "new chemical substances" under TSCA because they meet the standard of "organic or inorganic substance[s] of a particular molecular identity."[24] This would trigger TSCA section 5 pre-manufacture notice ("PMN") reporting requirements prior to the commercial manufacture or import of nanomaterials.[25] The U.S. Patent and Trademark Office issued more than 8,600 nanotechnology-related patents in 2003,[26] suggesting that at least one arm of the government already considers these materials to be new.

Existing environmental laws render federal agencies essentially impotent to regulate the nanotech industry.

In addition to PMN reporting, the 2005 NRDC comments urged the EPA to issue test rules under TSCA's section 4 by waiving the regulatory production volume thresholds that otherwise would not be triggered by the miniscule product volume of nanomaterials.[27] The groups also called for regulations under TSCA's section 6, requiring the EPA to prohibit or limit anyone manufacturing, importing, processing, distributing in commerce, using, or disposing of a chemical if there is a reasonable basis to conclude the chemical presents, or will present, an "unreasonable risk of injury to health or the environment." Tragically, the EPA has failed to regulate any new chemical using the TSCA's section 6 authority since that provision was gutted by the U.S. Court of Appeals for the Fifth Circuit in the 1991 case *Corrosion Proof Fittings v. EPA* (rejecting the EPA's application of the TSCA's section six to asbestos).[28] The court's decision and subsequent problematic EPA interpretations of that decision make it extraordinarily difficult for the agency to adopt regulations under section 6 of TSCA. Thus, NRDC stated that "while requiring [pre-manufacture notice], issuing test rules, and promulgating regulations under TSCA are necessary steps for nanomaterials, such actions will be insufficient to protect public health and the environment. Ultimately, additional legislative action by Congress, the states, and potentially the courts will be necessary to ensure that nanomaterials are adequately addressed."[29]

Other laws also are inadequate. For example, the Food, Drug, and Cosmetic Act ("FDCA") leaves all cosmetics essentially unregulated, and the chronically under-enforced Occupational Safety and Health Act ("OSHA") does not adequately protect worker health. Thus, neither the FDCA nor the OSHA is viable as a vehicle for protecting the public. Other environmental statutes are similarly ill-equipped to address nanomaterials – for example, these materials would be effectively unregulated under the Clean Air Act due to very small production quantities.

Voluntary Safety Testing is Not Enough

In response to the lack of a regulatory framework for nanotechnology, the EPA is developing a voluntary program that will ask nanomaterial producers to submit basic information on material characterization, toxicity, exposure potential, and risk management practices. A company would then be able to advertise its participation as a means of dispelling public fears about its product. A more in-depth level of participation would generate more detailed risk information. NRDC participated in an ad-hoc working group with industry, academic, and public interest groups to advise the EPA on a general framework for such a program.

While this program potentially would fill a gap in the absence of real regulations, it is severely limited in several important ways. Participation is not mandatory, and would only include those products that participating companies choose to disclose. Those companies with the riskiest products, as well as those with poor business ethics, are unlikely to participate. The program also lacks punitive measures; it will do little more than gather data – primarily industry-generated data, which experience has shown are less likely than data from the government or independent studies to report products' harmful effects.[30] In the past, industries have gone to great lengths to downplay the health risks of asbestos, lead, vinyl chloride, and other toxic materials, only to have them lead to devastating occupational and public health consequences.

EPA's White Paper Recommendations

In December 2005 the EPA issued the "External Draft Nanotechnology White Paper"[31] which made the following reasonable suggestions as first steps forward:

- Support approaches to promote pollution prevention, sustainable resource use, and good product stewardship in the production and use of nanomaterials;
- Support and undertake research on human health and ecological impacts of nanomaterials;
- Conduct case studies on the risks and information gaps of specific nanomaterials;
- Expand collaborations on the potential human and environmental health implications;
- Convene a standing cross-agency group to share risk

information and regulatory activities; and

- Expand efforts to train agency scientists and managers about the potential environmental applications and implications of nanotechnologies.

Public Interest Group Responses

An array of good stewardship approaches to nanotechnology development would increase public confidence and market stability. In NRDC comments to the EPA, signed by twenty other public interest groups, including Greenpeace International, the Sierra Club, Friends of the Earth, Environmental Working Group, ETC group, and Silicon Valley Toxics Coalition, the organizations insisted that the federal government take action on the following initiatives:[32]

- Prevent uses of nanomaterials that may result in human exposures or environmental releases unless reasonable assurances of safety are demonstrated beforehand;
- Label products that contain nanomaterials or are made with processes that use nanomaterials;
- Publicly disclose information on potential risks;
- Include toxicity information about nanomaterials on workplace hazard labels;
- Increase safety testing conducted by independent or government laboratories subject to "sunshine laws" that allow public access to information; and
- Conduct comprehensive assessment of the environmental and human health concerns that may arise across the life-cycle – including production, use, and disposal – of nanotech products.

Conclusion

While we know enough to want to avoid exposure to nanomaterials and releases into the environment, many issues need to be further studied. For example, we do not know much about how these materials harm our health over a lifetime of exposure; long-term effects have not been studied in experimental animal tests. While ingestion and skin penetration are potential routes of exposure, most studies have only tried to mimic inhalation. The majority of toxicological studies with nanomaterials have been *in vitro* (such as skin cell toxicity), or short-term animal studies. We do not know whether these materials penetrate through our skin, even though consumers use shampoos, cosmetics, and other household products with nanomaterial ingredients. We do not know if nanomaterials are aerosolized and then inhaled when we use shampoos with nano-ingredients. We do not know whether ingestion results in toxicity, although we have nanomaterials in food packaging and even in chocolate chewing gum. We know that toxicity of inhaled particles seems to increase as the particle size becomes smaller, but we lack efficient and cost-effective ways to measure the size distribution of airborne particles.

Many other questions remain unanswered. For example, we do not know the extent to which nanomaterials can penetrate the placenta and transfer from mother to baby. In addition, we are unaware whether nanomaterials are released from products when they are incinerated, buried, or degraded over time. These uncertainties indicate that a necessary first step to effective nanotechnology regulation will require investing in studies to evaluate the risks, as well as the benefits, of nanomaterials on human health and the environment.

Endnotes: Nanotechnologies: The Promise and the Peril

[1] At nano-size, opaque materials may become transparent, chemically stable materials may become reactive, and electrical insulators may become conductors, or vice-versa.

[2] *See* Anna A. Shvedova et al., *Unusual Inflammatory and Fibrogenic Pulmonary Responses to Single-walled Carbon Nanotubes in Mice*, 289(5) Am. J. Physiol. Lung Cell Mol. Physiol. 698-708 (Nov. 2005) (Epub June 10, 2005); *see also* David B. Warheit et al., *Comparative Pulmonary Toxicity Assessment of Single-wall Carbon Nanotubes in Rats*, 77(1) Toxicol. Sci. 117-25 (Jan 2004) (Epub Sept. 26, 2003) [hereinafter Warheit]; *see also* Ann C.W. Lam et al., *Pulmonary Toxicity of Single-wall Carbon Nanotubes in Mice 7 and 90 Days After Intratracheal Instillation* 77(1) Toxicol. Sci. 126-34 (Jan. 2004) (Epub Sept. 26, 2003) [hereinafter Lam]; *see also* Huckzko et al., *Physiological Testing of Carbon Nanotubes: Are They Asbestos-like?* 9(2) Fullerene Sci. Technol. 251-254 (2001); *see also* Adelman et al., Effect of Fullerenes on Alveolar Macrophages in Vitro 405–407 (ILSI Press 1994).

[3] Shvedova, *supra* note 2. (This study tested occupationally relevant exposure levels: 0-40 mg per mouse administered deep into the throat, based on the workplace limit for graphite (carbon) particles (a twenty mg dose in a mouse is roughly equivalent to twenty workdays of human exposure at the workplace permissible exposure limit for graphite)).

[4] Warheit, *supra* note 2.

[5] Lam, *supra,* note 2.

[6] The National Institute for Occupational Safety and Health ("NIOSH"), 1988 OSHA PEL Project Documentation: List by Chemical Name - Graphite, Synthetic: card number 0406 (1988), *available at* http://www.cdc.gov/niosh/pel88/npelname.html (last visited Mar. 12, 2006).

[7] Lam, *supra* note 2.

[8] Lei Yang & Watts DJ, *Particle Surface Characteristics May Play an Important Role in Phytoxicity of Alumina Nanoparticles,* 158(2) Toxicol. Lett. 122-132 (2005) (The same experiment also found that nanoparticles of silicon dioxide (used in anti-fogging coatings) promoted plant root growth, while titanium dioxide (used in sunscreen) seemed to have no effect).

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[10] Chris Johnston et al., *Pulmonary Effects Induced by Ultrafine PTFE Particles*, 168 Toxicol. Appl. Pharmacol. 208-215 (2000).

[11] *See* Gunter Oberdorster et al., *Role of the Alveolar Macrophage in Lung Injury: Studies With Ultrafine Particles*, 97 Env't Health Perspect. 193-99 (Jul. 1997); *see also* Raymond B. Baggs et al.,

Endnotes: Nanotechnologies: The Promise and the Peril *Continued on page 74*

The Color of Katrina: A Proposal to Allow Disparate Impact Environmental Claims

*by Rachael Moshman and John Hardenbergh**

As the floodwaters slowly receded from Hurricane Katrina in New Orleans and the Gulf Coast, the landscape revealed not only demolished neighborhoods but also the government's discrimination against the region's poor Black and Latino communities. Covering this landscape was a brown, filmy sediment left behind by Katrina's polluted floodwaters, which the U.S. Environmental Protection Agency's ("EPA") early tests showed had high levels of *E. coli* bacteria, oil and gas chemicals, lead, and varying quantities of arsenic.[1] Other tests also found benzo(a)pyrene and petroleum hydrocarbons at levels above the EPA's safe limit standards.[2] Coastal towns became contaminated when the hurricane lifted up bayou sludge, polluted for decades by industrial chemicals, heavy metals, and organic petrochemicals.[3]

Several months later, Louisiana State's chief environmental officer stated that the floodwaters, and what they left behind, did not contain chemical contaminants capable of causing harm.[4] Local doctors, however, reported widespread coughs, sore throats, runny noses, and respiratory trouble – dubbed the "Katrina Cough" – amongst people returning to New Orleans and other post-hurricane flooded areas.[5]

Hurricane Katrina proves that federal and state governments continue to engage in racist neglect.

Courtesy of Dr. Tamra Walthall.

One month after Katrina hits, still-soft silt covers the 9th Ward.

Environmentalists continue to caution returnees of the potential exposure to hazardous chemicals and assert that the EPA has not used stringent enough standards to establish the sediment's threats. At the same time, environmentalists demand that the U.S. government stop denying the risks of exposure and commit to a thorough clean-up.[6]

Communities at Risk

Poor people and people of color in Louisiana are already more vulnerable to toxic chemical contamination.[7] The U.S. Department of Agriculture ("USDA") defines 24 of 64 parishes in Louisiana as "persistent poverty parishes" and "32 as black high poverty parishes."[8] Some of these communities are found in the 70 miles between Baton Rouge and New Orleans called "Cancer Alley" because of the 93 oil refineries and chemical plants that emit toxins into the air and water.[9] A special report from the Times-Picayune in 2000 stated that minorities and the poor "bear more environmental burdens . . . than the rest of the population."[10]

For example, in 1999, the U.S. government highlighted the alarmingly high rate of organic pollutants found in the citizens of Mossville, Louisiana, a black community surrounded by over 30 petrochemical and industrial plants within a two-mile radius.[11] In an environment where communities are already over-exposed to environmental pollutants, the disproportionate impact of Katrina's environmental consequences are predictable. Speaking on the health impact of Hurricane Katrina on poor and African American populations, former U.S. Surgeon General David Satcher said, "the same things that lead to disparities in health in this country on a day-to-day basis led to the disparities in the impact of Hurricane Katrina."[12]

If the U.S. government continues to pretend that post-Katrina communities are safe to return to when they are truly not, it will continue contributing to the long history of governmental decision-making that disproportionately places environmental burdens on poor communities and communities of color. This pattern was first reported in 1983 when the General Accounting Office ("GAO") examined the racial and economic composition of the communities surrounding four of the largest hazardous waste landfills and discovered that all were located in majority black counties.[13] Four years later, the United Church of Christ studied the demographic make-up of 415 zip code areas that were known to contain haz-

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ardous waste facilities, and found that race was the most significant variable associated with the placement of these facilities.[14] A 1994 update of the study found that the concentration of people of color in these localities has only increased in the interim.[15]

Increasingly Narrowing Rights of Action

Courts have unfortunately foreclosed the possibility of using traditional civil rights remedies to address proven discriminatory effects in environmental policy. They have done so by narrowing the grounds on which plaintiffs can sue, and by requiring them to prove discriminatory intent in these policies.[16] However, evidence that governmental decision makers discriminated on the basis of racial animus is generally very difficult for plaintiffs to produce.[17] Government officials motivated by racism are unlikely to memorialize this intention in a discoverable form in today's world. Furthermore, it matters little to individuals subjected to such discriminatory effects whether the decision maker intended this discrimination or not. In the weeks following Katrina, media reports highlighted the obvious role that race played in the impact of the hurricanes. This consensus on the racial elements of this environmental disaster should be used to create momentum for legislative action against environmental racism. Hurricane Katrina proves that federal and state governments continue to engage in racist neglect. More importantly, the federal courts' narrowing of the rights available under civil rights laws highlight the need for Congress to create a private right of action to allow individuals to file suit against the government for disparate environmental impacts.

Katrina provides the opportunity to make environmental justice the next step in the civil rights movement.

Disparate Impact: A New Private Right of Action

Appropriate legislation enabling the creation of a private right of action for environmental discrimination would include several key threshold elements: first, that a plaintiff prove that a government environmental enforcement action had a disparate negative impact on a racial minority or low-income community as to be defined by the Department of Labor; and second, that he or she is a member of such a racial minority or low-income community. Expanding the class protected to include low-income communities would eliminate the need for courts to untangle the intimately related causes of race and economic class. Although this proposed legislation would be the first civil rights law prohibiting discrimination based on economic class, this principle is relatively uncontroversial in most countries in the world and is reflected in the United States' commitments under international human rights law as embodied in the Universal Declaration of Human Rights and the International Convention on Civil and Political Rights.[18]

Once the plaintiff meets these two threshold requirements, the burden would shift to the defendant to prove that the decision was justified by environmental necessity or other compelling governmental interest. Proof that a decision disproportionately burdening a racial minority or low-income community is economically efficient would not meet the defendant's burden. To permit otherwise would render the proposed provisions prohibiting class-based environmental discrimination completely ineffective.

Conclusion

Years from now, Americans may look back on Hurricane Katrina as the event that catalyzed concrete action addressing the disparities in race and class continuing four decades after the passage of the Civil Rights Act of 1964. Katrina provides the opportunity to make environmental justice the next step in the civil rights movement.

Endnotes:

[1] National Geographic News, *Gulf Wracked by Katrina's Latest Legacy – Diseases, Poisons, Mold* (Sept. 30, 2005), *available at* http://news.nationalgeographic.com/news/2005/09/0930_050930_katrina_health.html_(last visited Mar. 8, 2006) [hereinafter National Geographic News].

[2] Press Release, Subra Company and Louisiana Environmental Action Network, Results of Sediment and Water Sampling in Residential Areas Impacted by Hurricane Katrina (Oct. 7, 2005).

[3] *See* National Geographic News, *supra* note 1.

[4] Reuters, *Government Says New Orleans Environmentally Safe* (Dec. 9, 2005), *available at* http://www.alertnet.org/thenews/newsdesk/N09175559.htm (last visited Mar. 8, 2006).

[5] *See* Slate.com, *Katrina Cough: The Health Problems of 9/11 are Back* (Nov. 15, 2005), *available at* http://www.slate.com/id/2130421 (last visited Mar. 8, 2006).

[6] *Activists Weigh Litigation as EPA Downplays Risks from Hurricane*, Inside the EPA, Sec.50, Dec. 16, 2005, *available at* http://epa.iwpnewsstand.com/epanewsstand_spclsubj.asp?s=katrina (last visited Mar. 8, 2006).

[7] *See e.g.,* John McQuaid, *Too Close for Comfort*, The Times-Picayune, May 21, 2000 at J2, *available at* http://www.nola.com/speced/unwelcome/index.ssf?/speced/unwelcome/stories/0521close.html (last visited Mar. 8, 2006) ("In this landscape of belching flares, Superfund sites and rail cars filled with hazardous chemicals, poor African-Americans bear the lion's share of the environmental hazards and burdens.").

[8] LSU AgCenter, Louisiana's Rural Poverty (Sep. 2005), *available at* http://www.lsuagcenter.com/NR/rdonlyres/68AE9B71-F810-4741-A53F-CE2E5AEF36DF/16549/Poverty.pdf (last visited Mar. 8, 2006).

[9] *See* Conger Beasley, Jr., *Of Pollution and Poverty: Part 2: Keeping Watch in Cancer Alley*, 2 Buzzworm: The Envtl. J. 38, 39 (1990).

[10] McQuaid, *supra* note 7.

[11] World Council of Churches, *Environmental Racism: Old Wine in a New Bottl*e (2000), *available at* http://www.wcc-coe.org/wcc/what/jpc/echoes/echoes-17-02.html (last visited Mar.. 8, 2006).

[12] January W. Payne, *At Risk Before the Storm Struck*, Wash. Post, Sept. 13, 2005 at HE01.

Endnotes: The Color of Katrina *Continued on page 73*

The Need for an Independent Entity to Manage Global Chemicals Agreements

*by Kelly Rain**

Introduction

Protecting human health and the environment from pollution by chemicals and hazardous materials has become a global concern. Over thirteen key international chemicals/waste agreements and initiatives exist.[1] The United Nations Environment Programme ("UNEP") supports a majority of these agreements, but some are under the auspices of other UN bodies or governments, such as the UN Food and Agriculture Organization and the UN Commission for Europe.[2] As the need for chemicals regulation increases, managing the intricacies of these multilateral chemicals/waste agreements ("MC/WAs") to take advantage of their linkages and coordinate implementation continues to grow more complex.

This article explores the need for an independent governing structure for all MC/WAs. Inevitably, chemical agreements and initiatives inter-relate, and should not be completely separated. For example, there are common themes in many of the chemicals agreements such as dealing with import/export controls and developing strategies for waste management. The global chemicals community should consider the possibility of creating an independent entity to increase the effectiveness and promote the synergies of existing MC/WAs.

Chemical agreements and initiatives inter-relate, and should not be completely separated.

The goal of this article is to promote discussion on whether creating an independent governing structure will help harmonize existing and future MC/WAs, or just add bureaucracy to the institutions.

Is "Clustering" Enough?

The need for integrating MC/WAs is apparent through UNEP's current efforts to explore clustering multilateral environmental agreements ("MEAs") with similar focus areas.[3] Clustering tries to enhance synergies and linkages between MEAs by increasing collaboration among their secretariats in areas where common issues arise and the agreements have comparable areas of focus.[4] Clustering considerations take into account the need to promote capacity building, science and technology, reporting and monitoring, and more.[5]

The UNEP Open-ended Intergovernmental Group on International Environmental Governance has debated the concept of clustering certain MC/WAs since its creation in February 2001.[6] The three conventions widely considered for clustering include the Basel Convention on Transboundary Movements of Hazardous Wastes and Their Disposal,[7] the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,[8] and the Stockholm Convention on Persistent Organic Pollutants.[9] Together these conventions cover elements of "cradle-to-grave," or more optimistically, "cradle-to-cradle." In other words, combined these three conventions regulate new chemicals, existing chemicals, the import/export of chemicals, waste management, and environmental releases. Therefore, under these conventions chemicals are regulated through production, use, and disposal. Clustering them may thus facilitate a life-cycle approach to chemicals management.[10]

Clustering will likely increase the comprehensiveness and cooperation of similar MC/WAs. However, cooperation within clusters may be hindered by different stages of implementation, variances in development, and dissimilar memberships.[11] For example, different priorities exist during each stage of implementation, which may lead a convention's parties to decide cooperation is not in the convention's best interest.[12] Likewise, some conventions are more mature than others, resulting in a variance in their development needs. While clustering serves an important purpose in improving the chemicals/waste regime, an independent governing entity may allow better coordination for non-cluster concerns and crosscutting issues.

The Failure of SAICM to Fulfill This Goal

The Strategic Approach to International Chemicals Management ("SAICM") is one example of an attempt by UNEP, governments, and multi-sectoral stakeholders to increase coordination among MC/WAs. In February 2002, the UNEP Governing Council adopted a decision that there was a need to further develop SAICM.[13] In September 2002, the World Summit on Sustainable Development in Johannesburg called for the completion of SAICM by 2005.[14] The aim of SAICM is to achieve, by 2020, the production and use of chemicals in ways that leads to the minimization of significant adverse effects on human health and the environment.[15] The International Conference on

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Chemicals Management ("ICCM") adopted SAICM in Dubai, United Arab Emirates, from February 4-6, 2006.[16]

The original aim of SAICM, a voluntary agreement, was to provide a basic blueprint for the global management of chemicals. This included covering risk assessments of chemicals, harmonizing labeling, tackling obsolete and stockpiled products, and helping the developing world safely manage chemicals.[17] However, many participants at the ICCM felt that SAICM fell short of these goals, especially regarding perception of the global plan of action.[18] It is widely agreed that the tools for implementation of the SAICM are a key to its success. From the point of view of most developing countries, the main tool of implementation is money; however, at the ICCM new and additional funds did not come forth, with the exception of the "Quick Start" fund to provide seed money to start programs in the developing world.[19]

It is questionable whether meaningful chemical safety will be able to result from the implementation of SAICM. The main issue is whether another MEA will be able to promote the synergies of existing agreements. Each multilateral agreement comes with bureaucracy and its own internal mechanisms. As such, SAICM may just exacerbate the issue of lack of harmonization among MC/WAs by adding another secretariat to the existing group. An umbrella organization, without its own mission and agenda, would be better equipped to increase coordination amongst MEAs. The key feature of an independent entity is that it would not have any personal incentives; the impetus for its existence should be to promote coordination in the global chemicals/waste community.

UNEP has not been given, or has not used, the complete authority necessary to fulfill its task as a catalyst for MEAs.

The probability that SAICM will be able to reform international chemicals management appears unlikely; thus, there remains a strong need for an independent governing structure for all MC/WAs.

Current Shortcomings

Evaluation of some of the current shortcomings in the MC/WAs regime helps distinguish necessary steps to increase effectiveness; however, this discussion is far from conclusive. Still, motivation can be drawn from this limited critique towards creating a more effective organizational structure of all MC/WAs.

Current fragmentation between the various MC/WAs has led to numerous inefficiencies. For example, these agreements are not under the auspice of one governing body, and the secretariats of these Conventions are located throughout the globe.[20] This fragmentation, coupled with the increase in MC/WAs, has led to a diversified body of rules for each MEA. Likewise, a degree of "sovereignty" exists that some conventions are unwilling to give away, resulting in their disinclination to cooperate with other MEAs.[21] Such fragmentation places stress on States considering ratification because of their limited ability to handle the responsibility of complying with each MEA.

Inadequate compliance and enforcement have also plagued the MC/WAs. While the Montreal Protocol on Substances that Deplete the Ozone Layer[22] developed one of the first compliance regimes in the 1980s that focused on assisting parties in non-compliance, many of these regimes have only recently been formed.[23] For example, the Basel Convention Implementation Committee was adopted after three years of negotiations in 2002.[24] Moreover, numerous MEAs lack or have weak verification procedures.[25] Additionally, a successful compliance committee needs to be able to evolve based on experiences of the convention and must be adequately monitored.[26] The current structure of MC/WAs has mainly failed to provide sufficient compliance and supervising structures. A lack of compliance systems within MC/WAs makes these agreements defective – what is the point of an agreement if there are no provisions for enforcement?

Established in 1972, UNEP acts as the coordinator of environmental action and management within the United Nations.[27] While UNEP lacks formal powers, it is suppose to be the nucleus of the international environmental regime.[28] However, UNEP has not been given, or has not used, the complete authority necessary to fulfill its task as a catalyst for MEAs.[29] Limited membership in the governing council and lack of resources are other factors that hinder the authority of UNEP.[30]

MC/WAs utilize different financial mechanisms, some of which struggle with inadequate funding. Insufficient funds may hamper the implementation of agreements and prevent the development of synergies and cooperation among conventions.[31] A recent study by the Rotterdam Convention found that MEAs experience serious financial hardship when they rely solely on "(1) voluntary contributions for their financial mechanism, or (2) coordinating mechanisms instead of true financing mechanisms."[32] For example, the Montreal Protocol's "stand alone" financial mechanism has been attributed with this MEA's success.[33] Conversely, the voluntary mechanism of the Basel Convention has lead to a non-dependable stream of discretionary financial resources for the Convention.[34]

An Independent Governing Entity Should be Judged on How it Resolves These Issues

The creation of an independent governing entity for the expanding number of MC/WAs would likely help harmonize the conventions and increase effectiveness. The threshold question is whether the creation of such a body would alleviate some of the complications that currently plague the MC/WAs, or just create another administrative burden.

All chemicals/waste agreements would be altered to exist under the auspice of this independent entity, which would be under the United Nations umbrella. Each MEA would retain its secretariat and most of its other internal machinery. The chemicals/waste governing entity would have advising power, but no executive authority. Some of the functions of this organization would be to monitor compliance, encourage coordination, assist with dissemination of information, provide recommendations to individual MEAs, and serve as a resource of information. A major alteration would be the creation of a financing mechanism under this entity for all MC/WAs.

Possible Strengths of an Independent Governing Entity

Numerous strengths can be identified for uniting all MC/WAs under one roof. For example, when decision-making is integrated, it reduces the risk of repetition, inconsistencies, and conflict.[35] A greater chance of collaboration and identifying gaps in the research would also exist.

The pooling of scientific and technical knowledge and the avoidance of duplication would be one of the benefits of an independent governing entity. Increased dissemination of science and technology has always been an attraction to clustering conventions that are directly related.[36] An independent umbrella organization would allow the creation of a technical body that would facilitate the pooling of information on health and environmental impacts of chemicals. This body would serve as a library equipped with the information to help promote meaningful chemicals safety. Additionally, gaps in research would be identified more quickly.

An independent governing structure would reduce fragmentation and increase communication. . .

An independent governing structure would reduce fragmentation and increase communication between the conventions. Instead of having numerous UN bodies responsible for implementing MC/WAs, they would all be under the auspice of one entity. Thus, a degree of conformity would exist among all the MC/WAs, even if the secretariats are still located in different regions. Additionally, overarching committees for compliance, information, and financing will inspire the MEAs to work together to instill full authority into the governing entity, giving them the foundation that UNEP has not been able to provide.

Another strength would be the ability of the governing entity to try to establish an effective implementation and compliance committee. While this will prove to be challenging, the governing entity will be able to monitor the execution of each convention at a national level, and search for non-compliance. Additionally, there is a current need for a judicial instrument to help settle compliance disputes.[37] The governing entity could provide this venue, allowing a much needed arena for dispute resolution leading to greater compliance within the chemicals regime.

An independent entity would also lead to a more stable financing mechanism. Combining the financing mechanisms of all MC/WAs would increase the success of these agreements. The Global Environment Facility ("GEF") provides an example of a successful multipurpose operational entity. As the sole financing facility that serves more than one convention, the GEF provides insight into the possible establishment of a similar financial structure for chemicals.[38] The GEF also provides a sound model of sustainability since its donors have provided between $2 to $3 billion of financing for each of its first three replenishment periods.[39] The possibility of creating a separate entity, similar to GEF, with a focal area to support all MC/WAs has promise to help accelerate the progress of these agreements by assuaging financial problems.

There is also the consideration of expanding the mandate of GEF to include chemicals conventions that focus on more than persistent organic pollutants, ozone depletion, climate change, and international waters.[40] In other words, creating a "GEF Chemicals." The 2005 study to find lasting financial mechanisms for the Rotterdam Convention identified the option of "[e]xpanding the GEF focal area to serve a cluster of chemicals conventions and processes, including the Rotterdam Convention."[41] A study of financial considerations for implementation of the SAICM conducted in July 2005 also explored the possibility of funding SAICM under the GEF.[42]

Possible Weaknesses of an Independent Governing Entity

The possibility exists that creating a governing entity responsible for implementing all of the MC/WAs will not improve the current troubles experience by the agreements but will merely transfer them to a new entity.

While an independent governing body may be able to decrease external fragmentation among MC/WAs, it does not mean that the individual conventions will be willing to give up their autonomous nature. Each MEA has its own structure consisting of the secretariat, a conference of the parties, advisory bodies, technical experts, and more. An independent governing body does not impact the organization of each individual agreement. Thus, the people responsible for running each MEA may still be unwilling to cooperate even if there is an increase in external coordination.

While it is undisputable that there is much overlap between these agreements, it may be difficult to create effective machinery that provides technical bodies and committees for MEAs with different members and focal areas. For example, differing research needs of the convention may result in disputes of the allocation of research funding by the scientific and technical knowledge technical body. The administrative backlog from trying to coordinate the various chemicals/waste agreements may negate the purpose

of collaboration. Additionally, an MEA is not a stagnant agreement. Most MEAs evolve over time, with their needs and goals altering. The task of trying to create an implementation and compliance committee that is able to monitor and regulate all the MC/WAs may prove extremely difficult, if not impossible.

An important goal of many MC/WAs is to assist developing countries in protecting human health and the environment. It is possible that the balance of power may become skewed within an administrative structure trying to coordinate all of these important MEAs. In the end, developed nations, industry, and better funded organizations may end up with more control than is in the best interest of the parties of the Conventions.

Moreover, the creation of an independent financial mechanism for MC/WAs might experience a similar imbalance of power. The triumph of an MEA can be directly attributed to its financial resources, and developing countries are in dire need of money in order to have the tools to implement the sound management of chemicals. However, wealthy developed countries that contribute more financial resources tend to have a louder voice on the allocation of funds than developing countries. Pooling the resources of the MEAs into either a "GEF Chemicals" or an independent financial mechanism leads to issues of having to deal with a large amount of bureaucracy to accomplish the fair distribution of funds.

[P]eople responsible for running each MEA may still be unwilling to cooperation even if there is an increase in external coordination.

Conclusion

The creation of an independent structure to govern all MC/WAs would allow the greatest chance for successful international chemicals management. It can be debated whether creating this governing body to house all MC/WAs will help coordinate existing and future agreements, or just add another layer of complications. However, the global environmental community is running out of alternative options to help harmonize sound chemicals management.

Endnotes: Independent Chemicals Entity

[1] *See* Paul E. Hagen & Mateo Davis, *Key International Agreements and Initiatives Addressing Chemicals, Wastes, and Heavy Metals*, SK046 ALI-ABA 19 (2005).

[2] *See* Hagen & Davis, *id.*.

[3] United Nations Environment Programme, The Hazardous Chemicals and Waste Conventions, September 2003, *available at* http://www.pops.int/documents/background/hcwc.pdf (last visited Mar. 18, 2006) [hereinafter Hazardous Chemicals].

[4] *See* United Nations Environment Programme, Clustering of chemicals/wastes multilateral environmental agreements, UNEP/POPS/INC.6/INF/18, 2 April 2002, *available at* http://www.pops.int/documents/meetings/ inc6/englishonly/INC6INF18.doc (last visited Mar. 18, 2006) [hereinafter Clustering].

[5] Clustering, *id*.

[6] Clustering, *id*..

[7] The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted in 1989 and entered into force in 1992, http://www.basel.int.

[8] The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted in 1998 and entered into force 24 February 2004, http://www.pic.int.

[9] The Stockholm Convention on Persistent Organic Pollutants was adopted in 2001 and entered into force 17 May 2004, http://www.pops.int.

[10] Hazardous Chemicals, *supra* note 3.

[11] United Nations Environment Programme, International Environmental Governance: Multilateral Environmental Agreements (MEAs), UNEP/IGM/1/INF/3, 6 April 2001, at 28, *available at* www.unep.org/dpdl/IEG/docs/working%20documents/MEA_full/INF3_MEA_Add.doc (last visited Mar. 18, 2006) [hereinafter MEA Governance].

[12] MEA Governance, *id.* at iii.

