the LOUISVILLE CHARTER

BACKGROUND PAPER FOR REFORM NO. 5 OF THE LOUISVILLE CHARTER FOR SAFER CHEMICALS

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Reform No. 5 of the Louisville Charter for Safer Chemicals reads:

REQUIRE COMPREHENSIVE SAFETY DATA FOR ALL CHEMICALS

Require Comprehensive Safety Data for All Chemicals—For a chemical to remain on or be placed on the market manufacturers must provide publicly available safety information about that chemical. The information must be sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment, including hazard, use and exposure information. This is the principle of "No Data, No Market."

ABSTRACT

Reform No. 5 of the Louisville Charter addresses the pervasive lack of publicly available information about the effects of many chemicals on human health and the environment. This lack of information persists for the majority of chemicals in commerce because the current laws in the U.S. do not systematically require it to be produced or motivate its voluntary production. These information gaps undermine the effectiveness of the existing environmental statutes, the liability system, the ability of the market to stimulate development of safer chemicals and, if they persist, complete realization of the other elements of the Louisville Charter. Therefore, this Reform calls for manufacturers of chemicals to be required to provide health and safety information as a condition for placing and keeping a chemical on the market.

Introduction

Once a chemical or class of chemicals is identified as potentially dangerous, the other five principles of the Louisville Charter provide guidance on how society should respond: we should seek to switch to safer substitutes (Reform 1); phase it out if it is persistent, bioaccumulative or highly toxic (Reform 2); disclose the information to the public and workers (Reform 3); act with foresight to prevent harm (Reform 4); and act immediately to protect communities and workers (Reform 6). These principles constitute crucial elements of a precautionary response once chemicals are identified as potentially unsafe.

We already have enough information about many chemicals to take these precautionary actions, and should do so without delay. However, for a large portion, perhaps even most, of the chemicals currently in commerce, we do not have enough information to know whether precautionary action is appropriate. For most chemicals on the market, little or no evidence is publicly available about whether they are hazardous, in which products they are present, or whether and the degree to which humans and the environment are exposed to them.

These data gaps constitute a central problem confronting all efforts to protect human health and the environment from toxic chemicals. While they persist, none of the other reforms of the Louisville Charter can be fully implemented. They undermine the effectiveness of existing U.S. environmental and liability laws. Perhaps as importantly, they constitute a "failure" in the chemicals market economy that prevents buyers of chemicals from choosing safer alternatives and reduces market incentives for the chemical industry to innovate safer chemicals.

To remedy this problem, the Louisville Charter holds that the chemical industry must provide enough reliable information to the public to permit a reasonable evaluation of the safety of chemicals to human health and the environment. This information may in appropriate circumstances include hazard, exposure and use information, though precautionary action may be appropriate before all such information is obtained. This information should be required as a condition for placing or keeping a chemical on the market. For chemicals already on the market, the information should be required by a date certain. The information should be generated using as little animal testing as possible while remaining scientifically valid. This is the principle of "no data, no market."

The Pervasive Lack of Safety Information

Throughout the industrial development of the United States, tens of thousands of chemicals have entered the market with little or no government review or regulation. More than 80,000 chemicals are now listed in the U.S. Environmental Protection Agency's ("EPA's") inventory of commercial chemicals. Many of these have reached high levels of production and use in the absence of reliable publicly-available evidence as to whether they are safe for human health and the environment. There is little public knowledge of how they are used or the extent of their releases from products and into the workplace and the environment.

Illustrative of the scale of this problem are the nearly 3,000 chemicals manufactured in the U.S. at over one million pounds per year, the High Production Volume ("HPV") chemicals. A 1998 study by EPA analyzed the public availability for these chemicals of the basic Organization for Economic Cooperation and Development ("OECD") Screening Information Data Set ("SIDS") toxicity and environmental fate information. The SIDS information is merely preliminary screening information and does not include information on many chronic human health effects, on how chemicals are used or in what products, or on whether they are released into the workplace and environment. The SIDS information is far less than what will be required for the higher tonnage tiers under the proposed European legislation referred to as REACH (the Registration, Evaluation and Authorization of Chemicals, proposed in October 29, 2003). (See chart attached hereto for identification of SIDS information and REACH tiered information requirements.) The EPA study showed that a

full set of even this limited SIDS information was publicly available for only 7% of the HPV chemicals and that no basic toxicity information for either human health or environmental effects was publicly available for 43%. *Chemical Hazard Data Availability Study—EPA's 1998 Baseline of Hazard Information that is Readily Available to the Public*, Office of Pollution Prevention and Toxics (April 1998).