[13] United Nations Environment Programme, Decision Adopted by the Governing Council at its Seventh Special Session/Global Ministerial Environment Forum, SS.VII/3, 15 February 2002, *available at* http://www.chem.unep.ch/saicm/ssvii3en.pdf (last visited Mar. 18, 2006).

[14] Governing Council Decision, *id.*

[15] Governing Council Decision, *id*

[16] New Global Chemicals Strategy Given Green Light by Governments, Press Release, February 7, 2006, *available at* http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=469&ArticleID=5137&l=en (last visited Mar. 18, 2006).

[17] *See* New Global Chemicals Strategy, *id.*

[18] *See* American University Panel Discussion on the Future of Chemicals Management, http://www.wcl.american.edu/secle/video.cfm# (last visited Mar. 18, 2006).

[19] AU Panel Discussion, *id.*

[20] *See* Hagen & Davis, *supra* note 1.

[21] MEA Governance, *supra* note 11, at 28.

[22] The Montreal Protocol on Substances that Deplete the Ozone Layer was adopted in 1987 and entered into force 1 January 1989, http://ozone.unep.org/Treaties_and_Ratification/2B_montreal_protocol.asp.

[23] Patrick Széll, *Introduction to the Discussion on Compliance*, 31 August 2004, *available at* http://www.joensuu.fi/unep/envlaw/review2004/2004ReviewPartIII.pdf (last visited Mar. 18, 2006).

[24] Secretariat of the Basel Convention, http://www.basel.int/legalmatters/compcommitee/index.html (last visited Mar. 18, 2006).

[25] International Institute for Sustainable Development ("IISD"), *MEA Enforcement and Compliance Meeting Bulletin*, *available at* http://www.iisd.ca/download/pdf/sd/ymbvol121num1e.pdf (last visited Mar. 18, 2006).

[26] IISD, *id.*

[27] Dena Marshall, *An Organization for the World Environment: Three*

Endnotes: Independent Chemicals Entity *Continued on page 80*

Europe's REACH:

A New Chapter in International Chemicals Law

*by Marcos A. Orellana**

Introduction

For almost a decade, the deliberative bodies and Member States of the European Union have been developing a new legal framework to govern the marketing and trade of chemicals. When adopted, the proposed regulation on Registration, Evaluation, and Authorization of Chemicals ("REACH") will mark a fundamental change in the way chemicals are managed in Europe and around the world. This REACH reform process was driven by the recognition that the existing patchwork of EU law on chemicals was inadequate to securing a healthy environment for present and future generations. REACH was coined in the EU Commission's 2001 White Paper, but it builds on years of European experience combating regional pollution in the Baltic, the North Sea, the Mediterranean, the Rhine, the Danube, and elsewhere. It now stands as the EU's plan for meeting the global 2020 goal to minimize the health and environmental impacts of chemicals agreed by the governments of the world at the World Summit on Sustainable Development in Johannesburg in 2002.

This White Paper's high-minded proposal triggered a complex process within the Commission to draft the legislative text that was ultimately proposed in 2003. Economic concerns about the competitiveness of the EU chemicals industry, as well as the workability and transaction costs of proposed arrangements, led EU institutions to scale back on the grander vision of REACH. Very heavy lobbying by the chemical industry and some prominent countries outside the EU forced concessions on the scope of REACH, the duty of care, minimum data requirements, and the consideration of alternatives.[1] Intense debate within the European Parliament and the Council has produced two critical texts that supersede the Commission's drafts: the result of the Parliament's first reading vote; and the political agreement among the 25 Member States (the Common Position). At the time of writing, the parliament was preparing to take up the Council's agreed text and consider amendments in the second reading vote.

Despite the political influences, REACH is still guided by some important principles. For the first time REACH places the burden of proof on chemical makers and importers to demonstrate the safety of their products, rather than relying on authorities to prove them dangerous. REACH will generate valuable data about the properties and uses of several thousand chemicals and mixtures, which will be available to downstream customers and the public. REACH may drive adoption of safer substitutes or the generation of inherently greener solutions, especially if the Parliament's first reading vote prevails in the final political deal. Many countries outside Europe will feel the ripple effects of REACH through global supply chains and evolving international standards. Developing countries may benefit from safer products from the EU and access to new markets for products not requiring registration.

This article provides an international legal perspective on REACH. Since REACH is still under debate in the European Parliament and the Council, this piece addresses the basic contours of the likely political agreement expected in 2006, with a special focus on the relevance of human rights and trade law. After tracing the origins of REACH, this article explores the role of the main EU institutions involved in the development of the regulation. Next, this article looks at the core elements of REACH, focusing on objectives, principles, requirements, and impacts. An examination of some of the trade-related issues debated at the World Trade Organization ("WTO") sheds light on a possible trade challenge against REACH.

Roots of the Problem: Piecemeal Approaches to Chemicals Management

Over the course of many years, European authorities, elected officials, industry, and civil society have concluded that the existing EU legal framework for chemicals is unable to provide adequate information about the impact of many chemicals on human health and the environment. They are not alone. The national chemical laws developed in the 1970s and later, both inside and outside the EU, are antiquated and ineffective. At the turn of the 21st Century the EU had managed to fully assess approximately 140 chemicals; this nearly three decades under a web of directives on chemical labeling, transport, and restrictions. Current EU law distinguishes between "new" chemicals and "existing" chemicals. Existing chemicals were on the market before September 1981 numbering more than 100,000 substances and over 99 percent of commercial chemicals in terms of tonnage.[2] While existing EU Directives require that new substances are tested and their risks assessed, "existing" substances are not subject to the same testing requirements. As a result, EU law has not obtained basic screening data about the characteristics and impacts of most chemicals. Without such information, chemicals policy is blind to the risks posed by chemicals and frozen into inaction.[3]

In addition to the general lack of knowledge about the properties and the uses of existing substances, current EU law on chemicals suffers from other serious deficiencies. The duty to

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provide credible information about chemical safety falls on authorities instead of the enterprises that make and sell chemicals. The risk assessment process is slow and costly, allowing continued production, marketing, and use of potentially dangerous chemicals. Further, the Commission is responsible for carrying out risk assessments and adequate cost/benefit analysis prior to any regulatory proposal relating to marketing and use of dangerous substances.[4] Liability regimes are insufficient to ensure redress for injured parties when cause and effect are distanced and if adequate data on the effects of chemicals are not available. Finally, the EU's current legal framework on chemicals is a patchwork of Directives and Regulations that has been characterized as a barrier to innovation by discouraging research and favoring existing substances over new, safer chemicals.

The European Union is home to the 500 billion Euro chemicals industry, the world's largest. As the source of a third of global chemical production, and with an educated and environmentally aware citizenry, Europe is at the center of the contemporary struggle to reconcile its industrial economy with protection of public health and the environment. How REACH is ultimately agreed and how it is implemented will have important implications for the direction of international law and the evolving role of the EU as a leader internationally on matters of health and environmental protection.

REACH will ensure a common playing field within the EC internal market, where all chemical producers and traders will be subject to the same specific requirements.

REACH's Background: Evolution of EU Chemicals Policy and EU Institutions

A comprehensive narrative of the EU's reform of its chemicals framework would require extensive detail on the unprecedented and intense involvement of national governments, industry, and civil society in a broad debate handled largely by EU Institutions. Fortunately, up to 2004 that narrative can be found elsewhere.[5] This section provides a general overview of key events and actors, with a view to contextualizing the international law dimensions of REACH.

The Evolution of EU Chemicals Policy and Regional Agreements

In the late 1960s, at a time of increased environmental awareness, the first signs of what would later become a patchwork legislation concerning chemicals began to surface. The first EC legislative instrument on industrial chemicals was the 1967 Directive on Classification and Labelling of Chemicals,[6] which focused on harmonizing trade in chemicals and protecting workers from acute exposure, but did not require testing or other data. Subsequently, the 1976 Directive on Restrictions of Certain Substances[7] was an attempt to harmonize chemicals policy in response to trade obstacles resulting from some Members banning or restricting production or use of certain chemicals. Under this Directive, the Commission committed itself to carrying out risk assessments and cost/benefit analyses prior to any proposal or adoption of a regulatory measure concerning chemicals. In 1979, an important amendment to the 1967 Directive was adopted, establishing the "new" and "existing" distinction.[8] In 1988, the Council replaced several directives concerning preparations with the Directive on Classification and Labelling on Preparations.[9]

By 1993, disparities in the national legislations implementing the above-mentioned Directives and their impact on EC trade, coupled with increasing awareness of the substantial threat posed to human health and the environment by chemicals, led to the 1993 Council Regulation on Evaluation of Existing Substances. According to this regulation, certain categories of data were to be provided to the authorities. Progress on risk assessment was slow, however, and restrictions or bans could only be adopted if the authority could show strong evidence of the substance's negative effects. This business-as-usual approach ultimately proved unacceptable to countries particularly affected by persistent pollution.

Meanwhile, regional agreements were concluded to address pollution issues. Nordic and other countries such as Belgium, the Netherlands, the United Kingdom, and Germany have taken a lead in efforts to protect the marine environment of the North Sea, for example, including the phase-out of hazardous chemicals. The North Sea Conferences have produced political commitments which have played an important role in influencing legally binding environmental management decisions both nationally and within the framework of competent international bodies. The 1995 Ministerial Declaration adopted in Esbjerg, Denmark stands as a landmark in that it defines an operational objective: to cease all releases to the marine environment of human-made and natural hazardous substances, in order to achieve background levels of natural hazardous substances by 2020 (in one generation).[10] Similar wording was adopted in June 2001 by the EU Council to define the objectives of the new EU chemicals strategy and by the 2006 Strategic Approach to International Chemicals Management, adopted under the auspices of the United Nations Environment Programme.[11]

This objective was also adopted by the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") in its first meeting in Sintra, Portugal in 1998.[12] A review of its first five years experience in implementing activities to achieve the "one genera-

tion" goal led to the 2003 Hazardous Waste Strategy, which ultimately aims to achieve "concentrations in the marine environment near background values for naturally occurring substances and close to zero for manmade synthetic substances" by the year 2020.[13] In order to achieve this objective, the OSPAR Convention actively engaged EU institutions, contributing its expertise to the EU chemicals policy reform process.

EU Institutions and the Political Battle over REACH

Against this broader international legal background, in 1998 environment ministers of EU Member States initiated intensive public dialogue about chemicals, public health, and the environment. In an informal meeting in Chester, UK, the environment ministers concluded that a comprehensive review of the system was necessary, with a view to introducing principles of sustainable development in the chemicals sector. The Commission conducted this review in 1998, identifying major weaknesses in the current chemicals legislation. The Council welcomed the Commission's progress and requested it to organize a brain-storming meeting open to all relevant stakeholders that could inform a proposal. In February 2001, the Commission presented its White Paper on a Strategy for a Future Chemicals Policy (REACH), a prescient nickname for one of the hardest fought political battles in Brussels. All this led to an enormously contentious and complex political debate with unprecedented participation by NGOs, business, and others.

Many countries outside Europe will feel the ripple effects of REACH through global supply chains and evolving international standards.

As the administrative branch of the EU, the European Commission has particular responsibilities in preparing legislation proposals.[14] In the ambit of REACH, DG-Environment and DG-Enterprise were tasked to draft REACH together. The Commission has attempted an inclusive process of debate to address the complex issues associated with chemicals policy. In 2001, for example, after presenting its White Paper, the Commission organized a stakeholder conference and convened technical working groups. In May 2003, the entire draft regulation was posted on the internet for consultation, which enabled unprecedented participation by governments, industry, and a range of civil society. On October 29, 2003, the Commission sent its proposed REACH regulation to the Parliament. Since then, the Commission has been actively involved in consultation with Council and Parliament, and also managing a range of implementation projects with authorities, industry, and others.

The European Parliament is the elected political body of the EU, with a key role in the co-legislation process. Its Members ("MEPs") are elected in national elections and they are organized by political groups.[15] While the Parliament had a role during the discussion of the White Paper, when after the draft entered Parliament, it became the focus of intense committee debate (2003-2005). The Environment Committee took the lead, in what turned out to be a hard fought turf battle, and other committees gave "opinions." On November 17, 2005, Parliament adopted over one thousand amendments to the draft in its first reading vote. The Parliament has subsequently been involved in dialogue with Council on the draft, and is expected to hold a second reading vote in 2006.

The Council of the European Union represents the (now 25) Member States of the European Union and organizes its work on the basis of specialized topics, *e.g.* Environment Council, Competitiveness Council, etc.[16] This arrangement means that the Council reflects national political influence, but is also informed by technical experts from ministries, competent authorities, etc. This arrangement has also had profound influence on the Council's stance before REACH. In fact, while early discussions on chemicals policy were steered by the Environment Council, the draft REACH regulation was placed under the competence of the Competitiveness Council, which led to greater emphasis on issues of workability, innovation, and implementation costs. The Council also operates under the leadership of a presidency that sets the agenda on a rotating six-month basis. This has had implications for REACH process, as key decisions were made under the Italian, Dutch, and other presidencies. In December 2005 the Council reached a preliminary political agreement under the UK Presidency. After regular deliberations on most major aspect of the 2003 draft regulation, and after the 2005 preliminary political agreement, in February 2006 the Council adopted its "common position" regarding the Parliament's first reading vote, which essentially defines the practical bounds for an eventual compromise.[17] Any remaining differences between the Council and Parliament's second reading vote would be resolved through a formal conciliation process. REACH is now expected to enter into force in 2007.

REACH in Focus: Objectives, Requirements, and the New European Chemicals Agency

As the previous section shows, REACH is the result of a complex process, where multiple interests and players have engaged in a vigorous and heated debate over the future of EU chemicals policy. Given that REACH is still a live document and that a final regulation is expected in 2007, rather than attempting a comprehensive analysis of REACH, this section will only discuss some of its general features and central requirements, based on the Council's Common Position and the Parliament's first reading vote.

Objectives of REACH

The political objectives of the proposed strategy for a future

chemicals policy prepared by the Commission encompassed a range of important public policy goals. Pursuant to the challenge of sustainable development, and within the framework of the EC common market, REACH attempts to integrate environmental, economic, and social considerations in the design of the proposed chemicals strategy. As elaborated in the White Paper, the political objectives of REACH include:

Protection of Human Health and Promotion of a Non-toxic Environment

This objective requires a process for ensuring the safety of tens of thousands of chemicals, especially "existing" substances that have been held to a lower standard than new ones. This process would distinguish substances according to proven or suspected hazardous properties, uses, exposure, and volumes of production or trade, in order to prioritize actions. Industry, including companies along the manufacturing chain, would be responsible for generating and assessing data and assessing the risks of the use of the substances. Ultimately, this process would fill the large data gap concerning chemical hazards and uses, thereby enabling a sound chemicals policy for the protection of human health and the environment.

Maintenance and Enhancement of the Competitiveness of the EU Chemical Industry

Given the economic importance of the chemical industry in the EU, including with respect to jobs, the White Paper encouraged innovation and in particular the development of safer chemicals. In addition, a workable and realistic timetable for submission of data, coupled with flexible test data and other measures (*e.g.* testing thresholds) would limit the cost for enterprises.

Prevention of Fragmentation of the Internal Market

The White Paper places considerable importance on the internal market, following the Commission's role as the steward of the EC market. In this light, the White Paper views health and environment protection as fully compatible with the proper functioning of the internal market in the chemicals sector, as in any other industrial sector within the Union. The White Paper also proposes that to meet its objectives, the new chemicals policy be based on full harmonization.

Increased Transparency

Transparency in the White Paper is addressed from two angles. First is the "public right to know;" that is, the public's right to access information about the chemicals to which they are exposed. The economic implications of the public's right to know will center on the public's ability to make informed choices in the marketplace, avoiding dangerous products and preferring safer substitutes. The second angle relating to enhanced transparency is institutional and administrative; a single system applying to all chemicals will improve the transparency of the regulation.

Integration with International Aspects

This objective encompasses several dimensions, including recognizing test results carried out using globally harmonized methodology in order to reduce costs and animal testing; preventing distortions to the global market by covering importers; and supporting multilateral environmental initiatives relating to chemical safety. In this latter vein, the White Paper supports efforts by the OSPAR Convention, the Stockholm Persistent Organic Pollutants Convention, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. This objective also addresses the need to strengthen developing countries' capabilities and capacities for managing chemicals.

Promotion of Non-animal Testing

The White Paper recognized the difficulties and dilemmas surfacing from the need to tests chemicals in different ways, including on animals, in order to assess hazard and risk. This objective seeks to reduce animal testing to an absolute minimum by maximizing the use of existing non-animal test methods. Also, this objective calls for the development of new non-animal test methods, as well as for careful definition of testing thresholds, flexible test regimes, and sequencing in the production of information.

Conformity with EU International Obligations under the WTO

The White Paper is explicit about the WTO obligations contained in the Agreement on Technical Barriers to Trade ("TBT Agreement") (addressed below). In particular, this objective calls for preventing discrimination against imported products; ensuring that its measures are based on sound scientific evaluation of the potential threats to human health and the environment; and ensuring that its technical regulations do not create unnecessary obstacles to international trade.

The analysis of the objectives of REACH shows the close linkages between the economic, public health, and environmental dimensions of chemicals management under the broader umbrella framework of sustainable development. In this light, REACH is redefining the different roles of the various social actors involved in chemicals production and trade, and has introduced a "duty of care" approach to chemicals production and trade, where industry takes responsibility of the products that it places on the market. This duty of care is complemented by stringent requirements regarding information on chemicals, summarized by the "no data, no market" quote. REACH's requirements also show a preference for safer substitutes (without having to fully prove dangers) as a means to gradually secure health as well as stimulate innovation. These requirements and other specific obligations contained in the REACH regulation are examined next.

Requirements in REACH

As a regulation, REACH is directly applicable to EU Members States and enforceable in their domestic courts. Among other things, this "harmonization" feature contrasts REACH from the current EC Directives that concern chemicals, which have been implemented by multiple and varying domestic laws in Members. Thus, REACH will ensure a common play-

ing field within the EC internal market, where all chemical producers and traders will be subject to the same specific requirements. The central requirements of REACH are found in its acronym: Registration, Evaluation, and Authorization, examined in cursory fashion below.

Registration

Registration requires a manufacturer to notify an authority of the intention to produce or import a substance and to submit a dossier containing the information required by the legislation. Registration will be obligatory for all chemicals produced or imported in volumes exceeding one ton per year, including "existing" and "new" chemicals. In general terms, unless otherwise exempted, failure to register means that the substance will not be allowed in the market.

The timing and amount of information required for registration depends partly on the volume produced or imported. While risk of a chemical substance towards human health and the environment is not necessarily proportional to the volume of production, volume is a proxy for exposure, as it allows a clear, enforceable priority setting for registration which also gives legal certainty.[18] For substances above one ton, a technical dossier (containing information on the properties, uses, classification, and guidance on safe use) must be submitted to the authorities. For substances above ten tons, a chemical safety report ("CSR") is required. A CSR documents the hazard classification of a substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic ("PBT") or very persistent and very bioaccumulative ("vPvB"). Further, the CSR also describes exposure scenarios, including appropriate risk management measures, for all identified uses of dangerous, PBT, and vPvB substances.[19]

REACH allows for, but does not require, chemical makers and importers to share data for registration. There are also cost-sharing provisions among registrants, designed to respect property rights to data and to fairly allocate the cost of producing the required information. New tests are only required when it is not possible to provide the information in any other permitted way, in order to minimize animal testing. In these situations, the manufacturer or importer would submit proposals for testing, which will be scrutinized by the authorities in the evaluation process before the tests are performed.

Evaluation

The evaluation process consists of an examination of the data contained in the registration dossiers provided by industry. There are two types of evaluation: dossier evaluation and substance evaluation. The dossier evaluation includes a (1) *compliance check (*or completeness check), where authorities test the registration dossiers against the registration requirements, and a (2) *checking of testing proposals*, where authorities evaluate the animal testing proposals to prevent repetition of existing tests and poor quality tests. The substance evaluation focuses on suspicions of risks to human health or the environment and may lead to requests for further information or expedited action. The new chemicals agency will develop guidance on prioritization of substances for evaluation. Evaluation may lead to the conclusion that further action needs to be explored under the authorization procedures.

Authorization

An authorization is required for the use and marketing of "substances of very high concern." There are several categories of such substances of very high concern, constructed on the basis of their properties: (1) carcinogenic, mutagenic, or toxic for reproduction; (2) PBTs or vPvB; and (3) equivalent to the above in their potential to cause serious and irreversible effects to humans or the environment, such as endocrine disrupters. Authorization under REACH could include bans or restrictions on the manufacture or uses of these chemicals, but banning substances or uses will not occur by default. Of the estimated 30,000 produced above one ton per year, an estimated 1,500 chemicals may require authorization.

REACH ultimately … contributes to improving public health and the environment globally, and in meeting Europe's commitment to the global 2020 goal for a toxic-free future.

The authorization process consists of two steps. The *first step* focuses on identifying the substances that will be included in the system; the uses that will be exempted because of sufficient controls; and the deadlines that will have to be met. The new Chemicals Agency will make recommendations for priority substances for authorization based largely on risk, *i.e.* use, volume, and properties, while taking into account workability considerations. The *second step* requires industry to apply for an authorization for each use, demonstrating that either the risk of the use of the substance is adequately controlled, or that the socio-economic benefits outweigh the risks, taking account of alternative substitutes. In order to enable costs to be minimized, REACH allows groups of applications for authorization, such as by manufacturers, importers, and downstream users.

Registration, evaluation, and authorization are the supporting pillars of REACH's new approach to chemical safety. A critical question that surfaces with respect to the operation of the proposed REACH regulation is its scope, *i.e.* which substances are covered by these requirements. In that context, it is important to note that REACH only covers substances (chemicals) but does not cover preparations. Additionally, REACH exempts

inter alia radioactive substances, wastes, non-isolated intermediates and substances that Members States deem necessary for their defense interests.[20]

Yet another controversial aspect about REACH's scope is that it does not cover products.[21] This exclusion, however, is not absolute, and REACH may apply if certain conditions are present, such as if chemicals in products are dangerous and intended to be released from the article during normal and reasonably foreseeable conditions of use. While there is considerable uncertainty in regard to the exact meaning of this language, the exclusion of products (including imported products) represents a shortcoming of the system to the extent that these products may have been manufactured utilizing dangerous chemicals that could be released unintentionally to the environment, thereby threatening public health. Further, while release may not be intended, there may be cases or products where it could nevertheless be foreseen that some of the chemicals employed in their manufacture would be released to the environment. In such cases where substances may be released incidentally to the use of the article, a simple notification is required. From another perspective, the exclusion of products from REACH means that a plethora of difficult questions concerning WTO-consistency are left for a future day.

Another key question regarding the implementation of REACH's requirements concerns the timetable for registration. REACH envisages a tiered approach for registration to be phased in over eleven years, where deadlines hinge on production volume, *e.g.* above one ton, one-hundred tons, one-thousand tons, etc. At the same time, the system is expected to be flexible enough to allow for earlier registration of substances of concern, including those having proven or suspected hazardous properties and those intended for consumer use.

It is readily apparent that the requirements in REACH are varied and complex.[22] Several developing countries have commented on the difficulties that their chemical producers and exporters will face to maintain their market presence in the EC, as discussed further below. In order to facilitate the implementation of the new chemicals regulation, the creation of a new agency is envisaged, examined in turn.

A New European Chemicals Agency

In order to administer REACH and facilitate its implementation, a new European Chemicals institution is being established in Helsinki. The new Chemicals Agency is expected to build on the Commission's experience with other agencies in other fields, in particular those working on medicinal products and food safety. The agency is also expected to provide Member State authorities with technical and scientific support, as well as to coordinate the evaluation of substances by national environmental authorities. The Chemical Agency has no enforcement powers, and would rely on the Commission to enforce REACH.

A key aspect of the new European chemicals agency concerns its role with respect to information on chemicals. The central chemicals entity will manage the registration process, serving as receiving body for the registration dossiers and forwarding copies of the dossiers to the Member State authorities. The agency will also undertake compliance checks and evaluation of testing proposals of the dossiers. The agency will maintain a comprehensive central database on all registered chemicals, performing computerized screening for properties raising particular concern. Crucially, the new agency will provide access to non-confidential information about chemicals to the general public, thereby contributing to a better understanding of chemical safety to the public worldwide.

International Law Implications of REACH

REACH's multifaceted characteristics mean that it links with various dimensions of international law. By its own nature as an EC Council Regulation, REACH is binding on EU Member States, and directly applicable before their internal courts. This argues for a detailed analysis of EU law, however, this section explores some of REACH's implications for international human rights law and trade law.

Human Rights and Environment Dimension

Under human rights law, States are under an obligation to structure their legal systems in a way that ensures the free and full exercise of fundamental rights, including the right to health. In particular, international human rights law imposes upon States the duty to take concrete steps towards the full realization of the right to the highest attainable standards of physical and mental health.[23] More generally, the linkages between environmental health and human rights have been clarified by the work of UN Special Rapporteurs[24] and recognized by a number of international instruments.[25]

Further, States are under a positive duty to take reasonable and appropriate measures to secure certain civil and political rights particularly affected by pollution.[26] The European Court of Human Rights ("ECHR") in *Fadeyeva v. Russia* observed that the State's responsibility in environmental cases may arise from a failure to regulate private industry, and inquired whether the State could reasonably be expected to act so as to prevent or put an end to the infringement of the applicant's rights.[27] In *Oneryildiz v. Turkey,* the Grand Chamber of the ECHR further elaborated on the positive obligation to take all appropriate steps to safeguard life, including the duty to put in place a legislative and administrative framework. In the words of the Court, "This obligation indisputably applies in the particular context of dangerous activities, where, in addition, special emphasis must be placed on regulations geared to the special features of the activity in question, particularly with regard to the level of the potential risk to human lives." [28]

When viewed under a human rights and environment lens, REACH could represent (when completed and depending on the final outcome) a concrete step towards the realization of the right to health. This is important for the advancement of economic, social, and cultural rights, as well as for the protection of civil and political rights enshrined in the European Convention on Human Rights. In addition, in light of the persistence and long-range travel potential of certain chemicals and given the volumes of chemicals produced in the EU, REACH ultimately also contributes to improving public health and the environment

globally, and in meeting Europe's commitment to the global 2020 goal for a toxic-free future.

REACH and the International Trading System

Conformance with international trade law was an explicit consideration in the crafting of REACH. While the draft legislation was engineered by DG-Enterprise and DG-Environment, they deferred to DG-Trade on ways to steer clear of WTO violations. The treatment of substances in articles (*i.e.* chemicals in products) examined above illustrates the influence of trade law in REACH design. As noted earlier, the European Commission conducted a novel and broad Internet consultation in 2003 to hear concerns, including on trade.

On its part, the Bush administration worked with the U.S. chemical industry to undermine REACH, as a House Committee report describes.[29] The administration said publicly that REACH would threaten $20 billion in U.S. chemicals exported to the EU. The House Committee report also contains references to cables sent in March 2002 and April 2003 by U.S. Secretary of State Colin Powell to U.S. trading partners in Latin America and Asia as well as Europe to oppose REACH. It may be that some of the submissions to the WTO, presented below, are the result of the U.S. campaign against REACH. Further, the U.S. Department of Commerce developed an extensive outreach plan to influence "stakeholders" within the European Union and generate opposition to REACH, and also targeted countries of the Asia-Pacific Economic Cooperation ("APEC").[30]

In January 2004, in accordance with the WTO's TBT Agreement, the EU notified REACH to the WTO's Committee of Technical Barriers to Trade ("TBT Committee").[31] WTO Members raised a number of issues relating to the compatibility of REACH and the TBT Agreement, including questions concerning national treatment, unnecessary obstacles to trade, international standards, and special and differentiated treatment for developing countries. Some countries also mentioned concerns with respect to intellectual property rights and the treatment of confidential information in REACH. This section provides an overview of the relevant TBT issues identified in these submissions to the TBT Committee, with a view to identifying the potential claims in a possible WTO challenge to REACH by the United States or other nations.

National Treatment

The TBT Agreement provides that the WTO Members shall ensure that their technical regulations do not accord products imported from other Members with less favorable treatment than those accorded to like products of national origin.[32] WTO Members generally pointed out that REACH is more difficult for non-EU manufacturers to comply than for EU manufacturers, which leads to *de facto* discrimination.[33] Singapore elaborated on the *de facto* discriminatory effects by noting that due to long distance and unfamiliarity with REACH, non-EU producers and suppliers will face more hardship than EU producers to comply with REACH. Thailand also raised concerns about REACH's data sharing provisions (which allow the first registrant to charge 50 percent of the cost from subsequent registrants),[34] noting that such a scheme favors EU producers because they will likely register early and then charge subsequent non-EU registrants.[35]

Unnecessary Obstacles to International Trade

Under the TBT Agreement, technical regulations shall not be prepared, adopted, or applied to create unnecessary obstacles to international trade, and regulations shall not be more trade-restrictive than necessary to fulfill a legitimate purpose.[36] To some degree, every comment submitted to the TBT Committee regarding REACH raised concerns about unnecessary obstacles to international trade. The high costs associated with implementation and compliance, it was argued, would drive many competitors out of business, especially small and medium enterprises in developing countries. Some commented that the scope of REACH was broader than any OECD country, imposing administrative burdens on many substances that may pose negligible risk to health and the environment. Several countries commented that the hazard-based and volume-based approaches in REACH were incompatible with a scientific, risk-based evaluation of substances.[37] Finally, several WTO Members claimed that REACH did not recognize test results generated outside the EU, even where such data was obtained in conformity with the OECD Principles of Good Laboratory Practice, increasing compliance costs, frustrating cooperation, and imposing unnecessary obstacles to trade.[38]

Relevant International Standards

The TBT Agreement requires that Members use relevant international standards that exist unless such standards would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued.[39] This provision was directly at issue in *EC – Sardines*, where the Appellate Body held that where a Member departs from a relevant international standard because it considers it to be ineffective to achieve its legitimate objectives, the burden of proof will nevertheless fall on the complaining Member.[40] It is of course open to question whether existing international standards exist to achieve the goals of REACH. Several comments charged that REACH was incompatible with international efforts to control chemicals, such as the OECD High Production Volume ("HPV") initiative or the Globally Harmonized System ("GHS") for classification and labeling.[41]

Special and Differential Treatment for Developing Countries

The TBT Agreement requires that in the preparation and application of technical regulations, Members take into account the special developmental, financial, and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to exports from those Members.[42] Interpreting a similarly worded provision in the WTO Agreement on Sanitary and Phitosanitary Measures, the *EC-Biotech* Panel noted that "taking into account" does not prescribe a specific result to be achieved, and that in weighing and balancing the various interests at stake, the needs of a develop-

ing country did not have priority over, for instance, other legitimate interests.[43] The TBT Agreement also provides that the Member imposing technical regulations shall take reasonable measures to arrange for the regulatory bodies to advise other members, grant them technical assistance on mutually agreed terms and conditions.[44]

Brazil, China, Cuba, and Thailand raised particular concerns about REACH and these provisions of the TBT Agreement, noting that advice and technical assistance were necessary, including by way of implementation guidance by sectors.[45]

Next Steps

At the time of writing, the Council has been discussing the Parliament's November 17, 2005 vote. The Council struck a political agreement on Dec. 13, 2005 under the UK Presidency. A Common Position was approved in February 2006 reflecting some of the Parliament's first reading. The Parliament will take up the Council's draft in second reading in May or June 2006. The Parliament can then either accept the Council's amendments or pass certain amendments for consideration in the formal conciliation process. In the international sphere, the comments submitted to the TBT Committee may prelude a brewing trade challenge to certain measures adopted pursuant to REACH.

Conclusion

REACH is coming. After years of dialogue, debate and bruising politics, the EU has created a new model for regulating chemicals. Did the EU over-reach? Will the final compromises so weaken the system that few health benefits will result? Will REACH lead the world toward greener chemistry or burden EU producers and outsource pollution elsewhere?

REACH is motivated by a desire to eliminate substances that negatively impact on human health and its underlying determinants, including the environment. But this first requires an adequate understanding of the basic characteristics of chemicals – something that is impossible with the current level of knowledge and built-in incentives. By ensuring that much of this information on chemicals will be made publicly available, it is likely that governments, companies, and civil society beyond the EU will benefit as well.

Endnotes: Europe's REACH

[1] Inger Schörling, REACH - The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why? (Greens/European Free Alliance in the European Parliament, Brussels) April 2004.

[2] Commission of the European Communities, White Paper: Strategy for a Future Chemicals Policy, at 6, COM(2001) 88 final, Feb. 27, 2001 [hereinafter White Paper].

[3] It is important to distinguish "chemicals policy" (which focuses generally on what substances are allowed in commerce) from traditional pollution issues (which concern how to manage wastes, emissions, discharges, etc.).

[4] *See infra,* Evolution of EU Chemicals Policy.

[5] *See* Schörling, *supra* note 1.

[6] Dir 67/548/EEC.

[7] Dir 76/769/EEC.

[8] *See infra*, Roots of the Problem: Piecemeal Approaches to Chemicals Management.

[9] Dir 88/379/EEC.

[10] Norway Ministry of the Environment, Esbjerg Declaration, *available at* http://www.dep.no/md/nsc/declaration/022001-990243/dok-bn.html (last visited Apr. 17, 2006).

[11] *See generally*, UNEP Strategic Approach to International Chemicals Management, http://www.chem.unep.ch/saicm (last visited Apr. 17, 2006).

[12] The 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") replaced the Oslo and Paris Conventions as between the Contracting Parties (art. 31). "Oslo Convention" means the *Convention for the Prevention of Marine Pollution by Dumping from Ships and Aircraft* signed in Oslo on Feb. 15, 1972, as amended by the protocols of Mar. 2, 1983 and Dec. 5, 1989.

"Paris Convention" means the Convention for the Prevention of Marine Pollution from Land-based Sources, signed in Paris on June 4, 1974, as amended by the protocol of Mar. 26, 1986.

[13] Annual Report of the OSPAR Commission, 2002 - 2003, vol. 1, chp. 4, ¶ 75-76.

[14] *See* European Commission website, "REACH," http://europa.eu.int/comm/environment/chemicals/reach.htm (last visited Apr. 17, 2006).

[15] Currently there are 732 Members of the European Parliament after accession of ten new Member States. See generally, European Parliament website, "How Parliament is Organised," http://www.europarl.eu.int/parliament/public/staticDisplay.do?language=EN&id=45 (last visited Apr. 17, 2006).

[16] *See generally*, The Council of the European Union website, http://ue.eu.int/showPage.ASP?lang=en (last visited Apr. 17, 2006).

[17] For a detailed explanation of the co-decision process, see Co-Decision Guide, available at http://ue.eu.int/uedocs/cms_data/docs/2004/4/29/Codecision%20guide.pdf (last visited Apr. 17, 2006).

[18] *See* European Commission, Q&A on REACH, Mar. 23, 2006, at 14. (The tonnage-triggered system for registration is based on a trade-off between workability and the need to cover all substances, at 24).

[19] European Commission, REACH in Brief, Sept. 15, 2004, at 5. (Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control exposures of humans and the environment.)

[20] *See* Q&A on REACH, *supra* note 18, at 4.

[21] *See* Q&A on REACH, *supra* note 18, at 16-17; *see generally*, Trans Atlantic Consumer Dialogue, Briefing Paper on REACH, Doc No. Trade – 14pp-04 (June 2004), at 4.

[22] Other aspects of REACH not mentioned or elaborated here include, inter alia, classification and labeling, decision-making procedures, and downstream users.

[23] International Covenant on Economic, Social, and Cultural Rights ("ESCR"), entered into force January 3, 1976, Art. 2.1 and 12, 993 U.N.T.S. 3.; *see also*, World Conference on Human Rights, Vienna, 14-25 June 1993, Vienna Declaration and Programme of Action, 12 July 1993, A/CONF.157/23; World Health Organization, Health and Human Rights, July 2002; see generally, Sofia Gruskin & Daniel Tarantola, Health and Human Rights, The Oxford Textbook of Public Health (Detels et al. eds., 4th ed. 2004).

[24] *See generally*, Review of Further Developments in Fields with Which

Endnotes: Europe's REACH *Continued on page 65*

Safeguarding Organic Food:

The Need For International Certification Standards

*by Blase Kornacki**

The commonly acknowledged meaning of "organic" "prohibit[s] the use of synthetic fertilizers, pesticides, growth regulators, and livestock feed additives, and require[s] long-term soil management, emphasis on animal welfare and extensive record keeping and planning."[1] Despite these general guidelines, the world struggles to reach formal agreement on a global definition of "organic." As a result of this shortcoming, there is no uniform international standard for what makes a product organic.[2] The lack of a universal definition and the absence of a common organic certification standard presents formidable trade barriers to the expanding organic industry.

To certify an organic product, an accredited agent for the intended market must inspect each producer or manufacturer for compliance with that market's standards.[3] For example, the U.S. Department of Agriculture ("USDA") has established a set of national standards that "organic" food must meet, whether it is grown in the United States or imported from abroad.[4] Thus, a Brazilian farmer seeking to export his organic produce to the United States must obtain certification through one of the 95 Accredited Certifying Agents ("ACAs") recognized by the USDA.[5] Of the 95 ACAs, however, only 40 are located outside of the United States, unequally distributed amongst eighteen countries, and only one is located in Brazil.[6] The limited access to certifying agents makes certification difficult and expensive, and thus raises obstacles to trade in the U.S. organics market.[7] Moreover, the lack of uniform certification standards hurts the efficiency of organic trade, contributes to higher prices of organic goods, and fails to meet the growing demand for organic products.

The need exists to provide clear organic regulations for consumers and farmers across national borders. A progressive example of this is an adopted European Commission proposal that aims to unite the 25-member European Union under a common certification standard.[8] The proposal aims to clarify the criteria of organic certification while still considering local conditions and stages of development.[9] Despite this step towards uniformity, exporters will still have to seek certification through multiple agents for each country of import.

As the worldwide organics market continues to grow at the rapid rate of thirteen percent per year,[10] fluid mechanisms of international organic certification become increasingly necessary to satisfy demand and facilitate trade. Countries must agree on a common definition of organic and share the burden of certification. In 2002, Japan became the first company to accept organic products certified under the USDA standard.[11] However, Japan remains the only foreign country to recognize the USDA seal.[12] More recently, the United States recognized the ability of Canada, New Zealand, Denmark, and the United Kingdom to accredit agents who will certify organics under the USDA standard.[13] Sharing the task of certification with other governments is a good starting point in the search for a common organic standard and shows the potential for a common definition of "organic" sometime in the future.

Endnotes:

[1] Luanne Lohr, *Factors Affecting International Demand and Trade in Organic Food Products,* Changing Structures of Global Food Consumption and Trade, at 67 (May 2001), *available at* http://www.ers.usda.gov/publications/wrs011 (last visited Mar. 27, 2005).

[2] United States Department of Agriculture, USDA Market Profile for Organic Food Products, at 3 (Feb. 2005), *available at* http://www.fas.usda.gov/agx/organics/USMarketProfileOrganicFoodFeb2005.pdf#search='us%20market%20for%20organic%20food%20products' (last visited Mar. 27, 2005) [hereinafter USDA].

[3] USDA, *id.*

[4] USDA, *id.*

[5] The National Organic Program, Accredited Certifying Agents, *available at* http://www.ams.usda.gov/nop/CertifyingAgents/Accredited.html (last visited Mar. 27, 2005).

[6] National Organic Program, *id.*

[7] *Organic Food Market Waits for Regulations to Take Off*, VALOR ECONOMICO, South Am. Bus. Info., Jan. 26, 2006.

[8] *EU Proposes Harmonized Rules for Organic Food Products,* Eur. Rpt. (Dec. 23, 2005); *see also EU Adopts New Regulations for Production and Labeling of Spirits and Organic Food,* Food & Drink Weekly, (Jan. 2, 2006).

[9] Press Release, European Commission, Organic Food: New Regulation will Improve Clarity for Consumers and Farmers (Dec. 21, 2005), http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1679&format=HTML&aged=0&language=EN&guiLanguage=en (last visited Mar. 28, 2006).

[10] *Global Organic Food Market Seen Growing 13% a Year*, Fin. Times Info. Ltd. - Asia Intelligence Wire, Bus. line, Jan. 23, 2006.

[11] Press Release, U.S. Department of Agriculture, Japan Accepts U.S. Organic Standards for Some Food Exports, (Mar. 27, 2002), http://usinfo.org/wf-archive/2002/020328/epf409.htm (last visited on Mar. 27, 2005).

[12] USDA, *supra* note 2, at 10.

[13] USDA, *supra* note 2.

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Toxic Trains: Chemical Transportation Regulation, Terrorism, and the U.S. Capitol

*by Chris McChesney**

Introduction

Not far from the U.S. Capitol building in Washington, DC (the "District") runs a railroad track that is part of CSX Corporation's (a major North American railroad company) North-South railroad corridor along the Eastern coast of the United States.[1] While a railroad track is not normally a cause for concern, rail cars on this particular track carry large volumes of some of the world's most dangerous chemicals.[2] For instance, 90-ton rail tankers filled with hazardous chemicals such as chlorine gas regularly pass over a small bridge that is unsecured, in a low traffic area, and easily accessible to anyone.[3] A recent study by the Naval Research Laboratory estimated that a terrorist explosion set in such a strategic location, during a political rally or celebration on the National Mall, could result in the release of toxic gases with the potential to seriously injure or kill over one hundred thousand people within half an hour.[4]

The possibility of such a catastrophic event should be of major concern not only to the chemical transportation industry, but also to the federal and District government. While the federal government has done little to address this risk, the City Council of Washington, DC ("DC Council") has taken measures to regulate the transportation of hazardous materials (hereinafter "hazmats") around the Capitol.[5] The Bush Administration and CSX are currently fighting this regulation in the *CSX Transportation, Inc. v. Anthony A. Williams* case. This article will argue that the DC Council's regulation of hazmats in the District should be upheld, and will also explore other potential means to secure transportation of dangerous chemicals in and around the nation's Capitol.

Regulation of Hazmats Around the U.S. Capitol

The Terrorism Prevention in Hazardous Materials Transportation Emergency Act of 2005

The controversy over hazmat regulation around the U.S. Capitol began on February 1, 2005 when the DC Council approved the Terrorism Prevention in Hazardous Materials Transportation Emergency Act of 2005 (hereinafter "the DC Act").[6] The DC Act creates an area deemed the "Capitol Exclusion Zone," defined as: "all points within 2.2 miles of the United States Capitol building; provided, that the Capitol Exclusion Zone shall not extend beyond the geographic boundaries of the District of Columbia."[7] The Act prohibits the shipment of hazmats through the zone without a permit from the District's Department of Transportation ("DDOT").[8] The CSX Corporation controls the only two rail corridors that carry hazmats through the District, the North-South corridor and the East-West line, which originates in Washington, DC. This regulation effectively banned CSX from transporting hazmats through the District by either of these two tracks. Wishing to prevent increased costs of transportation, CSX brought suit against the District to enjoin the DC Act from going into effect.[9] This suit spawned continuing litigation that centers not only on the regulation of chemical transportation, but also on national security and federalism, including the precarious role the District has as both the federally controlled capital and a local state-like government. Although the DC Court of Appeals ultimately placed a stay on the DC Act,[10] CSX has agreed to temporarily halt transportation of hazmats through the District during the pending litigation.[11]

The CSX v. Williams Litigation

Procedural History

In *CSX v. Williams*, CSX sought to enjoin the enforcement of the DC Act, alleging that the act: (1) violated the Commerce Clause of the U.S. Constitution; (2) was preempted by federal law; and (3) went beyond the authority granted to the DC local government in the Home Rule Act.[12] In a well-reasoned opinion, U.S. District Judge Emmet G. Sullivan denied both CSX's Motion for Summary Judgment and Motion for a Preliminary

A map depicting the proximity of the CSX bridge to the U.S. Capitol Building.

Injunction.[13] Additionally, the United States was denied its Motion to Enforce a decision made by the Surface Transportation Board ("STB") against Washington, DC.[14]

Even though the U.S. Court of Appeals for the District of Columbia reversed the District Court's denial of a Preliminary

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Injunction, ruling in favor of CSX,[15] this article asserts that Judge Sullivan used the correct analysis. A preliminary injunction requires the court to consider four factors: likelihood of success of the moving party, irreparable harm to the moving party, a balancing of the harms/risks, and the public interest.[16] With respect to the likelihood of success, the District Court reviewed all of CSX's claims against the act and found it unlikely that CSX would prevail on the merits.[17] However, the Court of Appeals disagreed, finding that CSX was likely to prevail on the claim of federal preemption.[18] Because it is not contested that CSX will be unlikely to prevail on its claim of a violation of the "dormant" commerce clause, and because the United States will be unlikely to prevail on its Motion to Enforce the STB's opinion, this article will only discuss the issues surrounding the claim of federal preemption.

Issues of Federal Preemption

CSX and the United States claimed that the Federal Railroad Safety Act ("FRSA"), the Hazardous Materials Transportation Act ("HMTA"), and the Interstate Commerce Commission Termination Act ("ICCTA") preempted the DC Act.[19] The FRSA provides that "states may regulate in the area of railroad safety and security 'until' the federal government 'prescribes a regulation or issues an order covering the subject matter of the State requirement,'" and that for local hazards, states may impose more strict regulations "as long as they are not 'incompatible' with federal regulation, and do not 'unreasonably burden interstate commerce.'"[20] The District Court interpreted this to mean that the DC Act would survive a preemption challenge against the FRSA if the act was filling a gap in federal law or if it was addressing a mainly local hazard without interfering with federal law.[21] CSX and the United States argued that the DC Act facially violated the FRSA because Final Rule HM-232, issued by the U.S. Department of Transportation ("U.S. DOT"), addressed the same subject matter.[22] However, HM-232 merely requires private industry "to develop and implement *voluntary* security plans" [*emphasis added*].[23] As such, the District Court found that the rule did not conflict with federal law; rather, it helped further it.[24]

The HMTA similarly allows states to regulate the transportation of hazmats unless the non-federal regulation creates an obstacle to complying with federal law or if it is not possible to comply with both regulations.[25] Again, CSX and the United States argued that HM-232 preempted the DC Act under this standard.[26] According to the federal government, the purpose behind such lax regulation is to allow for flexibility in how industry provides for security.[27] CSX and the United States claimed that the DC Act hindered this flexibility.[28] While the District Court did not question the government's policy decision regarding the flexibility of security plans, it determined that the DC Act neither presented an obstacle to the federal policy, nor was it impossible for CSX to comply with both the DC Act and the federal policy.[29]

The ICCTA, unlike the FRSA and HMTA, does not expressly allow for state regulation; CSX and the United States thus argued that the ICCTA preempted any state attempt to regulate the railroads.[30] The District Court disagreed with this position, stating that such a position "interprets the ICCTA in a 'contextual vacuum', completely ignoring the existence of the surrounding statutory framework, including the FRSA."[31] The District Court went on to hold that the DC Act did not deal with interstate commerce or the infrastructure of the railroad – both of which would fall under the jurisdiction of the ICCTA – the DC Act only dealt with safety and security, and thus fell within the historical cooperation of state and federal regulation of the railroads.[32]

The District Court concluded that the DC Act would likely not be preempted by any of the federal laws presented by CSX and the United States.[33] The Court of Appeals, however, did not agree and ordered the reversal of the District Court's denial of a preliminary injunction.[34] The Court of Appeals found that CSX was likely to succeed in its argument that the FRSA would preempt the DC Act.[35] Accordingly, the court found a preliminary injunction to be appropriate.[36] The difference in opinions between the District Court and the Court of Appeals is based on conflicting interpretations of whether the current federal regulation HM-232, substantially covered the subject matter of the DC Act, and whether the DC Act was an obstacle to the implementation of the federal regulation or "unreasonably burden[ed] interstate commerce."[37] The Court of Appeals decided the District Court was incorrect in determining what HM-232 covered, and that the DC Act created both an obstacle to complying with HM-232 and "unreasonably burden[ed] interstate commerce."[38] For example, the Court of Appeals reasoned that because U.S. DOT specifically rejected routing requirements during the development of HM-232, the rule substantially subsumes the subject matter of the DC Act.[39] As such, HM-232 likely preempted the DC Act.[40]

The DC Act places tight regulations on the transportation of hazmats through a particularly high-risk area.

Pursuant to §20106 of the FRSA, however, both HM-232 and the DC Act can stand so long as the DC Act does not interfere with compliance of HM-232 and it does not "unreasonably burden interstate commerce."[41] Again, the Court of Appeals agreed with CSX and the United States, determining that the DC Act frustrated HM-232 by not allowing rail carriers the flexibility the regulation intended.[42] In addition, the court found that the DC Act likely would "unreasonably burden interstate commerce," because if allowed to stand, other local governments would enact a patchwork of similar bans that would interfere with the national hazmat transportation system.[43]

While CSX and the United States successfully moved the Court of Appeals to preliminarily enjoin the DC Act from being

enforced, it has yet to be determined whether the District Court will issue a permanent injunction. Though the Court of Appeals decided that CSX and the United States are likely to succeed on the claim of federal preemption, this reasoning was flawed. The DC Act deals with the unique potential for a chemical catastrophe to occur in a highly populated urban center that is also in the seat of the federal government. Although HM-232 gives private industry the responsibility of securing the nation's railroad system, it does not "substantially" cover the unique local safety risks that face Washington, DC. Rather, the rule merely touches the subject matter of security and does not "substantially subsume" it, as required by caselaw.[44] Additionally, the DC Act only prohibits the most hazardous of chemicals transported through the Capitol Exclusion Zone and allows an exception for permit holders. This does not create a significant obstacle in allowing industry flexibility in implementing self-determined security measures.

Critics might argue that the DC Act essentially bans hazmat transportation through the entire state, which would be a violation of the dormant commerce clause.[45] However, this is not what the DC Act does. The DC Act places tight regulations on the transportation of hazmats through a particularly high-risk area of the DC Council's jurisdiction.[46] As previously discussed, under the current federal statutory scheme regulating the transportation of hazmats, states are allowed to impose more stringent regulations than those of the federal agencies. As such, the District Court should not permanently enjoin the DC Act.

Alternative Means to Protect the Capitol Area

If the DC Act is permanently enjoined, there are other possible means to secure transportation of dangerous chemicals in and around the Capitol. Currently, CSX and the U.S. Department of Homeland Security ("DHS") are working to create a "virtual boundary" around the District's rail corridor.[47] Such a boundary would involve two hundred surveillance cameras around the rail corridor that would allow for 24-hour monitoring.[48] Also involved in the plan are several rapid response teams that would act in conjunction with the surveillance to increase security of the corridor.[49]

While this "virtual boundary" might increase security, it will not eliminate the threat. To more adequately address the issue, bills have been introduced in Congress, yet none have been passed.[50] One of the more comprehensive bills is Senator Joseph Biden's (D-DE) Hazardous Materials Vulnerability Reduction Act of 2005 (hereinafter "HMVRA") and its House companion bill.[51] The main purpose of HMVRA would be to require DHS to promulgate regulations to properly secure high-risk urban corridors involving the transportation of hazmats, including dangerous chemicals, via rail.[52] These regulations would include criteria for determining high-risk corridors, which would then require that any hazmats be rerouted around the corridor with few exceptions.[53] Additionally, the Secretary of Homeland Security would annually report to Congress on the frequency of and contents of hazmat transportation and owners of hazmat transportation operations would have to notify local government officials when transporting hazmats through their jurisdiction.[54] The other sections of the bill provide for increased hazmat transportation security not specifically related to urban areas. Section 4 of HMVRA would authorize the Secretary of Homeland Security to award grants to both local governments and private railroad companies for the purposes of training and providing safety equipment to those who work transporting hazmats. Section 5 of HMVRA would require the Secretary to report to Congress after studying potential new security technologies, and section 6 would provide for whistleblower protection.[55] Such legislation would be a tremendous step forward in securing the transportation of hazmats, including dangerous chemicals. Currently, the bill is still in committee, but the Bush Administration does not support it.[56]

Conclusion

In an era where defense against terrorism is a national priority, the chemical industry has the burden of addressing immense security concerns while still providing a national service. The government of Washington, DC has a unique obligation to protect not only a densely populated urban core, but also the seat of the federal government. The transportation of any dangerous chemicals or other hazmats, poses a threat in any location, but the transportation corridor through the District poses a unique risk that must be addressed. While the Administration has facially addressed the issue, the DC Council properly took action to protect the people within its jurisdiction. Because of industry complaint, this action has all but been destroyed, and now faces a permanent injunction. It is this article's position, however, that the Terrorism Prevention in Hazardous Materials Transportation Emergency Act of 2005 should not be permanently enjoined. In conjunction with the DC Act, or in light of the Act being enjoined, Congress should take action not only to protect itself, but the city it calls home. Senator Biden's bill, if passed, would be a step in the right direction in limiting the transportation of hazardous chemicals through Washington, DC.

Endnotes: Toxic Trains

[1] *Washington's Deadly Bridge*, N.Y. Times, July 5, 2005, at A1, *available at* http://www.nytimes.com/2005/07/05/opinion/05tue1.html?ex=1278216000&en=7806df7623b3d0a2&ei=5090&partner=rssuserland&emc=rss (last visted Mar. 19, 2006).

[2] *Deadly Bridge, id.*

[3] *Deadly Bridge, id.*.

[4] Senator Joseph Biden, Introductory Statement, S.1256: The Hazardous Materials Vulnerability Reduction Act of 2005, June 16, 2005, *available at* http://www.govtrack.us/congress/billtext.xpd?bill=s109-1256 (last visited Mar. 12, 2006).

[5] *See Court Orders Feds to Produce Documents in Toxic Trains Case*, Press Release, DC Councilmember Kathy Paterson (Dec. 14, 2005), *available at* http://www.dccouncil.washington.dc.us/patterson/pages/prinfo/Orderfor%20discovery%20in%20Toxins%20Case%2012.14.05.doc (last visited Mar. 12, 2006); *Cities Tackle Chemical Transportation*

Endnotes: Toxic Trains *Continued on page 81*

Strategic Approach to International Chemicals Management: Lack of Interest Belies Importance

*by Angela Logomasini**

Introduction

In February 2006, the United Nations Environment Programme ("UNEP") held the International Conference on Chemicals Management ("ICCM") in Dubai, United Arab Emirates at which more than one hundred nations adopted a plan for the Strategic Approach to International Chemicals Management ("SAICM"). SAICM is designed to coordinate management of chemicals, wastes, and other substances on a global scale, setting up a global chemicals agency to coordinate efforts. The program is dubbed as a voluntary initiative through which "stakeholders" will engage in efforts to ensure safe management of chemicals. Centralization of chemical policy is deemed important because of the number of chemicals in world commerce today (estimates range up to 100,000) and because it has been estimated that chemical production will increase by 80 percent within the next fifteen years.[1]

This issue has been under development at the United Nations since 1992 and is now maturing into an international initiative that promises far reaching impacts. Yet many of the businesses that will likely be affected probably have not heard of, or know little about, SAICM. That is not surprising given minimal press coverage of the issue. To date, the *New York Times*, *USA Today*, the *Financial Times*, and the *Wall Street Journal* have largely ignored the issue. Yet inadequate press coverage belies the importance of the issue.

The History of SAICM

SAICM began as an item discussed in Chapter 19 of *Agenda 21*[2] and the Rio Declaration on Environment and Development, which are products of the United Nations Conference on Environment and Development ("UNCED"), Rio de Janeiro in 1992. It proposed a system for global chemicals management, outlining six program goals that include:

- Expanding and accelerating international assessment of chemical risks;
- Harmonization of classification and labeling of chemicals;
- Information exchange on toxic chemicals and chemical risks;
- Establishment of risk reduction programs;
- Strengthening of national capabilities and capacities for management of chemicals; and
- Prevention of illegal international traffic in toxic and dangerous products.[3]

The Rio meeting led to the creation of the Intergovernmental Forum on Chemical Safety ("IFCS" or "Forum"), which was designed to facilitate these goals and set in motion a process for implementation. The Forum is described as follows in a document on its history:

> The IFCS is a non-institutional arrangement whereby representatives of governments meet, together with intergovernmental and non-governmental organi[z]ations, to consider all aspects of the assessment and management of chemicals. The aim is to integrate and consolidate national and international efforts to promote the objectives of Chapter 19 of *Agenda 21*. The IFCS provides policy guidance, identifies priorities, develops strategies and, where appropriate, makes recommendations to governments, international organi[z]ations, intergovernmental bodies and non-governmental organi[z]ations involved in chemical risk assessment and environmentally sound management of chemicals.[4]

In October 2000, the Forum met in Salvador da Bahia, Brazil where representatives of 83 governments produced and agreed to the Bahia Declaration, which reiterated and affirmed a commitment to the goals in Agenda 21, and resolved to set up institutions for implementing them.[5] In addition, the Bahia meeting produced a document setting the priorities for the program.[6] In 2002, the SAICM concept was endorsed by the World Summit on Sustainable Development in Johannesburg, South Africa, calling for completion of the program's founding documents by 2005.[7]

The first preparatory meeting for SAICM, referred to as "SAICM PrepCom1," took place in Bangkok, Thailand, immediately following another IFCS meeting. Since then the UNEP has hosted two additional meetings – SAICM PrepCom2 in Nairobi, Kenya, in October 2004; and SAICM PrepCom3 in Vienna, Austria in September 2005.

At the September 2005 meeting, it was expected that three framing documents for the SAICM program would be completed, which would then be finalized in February 2006. These are: the High Level Declaration,[8] the Overarching Policy Statement,[9] and the Global Plan of Action.[10] These documents with all the changes from the September meeting are included in the report for Prepcom3.[11]

The Establishment of SAICM

SAICM is supposed to be a voluntary initiative of world governments to ensure the proper management of chemicals and wastes through information sharing, harmonization of chemical risk standards and labeling, and training. In addition, it is sup-

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posed to ensure ratification and implementation of environmental treaties, but it is unclear as to how those goals will be pursued.

The objective of PrepCom3 (September 2005) was to produce a clean text that would be finalized at the Dubai meeting in February 2006. However, during the September meeting there apparently was considerable debate, with the United States taking a stand against language that set the "precautionary principle" as an object of the program.

Although there is no set definition for the precautionary principle, it essentially demands that products be proven safe before entering the marketplace. Currently, U.S. regulators follow a more risk-based approach. They assess the risks of products and set regulations that allow an "acceptable" level of risk. Under the present U.S. system, regulators must demonstrate products are unsafe before removing them from the market. Although this approach often produces very restrictive regulations – including bans of many products – it provides some protection against arbitrary governmental coercion.

In contrast, the precautionary principle reduces regulatory accountability by shifting the burden of proof, demanding that manufacturers prove that their products are safe before allowing them to enter into, or continue in, commerce. Since nothing in life is one hundred percent safe, the precautionary principle means that governments can regulate products simply because they decide that products *might* pose public health risks – making regulation arbitrary in nature and subject to political whims.

U.S. negotiators advocated a risk-based approach that is more compatible with our regulatory tradition during the September 2005 meeting. The result of that meeting was a document that included bracketed language that would be subject to negotiation at the Dubai meeting. Of note, at that time the term "voluntary" was also in brackets, throwing into question stated intentions that the program would be voluntary rather than binding international law.

[M]any of the businesses that will likely be affected probably have not heard of, or know little about, SAICM.

At the Dubai meeting, the policy declaration was approved, and renamed as the Dubai Declaration. It created the SAICM Secretariat housed in UNEP. In addition, nations pledged US $10 million for a program called Quick Start, which is to provide assistance to developing nations.

Opposition to some provisions by the United States and others nearly halted the SAICM process, but a last-minute compromise agreement was negotiated and agreed to just before midnight on the last day of the conference.[12] Language on the precautionary principle was removed and now the document reads that the program will "take into account" the wording of the Rio Declaration, creating confusion as to whether the program will follow the precautionary principle. There is reason to believe that it eventually will take a precautionary approach since the Rio Declaration endorses the principle.

Additional compromises secured by the United States and its allies included provisions to allow participating countries to exempt food and medicine from SAICM provisions because nations have domestic regulations governing such issues. The United States also demanded that the voluntary nature of the program be clear. Final language on that topic reads: "We acknowledge that as a new voluntary initiative in the field of international management of chemicals, the Strategic Approach is not a legally binding instrument."[13]

A number of environmental activists expressed dismay with the result. Clifton Curtis of the World Wildlife Fund's Global Toxics Program says the agreement result is "akin to achieving half a loaf of bread, not well baked."[14] According to news reports, environmentalists complained that the program has been rendered ineffective by officials from the United States, Australia, Japan, Korea, and Canada.[15]

Policy Implications of SAICM

Despite the paucity of coverage, SAICM represents a policy whose scope is as extensive as that of the Kyoto Protocol on climate change,[16] which seeks to control use of the world's energy. SAICM covers the other half of the universe. Whereas Kyoto attempts to regulate the world's energy, SAICM seeks to manage matter, or all non-living physical objects in the universe. Nonetheless, it is deemed somewhat innocuous because it is considered voluntary effort.

Despite its nonbinding nature, SAICM is likely to possess a substantial policy role – setting global standards that will likely become models for imposition by national governments to follow and serve as the basis for environmental treaties and other international agreements. And unlike the SAICM process, these treaties and laws will be binding.

In fact, one of SAICM's key goals is to ensure that existing chemical and waste disposal related treaties all become ratified and are subject to implementation legislation in the various nations. The United States is a likely target of ratification/implementation efforts. It has yet to ratify a number of treaties such as the Stockholm Convention of Persistent Organic Pollutants,[17] which bans a number of chemical internationally. In addition, United States has signed but not ratified the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal,[18] which regulates shipment of hazardous wastes.

SAICM supporters have indicated that the program is designed to have important policy impacts. For example, Klaus Toepfer, Executive Director of UNEP, commented that existing chemical treaties alone are not enough, concluding: "it has been clear for some time that simply ticking off groups of chemicals one by one are becoming impractical. A new approach, a new way forward for chemicals management was needed, which is what SAICM now offers."[19]

SAICM's "Global Action Plan" offers an idea as to the program's ambitious agenda for chemicals. It includes nearly 300 "concrete measures" for the various stakeholders to pursue. These include many items that are restrictive in nature. For example, among them are intentions to "restrict availability of" or "substitute" "highly toxic pesticides;" "promote substitution of hazardous chemicals;" "regulate the availability, distribution and use of pesticides"; "halt the sale of and recall products" that pose "unacceptable risks;" and "eliminate the use" of certain "hazardous chemicals."[20]

SAICM and REACH

Another reason to believe that SAICM will have a substantial regulatory role is that many see it as the perfect vehicle for the EU to globalize its REACH proposal, which is expected to become law in Europe by 2007. "REACH" stands for Registration, Evaluation, and Authorization of Chemicals. This program applies a precautionary approach to chemical regulation that will be followed by government regulation, demanding that firms demonstrate safety through a complicated registration and information collection program that inevitably results in the ban of some products.

Opposition to some provisions by the United States and others nearly halted the SAICM process. . .

Such globalization may be, in the minds of Europeans, a way to "level the playing field." Such intentions for SAICM were recently noted in one European publication:

> There can be no doubting the links between the future European system for the registration, evaluation and authori[z]ation of chemicals (REACH) and SAICM: the two mechanisms share the same general objective (minimi[z]ing the impact of chemicals on the environment and health). Moreover, many of the recommendations included in SAICM will also be implemented in the context of the new EU regulation (information on substances, minimi[z]ing risks, liability of industry in ensuring safety, etc.) … EU sources also point out that the REACH process was actually launched in the 1990s. At the international level, the approach can be traced back to the Johannesburg Summit Declaration of September 2002 in which the parties pledged to reduce the negative impact of chemicals by 2020. This concrete objective spurred the EU into pressing ahead. Work at the European and international level since 2002 has therefore followed a convergent parallel path.[21]

Europeans had previously considered other ways to globalize REACH. For example, there is considerable evidence that they planned to push international implementation of an early version of REACH through the Organisation for Economic Co-operation and Development.[22] Globalization of this program would expand regulatory controls and impose heavy costs on businesses around the world. Application of REACH in Europe alone is destined to be expensive for Europe and its trade partners. The European Commission-funded study estimated REACH's costs to fall somewhere between a low estimate of €2.8 (over eleven years) to a high estimate of €5.2 billion (over fifteen years).[23] However, these studies only assess a fraction of REACH costs. The likely benefits of the REACH program have not been adequately demonstrated.[24]

SAICM and Public Health

While it is true that some of SAICM's goals are reasonable, such as ensuring that developing nations gain information regarding the proper handling of chemicals, the program is likely to fail when it comes attaining these goals. It will fail for the same reasons centralized economic planning has failed: government officials are too removed from problems and lack the information necessary to solve the many diverse problems. Uniform policies will not work in the various situations around the world; such political processes tend to serve organized players rather than the common good, and policy goals are often based on misperceptions.