Chemical safety information is certainly even less complete for most of the tens of thousands of chemicals manufactured at less than one million pounds per year. Thus, even if we now have enough publicly available information to determine whether to take precautionary action on hundreds or even several thousand chemicals, these constitute only a small fraction of all the chemicals used in commerce today.

Concern over these chemical safety information gaps is not merely speculative or hypothetical, but reflects the growing recognition that many of the chemicals in commerce, and not just a few, are likely to constitute some type of hazard. Research over the last few decades has shown that many chemicals have a wide variety of adverse effects that may be acute, but often may emerge only many years after very low levels of exposure (including carcinogens, mutagens, reproductive toxins, neurotoxins, immunotoxins and others). The European Commission, which confronts regulatory structures and data gaps in Europe that are similar to those in the U.S., has concluded that 70% of the chemicals that have been evaluated under its new chemicals program since 1981 have been shown to have one or more dangerous properties. While it is difficult to estimate precisely what proportion of chemicals on the market are likely to be hazardous, it is also difficult to dispute the European Commission's conclusion that under the current regulatory systems, a "significant proportion of all chemicals will enter the environment and reach sufficiently high concentrations to induce adverse effects." European Commission, *Extended Impact Assessment,* COM(2003)644 final, SEC (2003) 1171/3 (October 29, 2003) ("EC Extended Impact Assessment"), at page 27.

The root of this problem is that our existing environmental laws reflect an outdated, incorrect view of chemicals, a belief that only some of the many important chemicals in commerce are likely to be hazardous. See, e.g., TSCA, Section 2(a)(2). As a result, our toxic chemicals laws do not provide for a systematic determination of whether the chemicals in commerce are safe. The shortcomings of the most important of these laws, The Toxic Substances Control Act of 1976 ("TSCA"), are worthy of review.

The Toxic Substances Control Act

TSCA, a federal statute passed by Congress and enacted in 1976, was intended to enable EPA to adequately regulate toxic chemicals in the United States. It is the only federal law that broadly provides for regulation of most chemicals both before and after they enter commerce. Some existing U.S. laws enable both pre-market and post-market controls, but they apply only to particular classes of chemicals such as pesticides or pharmaceuticals. Other U.S. environmental laws, such as the Clean Air Act, Clean Water Act, Superfund and RCRA, are essentially end-of-pipe statutes aimed at regulating clean-ups and releases to the environment and workplace only after chemicals are introduced into commerce.

Though TSCA is broad in theory, its legal structure presumes that manufacturers have the right to market chemicals and places a heavy burden on government to prove the need for regulation before it can interfere with that right. Many studies have outlined the myriad elements built into TSCA that impede EPA from both obtaining and acting on chemical safety information. E.g., General Accounting Office Report GAO-05-458, *Chemical Regulation—Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* (2005) ("GAO Report (2005)"); General Accounting Office Report GAO/RCED-94-103, *Toxic Substances Control Act-Legislative Changes Could Make the Act More Effective* (1994) ("GAO Report (1994)"); L. R. Goldman, "Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development, "32 *Environmental Law Review* 11018-11041 (September 2002) ("Goldman (2002)"); *Overview: Office of Pollution Prevention And Toxics Programs*, 12/24/03 Draft Version 2.0, prepared by OPPT for the National

Pollution Prevention and Toxics Advisory Committee ("OPPT Overview"). As explained in more detail below, these impediments pervade EPA's programs for (a) requiring generation of new safety information on chemicals already in commerce, (b) ensuring new chemicals are safe before they are introduced into commerce and (c) regulating or banning the use of chemicals.

Under TSCA, EPA has Difficulty in Requiring Industry to Generate Safety Information about Chemicals already in Commerce

Several sections of TSCA give EPA authority to require industry to generate and provide safety information about their marketed chemicals, but this authority is tightly circumscribed. First, all chemicals that were in commerce as of 1979 were "grandfathered" in to TSCA, meaning that TSCA does not require any systematic review of their effects on human health or the environment. About 62,000 chemicals were identified as being in commerce as of 1979 and are listed on the TSCA Chemical Substances Inventory ("TSCA Inventory"). These pre-1979 chemicals still constitute the vast majority by weight of the chemicals on the market today. Though EPA can require testing for a pre-1979 chemical under TSCA Section 4, the burden on EPA before imposing a testing requirement is high. TSCA requires that EPA must first establish that the chemical either (a) may present an unreasonable risk to human health or the environment or (b) the chemical is produced or imported in substantial quantities and enters the environment in substantial quantities or there is or may be significant or substantial human exposure to the chemical. EPA must also demonstrate the insufficiency of available environmental health safety information; and that testing is necessary to provide the needed data. See TSCA, Section 4. TSCA is clear that EPA must consider environmental, economic and social impacts when evaluating whether a risk is unreasonable. See TSCA Section 2(c). Thus, EPA is in the difficult position of needing substantial information about a chemical in order to request testing information. EPA may use this "Section 4" authority to promulgate a formal test rule, which take from 2 to 10 years to finalize and can then be contested in court by a manufacturer. GAO Report (2005). Or EPA can negotiate an Enforceable Consent Agreement ("ECA") for voluntary testing. EPA's difficulty in using Section 4 to require new test data is plain: between 1979 and 2003, EPA has been able to require testing under Section 4, using both test rules and ECA's, for only 200 chemicals. See OPPT Overview; GAO Report (2005).