Market economies are better situated to address problems associated with chemicals management and some of the larger problems that hinder human well being in developing nations. Indeed, many of the serious problems that SAICM proposes to address (the mismanagement of dangerous substances because poor nations lack the resources to pursue policies for proper handling) would be solved through the promotion of economic growth, not through expensive global governance. The costs of SAICM will likely have the opposite result, by diverting resources from more important issues and by undermining commerce and economic development.

In fact, most of the world's serious environmental problems are the effects of poverty in developing nations. According to a 2001 World Bank study, *Environment Strategy Papers: Health and Environment*, the most prominent environmental problem is inadequate sanitation. This is something that only economic growth can address through improved infrastructure and increased access to chemical disinfectants, such as chlorine. Next on the list of problems is limited access to modern energy sources, including such things as electricity and fossil fuels. Lacking such amenities means that rural poor around the world rely on burning biomass fuels (such as cow dung) in their homes as an energy source. Resulting pollution leads to an estimated 1.7 million deaths associated with respiratory illnesses each year.[25] And as international bureaucrats at the United Nations lament the potential that someone might consume trace levels of chemicals found in plastic packaging, the absence of such sanitary packaging and refrigeration in developing nations kills tens of thousands every year.

SAICM is not the solution to such problems and arguably represents a serious misallocation of limited resources. Indeed, these nations are least able to afford such regulatory burdens proposed by many of the world's environmental treaties, and many of the treaties promise to undermine economic growth. For example, a study produced by the Liberty Institute in India shows that the Basel Convention had proved counterproductive and detrimental to development in poor nations.[26]

SAICM is also unlikely to improve public health in developed nations by reducing cancer rates as some believe it will do. If chemicals were a source of health problems, one might expect that as chemical use has increased around the world, there would be some measurable adverse impact on life expectancy, cancer rates, or other illnesses. Yet in developed nations, where chemical use has greatly increased, people are living longer, healthier lives. According to the World Health Organization ("WHO") in its *World Cancer Report*, the average worldwide human life span has increased from 45 years in 1950 to about 66 in 2000 and will most likely continue to increase to 77 years by 2050.[27]

SAICM is also unlikely to improve public health in developed nations. . .

Nonetheless many complain that chemicals are causing a cancer epidemic in developed nations. But trace level chemicals have never been shown to be a significant cause of cancer. The WHO report estimates that at most one to four percent of cancers can be attributed to environmental pollution in developed countries, citing a world-renowned study by scientists Sir Richard Doll and Richard Peto.[28]

While Doll and Peto note that 80 to 90 percent of cancers are caused by "environmental factors," this phrase encompasses anything other than genetics. It does not include pollution alone. Environmental factors include smoking; diet; occupational exposure to chemicals; "geophysical factors" such as naturally occurring radiation; manmade radiation; medical drugs and radiation; and pollution. According to Doll and Peto, pollution accounts for only two percent of all cancer.[29] Neither Doll and Peto nor the WHO mention exposure to chemicals through consumer products as a serious cause of cancer, which is a key focus of the chemicals strategy. In addition, the EU policy will not likely affect occupational exposures in the developed world since, as the WHO notes, "most occupational carcinogens have been removed from the workplace."[30]

Doll and Peto report that tobacco use accounts for about 30 percent of all annual cancer deaths,[31] and dietary choices account for 35 percent of annual cancer deaths.[32] The WHO confirms these figures, attributing 30 percent of cancers to smoking and 30 percent to dietary factors.[33] The WHO notes that chronic infections – which are particularly a problem in developing nations – cause about eighteen percent of worldwide cancers.[34] Genetic factors may lead to an additional four percent of cancers. That means less than twenty percent of cancers result from all other causes including pollution, alcohol, occupational exposures, medical drugs, radiation, immuno-suppression problems, and reproductive factors and hormones.

Nonetheless, since cancer is a disease related to aging, the developed world's aging population does indeed present new health challenges that are important to address. The WHO suggests that cancer prevention efforts should focus on three factors: tobacco use, diet, and infections, which together account for 75 percent of cancer cases worldwide.[35] Efforts to encourage people to change personal habits by eating better are likely the most effective cancer prevention policy.

Conclusion

Despite limited coverage and interest in the media, SAICM represents a major international policy development. Businesses may soon be caught by surprise after the SAICM Secretariat begins to affect policy around the world. And despite the fact that SAICM is primarily intended to assist developing nations with the management of chemicals, developing nations stand to lose the most from the program.

Endnotes: SAICM

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[4] World Health Organization ("WHO"), *Intergovernmental Forum on Chemical Safety: Brief History and Overview*, Dec. 2005, *available at* http://www.who.int/ifcs/documents/ifcs_overview_dec05.doc (last visited Mar. 7, 2006).

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Endnotes: SAICM *Continued on page 73*

Sound Management of Chemicals in Developing Countries under the Rotterdam Convention

*by Sun Young Oh**

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade ("Rotterdam Convention") is a multilateral environmental agreement with the ultimate goal of protecting human health and the environment.[1] The Rotterdam Convention seeks to accomplish this by enhancing sound chemical management through the exchange of scientific, technical, economic, and legal information between exporting and importing states.[2] Fourteen new harmful chemicals and pesticides have been added into Annex III of the Rotterdam Convention,[3] which enumerates 41 hazardous chemicals subject to Prior Informed Consent ("PIC") procedures of the importing countries.[4] The PIC procedures require the importing country to formally consent before accepting dangerous pesticides and industrial chemicals in order to prevent their exportation.[5]

Many developing countries lack the necessary infrastructure and appropriate environmental regulations to handle hazardous chemicals in an environmentally sound manner.[6] Effective technical and financial assistance for developing countries is necessary to achieve the Convention's long-term success.[7] Since "developing nations are the main recipients of international trade in chemicals that the Rotterdam Convention addresses,"[8] it is vital that importing nations have the ability to evaluate the safety of the imported chemicals. This may prevent developed countries from exporting dangerous chemicals to developing countries as a way to cheaply dispose of them and avoid environmental regulations.[9]

Even though Articles 11(1)(c) and 16 of the Rotterdam Convention address international cooperation and technical assistance for developing countries to improve their chemicals management, they do not explicitly require developed countries to transfer technical support to developing countries, nor do they provide for specific measures to monitor compliance.[10] Many countries recommend close collaboration with the Secretariat of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal ("Basel Convention"), because it contains a specific mechanism to support regional assistance to developing countries in managing hazardous wastes.[11] The Basel Convention aims to control the transboundary movement of hazardous wastes and utilizes a compliance mechanism to help identify difficulties that arise in the implementation of the Convention.[12]

Building mandatory and binding financial mechanisms is an effective way to ensure that that the Rotterdam Convention's key goals are effectively carried out.[13] Since the Rotterdam Convention lacks provisions establishing a financial mechanism to promote the capacity-building activities of developing countries, mandatory financial contributions should be provided by developed countries to secure effective regional technical assistance.[14] Such options were recently studied by the Conference of Parties ("COP") to the Rotterdam Secretariat.[15] Some countries expressed disappointment with the COP's lack of flexibility regarding suggestions for financial re-structuring.[16] While a special trust fund has already been established for the Rotterdam Convention, which provides that both parties and non-parties may voluntarily contribute to the fund, the COP failed to suggest how to further enhance the existing fund and implement it successfully.[17] The performance of similar funds such as the Basel Technical Cooperation Trust Fund indicates that voluntary contributions are consistently lower than budgetary needs.[18]

In short, exporting countries are only obligated to advise and assist importing nations "upon request and as appropriate,"[19] while training and technical support aid to developing countries is not mandated. Developed nations should be obligated to provide technical assistance for developing countries and sound mechanisms for their implementation at all levels.[20] In addition, mandatory financial mechanisms should be maintained in order to promote the successful implementation of the Rotterdam Convention in both developed and developing countries.

Endnotes:

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[2] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 10, 1998, art. 1, 38 I.L.M. 1734 [hereinafter Rotterdam Convention].

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[4] Rotterdam Convention, *supra* note 2, at Annex III.

[5] Julie B. Truelsen, *Developments in Toxics in 2004: The Ratification of the Stockholm Convention and the Rotterdam Convention*, 2004 Colo. J. Int'l Envtl. L. & Pol'y 217, 225 (2004).

[6] Paula Barrios, *Rotterdam Convention on Hazardous Chemicals: A Meaningful Step Toward Environmental Protection?* 16 Geo. Int'l Envtl. L. Rev. 679, 733 (2004).

[7] Richard W. Emory, Jr., *Trade and the Environment: Probing the Protections in the Rotterdam Convention on Prior Informed Consent*, 2000 Colo. J. Int'l Envtl. L. & Pol'y 47, 52 (2000).

[8] Emory, *id* note 7, at 52.

[9] Barrios, *supra* note 6, at 681.

[10] Barrios, *supra* note 6, at 734.

[11] Second Meeting of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain

Endnotes: Rotterdam Convention *Continued on page 74*

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COMMENTARY: THE BASEL CONVENTION, BACK TO THE FUTURE

*by Pierre Portas**

INTRODUCTION

Once upon a time, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal ("Basel Convention" or "Convention") was a forum for North-South dialogue; a place where governments from all over the world worked together to bring a halt to the unscrupulous trade in hazardous wastes. The 1990s witnessed international solidarity and enthusiasm for the Convention's potential. But as the 1990s wore on, an identity crisis emerged amid globalization and an ever growing economy. As the world became more prosperous and the cross-border flow of goods and recyclables expanded, it appeared that the converse was designed for the Basel Convention. From vision to commitments, the Convention entered into a collision with globalization. The Convention faces a constant struggle to defend its relevance, competing with other issues for the attention of the international development and environmental communities. This article is a story about our common future. In a world of growing complexities and uncertainties, the Basel Convention brings certainty, transparency, and traceability as a means to protect human health and the environment worldwide.

BOX 1: TRENDS OF INCREASING HAZARDOUS WASTE PRODUCTION

- Effects of stabilizing non-hazardous industrial waste generation is bearing fruit, while hazardous waste generation will steadily increase due, in part, to the increase in the production of chemicals.
- Chemical releases from large-scale industrial plants will decrease, while such releases from small and medium size enterprises is likely to increase.
- Chemicals dumped in landfills are increasing.
- More and more complex chemicals are being put into products rendering such products potentially hazardous upon disposal.
- The fast-growing streams of post-consumer goods and end-of-life equipment are often overwhelming countries' capacity to manage such wastes in a way to protect human health and the environment.
- The quantities of household waste, as well as construction and demolition wastes, will increase.
- Stricter environmental laws and occupational health safety standards make the disposal of hazardous wastes more expensive, resulting in an increase of illegal traffic of these wastes to developing countries or massive influx of used or end-of-life equipment.
- Economic globalization results in globalized trade of hazardous and other wastes.

THE CHALLENGE OF HAZARDOUS WASTES

The 1989 Basel Convention, which entered into force in 1992, is the only global legal instrument to control transboundary movements of hazardous and other wastes and to ensure their environmentally sound management worldwide. As of February 2006, 167 Parties and the European Community are Parties to the Convention. Fourteen Basel Convention Regional and Coordinating Centers established on all continents under the authority of the Conference of the Parties facilitate and assist Governments and other public and private stakeholders in the implementation of the Basel Convention and related chemicals convention or protocols.

During its short life, the Basel Convention has been the place of many achievements. Its control system is applied worldwide, and its underlying concept of environmentally sound management is gaining broader acceptance. In short, the Basel Convention is functioning. At the national level, many countries have taken drastic measures to reduce environmental and public health harms from hazardous wastes and to improve performance of waste operators. In the past fifteen years, gigantic steps have been made in waste and hazardous waste management worldwide.

However, this progress is still not commensurate to the size of this multifaceted problem. Advances in technology and high consumerism accelerate the rate at which products become obsolete. Available estimates suggest that over one hundred million computers, monitors, and televisions become obsolete every year, and this number is growing. In many countries, hazardous products or substances make their way through the household waste stream and often end up in improperly managed disposal sites, which can impact human health and the environment. This is a burden with which public authorities have difficulties coping.

The Basel Convention is an indicator of the global response to hazardous waste issues. The increase in hazardous waste and its illegal trafficking do not reflect a failure of the Basel Convention. To the contrary, it points out the real need

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for bringing the Basel Convention to a new upward threshold so that the Convention can adapt itself to the expanding problems. Any measurable and recordable progress at the worldwide level requires a harmonized data set for policy-makers to adequately address the challenges, and the Convention provides a means to progress towards such harmonization. At the same time, the Convention is a unique forum where 167 countries and the European Community can work together and with other public and private partners to lay the foundation for bridging the technological gap among Parties. We have not done a good job in promoting the Basel Convention's relevance in terms of environmental and human health improvements. But this silence is not apathy.

The Continuing Role of the Convention

Some believe that the Basel Convention is moving towards extinction, and that the reasons that stimulated negotiations for the Convention in the late 1980s are re-surfacing and require a renewed commitment to the irreplaceable role of this Convention. The quantity of hazardous wastes generated is steadily increasing and cannot be de-coupled from economic growth. Illegal traffic in wastes, including hazardous wastes, has reached unprecedented levels. The past is in front of us. Over time, environmental conventions, like the Basel Convention, which address specific problems tend to become disconnected from the development agenda; and as such, disappear from decision-makers' radar screens.

However, as the amount of global trade increases, so does the need for the Basel Convention. Any transboundary movement of hazardous wastes could also be considered a part of the global trading system. Transactions involving hazardous wastes can be a commercial service. Incineration plants or recycling facilities operate as any other industrial establishment. Collection, segregation, and transport of wastes are services to the community. The safe and proper handling of all wastes and the reduction of their quantities and hazardous qualities will minimize risks of lead poisoning, waterborne diseases, and harm from toxic, poisonous, or infectious substances. These safer handling procedures will provide economic opportunities for developed and developing countries. The development of sound recycling schemes will generate employment and facilitate integration of the informal sector into the mainstream economy. In addition, such systems may contribute to the development of best practices and sound regional recycling schemes.

The implementation of the Basel Convention reinforces the United Nations' mission and work: the Convention provides its added value to a highly complex and specialized field that no other international body or agreement addresses at the global level. The United Nations' ongoing reform recognizes the need to adjust the system in order to support an increasingly field-oriented UN Secretariat. The Parties to the Basel Convention have recognized this shift of emphasis in their 1999 Basel Declaration on Environmentally Sound Management ("Basel Declaration" or "Declaration"). In order for the Convention to be effective, every country needs to establish hazardous waste systems and infrastructures that protect human health and the environment. Through the 2002 Draft Strategic Plan for the Implementation of the Basel Convention, the Parties are giving life to the Basel Declaration. For the past six years, Parties have re-emphasized the importance of working at the national level, involving municipalities, enriching nongovernmental organizations' on-the-ground experiences, and building partnerships with the private sector. The Basel Convention's influence and reach are growing worldwide and expanding regionally.

The Complexities of the Recycling Movement

The disposal or recycling of end-of-life equipment or post-consumer goods is an emerging global issue. For instance, electronic wastes, or e-wastes, are the fastest growing waste stream in the world: they represent both a high asset and a huge problem. The quick economic gain from exporting or importing e-wastes overshadows its potential harm. Many governments are reluctant to impose the Basel Convention's strict control procedures on trade when it brings in revenue and generates jobs. This resistance is due in large part to a transformation of the waste hierarchy promoted for many years (prevention, reuse, recycling, energy recovery, and final disposal). To illustrate, industry wants to make a profit from wastes, and at the same time, governments in many developed countries are convinced that the environmental problems of the 1980s are behind them. As a result, governments focus on new policies to address wastes that reflect the realities of today and the future and often forget the lessons learned from the past. Such an approach strays from the emphasis on how wastes contaminate or pollute the environment and instead, focuses on a life-cycle approach to materials.

Priority in Europe is now given to recycling strategies. Development of regional recycling systems and networks is gaining momentum. Companies cross borders to set up regional recycling centers, exercise corporate social responsibility, and extend producer responsibility. The G8 countries are promoting the concept of the 3Rs (reduce, reuse, and recycle) towards a sound material-cycle society. The European Commission is also tabling a thematic strategy on the prevention and recycling of waste. This strategy aims to transform Europe into a recycling society. As a consequence, many governments are working towards reducing barriers to trade and encouraging re-use and recycling of materials. Establishing a loop for recyclables relies on the dissemination of knowledge from facilities in different parts of the world.

However, the international flow of recyclables has a hidden side. Countries are at different levels of economic development, and recycling facilities operate at different standards depending on the country. A sizeable part of local recycling is done in the informal sector. For example, governments are dealing with the issue of e-wastes differently, which leaves room for unscrupulous trade. Rapidly developing international and regional recycling schemes must be combined with a mechanism capable of providing information about and monitoring such schemes to ensure their accountability and soundness from environmental,

health, and economic perspectives. The high quantities of e-wastes exported to Asia and Africa are overwhelming importing countries' capacity to deal properly with these wastes. The quantities in some areas are so voluminous that old computers are being burnt to reduce size, generating massive and permanent air pollution (particularly dioxins). Information is insufficient to provide a level of certainty to enable customs officers to make a clear-cut demarcation line between usable products versus wastes and hazardous wastes. Above all, it is inevitable that wastes will follow the path of least resistance. When it comes to obsolete ships on their last voyage to recycling yards, divergence of opinion on whether or not the Basel Convention should apply results in legal and technical uncertainties. A level playing field is needed in regards to handling end-of-life equipment.

The growing production of chemicals is one of the main contributors to the increase in hazardous wastes. More and more of these chemicals find their way into products, and these products, in turn, become hazardous wastes at the time of disposal. This proliferation of chemicals means that among the e-wastes exported to Asia or Africa, for instance, the chances of finding electronic hazardous wastes such as cathode tube rays with lead-containing glass, printed circuit boards with heavy metals, fluorescent tubes (from crystal displays) with mercury, nickel-cadmium batteries, or plastic components with brominated flame retardants are highly likely. No one can deny that these are hazardous materials. It is also important to recognize that one cannot leave waste to the sole principles of the market. Also clearly demonstrated is the pressing need for traceability of materials and transparency in the trade of recyclables.

In the case of end-of-life hazardous equipment destined for recycling, the Basel Convention will improve certainty (what to control), transparency (what moves across borders and how), and traceability (through its prior written notification procedure). A cross-border regional recycling system needs to integrate the international obligations of the Basel Convention to capture trade in hazardous wastes – not just a portion of the Convention but the treaty as a whole. Indeed, the temptation is great to use only parts of the Convention that are useful to economic objectives, while ignoring those that are perceived as obstacles to trade.

Next Steps for the Basel Convention

Economic globalization has encouraged the establishment of global and regional recycling zones. The world of trade is fast changing. The predictable bipolar division of the last century has become more complex. How can the architecture of the Basel Convention respond to these changes? Its future lies in the capacity of Parties to anchor the Convention into regional realities. They have the tools to do this. Indeed, the Basel Convention is unique in having established a regional network composed of fourteen autonomous institutions operating on all continents. The Convention should transform itself into a global convention for the environmentally sound management of wastes in which the prior written advance notification procedure remains central in achieving the goals of the Convention. The goals include, but are not limited to:

- Minimizing the quantity and hazardous quality of wastes;
- Treating and disposing of wastes within proximity to where they are generated; and
- Reducing transboundary movements.

In addition to the three pillars above, predictability, transparency, and traceability of trade in recyclables need to encapsulate the changing patterns of trade as a necessary set of measures to protect human health and the environment. The Convention should provide the global standards for managing all wastes. Today, in a large number of countries, hazardous wastes are mixed with household wastes. As a result, neither the hazardous wastes nor the household wastes can be managed properly. The "all wastes" coverage should be based on two basic principles, the life-cycle approach to materials and integrated waste management (taking hazardous wastes out of the household waste stream).

Any regional recycling network or zone will operate under the assumption that regulatory authorities would ease restrictions regarding the flow of recyclables. The net result would be an increase in industrial waste exportation, and importation of end-of-life equipment. Consequently, a large part of the respon-

Box 2: Unanticipated Causes of Waste Problems

Since 2005, a multi-billion dollar international commodities market to trade carbon emissions has developed: great financial opportunities for companies to either reduce direct emissions or buy someone else's unused allowance. Carbon dioxide is naturally occurring and is a by-product (a waste) of industrial processes, in particular when burning fossil fuels or biomass. Reduction of emissions will have a beneficial effect in reducing waste releases. However, as side effects, we will witness an increase in the disposal of obsolete or inefficient electrical equipment, like generators. Likewise, shifts in industrial processes in the oil, cement, pulp, paper , and other concerned sectors to meet CO_2 reduction will generate different types of wastes and hazardous wastes. Whatever we do, positive or negative, has an impact on the quantity and property of wastes.

Similarly, when you send used computers to Africa to narrow the digital gap, you enable people to gain access to a powerful tool for their own development. At the same time, however, these used computers will become wastes in Africa, and African communities will have the burden to dispose of them when they reach the end of their useful life. So, there is a lesson to learn about this. We need to constantly keep in mind the need to address the issue of wastes in development and environmental models. Otherwise, we create a liability and often displace the waste problem to others.

sibility would remain with private operators in terms of protecting human health and the environment. Because of the cross-border nature of the trade in recyclables, national standards will not be enough. In order to bring consistency to environmental standards and best practices among all countries, a global, or at least regional, playing field must be achieved. Reaching this goal would require establishing a regional certification scheme for the environmentally sound management of hazardous and other wastes that could be delivered by independent institutions such as the Basel Convention regional centers. Such a certification scheme will be built on the environmentally sound principles adopted at the global level by the Parties to the Basel Convention and should provide incentives to improve performance of the recycling industry in reaching acceptable common environmental standards. Environmentally sound management implies a continuous improvement in environmental performance. All of this is feasible and centers around values, ethics, solidarity, and commitment.

Conclusion

We cannot close the book now. We have not finished our story: it will remain an endless tale of hope and frustrations. Dollars and cents will continue to be the catalyst. Governments are sizing down budgets; the environment is no longer at the top of people's concerns. Unemployment and insecurity are driving the agenda. Internationally, developed countries – the so-called donor countries – have their eyes on climate change issues. Development co-operation rightly focuses on poverty reduction. The Basel Convention is below the threshold level of political awareness. But, in the meantime, the world continues to build a toxic heritage for future generations.

Recent EPA Ruling May Increase Brownfield Financing

*by Mark Wilson**

Job growth, increased tax revenue, and urban renewal are just a few of the benefits municipalities receive by redeveloping abandoned "brownfields." Brownfields are "property, the expansion, redevelopment, or reuse of which may be complicated by the presence … of a hazardous substance, pollutant, or contaminant." [1] Yet, while the benefits for municipalities are numerous, liability concerns among private investors make it difficult for potential developers to finance such cleanup projects. Fortunately, a recent ruling by the U.S. Environmental Protection Agency's Environmental Appeals Board ("EAB") may relieve some lender's concerns.[2]

Although clean-up costs are the responsibility of current or past owners, rather than prospective developers, the potential tort liability to residents and owners of nearby brownfields property are a major deterrent for private investors.[3] Under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"),[4] commonly known as "Superfund," strict, joint, and several liability for past contamination is imposed on all parties within the "chain of title" from the onset of contamination."[5] For instance, in *Interfaith Community Organization v. Honeywell International, Inc*., Honeywell, a recent successor of a brownfield site, was held liable under CERCLA for damages resulting from the prior owners' contamination that affected surrounding property owners.[6] Moreover, in *United States v. Fleet Factors Corp.*, the Eleventh Circuit held that a "secured creditor may incur CERCLA liability… by participating in the financial management of a facility … indicating a capacity to influence the treatment of hazardous waste."[7] Because investors can be held liable under CERCLA for damages incurred as a result of prior contamination that emanated to other properties, they hesitate to invest in brownfield redevelopments.[8]

While cases such as *Fleet* and *Interfaith* are rare, the perception of lender liability, especially third-party tort claims, is high among financial institutions.[9] The American International Group, Inc. ("AIG") testified before Congress that "third party liability for property damage and bodily injury due to pollution issues, go to the heart of what concerns many would-be Brownfield redevelopers."[10]

However, on October 28, 2005, the EAB denied Grand Pier Center, LLC, a Chicago redeveloper, reimbursement from the EPA for $200,000 the company incurred by cleaning up an off-site sidewalk area.[11] Grand Pier argued that they were solely responsible for costs incurred cleaning up contamination on the property they owned, but they were not responsible for the clean-up cost of the public sidewalk.[12] The EAB held instead that the "facility" encompasses all areas where the contamination occurred, including Grand Pier Center's property and the adjacent off-site sidewalk area.[13] The Grand Pier ruling clarifies that developers will be expected to address *all* contamination associated with a brownfield, including adjacent properties and right-of-ways.[14]

While it may appear this ruling makes developers more vulnerable, in reality it alleviates some investors' concerns over third-party liability, because lenders can be assured there will be no lingering contamination. Eliminating concerns over third-party liability from lingering contamination will strengthen investor confidence; thus, brownfield redevelopment can continue to revitalize communities and provide sustainable economic growth.

Endnotes: Brownfield Financing *Continued on page 81*

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Chemical Taking:

Glyphosate and the Eradication of Due Process in Colombia

*by David A. Wilhite**

Introduction

Cocaine politics continues to take a toll on Colombian social, political, economic, and legal stability. Coca[1] is indigenous to the Andean Mountains and for hundreds of years, native populations and immigrants to the region have consumed its leaves for both medicinal and customary purposes.[2] The United States consumes cocaine at a rate of over 300 metric tons per year.[3] Each year approximately 6,548,000 North Americans consume cocaine, annually spending $43.6 billion. [4] In an effort to curb this consumption, and because coca is the base of cocaine, the American and Colombian governments have combined forces using pesticide in an attempt to eradicate the problem at its perceived source, the coca plant.[5]

The legal, social, and political effects of spraying Glyphosate on coca plants demonstrate flaws in the policy of relying on a chemical to perform a government function. Glyphosate is a legal chemical, most famously the base of Monsanto's Round-Up. The chemical is produced in the United States, mixed in Colombia,[6] and sprayed by American planes on the Colombian countryside.[7] Despite this lawful chain, images, accounts, and notions of stripped tropical forest as well as bereft local farmers and indigenous communities raise questions as to the legality of spraying Glyphosate.[8] This article explores the effect of the spraying of Glyphosate with special attention to the issue of property rights. Through an analysis of Colombian expropriation laws, this article will argue that government reliance on aerial spraying of coca crops results in an illegal chemical expropriation.

[S]praying is for a public purpose, the resulting temporary disruption in productivity may constitute an illegal temporary taking. . .

The Use of Glyphosate: A Chemical Expropriation?

Part of Plan Colombia and the Andean Counterdrug Initiative ("CEI") involves the aerial spraying of illegal coca cultivations with Glyphosate.[9] The Colombian Government is currently spraying a Glyphosate cocktail on coca crops throughout its territory, from the Amazon River Basin to the Northern Caribbean coast.[10] This program is meant to eliminate the cultivation of coca by killing the plant before it can be converted to cocaine, illegally transported, and consumed in the lucrative American market.[11]

For decades in Colombia, three extra-military armed groups have battled with drug lords, the State, each other, and the civilian population, resulting in as many as 30,000 deaths in some years [12] and 2.5 million displaced persons (second only to Sudan in number of displaced persons).[13] These violent groups as well as political and diplomatic wrangling fuel a devastating guerilla conflict.[14] Armed groups and drug lords rely in large part on capital from the illegal drug trade,[15] as well as extortion, kidnappings, and forced displacement.[16] To dam the flow of illegal capital, the Colombian government cooperates with the United States in an attempt to eradicate the illegal cultivation of the coca plant.[17]

Dusting planes, Blackhawk helicopters, American military agents, and U.S. Department of Defense contractors work in unison with Colombian forces and under U.S. Congressionally mandated guidelines[18] to apply Glyphosate to coca cultivations using aerial spraying.[19] The aerial eradication program in Colombia sprayed a record 136,551 hectares of coca and over 3,000 hectares (7,000 acres) of opium poppy in 2004.[20] In 2005, Colombia cultivated 80,000 of the 158,000 hectares cultivated in Colombia, Bolivia, and Peru.[21]

Though scientists from the U.S. Environmental Protection Agency and Organization of American States have found Glysophate's negative environmental and human consequences to be negligible, controversy persists.[22] A sprayed field takes approximately six to eight months to recover productive crops.[23] The use of a second chemical in the Glyphosate cocktail, Cosmoflux, allows the Glysophate to penetrate the waxy leaves of tropical plants.[24]

Spray pilots apply the herbicide at altitudes of less than one hundred feet,[25] and "while every effort is made to minimize human and mechanical mistakes, occasional errors are unavoidable."[26] As such, many neighboring cultivations, both illicit and licit, have been destroyed. Glysophate spraying has allegedly resulted in harm to "food plots, including bananas, beans, plan-

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tains and yucca, as well as chicken and fish farms."[27] Further, according to some sources, an investigation by the municipal police of Valle del Guamuez found "that as of February 2001, fumigations killed 38,357 domesticated birds, 719 horses, 2,767 head of cattle, 128,980 fish, and 919 other animals such as pigs, cats, and dogs."[28]

The Colombian Ombudsman (*Defensoría del Pueblo*) has received 5,844 claims for damage to food crops since late 2001, claims that, under the Colombian Drug Commission Resolution 00017 guidelines, only warrant attention if they are found in licit crop zones.[29] Of those, the U.S. Department of State reports that 28 claims were paid with total compensation of $159,000.[30] The process of review has thus resulted in compensation payments to less than 0.5 percent of the claimants at $5,678.50 a payment. These figures leave questions as to the role of due process for property owners whose lands were destroyed incidentally, while neither hearings nor compensation exist for those lands sprayed purposefully by the eradications.

Though the spraying is for a public purpose, the resulting temporary disruption in productivity may constitute an illegal temporary taking by the Colombian government. Although the Colombian government has implemented laws that mirror international and U.S. expropriation laws, the aerial spraying does not meet legal standards contained therein.[31] Do these laws allow the elimination of due process standards by substituting a government presence with the use of Glyphosate?

Government Expropriations: Protection of Individual Rights

Colombian Expropriation Law

In order to be legal, any government expropriation must protect the individual property owner's rights. Private property rights, enshrined in the U.S. Constitution's Fifth Amendment and extended to the states through the Fourteenth Amendment, allow for the taking of private property by a government action only when that taking serves a public purpose, follows due process, is nondiscriminatory, and is accompanied by just compensation.[32] International standards closely replicate this formula.[33] For example, Article 21 of the American Convention on Human Rights, "Pact of San Jose," to which Colombia is a signatory, provides for expropriation protection.[34] Colombian national laws provide for protection against an expropriation, regulatory expropriation, and temporary expropriation without due process and compensation.[35] These standards create a balancing test between the use of police power for a public purpose on one side and the proprietor's privacy interest on the other.[36]

The Colombian standard for expropriation resembles international and U.S. laws on the subject and requires previous payments to property owners and direct legislative and judicial involvement.[37] Colombian expropriation laws are found in Article 58 of its Constitution.[38] Private property may not be violated save for public utility or social interest. Where such a conflict exists, the private right must give way to the social interest.[39] The law further mandates that the State may expropriate lands when the legislature establishes the need to meet a public purpose or a social interest. This finding must then be executed through a judicial sentencing and accompanied by previous indemnification.[40] Article 34 of the Colombian Constitution creates an exception to the basic standard established in Article 58 by permitting expropriation as part of a criminal sentence, allowing seizure of goods obtained through illegal enrichment.[41]

Of Temporary Taking and Incidental Damages

In Colombia, as in the United States, a temporary taking is a legal exercise of police power as long as it is accompanied by compensation and protection of due process rights.[42] For example, Article 59 of the Colombian Constitution specifically

Courtesy of David Wilhite.

The geography of the Andes Mountains is ideal for growing coca with its isolated and fertile fields.

declares that in times of war the government may temporarily expropriate lands without prior indemnification.[43] Decree 1420, Article 21, Paragraph 6 mandates that "for estates that are used for productive activities which will be subject to an affectation causing a temporary or definitive restriction to the generation of income derived from their development, independently from the assessment of the estate, a compensation for loss of income will be recognized, for up to a maximum of six (6) months."[44] This decree, intended for use in environmental regulation, requires compensation and due process protections for temporary takings of a "right of way" as well as "economic activity in the effected estate."[45] Article 90 of the Constitution provides that the State will be liable for any illegal damages caused by the actions or omissions of public authorities.[46] This standard requires government compensation for temporary takings as well as incidental damages to adjacent properties during a temporary taking.[47] This decree in conjunction with Article 34 of the Colombian Constitution demonstrates a legal responsibility on the part of the government to conduct a due process complaint hearing before a temporary expropriation or to provide post-expropriation indemnification if a temporary taking is effected under exigent circumstances, for instance during a time of war.[48] These laws parallel U.S. laws, where the Supreme Court has held that the standard bar on incidental damages to surrounding property subject to a taking does not apply in temporary takings.[49]

In standard expropriations, as well as the temporary taking and incidental damages taking, Colombian laws meet international standards and parallel U.S. laws on the subject. However, coca fields sprayed by Glyphosate as well as the incidental damages occurred to neighboring farms, and indigenous groups' lands result in a "chemical expropriation" that does not meet those standards. According to the official count, this equated to at least 137,000 hectares of chemically expropriated lands in 2004. Are due process protections absent from this action?

Exigent Circumstances: Due Process Casualties of Colombia's Many Wars

Colombia has been effective in creating a stable investment climate in part because of Article 58 of its Constitution.[50] Even in times of war, the Colombian Constitution protects private property rights faced with a temporary taking.[51] But Law 793 of 2002 creates a special harbor for expropriations of property "directly or indirectly" related to illicit drug activity without compensation.[52] Recently, President Alvaro Uribe Velez stated, "many times we have considered the fact that these lands belong to a *campesino* (low income land worker) or a small-farm owner, but this problem of coca in Colombia…financing terrorist groups, we cannot get stuck in just fumigation because we fumigate in one place and it comes back in another."[53]

Law 793 parallels attempts in U.S. law to allow broad police power expropriations in drug cases, attempts that were struck down in *United States v. James Daniel Good Real Property*.[54] The U.S. Supreme Court weighed heavily the possibility of mistaken seizures resulting from a lack of evidentiary findings.[55] Both the Constitutional Court of Colombia and the Supreme Court of the United States have upheld the notion that, barring exigent circumstances, both a government audience and compensation must off set any government taking. If exigent circumstances do exist, these Courts have held, then where a hearing could not be held prior, it must be held after to determine if the expropriation requires compensation.

In 2003, the Colombian Constitutional Court affirmed that the "public purpose" of illicit-property expropriations without compensation, codified into law 793, outweighed private property interests.[56] The Court authorized Law 793, declaring that through this law, the government has properly "*establecen las reglas que gobiernan la extinción de dominio,*" or that this law establishes rules that govern the execution of eminent domain.[57] Because this law provides for a legislative and judicial procedure, namely a hearing to verify the illicit connections of the condemned property, the Court found that it met a due process standard. The effect of this law is to allow government exercise of eminent domain on property proven to be directly or indirectly connected to illicit behavior without payment of just compensation.

The temporary chemical expropriations caused by the use of Glyphosate in Colombia do not meet this standard, nor any of the others presented above. Here, no legislative or judicial hearings take place. The failure to provide them cannot be excused by the exigent circumstances of the war on drugs, nor by the temporary nature of the taking. Yet, a "temporary restriction on economic activity" of six to eight months occurs as a result of a chemical spraying and no compensation is awarded, and post-expropriation hearings are provided for only those properties sprayed incidentally, as opposed to any property sprayed.[58]

Lastly, of the thousands of claims presented under the rubric of Resolution 00017 to the national Ombudsman, only a small fraction has been paid. As previously discussed, Colombian law requires compensation for temporary taking of the economically productive activities of an estate.[59] While Decree 1420 deals with environmental concerns, the tests it describes clearly exist to meet the expropriation standards set out in Articles 58, 59, and 34 of the Constitution. Resolution 00017, however, does not meet these standards and thus exposes a due process gap in the current use of Glyphosate.[60] Failure to provide hearings or pay compensation strongly contradicts Colombian expropriation law on several accounts.

The due process problems of these temporary "chemical takings" are rooted in the oft-noted absence of the State. . .

In contrast to the legal regime set up in Resolution 00017, Law 793 could be interpreted to require that property owners accused of growing coca be brought before the court for a pre-expropriation hearing to establish a direct or indirect connection to illicit activity.[61] Further, Articles 58, 59, and 34 of the Colombian Constitution most likely would require a hearing for all proprietors whose land have been taken, not merely those who may have suffered incidental damage.[62] Lastly, even in the exigent circumstances of the War on Drugs, in keeping with other wartime powers, the state must take steps to correct a temporary taking after the fact through compensation or a hearing to establish why compensation is not given.[63]

The Exigent Circumstances of War: Civilians in a Judicial No Man's Land

The due process problems of these temporary "chemical takings" are rooted in the oft-noted absence of the State in large swaths of the Colombian countryside. As a result of this absence, the legal infrastructure cannot or does not support hearings on and enforcement of expropriations, by fumigation or otherwise on licit or illicit crops.[64] Recent attempts at augmenting State presence have met with frustrating results.[65] On December 28, 2005, the Revolutionary Armed Forces of Colombia ("FARC") killed 29 Colombian Army soldiers as they

attempted to protect manual coca eradication workers in a National Park.[66] The surrounding towns of La Albania, Palestina, and Playa Rica suffered similar attacks and have been deserted by the banana farmers and others who lived in the area.[67] Emptied towns, displaced persons, and banana and coca fields peppered with anti-personnel mines are not the only casualties of this type of power vacuum.[68] This scene is repeated throughout the Colombian countryside and has been for many decades, leaving expectations of a prompt hearing less realistic with every abandoned town.[69]

While the total hectares of coca cultivations reduced dramatically from 2001 through 2004 thanks to the use of Glyphosate, recent analysis demonstrates that Colombia continues to be the highest exporter of coca and had a three percent increase in hectares of coca cultivation in 2005.[70] This new figure combined with the slowed trend of reduction in the 2003 and 2004 shows a tide change in the effectiveness of the program.[71] It appears that President Uribe Velez was correct in his observation that use of Glyphosate merely results in cultivation in other areas.[72] The U.S. State Department recently acknowledged that coca cultivations have not been stopped and that, in fact, attempts to eliminate them are creating a "ballooning" of the same problem into neighboring Peru, Bolivia, and Ecuador.[73]

Conclusion

The use of Glyophosate by the parties implementing CEI does not act as an effective substitute for the presence of the State in those areas where it is being sprayed. Rather, Glyphosate spraying results in a new kind expropriation, a "chemical taking." The resulting State deficit is made evident in an erosion of due process rights. While debate continues on the effectiveness of Glyphosate in fighting coca, it is evident that the government requires a normalized legal regime with stronger judicial system to hear the due process concerns of affected citizens and the political will to use them. Failure to do so creates a discriminatory effect whereby affected parties are forced to bear both the high economic burden of eliminated capital flows from coca and the social burden of a guerilla war. Using Glysophate as a means of enforcing the police arm of the state does not address the political, judicial, and economic deficit exposed by the temporary chemical taking.

Legal remedies for the chemical takings reach the international realm through the Inter-American Commission of Human Rights. However, legal remedies cannot address all the political problems that the use of Glyphosate demonstrates. If Colombia's troubles, as has been postulated, are a result of a lack of government presence, the use of Glyphosate, whether legal or not, only serves to deepen those troubles by widening the breach between citizen and government.

Endnotes: Chemical Taking in Colombia

[1] Coca cultivated for its narcotic effects are generally referred to as Coca Erythoxylum. *See* Bruce A. Bohm and Fred R. Ganders, *Biosystematics and Evolution of Cultivated Coca(Erythoroxylaceae)*, Systematic Botany, Vol. 7. No. 2 (Apr. 1982), 121,133.

[2] *See* Joel M. Hanna, *Coca Leaf Use in Southern Peru: Some Biosocial Aspects.* American Anthropologist, New Series Volume 7, No.3 (Sept. 1976) 630, 634.

[3] UN Office on Drugs and Crime, *World Drug Report Vol. 1*, *available at* http://www.unodc.org/pdf/WDR_2005/volume_1_web.pdf (*last visited* Mar. 4, 2006) [hereinafter *World Drug Rpt*.].

[4] *World Drug Rpt.*, *id*.

[5] *See generally*, Zachary P. Mugge, Note, Plan Colombia: The Environmental Effects and Social Costs of the United States' Failing War on Drugs, 15 Colo. J. Int'l Envtl. L. & Pol'Y, 309 (discussing the role of Aerial eradications in the War on Drugs). *See also* Resolution 00017, 04/10/2001 Dirección Nacional de Estupifacientes [National Drug Commission], (incorporating La Carta Acuerdo de Cooperación para la Prevención y el Control del Problema de las Drogas, the 1999 treaty between the United States and Colombia for the elimination of Coca and cocaine, into the larger framework of the Commission's hearing of claims resulting from aerial spraying of Glyphosate.) http://www.dnecolombia.gov.co/contenido.php?sid=103, (last visited (Mar. 19, 2006).

[6] Mugge, *supra* note 5. (outlining debate on between scientist on strength of Glyphosate mixes).

[7] Mugge, *id*.

[8] Danielle Knight, *Plan Colombia: Fumigation Threatens Amazon, Warn Indigenous Leaders, Scientists*, Nov. 21, 2000, Inter Press Service.

[9] *See* U.S. Department of State, Aerial Eradication of Illicit Coca and Poppy in Colombia http://www.state.gov/p/inl/rls/rpt/aeicc/c14651.htm (Outlining Andean Regional initiatives to combat cocaine production), (last visited Mar. 19, 2006).

[10] World Drug Rpt., *supra* note 3, at 62

[11] World Drug Rpt., *supra* note 3, at 62.

[12] Steven Dudley, *Walking Ghosts, Murder and Guerrilla Politics in Colombia* (2004).

[13] *Colombia's Displaced People*, Economist, Feb. 11, 2006, at 37. *See also* P.W. Fagen, A. Fernandez Juan, F. Stepputat & R.V. Lopez, G. Kongevej *Internal Displacement in Colombia: National and International Responses*, Inst. Int'l Stud., Working Paper 03.6, June 2003.

[14] Country Information for Colombia, U.S. Department of State, http://www.state.gov/r/pa/ei/bgn/35754.htm (last visited Mar. 19, 2006).

[15] Country Information for Colombia, *id*.

[16] *See* Luz E. Nagle, *Colombian Asylum Seekers: What Practitioners Should Know About The Colombian Crisis.* 18 Geo. Immigr. L.J. 441, Spring, 2004.

[17] Coca leaves, mashed into a paste or pasta, are in fact only one of the ingredients of cocaine. "The pasta is first washed in kerosene. It is then chilled. The kerosene is removed. Gas crystals of crude cocaine are left at the bottom of the tank. Typically, the crystals are dissolved in methyl alcohol. They are then recrystallised and dissolved once more in sulfuric acid. Further washing, oxidation and separation procedures involve potassium permanganate, benzole, and sodium carbonate." http://www.cocaine.org/process/html (last visited Mar. 19, 2006).

[18] Act. Pub. L. No. 107-115, 567, 115 Stat. 2118, 2165 (2002), http://law2.house.gov/download/pls/22C32.txt, (last visited Mar. 4, 2006).

[19] Mugge, *supra* note 5.

[20] *Plan Colombia: Major Successes and New Challenges*, Roger F. Noriega, Assistant Secretary for W. Hem. Aff. Statement Before the House Int'l Rel. Com. Washington, D.C. May 11, 2005.

[21] *Colombia Sigue Siendo el Mayor Exportador Mundial de Cocaína, Dice Informe de la ONU*, El Tiempo,

Endnotes: Chemical Taking in Colombia *Continued on page 75*

NANOTECHNOLOGY: GETTING IT RIGHT THE FIRST TIME

*by Karen Florini, Scott Walsh, John M. Balbus, and Richard Denson**

INTRODUCTION

Nanotechnology, the design and manipulation of materials at the atomic scale, may well revolutionize many of the ways our society manufactures products, produces energy, and treats diseases. Hundreds of large and small nanotechnology companies are developing a wide variety of materials for use in electronics, medical diagnostic tools and therapies, construction materials, personal care products, paints and coatings, environmental cleanup, energy production and conservation, environmental sensors, and many other important applications. The National Science Foundation predicts that the global market for nanomaterial products could reach $1 trillion within a decade.[1]

Deliberate exploitation of properties evident only at the nanoscale is central to these applications. Such properties include the large surface area of various nanomaterials, which arise from their tiny particle size, absorption and radiation of highly specific wavelengths of light, ability to penetrate cellular barriers, and high tensile strength and durability. Carefully controlled, these properties may provide highly beneficial products. However, these new and enhanced properties also raise the possibility of unintended and adverse consequences, both for human health and for the environment. For example, the same binding properties that allow nanomaterials to deliver therapeutics to cancer cells might also allow nanomaterials with these properties to deliver toxic substances to aquatic organisms. Likewise, the electrical properties that drive applications in computers may lead to oxidative damage in living tissues. It is in the best interest of companies and society that these potential harms are identified prospectively, and are addressed, ideally through material design, or alternatively, through safeguards on production, use, or disposal.

Available data, while limited in scope, clearly indicate both that some nanomaterials have hazardous properties and that growing numbers of nanomaterials are reaching the market. Unfortunately, it is far from clear whether existing federal regulatory programs will provide an effective means of addressing nanomaterial risks, particularly in the foreseeable future. As an interim measure, several voluntary initiatives to develop standards for the safe production, use, and disposal of nanomaterials are now underway. The rigor of such standards, the degree to which mandatory safeguards are adopted, and the extent to which risk-related data are generated prior to widespread dispersion of nanomaterials will jointly indicate whether previous technological mishaps will be avoided in developing nanotechnology.

WHY "GETTING IT RIGHT THE FIRST TIME" IS IN THE NANOTECHNOLOGY INDUSTRY'S INTEREST

Environmental law is replete with illustrations of how ignorance failed to produce bliss for industry, workers, consumers, the public, and the environment. When the harmful effects of asbestos were widely recognized, years after the material had been extensively distributed in commerce, many makers and users of asbestos products found themselves embroiled in costly litigation brought by victims and their families. As of 2002, more than half a million people had filed claims related to asbestos exposure.[2] Notably, five corporations have spent more than $1 billion each on asbestos litigation; indeed, one company alone recently agreed to pay more than $4 billion to settle pending claims for asbestos exposure.[3] Standard & Poor's has estimated that the total cost of liability for asbestos-related losses could reach $200 billion.[4]

Tort liability is not the only route by which actions that are lawful today can become major headaches for industry tomorrow. In 1980, the U.S. Congress enacted the Superfund law, under which dumpsite operators, along with those who generate or transport the wastes, are legally responsible for cleaning up properties contaminated by toxic wastes, regardless of whether the contamination arose from illegal activities.[5] Indeed, under Superfund's "joint and several liability" provisions, a company that contributes any amount, no matter how small, to the contamination of a Superfund site may, theoretically, be held liable for the cleanup of the entire site (though the company can then seek cost-recovery against other contributors).[6] To date, the industry has expended more than $20 billion in remediation and related costs.[7]

Even without conclusive proof linking a new technology or material to an environmental or health harm, companies may be severely penalized for failing to demonstrate the safety of their products at the onset. When European nations contested the safety of bioengineered foods, their refusal to accept imports of such foods cost U.S. farmers an estimated $300 million annually in lost crop export revenues.

Each of these examples illustrates that the failure to identify and address the risks – real or perceived – of new technologies and materials can lead to immense costs, from financial and managerial perspectives, as well as from human and environmental standpoints.[8]

At present, most consumers have such limited familiarity with nanotechnology that they have formed few impressions.

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However, a recent study provided basic information on nanotechnology to representative groups of citizens in three locations. After reviewing that information, a substantial majority of participants said that although they anticipate major benefits from nanotechnology, they are concerned that industry is pushing products into the market without conducting adequate safety testing.[9] As nanotechnology products continue to increase their presence in the market and in the news, such views may become more widespread. Indeed, although relatively few studies have been conducted on nanomaterials, the initial results have identified surprising, hazardous properties, *i.e.* intrinsic abilities to cause adverse effects. At the same time, the rapid pace of commercialization suggests that the potential for human and environmental exposure will grow dramatically. Available information on both of these elements of risk – hazard and exposure – is briefly summarized below. Complicating the process of both obtaining and evaluating such information is the lack of an agreed-upon system for naming and uniquely describing nanomaterials of various structures and the limited ability to detect and characterize nanomaterials in many biological and environmental media.

Nanomaterial Hazards: Flashing Yellow Lights

The inherent nature and novel properties of certain nanomaterials, and the results from many of the relatively small number of nanotoxicity studies conducted to date, lead to concerns about nanomaterials' health and safety impacts. Many of the very properties that make nanomaterials useful also raise the potential for these materials to present novel mechanisms and targets of toxicity. For a given mass of particles, surface area increases dramatically as the diameter of the individual particles decreases. This increased surface-area-to-mass ratio appears to be a critical feature in understanding some aspects of the toxicity of nanomaterials. For example, in a study comparing the toxicity of conventional versus nano-sized particles of titanium dioxide, the nanoparticles appeared significantly more toxic than the conventional particles when the dose was reported on a mass basis, but this distinction essentially disappeared when the dose was reported on a surface area basis.[10] The higher surface area also leads to higher particle surface energy, which may translate into higher reactivity.[11] Lastly, the combination of high surface area and small size may give nanoparticles unusual, catalytic reactivity, such as those seen with gold nanoparticles.[12] This combination of enhanced surface area and enhanced surface activity lends far greater complexity to the characterization of nanoparticles when compared to bulk and conventional substances, and also precludes easy extrapolation about potential toxicity.

Presently, quantitative data on exposure to nanomaterials are almost nonexistent.

Moreover, at least some nanoparticles can readily penetrate cell membranes, which enables them to deliver targeted drug therapies. Evidence suggests that some nanoparticles can also cross physiologic barriers (including the lung-blood, blood-brain, and placental barriers), and can enter body compartments that neither larger particles nor smaller molecules can readily access. One study of twenty nanometer polystyrene beads suggests that they enter cells by passing directly through membranes, without requiring specific transport mechanisms. Once inside the cells, the nanoparticles distribute throughout the cytoplasm and appear to bind to a variety of key cellular structures.[13]

Surface modifications may allow nanoparticles to bind to cell surface receptors and potentially to interact with internal cell structures.[14] Subtle variations in nanoparticle surfaces, whether due to intentional coating prior to entry into the body, unintentional surface binding, or coating degradation once inside the body, can have dramatic impacts on where and how nanoparticles gain entry into organs and cells, as well as where and how they are transported after entry. These complexities increase the difficulty of understanding nanomaterial hazards.

In addition to these inherent characteristics, the limited empirical data available adds to the concerns. As of yet, no studies on any nanomaterial's reproductive toxicity, immunotoxicity, developmental toxicity, or chronic health effects, such as cancer, have been published, although some are underway.[15] The limited number of short-term studies completed to date demonstrate a variety of adverse effects. Studies in which single-walled carbon nanotubes ("SWCNTs") were implanted into the lungs of rodents have consistently demonstrated that they cause unusual lung granulomas and have shown other signs of lung inflammation.[16] Moreover, one study found that SWCNTs also cause dose-dependent, diffuse interstitial fibrosis, a form of lung disease.[17] A study of multi-walled carbon nanotubes ("MWCNTs") showed similar lung toxicity, especially after the MWCNTs were finely ground.[18] Single- and multi-walled carbon nanotubes also induce oxidative damage to skin cells, which can result in membrane damage that leads to cell death.[19] These studies raise questions of potential toxicity at the beginning and end of the carbon nanotube ("CNT") lifecycle. This can occur through workplace exposures or when CNT-containing products undergo weathering, erosion, or grinding during recycling or disposal.

The toxicity of C_{60} fullerenes (commonly known as buckyballs) is particularly unclear at present. Computer modeling suggests that fullerenes can bind to DNA and have "negative impact on the structure, stability, and biological functions of DNA molecules."[20] As a result, if fullerenes gain access to cell nuclei, they may interfere with critical cellular machinery. While fullerenes are insoluble as single particles, they can form crystalline aggregates that are readily soluble in water; these aggregates appear to be toxic to bacteria.[21] In addition, studies in fish

have shown that fullerenes can be transported via the gills from water to the brain, where they can cause oxidative damage to brain cell membranes.[22] Uncoated fullerenes have also been found to cause oxidative stress in *in vitro* testing systems, *i.e.* cell-based systems as distinguished from whole-organism ones.[23] However, some scientists have questioned whether observed toxicity is caused by contaminants, specifically organic solvents, rather than the fullerenes themselves, and have pointed to studies that show negligible toxicity and even protective effects from pristine fullerenes that are made into water-soluble aggregates, without the use of organic solvents.[24] This alternate hypothesis, however, disregards indications that the fullerene aggregates produced without solvents are significantly larger, and thus less able to penetrate cells, than those formed with solvents. This ongoing debate highlights the importance of understanding nanomaterials' physical form, as well as the limitations of current scientific understanding about nanomaterial toxicity.

Finally, quantum dots can be composed of a variety of inherently toxic materials, including cadmium and lead. Because some of the key potential applications of quantum dots include diagnostic imaging and medical therapeutics, quantum dots have been studied relatively extensively in biological systems. However, only a small portion of this research has focused on potential toxicity, and those studies performed to date have mainly been *in vitro* assays. While results have been somewhat inconsistent, studies that used longer exposure times were more likely to demonstrate significant toxicity.[25] Inorganic elements typically make up the core of quantum dots, but these elements are generally coated with organic materials, such as polyethylene glycol, in order to enhance their biocompatibility or target them to specific organs or cells. While many coatings initially decrease toxicity by one or more orders of magnitude, the coatings might degrade when exposed to air or ultraviolet light, which could lead to toxicity increases. While the presumption has been that this cytotoxicity is caused by leakage of cadmium or selenium from the core, there is evidence that some of the molecules used as coatings may have independent toxicity.[26]

[T]he pace of the regulatory process lags far behind the speed at which nanomaterials are being introduced into the market.

Nanomaterial Exposures: A Lifecycle View

Some nanomaterials now on the market, and others in development, can clearly result in human and environmental exposures to nanoparticles. Examples include uses in drugs and cosmetics, and remediation of groundwater contamination.

However, other products may also lead to substantial exposure, though the exposure does not necessarily occur during a product's useful life. For example, nanotubes or other nanomaterials embedded within resins or other matrices may be incorporated into tennis rackets, automobile running boards, or other products. Although risk of exposure to these nanotubes (which, as noted above, have been shown to damage lung tissue)[27] appears minimal during product use, pre- and post-use exposure must also be considered. Such exposure may occur during the manufacture of the product and its components, or during disposal, recycling, or reclamation. Human and environmental exposure during these other stages may be substantial. For instance, although computer users are highly unlikely to inhale carbon nanotubes bound in their computer screen, the exposure potential may dramatically increase if recyclers ultimately grind up those screens for other uses, such as road aggregate. Human exposure is most obvious for the workers doing the grinding, but may also harm road-construction workers, travelers, and neighbors as the road's surface weathers with time and traffic. Occupational exposure to researchers and students may also occur in research and development settings. In sum, it is necessary to consider a product's complete lifecycle in order to understand the effects of exposure and address risks effectively.

Presently, quantitative data on exposure to nanomaterials are almost nonexistent. However, sources indicate that numerous nanomaterial-containing products are entering commerce, thus creating the potential for human and environmental exposure at various stages of their lifecycles. According to the U.S. Environmental Protection Agency ("EPA"), "a survey by EmTech Research of companies working in the field of nanotechnology has identified approximately 80 consumer products, and over 600 raw materials, intermediate components and industrial equipment items that are used by manufacturers," though detailed results of this survey do not appear to be public.[28] Lux Research, a nanotechnology research and advisory firm, projected in 2004 that: "Sales of products incorporating emerging nanotechnology will rise from less than 0.1 percent of global manufacturing output today to fifteen percent in 2014, totaling $2.6 trillion. This value will approach the size of the information technology and telecom industries combined."[29] More informally, an eBay search using the word "nano" produces items such as golf clubs, tennis racquets, face lotions, and sun blocks; notably, however, these references may reflect marketing initiatives rather than actual nanomaterial use. Certain nanomaterials are also readily available for direct purchase, as illustrated by a Google search producing sources for nanotubes, buckyballs, quantum dots, and metal oxide nanoparticles.

Other information suggests that nanomaterial uses and exposures in the United States are about to increase significantly. For example, the President's Council of Advisors on Science and Technology concluded in a 2005 report that the United States is the world leader in nanotechnology by a variety of

measures, including public and private spending, numbers of start-up companies, and numbers of scientific research articles. The NanoBusiness Alliance states that there are 613 companies involved with nanotechnology within the United States, while noting that "it is notoriously difficult to track commercial developments in nanotechnology, so [the Alliance] cannot be precisely sure."[30] Likewise, the dramatic growth in the number of nanotechnology patents issued by the U.S. Patent Office suggests that increasing numbers of nanomaterials are being introduced into the market.[31]

With the commercialization of more products containing nanomaterials comes the risk for more human and environmental exposure, which lends urgency to the need for understanding the potential hazards of nanomaterials. It also raises the questions of whether, and how carefully, regulators are reviewing the lifecycle impacts of these new materials before they reach the market.

Nanomaterial Risks: Will Existing Regulatory Programs Protect Workers, the Public, and the Environment?

Effectively managing nanomaterials' potential risks will prove to be a challenge for existing occupational and environmental regulatory frameworks for at least five reasons. First, in most of the current regulatory programs, standards and their exemptions are based on mass and mass concentration. Because of their high surface-area-to-mass ratios, and enhanced surface activity, nanomaterials are likely to prove potent at far lower concentration levels than envisioned when these thresholds were initially set.

Second, although regulators can often reasonably predict at least some types of toxicity for new conventional materials based on extrapolation from conventional materials having a similar chemical structure, too little is currently known about nanomaterials to enable such extrapolation.

Third, it appears that many nanomaterials are being developed in a decentralized fashion, with a significant percentage of production coming from small, dispersed facilities. As a result, the sheer number of facilities involved will hamper the gathering of information on which materials are produced, and the purpose and specific applications of the materials, as well as directing compliance and enforcement efforts to where they are needed. Additionally, much of the production, processing, and use of these materials will take place in facilities that may lack the expertise and resources to understand and comply with environmental and occupational safeguards.

Fourth, some potential nanotechnology applications may fall through the cracks among the jurisdictions of multiple regulatory programs. For example, the Food and Drug Administration ("FDA") reviewed sunscreens using nanoparticles of titanium dioxide for potential of immediate health effects on consumers.[32] However, neither the FDA nor the EPA appears to have reviewed how titanium dioxide nanoparticles could affect aquatic ecosystems once these sunscreens wash off.

Lastly, the pace of the regulatory process lags far behind the speed at which nanomaterials are being introduced into the market. While substances marketed as pesticides,[33] fuel additives,[34] or drug or food additives[35] regularly receive significant scrutiny when first introduced, most other substances do not.[36] As a result, occupational and environmental protections are generally developed only after problems are identified or strongly suspected in regulatory proceedings that typically take several years to complete. A more detailed discussion of specific regulatory issues under key U.S. laws follows.

U.S. Occupational Safety and Health Act

Under the Occupational Safety and Health Act ("OSHAct"),[37] four types of regulatory mechanisms are available for protecting workers from overexposure to chemicals: substance-specific standards, general respiratory protection standards, hazard communication standards, and the "general duty clause." Each is examined below.

[V]oluntary "standards of care" for nanomaterials must play a role in guiding the safe use of nanomaterials in the near term.

As a practical matter, substance-specific occupational standards are unlikely to be set in the absence of extensive toxicology data. Currently, the vast majority of standards adopted have been based on findings of human epidemiological studies, which follow widespread exposure and take years, or even decades, to conduct. Given the relative paucity of health data on nanoparticles, it is unlikely that any nanoparticle-specific standards will be established in the reasonable future. In their absence, inhalable nanoparticles will automatically be covered by the 5 micrograms per cubic meter ("mg/m_3") standard that applies to "particulates not otherwise regulated," sometimes called "nuisance dust."[38] Unfortunately, these mass-based standards, developed for conventional particles, are unlikely to protect workers from adverse effects of nanoparticle exposures; indeed, one study has suggested that exposure to carbon nanotubes at 5 mg/m_3 for several weeks would be analogous to exposure levels found to cause lung granulomas and inflammation in rats.[39]

Second, the respiratory protection standard requires employers to provide workers with respirators or other protective devices when engineering controls are not adequate to protect health.[40] The standard provides guidance in selecting specific personal protective equipment and in implementing workplace respiratory protection programs. Only respirators certified by the National Institute of Occupational Safety and Health may be used, and employers must assess the effectiveness of the respirators they supply. The current lack of validated means to

measure and characterize the form and size of nanoparticles in the air, as well as the uncertainties regarding respirator performance, especially in relation to particles between 30 and 70 nanometers and potential agglomerates around 300 nanometers, will complicate implementation of this standard.[41]

Third, OSHAct's hazard communication standard[42] stipulates that all producers or importers of chemicals are obligated to develop Material Safety Data Sheets ("MSDSs"), which are intended to provide workers with available information on hazardous ingredients in products they handle and educate them on safe handling practices. However, even when accurate and up-to-date, MSDSs have significant limitations; most notably, there is no requirement to either generate data on potential hazards or disclose the absence of any data. Moreover, in some instances, a nanomaterial's MSDS has simply adopted the hazard profile for a presumedly-related bulk material. For example, an MSDS for carbon nanotubes identifies the primary component as graphite, and cites information on the hazards of graphite, without acknowledging any dissimilarity between the two substances.[43] From a scientific perspective, this makes no more sense than considering carbon nanotubes equivalent to diamonds. While graphite, diamonds, and carbon nanotubes are all composed of carbon, the physical and chemical properties of these three substances are quite distinct, reflecting their radically different molecular structures.

Finally, OSHAct's general duty clause[44] is intended as a backstop to protect workers from certain exposures that are widely known to result in toxic effects but are not addressed specifically by an OSHA standard. The general duty clause, however, applies only to "recognized" hazards, a difficult criterion to meet in light of the current paucity of toxicity data on specific nanomaterials.

U.S. Toxic Substances Control Act

Beyond the occupational realm, the array of potential environmental regulatory authorities initially appears impressive. These include the Clean Air Act, the Clean Water Act, the Resources Conservation and Recovery Act, which addresses management of hazardous and other solid wastes, and the Toxic Substances Control Act ("TSCA"), which covers commercial chemicals other than those used as drugs, food additives, cosmetics, fuel additives, and pesticides. Yet, most existing regulations under these statutes are not directly relevant to nanomaterials. Moreover, adopting new standards would require that the EPA launch lengthy, data-intensive rulemaking processes that would take years to complete.[45]

Certain provisions of TSCA, however, currently apply and may be the most immediate way for the EPA to regulate at least some nanomaterial applications. Enacted in 1976, TSCA authorizes the EPA to regulate chemicals that are processed, imported, manufactured, distributed in commerce, used, or disposed of in the United States upon finding that they pose an "unreasonable risk."[46] As further discussed below, TSCA also has certain provisions under which the EPA can review the safety of new chemicals before they enter commerce. "New" chemicals, as defined by the TSCA, are those not included in the initial Inventory of Chemicals in Commerce completed in 1980, or subsequently added to the Inventory after going through the new-chemical review process.[47] As of 2005, the EPA had reviewed more than 40,000 new chemicals prior to their introduction into commerce, and had restricted or otherwise regulated 1,600, or four percent, of these chemicals.[48]

At first blush, TSCA appears to provide the EPA with a fairly broad authority to regulate new chemicals. As noted in the Conference Report accompanying TSCA's enactment:

> [T]he most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but also the cost of any regulatory action in terms of loss of jobs and capital investments is minimized. For these reasons the conferees have given the Administrator broad authority to act during the [pre-manufacture] notification period.[49]

Specifically, section 5 of TSCA requires the producer of a "new" chemical substance to send EPA a "Pre-Manufacture Notification" ("PMN") before beginning to produce a substance. At least in theory, PMNs allow the EPA to review and assess the potential risks of a new material before it reaches the market and, if necessary, to require that a producer provide further information, or limit the chemical's use.

Unfortunately, there are no baseline data requirements for PMNs, and 85 percent of PMNs are submitted without any health data.[50] Although the EPA can request additional data, it rarely does so; instead, it typically conducts its review based on use of structure-activity relationship models. This model estimates the toxicological properties of an unstudied substance, based on the extent of molecular structural similarity to substances with known toxicological properties. Existing models have little applicability to nanomaterials, because the models are based on the properties of bulk forms of conventional chemical substances, and because nanomaterials' novel and enhanced properties result from characteristics other than their molecular structure, *e.g.* size or shape. It remains to be seen whether the EPA will require actual toxicity data on nanomaterials to be submitted as part of the PMN review process.

Other key questions also remain unresolved, including the extent to which nanomaterials qualify as "new" chemicals, which is necessary to trigger PMN requirements. Under TSCA, a "new" chemical is one that is not already listed on the TSCA Inventory of chemicals in commerce and is of "a particular molecular identity."[51] Although it is obvious that a nanomaterial constitutes a "new" chemical if its molecular formula is not already on the TSCA Inventory, some parties assume that a nanomaterial qualifies as "existing," *i.e.* not new and therefore not subject to PMN review, if its molecular structure is identical to a substance already on the Inventory. By this logic, carbon nanotubes would not require PMNs, because graphite is already listed on the TSCA Inventory. As of January 2006, only about ten PMNs or PMN

exemption requests had been submitted to the EPA, even though a much larger number of nanomaterials appear on the market in the United States.[52] Of these, the EPA had approved only one: a low-release/low-exposure PMN exemption for a carbon nanotube,[53] under which the manufacturer typically must submit a full PMN once production exceeds a specified volume.

Environmental Defense has urged the EPA to clarify that nanomaterials with existing molecular structures still constitute "new" substances unless their chemical and physical properties are demonstrably identical to those of the conventional substance. This definition is based on the grounds that only substances with the same properties, as well as the same molecular structure, share "a particular molecular identity."[54] Environmental Defense also urged the EPA not to apply mass-based, or other exemptions in the PMN program, unless the underlying scientific rationale is appropriate when applied to nanomaterials.[55]

In addition to its pre-manufacture review provisions, TSCA also provides for certain information-gathering authorities. For example, section 8(a) authorizes the EPA to require that manufacturers provide use and exposure information; section 8(e) requires manufacturers to submit any information indicating that a substance may pose a "significant risk" to health or to the environment; and section 8(d) authorizes the EPA to require manufacturers to submit all toxicity-related studies already in their possession. As further discussed below, the EPA is currently conducting a multi-stakeholder process on nanomaterial risks in order to design a voluntary initiative and consider possible uses of TSCA authorities.

Finally, section 6 of TSCA theoretically authorizes the EPA to restrict the manufacture, processing, distribution in commerce, use, and disposal of chemical substances if "there is a reasonable basis to conclude" that its manufacture, distribution in commerce, use, or disposal "presents or will present an unreasonable risk of injury to health or the environment."[56] However, as a practical matter, the procedural requirements associated with section 6 are so complex that these provisions have seldom been used.[57]

Federal Consumer Products Laws

As noted above, TSCA does not cover certain chemical substances. In particular, TSCA does not cover pesticides, which the EPA regulates under the Federal Insecticide, Fungicide, and Rodenticide Act. TSCA additionally does not cover food, food additives, drugs, cosmetics, or medical devices, which the FDA regulates under the Federal Food, Drug, and Cosmetic Act. However, although cosmetics are excluded from TSCA, they are not subject to FDA pre-market approval authority.[58] As also is noted above, fuel additives, including a nanomaterial-based additive now under review by the EPA,[59] are covered by specific provisions of the Clean Air Act.

Unlike TSCA, the other programs require companies to submit specified data on the safety of new products before they are introduced into commerce. By definition, however, only nanomaterials used for these specific types of applications are covered by these particular programs. Moreover, the FDA acknowledges that, even if a product involving nanotechnology falls within its ambit, the agency may not even be aware that the product contains a nanomaterial, "if the manufacturer makes no nanotechnology claims regarding the manufacture or performance of the product."[60]

Finally, the Consumer Product Safety Act ("CPSA"), like TSCA, does not require pre-market testing of new products.[61] As a practical matter, the U.S. Consumer Product Safety Commission, which administers the CPSA, focuses largely on injuries and poisonings, rather than chronic toxicity issues.[62]

Addressing Nanomaterial Risks: Next Steps

Given the limitations of existing regulatory tools and policies, three distinct kinds of initiatives are urgently needed: *first*, a major increase in nanomaterial risk research; *second*, rapid development and implementation of voluntary standards of care, pending development of adequate regulatory safeguards; and *third*, updates of existing policies to address the shortcomings described above in addressing nanomaterial risk management. A wide array of stakeholders must be involved in all components of these processes, including labor groups, health organizations, consumer advocates, community groups, environmental organizations, as well as large and small businesses and the academic community.

Increase Governmental Investment in Risk Research

The U.S. government, as the largest single investor in nanotechnology research and development, needs to spend more time and money to assess the health and environmental implications of nanotechnology, and to ensure that the critical research needed to identify potential risks is conducted expeditiously. Through the National Nanotechnology Initiative, the federal government spends more than $1 billion annually on nanotechnology research and development.[63] Of this amount, environmental and health implications research accounted for only $8.5 million (less than one percent) in fiscal year ("FY") 2004.[64] This funding is expected to increase to $38.5 million (less than four percent) in FY 2006.[65]

The U.S. government should spend at least $100 million annually on risk research for the next several years. While an annual expenditure of $100 million represents a significant increase over current levels, it is still less than ten percent of the overall federal budget for nanotechnology development. Moreover, this amount is a modest investment compared to the potential benefits of risk avoidance and the $1 trillion role that nanotechnology is projected to play in the world economy by 2015.

Given the wide-ranging set of research issues that need to be addressed, and the significant uncertainties associated with the anticipated results, there is no single "magic number," nor precise method to determine the right dollar figure that should be expended. Nevertheless, $100 million per year represents a reasonable, lower-bound estimate of what is needed. Experts broadly agree that addressing the potential risks of nanotechnol-

ogy will be an unusually complex task. Despite its name, nanotechnology is anything but *singular*; it is a potentially limitless collection of technologies and associated materials. The sheer diversity of potential materials and applications, which is a source of nanotechnology's enormous promise, also poses major challenges with respect to characterizing potential risks.

A wide range of stakeholders are calling for increased research. In a rare example of convergence from sectors that often have highly divergent views, representatives from the environmental, manufacturing, investment, and insurance communities have all advocated dramatic increases in federal funding on the health and environmental implications of nanotechnology. For example, in June 2005, the CEO of DuPont and the President of Environmental Defense coauthored an Op-Ed in the *Wall Street Journal*, calling for an increase in such funding.[66] That same month, the American Chemical Council's Chemstar Panel on nanotechnology and Environmental Defense issued a Joint Statement of Principles, stating that "[a] significant increase in government investment in research on the health and environmental implications of nanotechnology is essential."[67] A recent report on nanotechnology by Innovest, an investment research and advisory firm, "strongly support[ed] calls by others in the investment community for increased government funding of toxicology research," and noted that the National Nanotechnology Initiative's "lack of priority for this issue represents a missed opportunity to minimize uncertainty."[68] Additionally, several of the world's largest insurance firms, including Swiss Re,[69] Munich Re,[70] and Allianz,[71] have called for greater scrutiny of the potential risks of nanotechnology.

Experts' assessments, testing costs associated with hazard characterization programs for conventional chemicals, and comparison to the research budgets for a roughly analogous risk characterization effort on risks of airborne particulate matter further buttress the call for greatly expanded health and environmental research spending.[72]

Current federal initiatives on nanotechnology have made significant achievements in accentuating and accelerating the enormous potential benefits of nanomaterials. To date, however, federal agencies have not fulfilled their equally critical role in identifying, managing, and ideally avoiding the potential downsides. A far better balance between these two roles must be struck if nanotechnology is to deliver on its promise, without delivering unintended and unforeseen adverse consequences.

But the U.S. government should not be the sole, or even the principal, funder of nanomaterial risk research. Other governments are also spending heavily to promote nanotechnology research and development, and they too should allocate some portion of their spending to address nanotechnology risks. Indeed, the United Kingdom's Royal Society and Royal Academy of Engineering, in its seminal July 2004 report, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties,* calls for the U.K. government to devote £5-6 million (US $9.5-11.3 million) per annum for ten years, to do its part to develop the methodologies and instrumentation needed to set the stage for actual testing of nanomaterials.[73]

Although government risk research plays a critical role in the development of basic knowledge and methods for characterizing and assessing the risks of nanomaterials, private industry should fund the majority of the research and testing on the products they are planning to bring to the market. In turn, governments should focus on providing the "enabling infrastructure" for nanotechnology research. Such research cuts across a broad range of disciplines, and will have broad impacts on society. In particular, the government can mobilize the research industry to create a database of representative, model nanomaterials. The government can also develop methods and tools needed to characterize, detect, and measure nanomaterials; to assess their biological fate and behavior; and to assess acute and chronic toxicity. Most importantly, the government can coordinate this research, and disseminate the results, thereby increasing efficiency and reducing redundancy. Clearly, all parties involved will benefit if governments and industry coordinate their research to avoid redundancy and optimize efficiency.

Develop Voluntary Standards of Care

Given that federal agencies are unlikely to develop and implement adequate regulatory programs for nanomaterials quickly enough to address the products now entering or poised to enter the market, voluntary "standards of care" for nanomaterials must play a role in guiding the safe use of nanomaterials in the near term. These standards should include a framework and a process by which to identify and manage nanomaterials' risks across a product's full lifecycle, taking into account worker safety, manufacturing releases, product use, and product disposal. In addition, these standards should incorporate feedback mechanisms, including environmental and health monitoring programs, to check the accuracy of judgments made about a nanomaterial's risks, and the effectiveness of risk management practices. Such standards should be developed and implemented in a transparent and accountable manner, including public disclosure of the assumptions, processes, and results of the risk identification and risk management systems.

Several voluntary programs are currently at various stages of evolution, though their eventual outputs are still far from clear. In November 2005, a workgroup of an EPA advisory committee proposed a framework for a voluntary program aimed at producers, processors, and users of nanomaterials. The group also recommended using certain TSCA regulatory authorities to address nanomaterial risks.[74]

In addition, both ASTM International[75] and the American National Standards Institute (with the International Standards Organization)[76] have recently initiated multi-stakeholder efforts to develop voluntary standards for nanotechnology. Both initiatives are at an early stage, and have not yet produced substantive drafts.

Finally, Environmental Defense and DuPont are working together to design and demonstrate a framework for the responsible development, production, use, and disposal of nanoscale materials. While the project will initially pilot-test the framework on specific nanoscale materials, or on applications of interest to DuPont, the organizations intend to develop a framework that

can be adapted for use by a broad range of stakeholders.

But voluntary standards by themselves are only a temporary expedient; in the longer term, regulatory programs will be essential to securing long-term public confidence and support for nanotechnology. Here again, a wide range of stakeholders believe that a nanotechnology regulatory scheme is needed. In a survey conducted by the Wilson Center, 55 percent of the 1,250 respondents stated that government control beyond voluntary standards was necessary, while only eleven percent felt that voluntary standards were adequate.[77] According to a recent report on nanotechnology by Innovest, "[a] significant portion of the more than 60 companies we interviewed indicated an interest in having some sort of standards in place. In many cases, they felt that science-based regulation would provide a more level playing field."[78] In a Joint Statement of Principles submitted to the EPA, both Environmental Defense and the Nanotechnology Panel of the American Chemistry Council stated that the responsible regulation of nanomaterials "will best assure that nanomaterials are being developed in a way that identifies and minimizes potential risks to human health and the environment."[79] In an Op-Ed in the Wall Street Journal, Environmental Defense's President, Fred Krupp, and Dupont's Chairman and CEO, Chad Holliday, agreed that "both public and business interests will inevitably compel regulatory protection to ensure product safety and to create a level playing field for business."[80]

Conclusion

As recently noted by a columnist for the *Motley Fool* investment newsletter, "the scientific community will inevitably determine that at least some nanoscale materials pose unnecessarily high risks."[81] If the public, however, were to discover that companies knowingly hid or downplayed the risks, it could not only lead to lawsuits, but might also create a serious backlash against all things nano. The best-case scenario might be over-regulation, while the worst case may be that many nanotechnology-related products are banned altogether.

In an ideal world, adequate data on nanomaterials' hazards and exposure would already exist, allowing governments to establish appropriate safeguards through a transparent public process that would generate long-term public confidence in nanotechnology. In reality, such data are extremely limited, and regulatory programs are undeveloped. Substantially greater amounts of government and corporate support for research into the health and environmental effects of nanomaterials are urgently needed, along with rapid development of voluntary standards of care that can help address the issues until meaningful regulations can be put into place.

Endnotes: Getting it Right the First Time

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Endnotes: Getting it Right the First Time *Continued on page 77*

Bisphenol-A and its Harmful Effects on Human Development

*by Letty Guerra**

Bisphenol-A ("BPA"), the endocrine-disrupting chemical used to create polycarbonate plastics, such as baby bottles, microwavable plastics, and children's toys, may interfere with human brain development.[1] BPA is consumed when it leaches from plastic containers into foods or drinks as they are heated or when they become broken or cracked.[2] BPA has been linked to a numerous adverse effects, including an increase in breast and prostate cancer cell growth,[3] obesity when exposed early in life, gestational diabetes in women,[4] damage to human brain development, diminished sperm production,[5] early puberty,[6] and insulin-resistance, which leads to diabetes.[7]

An ongoing concern in the scientific community is the effect of prenatal and childhood exposure to BPA and other endocrine-disrupting chemicals ("EDCs"). The relation of these chemicals to "abnormalities in human sexuality, gender development and behaviors, reproductive capabilities, and sex ratios" is a major distress among scientists.[8] Although high-level exposure to EDCs clearly has gender-related effects on human development, today's debate centers around low-dose exposures, "generally defined as doses that approximate environmentally relevant levels."[9] BPA studies have demonstrated that exposure at quantities lower than the EPA's reference dose has detrimental effects on fetal development.[10] Additionally, the possibility that harmful effects from exposure to EDCs can be passed down through generations is extremely alarming.[11]

The current U.S. Environmental Protection Agency ("EPA") standard for tolerable levels of BPA exposure was set in 1982 and is known as the "reference dose."[12] This dose, 50 mg/kg/day, reflects the level of BPA that the EPA has determined is safe for human exposure. However, studies indicate that lower exposure doses of BPA have profound impacts on human development that can last throughout adulthood.[13] Despite the fact that BPA's presence is highly widespread – it was detected in the blood and urine of 95 percent of people tested in the United States – the EPA's standard remains unchanged.[14] The restriction of this chemical should be the EPA's top priority.

As part of the agency's Endocrine Disruptors Research program, the EPA Office of Research and Development will examine the effects of EDC exposure.[15] In response to a 2000 peer reviewed report, which found that "low-dose effects had been sufficiently documented at that point in time for the EPA to consider revisiting its current testing paradigm on the issue of low-dose adverse affects," the EPA "is currently funding three research grants in the area of low-dose EDC exposures."[16]

On a grassroots level, there are various ways to limit our exposure to BPA. For instance, some stores have decided to stop selling the popular water bottle, Nalgene.[17] Nalgene bottles are composed of lexan polycarbonate resin.[18] In 1998, Dr. Patricia Hunt of Case Western Reserve University stumbled upon an unexplainable result of aneuploidy[19] in one of her experiments.[20] It was traced to a harsh detergent that was used to clean the polycarbonate mice cages and water bottles.[21] The detergent caused the plastic to leach BPA, and this accident was duplicated in another study.[22] Even though another study conducted in 2003 confirmed Dr. Hunt's results, the polycarbonate industry has harshly criticized Dr. Hunt's findings.[23]

Additionally, California's Assembly recently proposed Bill 319, which would have banned some products that contained BPA and phthalates[24] intended for use by children.[25] Assembly Bill 319 "sought to limit some transitional phthalates that have been shown to be especially deleterious to normal development, especially sexual development,"[26] but was unfortunately defeated on January 19, 2006.[27] However, it provides a useful model for other states looking to take action on BPA exposure.

Becoming informed consumers allows individuals to limit the exposure to themselves and their families, and to inform others in their communities of the risks of using plastics containing BPA. Additionally, the EPA should re-evaluate its risk assessment process, and more state legislatures should try to ban BPA. In short, the public must take the responsibility for making wise decisions when purchasing merchandise composed of plastic.

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[5] *See* News-Medical.Net, *supra* note 1.

[6] *Id.*; *see also* Roger Highfield, *Are These Sperm Doomed?*, The Telegraph, telegraph.co.uk, *available at* http://www.telegraph.co.uk/connected/main.jhtml?xml=/connected/2005/06/15/ecfsperm15.xml (last visited Mar. 24, 2006) (discussing how even very low doses of BPA can alter the develop-

Endnotes: Bisphenol-A *Continued on page 78*

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A Moral Justification for Comprehensive Safety Testing of Industrial Chemicals

*by Ted Schettler M.D., M.P.H.**

Introduction

Dramatic advances in chemical research and development during the 20th century have made it possible to synthesize molecules that were once unimaginable and that have never previously existed. Chemists have produced millions of unique chemicals. Tens of thousands of these are in commerce, and thousands are produced in excess of one million pounds annually. Inventories grow by several thousand new chemicals annually. With over $587 billion in global annual sales, and a projected increase of 85 percent in the next twenty years, this far-reaching industrial sector creates materials for myriad consumer products, pesticides, pharmaceuticals, and industrial manufacturing.[1]

The Extent of the Problem

Commercially successful chemicals usually do what they are intended to do, but many are unintentionally hazardous. Unfortunately, with the exception of pesticides and pharmaceuticals, the large majority of industrial chemicals in commerce today have never been fully studied for their toxicity to people or wildlife, despite widespread exposures.[2] This has been a source of trouble.

Sometimes chemicals act in surprising ways – either because their behavior is unpredictable or because no one has bothered to investigate their properties. In the 1960s, for example, scientists discovered that the insecticide dichloro-diphenyl-trichloroethane ("DDT") contaminated human breast milk throughout the world. It also turned up in Antarctic penguins, thousands of miles from where DDT was used. Now we know that the behavior of DDT is similar to other chemical compounds that are fat soluble, persistent in the environment, and bioaccumulate in the food web. Once loose in the world, these chemicals travel to the far reaches of all global ecosystems, contaminate most living things, and persist for decades or longer. Whatever toxic properties they have will be widely expressed.

Recent reports have identified similarly-behaving compounds in the blood of almost all newborn infants and adults. Examples of these compounds include brominated flame retardants and fluorinated chemicals used in Teflon and other non-stick, stain-resistant products. But persistent bioaccumulative compounds are not alone. Non-persistent but pervasive and continuously-used compounds such as plasticizers, organic metals, pesticides, solvents, and many others add to this complex cocktail with unknown hazardous properties.[3]

Available data show that individually some industrial chemicals alter gene expression; brain development; immune, reproductive, and endocrine systems; and can cause birth defects and cancer. Often, exposures in developing organisms (humans, wildlife, and laboratory animals) during critical windows of vulnerability can have permanent impacts at doses far lower than those necessary to cause health effects in adults. Some impacts are heritable and can be passed from generation to generation.[4]

Although it is certain that industrial chemicals contribute to disease and disability in the general population of humans and wildlife at current levels of exposure, the extent to which they are responsible for individual cases and disease patterns is often uncertain and vigorously debated. Some uncertainty results from the inherent complexity of biological organisms and the limits of science. However some uncertainty is plainly due to lack of good information, because chemical manufacturers often refuse to develop and provide it to the public.[5]

A Moral Responsibility

Our current political and common law legal systems presume that people and corporations are allowed to do whatever they want, within some contested constraints of safety and the rubric of cost-benefit analyses. In these systems, the burden of proof falls most often on people who raise safety concerns rather than promoters of technologies. Underlying these systems is also a presumption that economic growth, as measured by the gross domestic product, is always beneficial. These ideas were fully developed during the 19th century and continue to underpin our industrialized economy.[6]

[T]he burden of proof falls most often on people who raise safety concerns. . .

The world is now very different from what it was 150 years ago. Over six billion people inhabit the planet and mid-level projections anticipate nine billion within 50 years. Humans have altered planetary systems in fundamental ways. For example, climate, soil, water and air quality, fisheries,

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forests, pollinators, wetlands, coral reefs, and biological diversity are under severe stress. Industrial chemicals universally contaminate global ecosystems and their inhabitants with troubling but inadequately understood consequences. The reach of modern human technologies over great sweeps of time and space requires a re-evaluation of their ethical underpinnings.

In the United States and many other countries, dominant ethical frameworks that influence decision making are largely based on human rights and utilitarian cost-benefit analysis. The tension that sometimes develops between the rights of individuals and aggregate costs and benefits is resolved in political and judicial settings. However, several important ethical principles that are essential to human survival over the long term are missing. They include acting with a respect for living things, a realistic understanding of interconnectedness, an acknowledgement of the limits of the earth to assimilate human activity without becoming inhospitable to human existence, and moral responsibility. To be sure, all human activities and technologies should be subject to more extensive ethical screens, but the focus here is on chemical manufacturing and moral responsibility for safety testing.

Industrial chemicals universally contaminate global ecosystems and their inhabitants. . .

In common-law proceedings, parties may be held legally responsible for harm that they cause others, though even here costs and benefits are weighed. But the idea of moral responsibility either to take or refrain from some activity is different. Philosopher Hans Jonas argues that modern technology has introduced actions of such novel scale, objects, and consequences that the framework of former ethics can no longer contain them.[7] Jonas begins with the undeniable moral responsibility inherent in the parent-infant relationship.[8] Extrapolating from that starting point, Jonas then persuasively argues that, since future generations will exist, the power of our technologies to reach far into time and space is sufficient to establish a similar moral responsibility to future generations.[9] This is not an argument based on rights of future generations, but rather on our moral responsibility to them.

Much of our behavior suggests that we do not recognize responsibilities to future generations. We continue to draw down the earth's natural capital, squander resources into scarcity, and contaminate ecosystems with untested chemicals. We seem to be unable to recognize natural planetary limits and the need for restoration and regeneration. Optimists hold that recurrent damage and scarcity will forever drive us to invent our way successfully out of one crisis after another, but they are living in an imaginary 19th century world without limits.

Conclusion

Meeting a moral responsibility to future generations requires comprehensive attempts to try to understand the impacts of newly acquired powers. The chemical industry creates and disperses thousands of novel substances, many of which are known or likely to have biologic activity in humans and wildlife, with far-reaching consequences for human and ecological health. This technological prowess creates a moral responsibility to thoroughly test existing and newly developed chemicals for their safety before releasing them into the world. Some uncertainty will always remain, but it is precisely the scope and scale of technologies, coupled with uncertainty, that establish the moral responsibility for prospective, unbiased, comprehensive evaluation with future generations in mind.

Endnotes: Comprehensive Safety Testing of Industrial Chemicals

[1] Patricia L. Short, *Global Top 50*, Chemical & Engineering News, July 18, 2005, at 20-23, *available at* http://pubs.acs.org/cen/coverstory/83/8329globaltop50.html (last visited Mar. 10, 2006).

[2] Pesticides are regulated under the Federal Insecticide, Fungicide, Rodenticide Act and some pre-market safety assays are required. Pharmaceuticals are regulated by the U.S. Food and Drug Administration, and premarket testing and clinical trials are required. But the large majority of industrial chemicals are regulated under the Toxic Substances Control Act ("TSCA") administered by the U.S. Environmental Protection Agency ("EPA"). Although TSCA authorizes the administrator to require pre-market safety testing of newly proposed chemicals, formal rule making rarely occurs and must be balanced against costs and benefits. Many pre-TSCA, untested chemicals were simply allowed to remain in commerce when TSCA was adopted. Many of them remain in use today and have not undergone even screening safety assessment. *See* David Roe, Dr. William Pease, Karen Florini, & Dr. Ellen Silbergeld, *Toxic Ignorance*, *available at* http://www.healthy-communications.com/environmentaldefense.html (last visited Mar. 10, 2006).

[3] *See* Ctrs. for Disease Control and Prevention, Third National Report on Exposure to Environmental Chemicals, July, 2005, *available at* http://www.cdc.gov/exposurereport/3rd/ (last visited Mar. 10, 2006).

[4] Matthew D. Anway, Andrea S. Cupp, Mehmet Uzumcu, & Michael K. Skinner, *Epigenetic Transgenerational Actions of Endocrine Disruptors and Male Fertility,* Science, 308(5727), 2005 at 466.

[5] *See* Roe, *supra* note 2. It should also be noted that a voluntary chemical testing program negotiated between chemical manufacturers and the EPA has provided limited basic screening data for a small number of high volume chemicals, but has little prospect for providing any comprehensive data like, for example, neurodevelopmental toxicity testing. *See* EPA's Voluntary Children's Chemical Evaluation Program, *available at* http://www.epa.gov/chemrtk/vccep/index.htm (last visited Mar. 10, 2006).

[6] J. Guth, *Transforming American Law to Promote Preservation of the Earth*, The Networker, V.11-12 (Mar. 2006), *available at* http://www.sehn.org/Volume_11-2.html (last visited Mar. 29, 2006).

[7] *See* Hans Jonas, The Imperative of Responsibility: In Search of An Ethics for the Technological Age (Univ. of Chicago Press 1984).

[8] *See* Jonas, *id.*

[9] *See* Jonas, *id.*

Enforcing the Ban on Chemical Weapons

*by Mea Sucato**

Chemical weapons present a great risk to international security as a result of the low costs and ease with which they can be purchased, used, manufactured, and stored.[1] One of the most notorious examples of chemical weapons use occurred on March 16, 1988, when Saddam Hussein unleashed a mixture of mustard gas and nerve agents on Kurdish civilians in Halabja, Iraq.[2] At least 5,000 civilians, including women, children, and the elderly, died immediately as a result of the attack and 10,000 more were blinded, maimed, or disfigured.[3] In subsequent years, thousands more died from debilitating diseases and birth defects associated with the after-effects of chemical weapons.[4]

A study conducted in Halabja of the long-term effects of chemical weapons exposure showed that "[t]hese chemicals seriously affected people's eyes, and respitory and neurological systems. Children are dying … of leukemia and lymphomas … [there is a] large proportion of pregnancies [with] major malformations … [which] suggest[s] that the effects from these chemical warfare agents are transmitted to succeeding generations."[5] This indicates that chemical weapons exposure causes "long-term damage to the DNA"[6] and can affect the ability of an ethnic group to produce healthy offspring. By affecting the reproductive health of an ethnic group, countries that use chemical weapons, particularly against civilian populations, arguably commit crimes against humanity that rise to the level of genocide.[7]

The Chemical Weapons Convention ("CWC") prohibits the use of chemical weapons and further mandates that State Parties shall not "develop, produce, otherwise acquire, stockpile or retain chemical weapons."[8] Each State Party must undertake to destroy all chemical weapons and production facilities.[9] The Organization for the Prohibition of Chemical Weapons ("OPCW") is the enforcement body of the Convention,[10] and State Parties must grant the OPCW access to conduct inspections inside their territory.[11] A State Party may also call upon the OCPW to inspect the territory of another State Party to investigate allegations of non-compliance.[12]

The CWC is widely criticized for its failure to ensure adequate compliance; the primary complaints are: (1) its inability to enforce its provisions over countries that have not yet ratified the treaty; (2) its failure to impose its provisions with respect to terrorist groups; and (3) that the OPCW only has power to issue sanctions after a violation is found, but cannot authorize military force.[13] These criticisms are not particular to the CWC, but to all international treaties, and describes the problems of an international system that is largely based on comity.

While far from perfect, the CWC is an effective step towards the ban of chemical weapons. First, while the OPCW is not authorized to use force, it can consult with the UN Security Council to request military action if needed.[14] Second, the CWC makes it difficult for non-Party States and terrorist groups to acquire both the chemicals and the equipment needed for their manufacture.[15] The CWC induces its ratification by limiting the transfer of controlled-chemicals, which a non-State Party may need for industrial purposes.[16] Third, the CWC slows chemical weapon proliferation by isolating a small number of "rogue states," such as Iraq, Libya, and North Korea, which brings shame onto these countries, along with political and economic pressures.[17]

As with all treaties, the CWC cannot ensure complete compliance. The looming threat to international security posed by chemical weapons warrants a complete ban on such weaponry. Further, the incredible and unnecessary suffering caused by chemical weapons, such as those used in Halabja, in addition to the devastating consequences extending to subsequent generations, shows that the use, development, or transfer of such weapons should be considered a universal crime against humanity. The international community should consider the prohibition against chemical weapons to be a *jus cogens* norm, a law that is so fundamental to international law that no State may derogate from it.

Endnotes:

1 Guy B. Roberts, *The Counterproliferation Self-Help Paradigm: A Legal Regime for Enforcing the Norm Prohibiting the Proliferation of Weapons of Mass Destruction,* 27 Denv. J. Int'l L. & Pol'y 483, 492 (1999); *see also* Megan Eshbaugh, *The Chemical Weapons Convention: With Every Step Forward, We Take Two Steps Back,* 18 Ariz. J. Int'l & Comp. Law 209, 210 (2001).

2 Press Release, U.S. Dep't. of State, Bureau of Pub. Affairs Saddam's Chemical Weapons Campaign: Halabja (March 14, 1988) [hereinafter Chemicals Campaign], *available at* http://www.state.gov/r/pa/ei/rls/18714.htm (last visited Mar. 8, 2006).

3 Chemicals Campaign, *id.*

4 Chemicals Campaign, *id.*

5 Christine Gosden, *Why I Went, What I Saw,* Wash. Post, Mar. 11, 1998, at A19.

6 Gosden, *id.*

7 *Cf.* Margaret Sewell, *Freedom from Fear: Prosecuting the Iraqi Regime for the Use of Chemical Weapons*, 16 St. Thomas L. Rev. 365 (2004) (arguing that Saddam Hussein's attack on the Kurds with chemical weapons constitutes genocide and should be prosecuted as such).

8 Convention on the Prohibition, Development, Production, Stockpiling and Use of Chemical Weapons and their Destruction, art. I, *opened for signature* Jan. 13, 1993, 32 I.L.M. 800.

9 Convention on the Prohibition, *id.*

10 Convention on the Prohibition, *id.* at art 8.

11 Eshbaugh, *supra* note 1, at 223.

12 Eshbaugh, *supra* note 1, at 223.

13 *See* Matthew Linkie, *The Defense Threat Reduction Agency: A Note on the United States' Approach to Threat of Chemical and Biological Warfare,* 16 J. Contemp. Health L. & Pol'y 531, 552-53 (2000); Kevin J. Fitzgerald,

Endnotes: Ban on Chemical Weapons *Continued on page 72*

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India's Toxic Landfills: A Dumping Ground for the World's Electronic Waste

*by Nisha Thakker**

Introduction

From New Delhi in the north, to Calcutta in the south, a repetitive striking image is found in India's metropolises. One reporter writes of a "hostile zone" in Calcutta where "high brick walls block the views of activities going on within."[1] What hides behind those walls, however, tells a chilling tale of what happens to the discarded electronics of developed countries. These electronic waste ("e-waste") scrap yards have become common in India. Within these landfills children "as young as eight-years-old tear apart electronic components with bare hands, while vats of acid lying just a few feet away bubble like giant black cauldrons, spewing out strange-smelling fumes."[2] Another report tells of a teenager cutting into a car battery with a torch – wearing no mask or protective clothing.[3] Workers in these scrap yards expose themselves to hazardous materials seven days a week, for twelve to fourteen hours a day.[4]

These are common stories of individuals ranging from eight-years-old to the elderly, all dismantling e-waste dumped in India by developed countries. India's less stringent environmental standards allow for frequent, unregulated e-waste dumping within its borders.[5] Moreover, dumping e-waste in India and other developing countries allows all parties involved to make money. In the United States, it costs approximately twenty U.S. dollars to recycle an old computer. However, when waste brokers sell that same computer for export, they make about five U.S. dollars a piece, while the recycling in India costs just four dollars.[6]

The world is currently in an e-waste crisis…

What is E-Waste?

E-waste can be defined as "a collective name for discarded electronic devices that enter the waste stream."[7] E-waste includes refrigerators, cellular phones, personal stereos, air conditioners, computers, and consumer electronics.[8] Over one thousand different "substances and chemicals, many of which are toxic and are likely to create serious problems for the environment and human health if not handled properly," can be found in e-waste.[9]

The world is currently in an e-waste crisis, with technology rapidly advancing and older models becoming obsolete faster than they can be dealt with. In New Delhi alone, about 25,000 workers are employed in scrap yards, "where 10,000 to 20,000 tons of e-waste are handled every year."[10] It was estimated that in 2005, one personal computer was discarded for "every new one put on the market."[11]

How Much E-Waste is There?

India and other developing nations are easy targets for e-waste dumping by developed countries due to the fact that "generous import policies on second-hand computers, aimed at helping charities and schools, is being abused."[12] Under the guise of donating used electronics, especially computers, developed countries are able to discard e-waste far more cheaply than disposing of it within their own borders. Toxics Link, a New Delhi based organization dedicated to environmental justice and a toxic-free environment, estimates that 20,000 kilograms of e-waste finds its way through India's borders every day.[13] In the United States, an estimated 40,000 computers are discarded every year, and it is believed that another 300 million to 700 million units are being stored in houses and businesses waiting to be dumped.[14] Furthermore, experts estimate than "more than 500 million computers will become obsolete in the [United States] alone between the years 1997 and 2007."[15] Worldwide, twenty to fifty million tons of e-waste are generated annually.[16]

It has been estimated that e-waste is increasing by three to five percent per year.[17] In 2002, the Basel Action Network ("BAN") released a report stating that over five percent of municipal solid waste was comprised of electronic waste.[18] According to BAN, the U.S. government does not know how much e-waste is exported every year; however, estimates based on other studies conclude that 10.2 million computer units were sent to Asia in 2002 alone.[19] Toxic Links discovered that 70 percent of electronic waste present in recycling facilities located in New Delhi, India, has been exported or left by developed countries.[20]

Where Does E-Waste Come From?

BAN notes that electronic waste in the United States is generated by three major sectors: "individuals and small business; large businesses, institutions, and governments; [and] original equipment manufacturers."[21] Much of the electronics that households and small businesses discard is not broken, but simply obsolete or outdated.[22] With constantly advancing technology and upgrades, computer owners are now buying new computers and disposing of their old ones about every two years.[23]

Employee computers at large institutions are upgraded on a regular basis. For example, in 2002, Microsoft had approximate-

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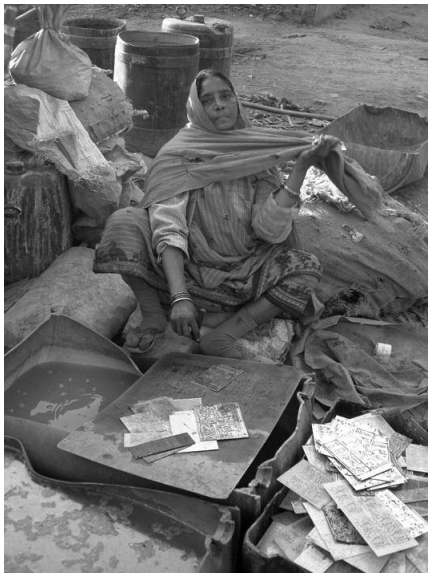
ly 50,000 employees worldwide[24] with all employees having at least one computer of their own. According to a Microsoft spokesman, the company replaces each computer every three years.[25] U.S. law forbids large users from disposing of their computers in landfills (unlike individuals and small business) and therefore, "this e-waste goes to the re-use/recycling/export market."[26] Finally, equipment manufacturers also contribute to the e-waste problem in the United States because, when products do not "meet quality standards, [they] must be disposed of."[27]

However, it is important to note that the Indian Supreme Court, in compliance with the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, prohibits the exportation of hazardous waste into India.[28] Thus, the e-waste coming into India enters under a deceptive guise or illegally.[29]



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A woman in India recovers metals from circuit boards using an acid bath process.

How Toxic is E-Waste?

E-waste includes over one thousand different substances, and this article would not be complete without discussing these hazards and the serious health risks that they present.[30] Scrap yard workers are exposed to these toxins on a daily basis through their unprotected dismantling of e-waste in an effort to extract gold, platinum, and copper. Without proper recycling, 315 million computers will release 550 million kilograms of lead, 900,000 kilograms of cadmium, and 180,000 kilograms of mercury into the environment.[31] Other chemicals released include barium, toners, phosphor and additives, and beryllium.[32] Each of these toxic substances is found in different parts of computers and other electronics.

Lead can be found in "glass panels and gaskets in computer monitors" as well as being used as the "solder in printed circuit boards."[33] Lead causes damage to humans' nervous, blood, and reproductive systems.[34] In children, lead has been found to impede brain development, causing what one doctor terms "brain drain."[35] Lead has no biological function and should not be present in the human body; however, a person living in areas surrounded by e-waste will have about eight to ten micrograms of lead per deciliter.[36] In children, a measurement of anything close to ten micrograms of lead per deciliter can lower the IQ.[37]

Cadmium compounds accumulate in the human body, causing potentially irreversible effects on human health, especially the kidneys.[38] Cadmium is generally found in "SMD chip resistors, infra-red detectors, and semiconductor chips."[39] Additionally, it is estimated that nearly one-fourth of the world's yearly consumption of mercury is by electronic equipment.[40] Mercury can cause damage to the brain and kidneys, as well as a developing fetus.[41]

Functioning as a radiation protector, barium is used in the front panels of computers.[42] While long-term effects of exposure to barium are not documented, studies have found that short-term effects of barium exposure include "brain swelling, muscle weakness, damage to the heart, liver, and spleen."[43]

Plastic printer cartridges containing toner are one of the most common forms of e-waste.[44] Carbon black is the main ingredient of the black toner.[45] Entering the human body through inhalation, carbon black causes respiratory irritation if a person is subjected to prolonged exposure.[46] The International Agency for Research on Cancer classifies carbon black as a possible carcinogen.[47]

Phosphor "is applied as a coat on the interior of the [cathode ray tube faceplate]" and it "affects the display resolution and luminance of the images that is seen in the monitor."[48] Contained within the phosphor coating on cathode ray tubes are heavy metals such as cadmium, zinc, and vanadium.[49] While the hazards of phosphor used for this purpose are not reported, the U.S. Navy issued a directive regarding this coating: "NEVER touch a CRT's phosphor coating: it is extremely toxic. If you break a CRT, clean up the glass fragments very carefully. If you touch the phosphor, seek medical attention *immediately*."[50]

Beryllium is found on motherboards and finger clips in computers, used to "strengthen the tensile strength of connectors and tinyplugs while maintaining electrical conductivity."[51] Beryllium is classified as a human carcinogen since exposure to it can cause lung cancer. Workers can develop beryllicosis, a disease that primarily affects the lungs, if they are constantly exposed to beryllium, even in small amounts.[52] Beryllium exposure also causes a type of skin disease, such as the inability to heal property and the development of wart-like bumps.[53]

The e-waste coming into India enters under a deceptive guise or illegally.

Why Risk It?

People collecting e-waste boil, crush, or burn electronic parts to extract valuable materials like gold, platinum, and copper that can then be resold.[54] Each component that is retrieved has its own value and market.[55] The monetary value for each of these materials hardly seems worth the health risks the workers endure everyday; however, most of these workers have no other steady-paying jobs and must find some way to support their families.

In a 2002 study, Toxics Link followed the money trail for each component of a broken down computer and monitor, finding that the majority of the profit is taken by the trader,

not the worker collecting the e-waste.[56] When a local trader buys a single computer with monitor for US $10 to $15, he can then earn up to US $50 in profit by selling the disassembled parts.[57] For example, a trader can buy a circuit board for thirteen cents per kilogram, and then resell it for ten cents per kilogram after the metals, such as lead, copper alloy, and gold, are recovered.[58] A profit is made when acid battery manufactures buy the recovered lead for US $2.17 per kilogram.[59] The copper recovered fetches US $1.74 per kilogram from copper wire manufacturers.[60]

In order to retrieve all of these valuable materials, workers subject themselves daily to hazardous conditions as fumes are released into the environment and absorbed into their bodies by the melting of computer parts. Long-term health risks have not been documented for e-waste workers, but the effects of these toxic chemicals are clear. One worker in New Delhi said that the pay in e-waste work is good "compared to what he could make doing other kinds of labor" – he earns around 3,000 rupees, or US $66, a month, "working six days a week in eight-hour shifts."[61] That kind of repeated exposure will most certainly lead to health problems. In some areas, doctors have noticed an increase in lung ailments in laborers, attributed to "the burning wires."[62] A study by the Chittaranjan National Cancer Institute found that people in New Delhi are nearly "twice as likely to suffer from lung ailments as those in the countryside."[63] Though traffic pollution is the primary cause, "doctors say the smelting electronic parts at factories on the city's edges should not be discounted."[64]

People collecting e-waste boil, crush, or burn electronic parts to extract valuable materials.

Without stricter regulations and enforcement, hundreds of thousands of India's poor will be forced to endure these conditions – conditions that would not be tolerated in the United States or other developed countries.

E-Waste Management: International Conventions and Regulations

The Basel Convention is a major international agreement that addresses the need to regulate e-waste. Adopted in response to the "public outcry against the indiscriminate dumping of hazardous wastes in developing countries by developed-world industries," India ratified the treaty in 1992.[65] However, the Convention is helpless to restrict the import of waste from nations that have not ratified the Convention, such as the United States.[66] States that have ratified the Basel Convention need to endure complex government-level processes before they can export non-working computers.[67] The goal of these regulations is to ensure proper disposal in the importing countries; however, even countries that have ratified this Convention often ignore these procedures.[68]

Currently, under U.S. domestic law it is legal to export potentially hazardous e-waste from the United States. In fact, the U.S. Resource Conservation and Recovery Act ("RCRA") appears to encourage the export of hazardous e-waste by exempting it from export controls of any kind."[69] According to the BAN report, RCRA "has exempted more and more toxic wastes simply because they are claimed to be destined for recycling operations."[70]

The Rotterdam Convention on the Prior Informed Consent ("PIC") Procedure for Certain Hazardous Chemicals and Pesticides in International Trade entered into force on February 24, 2004.[71] The procedures of the Convention require exporters to obtain the prior informed consent of importers before proceeding with the transaction, providing an international method to monitor and control the trade of hazardous materials.[72] While the accession of the Rotterdam Convention by India has occurred, the United States has failed to ratify the treaty.[73]

The EU has enacted two model regulations in the disposal and reuse of e-waste. Each member state of the European Community must implement both the Directive on Waste Electrical and Electronic Equipment ("WEEE") and the Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment ("RoHS") into their national laws.[74] The priorities of WEEE are to prevent the creation of e-waste and also to encourage companies and individuals to reuse or recycle e-waste to reduce disposal.[75] The RoHS directive complements the WEEE Directive and restricts the use of certain hazardous materials in new equipment in order to protect human health.[76] Beginning July 1, 2006, manufactures are not permitted to use lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ethers in creating their new electronic equipment.[77]

Conversely, the United States has failed to create a domestic law regulating e-waste. However, California, Maryland, Maine, and Washington [state] have created their own set of laws. For example, the California Electronics Waste Recycling Act was signed into law in 2003, and then amended in September of 2004.[78] The Act establishes a program to safely dispose of video display products, like televisions and computer monitors.[79] As of January 1, 2005, California consumers began paying a fee at purchase when buying video displays, the money is then funneled into a special account from which qualified recyclers and collectors are paid to cover their costs.[80]

Similarly, the Maryland Department of the Environment requires the registration of certain computer manufacturers.[81] Manufacturers that sell an average of more than one thousand computers annually are required to pay a $5,000 fee, or reduce the payment by creating a free recycling program for consumers.[82] Likewise, municipalities in Maine have until July 20, 2006 to ensure that discarded televisions and computer monitors generated by households are recycled, or the manufacturers will be required

to pick up the tab.[83] The latest e-waste legislation has been enacted by Washington State on March 8, 2006,[84] Requiring manufactures to carry the cost of collection, transportation, and recycling of old computers, monitors, and televisions, the statute also prohibits exporting e-waste to developing countries.[85]

On March 3, 2005, U.S. Senators Ron Wyden (D-OR) and Jim Talent (R-MO) introduced a bill that would incentivize the safe disposal of outdated electronics.[86] Included in the proposed bill is a directive authorizing the U.S. Environmental Protection Agency to recommend a national program based a cost-benefit analysis of various e-waste recycling programs. However, the proposed legislation lacks a complete ban on the export of hazardous waste to developing nations.

The United States has failed to create a domestic law regulating e-waste.

Indian Domestic Laws and E-waste

Currently, e-waste is not defined in Indian domestic environmental law.[87] In 2003, India amended the Hazardous Waste (Management and Handling) Rules of 1989.[88] The rules advise that "waste generated from the electronic industry is considered as hazardous waste."[89] That means that once e-waste *becomes* hazardous waste, it is covered under the hazardous waste rules; however, the hazardous waste contained in the electronics must first be taken out for it to be considered "hazardous waste."[90] Though this law is in place and has been amended as recently as 2003, there is no specific legislation for the handling of e-waste in India.[91]

Additionally, the Supreme Court in India set up India's Supreme Court Monitoring Committee on Hazardous Wastes ("Committee") in November 2003.[92] The goal of the Committee is to pursue "certain serious and chronic situations relating to the management of hazardous wastes."[93] The Committee recently returned hazardous wastes that were wrongly imported into India in accordance with Basel Convention.[94] Zinc from Bangladesh and a container full of garbage from Ireland were part of the returned waste.[95]

The Future of E-waste in India

In New Delhi, the Indian government has plans for three potential waste dumps.[96] The sites would be used for "scientific disposal of hazardous household waste and e-waste generated from processing of electronic goods."[97] The Energy Resources Institute ("TERI") estimates that fifteen to twenty acres of land will be needed to develop a scientific landfill site, at a cost of about 310 million Indian rupees, to deal with the over 45,000 tons of e-waste in New Delhi.[98] TERI further estimates that overhead expenses will cost around 30 million Indian rupees annually.[99]

Additionally, the United Nations Environment Programme started a two-year project in India in September 2005 called "Environment and E-waste India."[100] The project's goals are to reduce the environmental and health impacts "due to improper e-waste recycling in India."[101] The project also provides support in implementing national policies as well as improving income opportunities, "particularly of poor communities, by changing the working conditions and job security in informal e-waste recycling sectors."[102] This project should, hopefully, rid India of the "backyard scrap yards" and allow Indian to run a more environmentally sound e-waste recycling program.

Conclusion

With the rate of electronic obsolescence increasing each year, it is imperative for the international community to take a stronger stand against dumping toxic e-waste into developing countries. Dismantling e-waste is a relatively new phenomenon, resulting in individuals dangerously exposing themselves to toxic substances. Without proper controls and regulations from India and the international community, India's population will face a certain environmental and public health crisis.

Uninformed imports of hazardous waste material into developing countries should be banned. These countries do not have the resources to deal with the massive quantities of e-waste coming into their territories. It is not a morally or legally sound practice to allow those that have not benefited from electronic products bear the burden of dealing with the dangers of their unregulated disposal.

Endnotes: India's Toxic Landfills

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[3] Associated Press, *India Becoming World's Toxic Trash Bin,* Straits Times, Jun. 6, 1995, *available at* http://www.recyclingpoint.com.sg/Articles/1995Jun6IndiaToxictrash.htm (last visited Mar. 5, 2006).

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[5] The Basel Action Network, Exporting Harm: The High Tech Trashing of Asia (2002), *available at* http://www.svtc.org/cleancc/pubs/technotrash.pdf (last visited Mar. 5, 2006) [hereinafter BAN].

[6] Basu, *supra* note 1.

[7] *E-waste Crisis: Around the Corner*, India Together, May, 2003, *available at* http://www.indiatogether.org/2003/may/env-ewaste.htm (last visited Mar. 5, 2006) [hereinafter India Together].

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Endnotes: India's Toxic Landfills *Continued on page 79*

Native Americans Confront Mercury Threat to Health, Culture

*by Abigail Okrent**

Methylmercury is a potent neurotoxin that can cause serious neurological and developmental damage.[1] Emissions from coal-burning plants are the main source of mercury pollution in the United States.[2] When mercury emissions deposit into water, they bioaccumulate as methylmercury in the tissue of fish, exposing fish consumers to high magnitudes of mercury.[3] The U.S. Environmental Protection Agency ("EPA") notes that some Native Americans are among the highest risk groups for mercury contamination due to their heavy fish consumption.[4]

Four Maine Indian tribes are parties in a series of legal challenges filed against the EPA and consolidated in *New Jersey v. EPA* in December 2005.[5] The lawsuits are a response to two new mercury rules announced by the agency in March 2005.[6] The tribes, along with some environmental groups and states, allege that these rules weaken emissions regulations, threaten human health, and permit three times as much mercury pollution as would occur in full compliance with the Clean Air Act ("CAA").[7] For the tribes opposing the new regulations, reducing mercury pollution is about more than health. The Penobscot nation hopes that by eliminating mercury contamination they can "salvage a cultural identity."[8] "Fishing is one of the social and cultural ties that bind our tribal communities together," explains the Houlton Band of Maliseet's chief, "[and] that link has been stretched very thin because of mercury contamination."[9]

Penobscot children fishing.

The two rules issued on March 15, 2005 fall under the CAA. The first rule, passed pursuant to CAA section 112(c),[10] removes mercury from the list of the most stringently regulated chemicals.[11] Essentially it reclassifies mercury as non-toxic.[12] Called the "Section 112 rule" by the EPA and "delisting" by opponents, this provision is an essential precursor to the cap-and-trade system proposed by the second regulation, the Clean Air Mercury Rule ("CAMR").[13] The cap-and-trade approach, which falls under CAA section 111,[14] allows power plants to purchase emissions credits rather than reduce their own emissions.[15]

The National Tribal Environmental Council, one of many groups to submit comments on the cap-and-trade provision, expressed concern that it will create hot spots of mercury depositions.[16] EPA's Children's Health Protection Advisory Committee noted that the proposed rule may create new hot spots and fail to address existing ones.[17] The EPA recently opened the delisting rule for reconsideration after receiving two petitions, from over a dozen states, environmental groups, and Indian tribes,[18] and hopes to have a decision on the final rule by May 2006.[19] EPA is also reconsidering the CAMR cap-and-trade.[20] Both provisions are pending review in the case before the D.C. Circuit.[21]

If mercury output is not curtailed, the burden shifts to consumers to protect themselves from contamination by avoiding fish consumption. Currently, 45 states have issued fish consumption advisories,[22] which cover 35 percent of all lakes and 24 percent of all river miles nationwide.[23] For an Indian tribe whose members may eat up to ten times as much fish as the average American,[24] fish advisories create "a harsh choice: either risk the health of tribal members by continuing a now dangerous cultural tradition, with all the language, behavior, and spiritual connections that go with it, or heed the warnings and see centuries-old components of culture and religion slip away."

Endnotes:

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[3] U.S. Environmental Protection Agency ("EPA"), Mercury White Paper, *available at http://*www.epa.gov/ttn/atw/combust/utiltox/hgwt1212.html (last visited Feb. 10, 2006.)

[4] EPA, *id.*

[5] *State of New Jersey, et al., v. Environmental Protection Agency,* No. 05-1097, 2005 U.S. App. LEXIS 26926 (D.C. Cir. Dec. 8, 2005.) [hereinafter New Jersey v. EPA]; *see also* Missy Edgecombe, *Maine Indians join EPA challenge*, Bangor Daily News, June 15, 2005, at B6, *available at* http://www.penobscotnation.org/DNR/Air%20news/challenge.htm (last visited Mar. 22, 2006).

[6] *See* Mercury, U.S. Environmental Protection Agency website, http://www.epa.gov/mercury (last visited Mar. 27, 2006).

[7] Press Release, Natural Resources Defense Council, States Sue EPA Over New Mercury Rule, (Mar. 29, 2005), *at* http://www.nrdc.org/bushrecord/

Endnotes: Mercury Threat *Continued on page 80*

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Product-Based Environmental Regulations: Europe Sets the Pace

*by Paul E. Hagen**

Introduction

Following several years of successful political integration, the adoption of a single currency, and an expansion from fifteen to twenty-five Member States in 2004, the European Union now boasts a single market comprised of over 455 million people. The emergence of an expanded single market has coincided with a sustained effort on the part of the EU to advance environmental protection through the increased products regulation. While not without some controversy, the EU has in recent years adopted legal measures that condition market access for automobiles, household appliances, electronic equipment, and biotech products on compliance with new product-based environmental requirements. In the coming years, the EU is expected to adopt additional measures that would similarly regulate imports of chemicals, energy using products, and certain timber products.

Environmental law practitioners in the United States will want to take note of these new product-based measures for several reasons. First, as the EU is the largest trading partner of the United States, these new product-based measures are critically important to U.S. companies. Second, in conditioning market access to adherence with new product standards, the EU is, in effect, establishing global product standards, as few U.S. companies can afford to ignore a potential consumer market that is now much larger than the United States or even all of North America. In this regard, in-house counsel and environmental health and safety managers face new and difficult challenges as they work to understand and anticipate new product-based mandates in Europe.

To better understand the significance of the EU's new emphasis on product regulation, it is helpful to review some of the more significant legislation that has been enacted or proposed in recent years.

End-of-Life Vehicles Directive

Consistent with the EU's policy on waste management, which seeks to avoid waste by improving product design and increasing the recycling and re-use of waste, the EU adopted the End-of-Life Vehicles Directive ("ELV Directive") in 2000.[1] Among other things, the ELV Directive requires Member States to establish systems for the collection and recycling of all end-of-life vehicles and sets ambitious re-use and recycling goals. The ELV Directive also imposes several design mandates on automobile manufacturers by requiring Member States to ensure that vehicles "put on the market" after July 1, 2003, do not contain lead, mercury, cadmium, or haxavalent chromium, except as allowed under the limited exemptions set forth in Annex II of the Directive. The legislation also calls on manufacturers to implement design changes to facilitate dismantling, re-use, and recycling, and to increase the quantity of recycled material used in vehicles and other products. The EU's ELV Directive has driven changes in automotive component design and supply chain management not only in Europe but across the globe.

With its push into new product-based environmental requirements, the EU is breaking ground on a new generation of environmental legislation. . .

WEEE and RoHS Directives

The EU has recently adopted two new directives aimed at the design and end-of-life management of a wide range of household appliances, information technology and telecommunications equipment, consumer electronics, lighting products, and other electrical equipment. Under the Directive on Waste Electric and Electronic Equipment ("WEEE Directive"), Member States are to establish new systems for managing WEEE (defined broadly).[2] The new systems are to allow consumers to "take back" their used electrical and electronic equipment to retailers selling the equivalent type of equipment. Retailers, in turn, are obliged to accept the products free of charge. The WEEE Directive also establishes new product marking, registration, and ambitious materials recovery rates for collected products.

A companion directive establishes new material bans for a wide range of recent electrical and electronic equipment "put of the market" after June 30, 2006. Under the Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment ("RoHS Directive"), manu-

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facturers and importers are barred from placing on the market electrical and electronic equipment containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls ethers ("PBB"), and polybrominated diphenyl ethers ("PBDE").[3] Limited exceptions to these prohibitions for certain applications are set forth in an Annex to the Directive. By conditioning market access for thousands of products ranging from dishwashers to cell phones on new environmental requirements, the EU has, in effect, set new global product standards that will drive design changes for covered products regardless of where they are manufactured and sold. Member States are now in the process of implementing both of these directives at the national level.

Products Derived from Biotechnology

With respect to biotechnology products, the EU has had a de facto moratorium on the approval of new biotech crops arising out of the lengthy process currently in place for approvals. In September 2003, the EU adopted new requirements for labeling, traceability, and placing on the market of biotech crops and food and feed products derived from biotech crops.[4] The new EU regulations require that all pre-packaged products containing more than trace amounts of genetically modified organisms ("GMOs") bear a label reading: "This product contains genetically modified organisms" or "This product contains genetically modified [name of organism(s)]." The regulation further requires that all covered operators (*i.e.* those who place a biotech product on the market or receive a biotech product placed on the market within the EU) be able to identify their supplier and the companies to which they have supplied the products. Operators must keep documentation of each transaction involving biotech crops for five years and must make such records available to public authorities on demand.

[T]he EU will continue to set the pace when it comes to product-based environmental regulation.

The EU has recognized that, as a practical matter, it is virtually impossible to ensure that a small amount of biotech product will not commingle with a conventional product in the course of harvesting, storing, transporting, or processing the products. The EU, however, has set particularly low thresholds for the so-called "adventitious" (or technically unavoidable) presence of traces of GMOs in conventional products. The EU's tolerance for unapproved varieties that have not been endorsed by a European Community Scientific Committee is zero. The extent of the EU's impact in the Ag-biotech arena is significant and could have a dramatic impact on global trade in agricultural products if other governments decide to follow the EU's approach to regulating agricultural commodities.

EuP Directive

In July 2005, the EU adopted a directive establishing a framework for setting eco-design requirements for energy using products ("EuP Directive").[5] The EUP Directive establishes a framework under which the EU will establish product-specific eco-design and performance standards through subsequent implementing measures. The legislation will require conformity with future implementing measures and standards as a condition to market access for covered energy using products. This Directive has the potential to regulate a wide range of energy using products marketed in Europe and contemplates new environmental performance and product design requirements.

REACH

The EU is also developing legislation that would create a new EU regulatory framework for chemicals. The legislation is known as REACH (shorthand for Registration, Evaluation, Authorization, and Restriction of Chemicals), and is expected to be finalized in 2007. The legislation is an effort to address "existing chemicals" – those chemicals in production prior to 1981 and for which limited health and safety information is available. REACH would replace over 40 existing directives and regulations, and would require companies that produce and import chemicals to assess the risks arising from use of the chemicals and take necessary measures to manage any risks they identify. As proposed, the new regime would impose new requirements on a wide range of U.S. companies seeking to import or use chemicals in Europe, including products containing chemicals.

Impacts Beyond Europe

With its push into new product-based environmental requirements, the EU is breaking ground on a new generation of environmental legislation that looks beyond the environmental impacts associated with production and manufacturing alone. The EU's approach to product regulation is also serving as a catalyst for similar environmental initiatives in the United States and elsewhere. For example in the past year, legislation addressing the management of end-of-life electronics has been introduced in 28 states and in the U.S. Congress. California, Maine, Maryland, Washington, and the Province of Alberta in Canada have all recently adopted new laws addressing e-waste.

With respect to material bans, legislation passed in California in 2003 calls for the adoption of regulations that will prohibit the sale of certain types of electronic devices in California where the product is prohibited from being sold in Europe under the RoHS Directive. California, Illinois, Maryland, and Oregon have also recently adopted new restrictions on the use of certain brominated flame retardants in products. At the federal level, some members of Congress are pressing for amendments to the Toxic Substances Control Act ("TSCA") based in part on work underway in the EU on the REACH proposal.

While the EU has moved quickly to enact new laws targeting products, questions remain about the overall environmental benefits to be gained and the impacts on international trade. For

example, in the course of recent Congressional hearings on e-waste, the U.S. Environmental Protection Agency reported that the disposal of electronic waste in modern municipal landfills presented few environmental risks. The EU's actions to slow the introduction of products derived from biotechnology has been challenged by the United States under World Trade Organization ("WTO") rules as an illegal restraint on trade. Similarly, Japan has threatened to bring a WTO challenge against the EU if the REACH proposal is adopted in its current form.

Conclusion

For the near term, it appears that the EU will continue to set the pace when it comes to product-based environmental regulation. In the United States, it seems likely that an increasing number of state legislatures and even members of Congress will take a closer look at Europe's new emphasis on regulating products. Other countries outside of Europe, most notably the People's Republic of China, are also following the EU approach by adopting their own product-based environmental requirements. Whether these new national and sub-national initiatives gravitate toward harmonized product standards or instead evolve into a patchwork of competing mandates that undermine international trade remains one of the most important environmental and economic policy questions of the next decade.

Endnotes: Product-Based Environmental Regulations

[1] Directive 2000/53/EC of the European Parliament and of the Council of 18 Sept. 2000 on End-of-Life Vehicles.

[2] Directive 2002/96/EC of the European Parliament and of the Council of 27 Jan. 2003.

[3] Directive 2002/95/EC of the European Parliament and of the Council of 27 Jan. 2003.

[4] *See* Regulation (EC) No. 1829/2003 and Regulation (EC) 1830/2003.

[5] Directive 2005/32/EC of the European Parliament and of the Council of July 2005.

Endnotes: Europe's REACH *Continued from page 28*

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[26] *See* Powell & Rayner v. United Kingdom, 172 Eur. Ct. H.R. (ser. A) (1990), at ¶ 41; Guerra and others v. Italy, 26 Eur. Ct. H.R. 357 (1998), at ¶ 58; Taskin and others v. Turkey, Eur. Ct. H.R., Nov. 10, 2004, ¶ 113, *available at* http://www.echr.coe.int/echr (last visited Apr. 17, 2006).

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[30] U.S. House of Representatives, *id*. at 13. (The Commerce Department Report (Feb. 18, 2003) "notes that Mexico and Japan had expressed concern about REACH to the European Union. The Commerce Department report states: "We will be encouraging other delegations here to do likewise.")

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[32] World Trade Organization, Agreement on Technical Barriers to Trade, art. 2.1, available at http://www.wto.org/English/docs_e/legal_e/17-tbt.pdf (last visited Apr. 17, 2006) [hereinafter TBT Agreement].

[33] *See* Submissions to the TBT Committee concerning REACH regarding Taiwan & Japan.

[34] *See* Submissions to the TBT Committee concerning REACH regarding Thailand ¶ 3.6.

[35] *See* Submissions regarding Thailand, id.

[36] TBT Agreement, *supra* note 32, at art. 2.1.

[37] Submissions to the TBT Committee concerning REACH regarding Brazil ¶ 6, Taiwan, Chile, United States ¶ 17, China ¶ 6.

[38] Submissions to the TBT Committee concerning REACH regarding Japan III.2. Brazil ¶ 3, Australia, Canada, USA ¶¶ 36-37.

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[41] Submissions to the TBT Committee concerning REACH regarding Brazil ¶ 3, Thailand ¶ 5, Canada, China ¶ 6.

[42] TBT Agreement, *supra* note 32, at art. 12.3.

[43] EC-Biotech, Interim Panel Report, WT/DS291/, WT/DS292/, WT/DS293/, ¶¶ 7.16, 13-4.

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Litigation Update

Key Teflon Chemical:
Center of Lawsuits and Debates

*by Mary Ashby Brown**

Introduction

Perfluorooctanoic acid ("PFOA") is everywhere – and in more ways than one would probably think. PFOA is an essential processing aid in the production of fluoropolymers, or high-density plastics, which are used to create computer chips and aerospace parts as well as everyday consumer products such as paints, food wrappers, stain-resistant furniture, carpets, paper products, weatherproof clothing, and Dupont's Teflon® non-stick cookware.[1]

PFOA is also disturbingly ubiquitous in the blood of the general population in the United States, and pervasive throughout the environment, even appearing in Arctic animals.[2] In February 2006, researchers at Johns Hopkins University found PFOA present in the umbilical cord blood of 99 percent of 300 newborn infants.[3] The chemical is bioaccumulative, meaning it remains in human bodies and in the environment for an extended period of time.[4]

PFOA is … disturbingly ubiquitous in the blood of the general population. . .

Despite its widespread prevalence in the environment and in blood, there is no scientific consensus on how PFOA enters the system, or on its toxicity in humans. In addition, although it is known that the chemical has been deliberately released through factory emissions, it is not clear how consumer products might degrade to release PFOA.[5] Studies to understand the chemical, its pathways, and human toxicity are underway, but the production and release of PFOA is currently unregulated by the government.

The EPA's Investigation of PFOA

Concern over the prevalence of PFOA in human blood and in the environment, the lack of understanding concerning the chemical's pathways, as well as studies linking PFOA to cancer in lab animals, prompted the U.S. Environmental Protection Agency ("EPA") to begin formal investigation of the chemical in 2003.[6] During the investigation, evidence released in a separate lawsuit revealed that DuPont – the largest North American producer of PFOA – failed to report data to the EPA regarding the presence of the chemical in human fetal cord blood and local tap water for more than twenty years.[7] The EPA charged DuPont with two violations of the Toxic Substances Control Act ("TSCA") section 8(e), legislation which requires companies to report within fifteen days any evidence that a chemical may pose a substantial health risk.[8]

Most seriously, DuPont withheld information that PFOA could be transferred from a woman to her fetus via the placenta, the rate of this transfer, and levels of PFOA in newborns and two-year olds.[9] In 1981, DuPont scientists at a West Virginia Teflon® plant found PFOA in blood samples taken from pregnant Teflon® plant workers as well as in local drinking water.[10] In addition, DuPont failed to report serious birth defects in two infants who were monitored by company medical staff.[11]

The EPA settled its case against DuPont in December 2005 for $10.25 million in administrative fines, the largest environmental penalty ever won by the EPA.[12] DuPont pledged another $6.25 million to environmental programs.[13] The company maintains that it did not intentionally withhold information from the EPA, and thus did not admit legal liability.[14]

Recent Developments Between the EPA and DuPont

In January 2006, the EPA launched a landmark voluntary stewardship program, enlisting DuPont and seven other companies to reduce their emissions of PFOA and its presence in consumer products by 95 percent of year 2000 levels by 2010, and aiming toward 2015 for its elimination.[15] Although DuPont continues to hold that PFOA is non-toxic and undetectable in its Teflon products when used normally, the company agreed to the EPA program citing that "the presence of PFOA in people's blood raises questions that should be addressed."[16]

DuPont's cooperative response proved timely – only two days later, after reviewing the EPA's draft risk assessment of PFOA, the agency's Science Advisory Board ("SAB") deter-

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mined that the EPA should classify PFOA as a likely carcinogen; a recommendation that exceeds the EPA's assessment that there is only suggestive evidence that PFOA is carcinogenic.[17] The SAB recommended that, in order to provide a more scientifically rigorous risk assessment of PFOA, the EPA should conduct a heightened investigation of the links between PFOA and liver, testicular, pancreatic, and breast cancers, as well as the chemical's effects on the nervous and immune systems.[18]

Conclusion: Is the Real Danger in TSCA?

Should the public be made to wait for increased information on PFOA through the EPA's PFOA risk analysis, until the chemical, omnipresent in the environment and in the bloodstream, is (or is not) determined to be toxic to humans? Critics like the Environmental Working Group ("EWG") argue that such a delay is unacceptable, and that the TSCA is to blame for this dangerous lag.[19] Under TSCA, the EPA has few options to gain information on potentially harmful chemicals other than initiating largely voluntary consultations with chemical companies.[20] These options render TSCA a largely toothless statute,[21] according to the EWG.

DuPont withheld information that PFOA could be transferred from a woman to her fetus via the placenta. . .

The EPA is, however, moving to add PFOA to the list of Toxic Release Inventory, which would give the EPA regulatory authority to track the release of PFOA in the environment by requiring companies to report emissions of the chemical.[22] The EPA will likely classify PFOA as a persistent, bioaccumulative, and toxic ("PBT") chemical, which requires reporting of the chemical in smaller releases than non-PBT chemicals.[23]

Nevertheless, the EPA is still a long way away from limiting production and/or banning the chemical. Currently, only five chemicals out of 80,000 chemicals in commercial use are regulated by the government: PCBs, halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavelent chromium.[24] For PFOA to take a place among this list, the EPA will likely require much more research on the dangers and toxicity of PFOA, an effort which is only newly underway in the year 2006 – more than 50 years after the chemical was first produced.

Endnotes: Litigation Update

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[10] Press Release, *supra* note 8.

[11] EWG, *DuPont Has Withheld Company Study From EPA for 22 Years* (April 11, 2003) *available at* http://www.ewg.org/issues/pfcs/20030411/index.php (last visited Mar. 20, 2006).

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[14] Eilperin, *id.*

[15] EPA, 2010/15 PFOA Stewardship Program, http://www.epa.gov/opptintr/pfoa/pfoastewardship.htm (last visited Mar. 29, 2006) [hereinafter PFOA Stewardship Program].

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Book Review

Fair Trade for All: How Trade Can Promote Development

by Joseph Stiglitz and Andrew Charlton
Oxford University Press, 2005
*Reviewed by Maria Vanko**

Both civil society and the international community recognize the importance of global poverty alleviation. From grassroots movements demanding debt relief to international support of UN Millennium Development Goals, a global consensus places the plight of poor countries on its agenda. In 2001, the World Trade Organization ("WTO") launched the "Doha Round" of trade negotiations (also known as the "Development Round") aiming to benefit developing countries. However, the Development Round has not delivered practical results for the developing countries. It has done little to address concerns about agricultural subsidies in developed countries, has not prioritized the agendas of developing countries, and has failed to reform the WTO dispute procedures to mitigate power inequalities between developed and developing countries. These disputes led to the collapse of the talks in Cancun, Mexico in 2003, and resulted in both sides walking away from the negotiations without reaching a development consensus.

Joseph Stiglitz and Andrew Charlton recently released a book that aims to bridge the gaps felt by both developed and developing countries. *Fair Trade For All* presents a broad agenda by which trade policies can integrate developing countries into the world market. With the presumption that trade is good for development, Stiglitz and Charlton suggest a carefully managed trade liberalization agenda. They criticize the Washington Consensus' simple prescription of rapid liberalization and privatization of markets as causing instability and inequality, and instead propose an alternative model that emphasizes fairness. They contend that the assumption that broad market liberalization makes countries better off is based upon nonexistent variables such as full employment, perfect capital and risk markets, and perfect competition that most developing countries lack.

Before examining their proposal, Stiglitz and Charlton remind their readers that developed countries progressed by using a wide range of policy instruments which "[w]ould make their WTO ambassadors blush" in light of today's negotiations with developing countries. The book explores lessons from Latin America's import substitution and East Asia's export oriented strategies, and argues that a uniform model is inappropriate because the benefits of liberalization depend on factors unique to the particular circumstances of individual countries. Moreover, the developing world is limited by pervasive market failures that impede the effectiveness of a simple liberalization scheme, such as a lack of credit and insurance markets and an undersupply of public goods.

Fair Trade for All advocates transparency in the negotiating process to ensure fair agreements result.

The authors view fairness as a central tenet of trade negotiations. They propose that the distributive impact of any trade agreement must be assessed in light of any proposals that could have negative effects on development. On the basis of fairness, such proposals must not be placed on the agenda. The authors task the WTO Secretariat with ensuring that such analysis is tailored to the unique circumstances of individual developing countries.

Because developed nations are better positioned than developing countries from the negotiating table to the dispute resolution process, Stiglitz and Carlton urge that this power relationship not be exploitative. *Fair Trade for All* advocates transparency in the negotiating process to ensure fair agreements result. Responding to criticisms that participation in the WTO is voluntary, the authors counter that agreements must be entered into democratically by the developing countries, without fear of

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retaliation such as the withholding of development aid. Moreover, the authors propose that a pro-development trade agenda be limited to poverty reducing issues. While many international problems can be broadly defined to encompass trade-related issues, issues such as intellectual property rights and protection of foreign investors should not be resolved during trade negotiations because developing countries have limited capacity to analyze such additives.

The central trade agenda Stiglitz and Charlton propose in *Fair Trade for All* is simple and straightforward: all WTO members should provide free market access to all goods from developing countries poorer and smaller than themselves. Their proposal opposes traditional reciprocity agreements and requires open access for any country with a smaller GDP and GDP per capita. The proposal is intended to create a well-defined, transparent, and enforceable system of market access using objective criteria, and would result in significant trade opportunities between developing countries. The proposal is progressive in that it requires very little from the poorest countries and poses no obligation to open markets to countries more developed than itself. This allows developing countries to engage in some degree of protectionism for goods from countries richer than themselves. Developing countries have been reluctant to commit to large reductions in tariffs due to concerns over floods of cheap imports hurting local producers. Instead, the authors' proposal ensures that the largest and richest countries liberalize the most.

WTO members should provide free market access to all goods from developing countries. . .

In addressing the failure of the 2003 Cancun meeting, *Fair Trade for All* recommends that developed countries eliminate agricultural subsidies to ensure competitiveness for the developing countries' agricultural sectors – currently Organisation for Economic Co-operation and Development expenditures on agricultural subsidies are almost six times the total aid to developing countries. Stiglitz and Charlton approach agricultural liberalization to favor the least developed countries by recommending a rapid reduction on tariffs for goods produced and consumed in developing countries, and a slower reduction on subsidies for those goods consumed in the developing world. Accordingly, they propose the WTO focus on liberalizing the commodities in which price increases have had the largest positive effects on producers and the smallest effects on consumers.

Additionally, the authors propose that the WTO enforce environmental policies, pointing to the *Shrimp-Turtle* case in which the United States placed trade restrictions upon imports of shrimp captured by practices harming migratory turtles. In noting that the WTO Appellate Body has recognized the right of trade action to protect the environment, the authors propose that where multilateral environmental agreements contain the right to use trade policy to enforce the agreement, countries should use the WTO as a tool of enforcement.

Overall, *Fair Trade for All* succeeds in presenting a simple agenda for developing countries to ensure benefits in the trade negotiation process. Implicit in the book is that the developed world must make accommodations to mitigate the entrenched power asymmetries in the WTO to ensure fairness and positive outcomes in trade. *Fair Trade for All* advocates that developing countries utilize a precautionary approach to liberalization and discourages the use of the WTO negotiation process as a method to pressure developing countries to adopt policies and programs that may not result in direct gains for the developing world. This book is an excellent tool for those who desire policy prescriptions with empirical evidence to pursue an agenda for fairer trade.

World News

*by J.C. Sylvan, Cari Shiffman, Frank Pigott, and Abigail Okrent**

Asia

Toxic Spill at Chinese Factory Highlights Widespread Risk of Spills in China

Since an explosion on November 13, 2005 at Jilin Petrochemical Corporation's benzene factory in the northeastern city of Harbin, 45 other pollution accidents were reported to China's State Environmental Protection Administration ["SEPA"],[1] including six "major disasters."[2] The Harbin explosion poured one hundred tons of the carcinogenic benzene and nitrobenzene into the Songhua River in a plume of contaminated water 150 kilometers long.[3] Ten thousand people were evacuated[4] and four million people had no public water services for several days.[5] On February 14, 2006, another major spill in the Yuexi River left 20,000 residents of the Sichuan village of Guanyin without water when high concentrations of fluorine, amine-nitrate, and phenol were discovered in the river.[6]

The Harbin spill raised national concern in China about the damage China's industrial boom may be inflicting on the environment.[7] In response, SEPA has demanded that officials report spills within an hour of their outbreak.[8] SEPA's own director Xie Zhenhua was forced to resign when officials failed to report the spill for three days, resulting in dozens of lawsuits.[9] Moreover, in a recent nationwide survey, SEPA found that China has 21,000 chemical plants situated on its major rivers.[10] Over 70 percent of China's rivers and lakes are polluted; water sources in 90 percent of cities are contaminated.[11]

Americas

Increased Movement of Greenland's Glaciers May Indicate Climate Change

Researchers at the University of Kansas and National Aeronautics and Space Administration's ("NASA") Jet Propulsion Laboratory recently released a study revealing that the rate of ice streaming into the sea from glaciers in Greenland has doubled in the past decade, in part due to climate warming and ice dynamics.[12] Through the use of satellite data to follow the glaciers,[13] the researchers indicated that widespread increased glacier movement is "clearly a climate signal."[14] Greenland's glaciers lost 59 trillion gallons of ice in 2005, as compared to 24 trillion gallons in 1996, and Greenland's largest glaciers have increased their speeds by approximately 57 percent over the past decade.[15]

The study further reveals that the ice dumped from these glaciers may be contributing more to rising sea levels than previously predicted.[16] Streaming ice, together with the melting of Greenland's ice sheet, may annually contribute to seventeen percent of the global sea-level increase.[17] This contribution to the global sea-level rise "is a problem of considerable societal and scientific importance."[18] With the possibility of rising global temperatures, the contribution to sea-level rise from Greenland's glaciers will likely continue to increase.[19]

Rising Ethanol Demand Boosts Brazil's Sugar Cane Industry

Due to rising ethanol demand, Brazil's state-run oil company, Petreleo Brasileiro SA ("Petrobras"), has announced the possibility of building an ethanol pipeline through Brazil's primary ethanol producing areas to a refinery located near São Paulo. The estimated price tag would be US$226 million and would transport one billion gallons of ethanol per year.[20] Petrobras Chief Executive Sergio Gabrielli stressed that ethanol is cheaper to produce in Brazil, whose current ethanol supplies derive from sugar cane, than in the United States, which produces its ethanol from corn.[21] Gabrielli further contended that Brazil is "the only country in the world that has the technology to build an ethanol pipeline," thus making the project significant for the global ethanol market.[22]

Some industry analysts question Brazil's ability to emerge as a consistent ethanol supplier in the global fuels market.[23] While Brazil's sugar cane industry is the largest in the world,[24] its supplies are currently stretched, and the sugar cane industry is projected to need US$10 billion investment capital for new mills and more sugar cane to meet ethanol demands.[25] The International Energy Agency predicts that by 2025 ethanol may account for ten percent of the global gasoline supply, as countries begin to increasingly look to ethanol as a fuel source,[26] either to meet carbon dioxide emissions targets set by the Kyoto Protocol or to break from oil dependencies.[27] Brazil can serve as an example for other countries wanting to switch to ethanol-based fuel, as Brazilian laws require that its domestic gasoline contain 25 percent ethanol and as the majority of Brazilian vehicles currently are able to use either ethanol or traditional gasoline sources.[28]

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Africa

Security Problems Hamper Aid Efforts in Somalia

As southern Somalia faces its worst drought in more than a decade, security issues have hampered aid efforts there.[29] Rainfall, cereal production, and pastoral land have all approached seven-year lows,[30] while famine threatens more than two million people in the region, including 400,000 internally displaced people.[31] Moreover, since March 2005 some 35 acts of piracy in Somali waters, including the hijacking of a vessel chartered by the World Food Programme,[32] have forced aid agencies to deliver food by land, where it is vulnerable to seizure by local militias.[33] Making things worse, Somalia has had no central government to enforce the rule of law for fifteen years, allowing rival warlords to loot the country and fuel internal conflicts.[34]

Europe

WTO Rejects EU's Ban on Biotech Crops

This February, the World Trade Organization ("WTO") ruled in favor of the United States, Argentina, and Canada that the European Union illegally banned imports of genetically modified crops.[35] European governments resisted the use of genetically altered seeds to resist pests, disease, and drought, claiming that biotech crops threaten human health and the environment.[36] However, the ruling might not signal immediate changes in the EU's policies since the EU can appeal or simply refuse to comply and accept the requisite penalties.[37]

The EU has a history of disregarding WTO decisions that conflict with its food policies.[38] For example, in 1998 the WTO ruled that the EU's ban on hormone treated beef, based on a heightened cancer risk, was not sufficiently rooted in science.[39] However, the EU opted to pay US $116 million in fines rather than comply with the WTO's beef ruling.[40] According to an EU poll, over fifty percent of the EU's 450 million consumers consider gene-engineered foods to be dangerous.[41]

Europe's Quest for Oil Independence

Britain and Sweden have set lofty goals to reduce oil consumption. For instance, Sweden plans to be a completely oil-free economy by 2020.[42] A Swedish government official stated, "The plan is a response to global climate change, rising petroleum prices, and warnings by some experts that the world may soon be running out of oil."[43] Sweden leads Europe in the race for oil independence with 26 percent of its energy coming from renewable sources (the EU averages six percent). Only 32 percent of Sweden's energy comes from oil, down from 77 percent in 1970.[44]

Meanwhile, Britain plans to meet its Kyoto obligation of reducing emissions twenty percent by 2010 by using the three million tons of excess wheat it produces each year to make bioethanol.[45] However, Britain's plan could prove costly, as bioethanol is twice as costly as gasoline production, and could likely prove viable only with the help of government subsidies.[46] In addition, petrochemical companies own many of Britain's gas stations and have little interest in endorsing a product that would reduce their sales.[47] Yet, the British government recently ordered that petrochemical companies make a certain portion of their products (close to three percent) from renewable resources.[48]

Middle East

Yemen on Verge of Water Crisis

Yemen, one of the most water scarce countries in the world, is on the verge of a water crisis.[49] The water table in Yemen is falling by more than two meters a year.[50] Additionally, Yemen's population is one of the fastest growing in the world, compounding the problems of a water shortage.[51] Yemeni engineers suggest that additional desalination plants could be built along the coastline to augment the potable water supply.[52] A national plan announced in 2004 for 2005-2009 calls for confronting the shortage through a mixture of legal and political measures, as well as privatization and investment.[53] Observers are skeptical that the plan can be implemented, especially since Yemen lost part of its funding from the World Bank[54] and was suspended from the U.S. Millennium Challenge Corporation's Threshold Program in late 2005, both citing corruption.

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[31] Doll & Peto, *supra* note 28, at 1224.

[32] Doll & Peto, *supra* note 28, at 1224.

[33] WORLD CANCER REPORT, *supra* note 27, at 33, 62.

[34] WORLD CANCER REPORT, *supra* note 27, at 61.

[35] WORLD CANCER REPORT, *supra* note 27, at 321.

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[15] *See* Annette Peters et al., *Respiratory Effects Are Associated with the Number of Ultrafine Particles*, 155(4) AM. J. RESPIR. CRIT. CARE MED. 1376-83 (Apr. 1997); *see also* Gunter Oberdorster et al., *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113(7) ENV'T HEALTH PERSP. 823-39 (Jul. 2005); *see also* A.M. Maynard & E.D. Kuempel, *Airborne Nanostructured Particles and Occupational Health*, J. NANOPARTICLE RES. 2005 (in press).

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[23] U.S. ENV'T PROT. AGENCY ("EPA"), NANOSCALE MATERIALS; NOTICE OF PUBLIC MEETING -DOCKET ID NO. OPPT–2004–0122, FED. REGISTER Vol. 70, No. 89 (May 10, 2005), *available at* http://www.epa.gov/fedrgstr/EPA-TOX/2005/May/Day-10/t9324.htm (last visited Mar. 18, 2005).

[24] Toxic Substances Control Act ("TSCA") § 3(2)(A); 42 U.S.C. § 2602(2)(A).

[25] *See* TSCA, *id.*, at § 5 (authorizing the EPA to review activities associated with the manufacture, processing, use, distribution in commerce, and disposal of any new chemical substance before it enters commerce, and requiring pre-manufacture notice ("PMN") reporting prior to commercial manufacture or import under § 5 and 42 U.S.C. §2604).

[26] PCAST, *supra* note 16.

[27] *See* TSCA, *supra* note 24, at § 4(a) (stating that where there are insufficient data to assess the effects of the manufacture, distribution, processing, use or disposal of a chemical substance, and testing is necessary to develop such data, the TSCA provides that the EPA shall promulgate regulations requiring manufacturers and/or processors of such substances to develop new data that are needed to assess potential risks to human health and the environmental if the administrator finds: (1) that manufacture, distribution, use, and disposal practices may present an unreasonable risk of injury (§ 4(a)(1)(A)(i)); or (2) that the chemical will be produced in substantial quantities and that it enters or may be reasonably anticipated to enter the environment in substantial quantities or that there is or may be significant or substantial human exposure to the substance, § 4(a)(1)(B)(i)).

[28] Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

[29] NATURAL RESOURCES DEFENSE COUNCIL (NRDC) ET AL., NRDC AND OTHERS COMMENT ON EPA PROPOSAL TO REGULATE NANOMATERIALS THROUGH A VOLUNTARY PROGRAM, OPPT-2004-0122 (Jun. 2005), *available at* http://www.icta.org/doc/OPPT-2004-0122-0037.pdf (last visited Mar. 12, 2006).

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[12] Introduction, Secretariat of the Basel Convention website, http://www.basel.int/pub/basics.html, (last visited Feb. 05, 2006).

[13] Barrios, *supra* note 6, at 738.

[14] Barrios, *supra* note 6, at 748-49.

[15]Second Meeting of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 27-30, 2005, *Study on Possible Options for the Establishment of a Financial Mechanism for the Implementation of the Rotterdam Convention*, UNEP/FAO/RC/COP.2/10 (Sept., 2005) *available* at http://www.iisd.ca/chemical/pic/cop2/ (last visited Mar. 7, 2006).

[16] Second Meeting, *id.*

[17] Second Meeting, *id.*

[18] Second Meeting, *id.*

[19] Rotterdam Convention, *supra* note 2, at art. 11(1) (c).

[20] Barrios, *supra* note 6, at 744.

http://eltiempo.terra.com.co/judi/2006-03-01/ARTICULO-WEB-_NOTA_INTERIOR-2766271.html (last visited Feb. 28, 2006). [Colombia Continues to be the World's Largest Exporter of Cocaine, Says U.N. Report].

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[23] Mugge, *supra* note 5.

[24] *See* Sheridan Pauker, *Spraying First and Asking Questions Later: Congressional Efforts to Mitigate the Harmful Environmental, Health, and Economic Impacts of U.S.-Sponsored Coca Fumigation in Colombia*, 30 ECOLOGY L.Q. 661 at 666 (2003).

[25] Joseph Weir, *The Aerial Eradication of Illicit Coca Crops in Colombia, South America: Why the United States and Colombian Governments Continue to Postulate its Efficacy in the Face of Strident Opposition and Adverse Judicial Decisions in the Colombian Courts,* 10 DRAKE J. AGRIC. L. 205 at 218, (2005).

[26] Weir, *id*. at 218.

[27] Pauker, *supra* note 24 at 667.

[28] Mugge, *supra* note 5 at 330.

[29] Int'l Narcotics Control Strgy. Rep., 2006, Bureau for Int'l Narcotics and L. Enforcement Affairs, March 2006, http://www.state.gov/p/inl/rls/nrcrpt/2006/vol1/html/62106.htm (last visited Mar. 3, 2006). *See also National Drug Commission, supra* note 5 (outlining the mechanism for presenting claims of damages incurred by the spraying of Glyohosate in its Resolution 0017 of 2001 and, under Article 9, limiting response exclusively to licit crops and only when a judicial action has not been brought.) "Artículo 9°. Reposición de cultivos. El grupo de quejas repondrá exclusivamente a los afectados en sus plantaciones lícitas como consecuencia directa de la aspersión aérea con el herbicida glifosato en aplicación del Programa de Erradicación de Cultivos Ilícitos, siempre y cuando éstos no hubieren iniciado una acción prejudicial o judicial.", http://www.dnecolombia.gov.co/contenido.php?sid=103, (last viewed Mar. 19, 2006).

[30] Int'l Narcotics Control Strategy Rpt., *supra* note 29.

[31] *See* C-1065/03, Expediente D-4691 Demanda de Inconstitucionalidad en Contra de los Artículos 2, 3, 4, 5, 6, 7, 9, 11, 12, 13, 16, 17, 20 y 24, parciales, de la Ley 793 de 2002, http://www.ramajudicial.gov.co/csj_portal/jsp/frames/index.jsp?idsitio=6&ruta=../jurisprudencia/consulta.jsp, (analyzing the constitutionality of Colombian expropriation laws), (last visited Mar. 5, 2006).

[32] *See* Kelo v. City of New London, 125 S. Ct. 2655, (2005) (recounting the Courts analysis of takings law as applied to a government taking for the public purpose of economic revitalization).

[33] *See generally* Antonio R. Parra, *Applicable Substantive Law in ICSID Arbitrations Initiated Under Investment Treaties*, ICSID News Vol. 17, No. 2 Fall 5, 9 (2000).

[34] *See* American Convention on Human Rights art. 21, http://www.oas.org/juridico/english/Treaties/b-32.htm (last visited Mar. 3, 2006).

[35] COLOM. CONSTIT. Art. 58 reads "Se garantizan la propiedad privada y…Por motivos de utilidad pública o de interés social definidos por el legislador, podrá haber expropiación mediante sentencia judicial e indemnización previa…dicha expropiación podrá adelantarse por vía administrativa, sujeta a posterior acción contenciosa administrativa, incluso respecto del precio." Constitución Política de Colombia Art. 58, http://www.presidencia.gov.co/constitu/titulo2_2.htm (last visited Mar. 6, 2006).

[36] *Restatement of the Law Third, The Foreign Relations Law of the United States*, American Law Institute, Vol. 1, 1987, § 712.

[37] COLOM. CONSTIT., *supra* note 35, art. 58.

[38] COLOM. CONSTIT., *supra* note 35, art. 58.

[39] COLOM. CONSTIT., *supra* note 35, art. 58.

[40] COLOM. CONSTIT., *supra* note 35, art. 58.

[41] COLOM. CONSTIT., *supra* note 35 art. 34.

[42] *See* Kimball Laundry Co. v United States 338 US 1 (1949) (finding that proper measure of compensation for a temporary taking is the economic productivity that the property would have acquired during the time of the taking.)

[43] COLOM. CONSTIT., *supra* note 35 art. 59.

[44] Decree 1420, art. 21, ¶ 6 of the Ministerio de Medioambiente de Colombia (Colombian Environmental Ministry) Resettlement Policy Framework, http://www.minambiente.gov.co/viceministerios/ambiente/dir_agua_potable_saneam_basico/direccion/politica_agua_saneam_basico/ressetlement_policy_framework.pdf. (last visited Mar. 4, 2006).

[45] Decree 1420, *id*.

[46] Decree 1420, *id*.

[47] Decree 1420, *id.; see also,* COLOM. CONSTIT., *supra* note 35, at art. 90.

[48] S*ee Decree 1420, supra* note 44.

[49] *See* Kimball, *supra* note 42.

[50] *See* Alexander's Gas and Oil News and Trends, http://www.gasandoil.com/goc/news/ntl93265.htm.

[51] COLOM. CONSTIT., *supra* note 35, Art. 58

[52] Law 793, Dec. 27 2002 Art. 1 and Art. 2, http://www.presidencia.gov.co/leyes/2002/diciembre/dominio.htm (last visited Mar. 6, 2006).

[53] *Presidente Alvaro Uribe Oredeno Expropriacion de Predios Donde Haya Cultivos de coca y Amapola*, El Tiempo, Sept. 2004 http://eltiempo.terra.com.co/coar/NARCOTRAFICO/narcotrafico/ARTICULO-WEB-_NOTA_INTERIOR-1787925.html, (Mar. 6, 2006). [President Uribe Orders Expropriation of enclosures where Coca and Poppy are cultivated].

[54] Bruce Voss, *Recent Developments: Even a War has Some Rules: the Supreme Court Puts the Brakes on Drug–Related Civil Forfeitures* University of Hawai'i Law Review, 493, 532 (1994). (In Good, a landlord's property was seized as part of a narcotics bust. The Court balanced Mr. Good's due process rights in controlling his property, the possibility of error when property owners cannot protect themselves through a hearing, and lastly, by showing that the government purpose did not outweigh the private interest because, unlike seizures of movable property, there was not a "pressing need for prompt action." The Court further rejected the government's assertion that in a criminal setting, the public interest in a criminal taking outweighed the private property interest. The Court rejects this argument and further explores exceptions to due process obligations stating that "[w]e tolerate some exceptions to the general rule requiring pre-deprivation notice and hearing, but only in 'extraordinary situations where some valid government interest is at stake and justifies postponing the hearing.'").

[55] United States v. Good Real Prop. 510 U.S. 43, 52 (1993).

[56] Corte Constitucional ("CC"), 2003, C-1065/03 Cosa Juzgada Constitucional/ Demanda de Inconstitucionalidad (Colom.), http://www.ramajudicial.gov.co/csj_portal/jsp/frames/index.jsp?idsitio=6&ruta=../jurisprudencia/consulta.jsp (last visited Mar. 5, 2006). [Question of Constitutionality of Law 793 before the Consitutional Court]

[57] Const. Court, *id*.

[58] *See* Decree 1420, *supra* note 44, (discussing the time limitations on a temporary taking under the environmental conditions of the decree). *See also* Resolución 00017, *supra* note 5, (creating a timetable of one rotation and two rotation crops where by damages are measured based on the number of harvests land may produce per year). *Id.*

[59] Decree 1420, *supra* note 44.

[60] *Colom. Const. supra* note 35; *see also* Resolution 00017, *supra* note 5.

[61] Law 793, *supra* note 52, at art. 2.

[62] COLOM. CONSTIT., *supra* note 35, at arts. 34 & 59.

[63] COLOM. CONSTIT., *supra* note 35.

[64] *See supra* note 20 (reaffirming analysis that "[t]here is no single explanation for the wide range of Colombia's troubles, but they are rooted in the traditionally limited government presence in large areas of the interior…" (http://www.state.gov/p/wha/rls/rm/2005/q2/46564.htm).

[65] *La Violencia Deja Pueblos Fantasmas en Colombia*, La Razón, Feb. 28, 2006. [The Violence Leaves Ghost Towns in Colombia].

[66] *La Violencia*, *id*.

[67] *La Violencia*, *id*.

[68] *La Violencia*, *id*.

[69] *Compare* www.Semana.com (outlining attacks by all armed groups and an explanation of the populations in areas surrounding the attacks, http://www.semana.com/wf_InfoSeccion.aspx?IdSec=25.) *with* UNODC *Colom. Coca Cultivation Survey*, June 2005 (showing maps of coca cultivation that significantly overlap areas of violence but negating a linear relationship between coca cultivation and poverty). (last visited Mar. 6, 2006).

[70] *Cientificos*, *supra* note 22

[71] *Cultivation Survey*, *supra* note 68 at 70.

[72] *Presidente Alvaro Uribe, supra* note 53.

[73] *Departamento de Estado de E.U. Reconoce que Cultivos Ilícitos en Colombia no Ceden*, El Tiempo, Mar. 1, 2006, http://eltiempo.terra.com.co/judi/2006-03-01/ARTICULO-WEB-_NOTA_INTERIOR-2768934.html (last visited Mar. 19, 2006). [U.S.

Endnotes: U.S. Toxic Substances Law *Continued from page 10*

[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.nwsource.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.*

[49] Press Release, Asbestos Litigation Costs and Compensation: An Interim Study, Sept. 24, 2002, *available at* http://www.rand.org/news/press.02/asbestos.html (last visited Mar. 18, 2006).

[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/manangingeffects.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

[18] J. Muller et al., *Respiratory Toxicity of Multi-wall Carbon Nanotubes*, 207 TOXICOLOGY & APPLIED PHARMACOLOGY 221, 221-31 (2005).

[19] N. A. Monteiro-Riviere et al., *Multi-walled Carbon Nanotube Interactions with Human Epidermal Keratinocytes*, 155 TOXICOLOGY LETTERS 377, 377-384 (2005); S. Manna et al., *Single-walled Carbon Nanotube Induces Oxidative Stress and Activates Nuclear Transcription Factor- kb in Human Keratinocytes*, 5 NANOTECH. LETTERS, 1767, 1676-1684 (2005); A. A. Shvedova et al., *Exposure to Carbon Nanotube Material: Assessment of Nanotube Cytotoxicity Using Human Keratinocyte Cells*, 66 J. TOXICOLOGY & ENVTL. HEALTH 1909, 1909-1926 (2003).

[20] Xiongce Zhao et al., *C_{60} Binds to and Deforms Nucleotides*, 89 BIOPHYSICAL J. 3856, 3856–3862 (2005).

[21] J. D. Fortner et al., *C_{60} in Water: Nanocrystal Formation and Microbial Response*, 39 ENVTL. SCI. & TECH. 4307, 4307-16 (2005).

[22] Oberdörster, *supra* note 11.

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