Section 8 of TSCA gives EPA authority to request or require reporting of existing safety test information that companies generate on their own or otherwise possess about their chemicals in commerce. It also authorizes EPA to request volume and production information to update the TSCA Inventory. But it does not provide any additional authority over that granted by Section 4 for EPA to require a generation of new safety testing and hazard identification information. See OPPT Overview; GAO Report (2005).

Much of the chemical information received by EPA under TSCA is not available to the public. Manufacturers may designate much of the information they submit to EPA as confidential business information, and they do so routinely. The confidentiality provisions of TSCA then bar EPA from divulging useful chemical information to the states, the public or even, under some circumstances, other federal authorities. While EPA may challenge mis-designations, it must do so on a case-by-case basis and seldom does. See GAO Report (2005); GAO Report (1994), Chapter 5; Goldman (2002); OPPT Overview.

Moreover, TSCA provides few mechanisms for oversight, auditing, penalties for providing incomplete or incorrect information or otherwise ensuring the reliability and credibility of information provided by industry. Examples of biased data and misleading studies are all too common. As a result, many scientists and others in government, academia and in the environmental health advocacy community are deeply skeptical of the credibility and reliability of the chemical safety information that is being produced by industry. See, e.g., Michaels, D., "Doubt is Their Product," *Scientific American*, pp. 96-101 (June 2005); Sass, J.B., et al., "Vinyl Chloride: A Case Study of Data Suppression and Misrepresentation," *Environmental Health Perspectives Online* (March 24, 2005) (doi:10.1289/ehp.7716, available at *http://doi.org/*). Industry as well has voiced criticism of the consistency and quality of the information contained in the publicly-available databases. This lack of credibility and reliability undermines the usefulness of the information that is available and, to the extent it is wrong or incomplete, leads to incorrect management of hazardous chemicals.

Thus, EPA faces serious constraints in its ability to effectively require

manufacturers to create publicly available reliable safety information about chemicals once they are in commerce. Instead, for any review of chemicals already in commerce, EPA must rely as best it can on data that is published by entities such as academic or government researchers or that is created voluntarily by manufacturers. Perhaps due in part to these limitations, the safety of pre-1979 chemicals has never been systematically studied, and no systematic review is ongoing today. Only about 2% of pre-1979 chemicals have been reviewed at all by EPA. See GAO Report (2005), page 18.

Some efforts to improve this situation are being undertaken, but they are at best regarded as first steps. Starting in 2006, the TSCA Inventory Update Rule Amendments (IURA) will require manufacturers of chemicals marketed at over 300,000 pounds/year/producer to report every five years certain processing, use, exposure, site and production volume information. Also, in the U.S. HPV Challenge, EPA has entered into a voluntary "challenge" with the American Chemistry Council for industry to provide the SIDS data set for the HPV chemicals. About 1,400 of these chemicals are being handled directly in the US HPV program, and SIDS data should be publicly available by the end of 2005. About 800 other HPV chemicals are proceeding through the OECD SIDS program, but will likely not be completed until at least 2010 because of the consensus assessment requirement of that program. However, this program will provide only the SIDS screening-level data set of information, which is insufficient to permit more than preliminary evaluations of the health and environmental effects of the HPV chemicals. EPA has been able to institute other small programs including the Endocrine Disruptor Screening and Testing Program, the Voluntary Children's Chemical Evaluation Program Pilot and others. See Goldman (2002) and OPPT Overview for summaries of these programs. These programs constitute what Dr. Lynn Goldman, Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, U.S. EPA, 1993–1998 has called a "hodgepodge" of voluntary and mandatory programs that do not constitute the "logical and methodical process of evaluating existing chemicals" that we need. Goldman (2002) at 11026.

TSCA's New Chemicals Program for Post-1979 Chemicals

The situation is slightly better for chemicals introduced since 1979. Ninety days before manufacturing or importing new chemicals, industry must provide EPA with a pre-manufacture notice ("PMN"). EPA processes about 1,500 PMN's every year, over 36,000 between 1979 and September 2002. About 18,000 of these chemicals have gone on to be marketed and listed on the TSCA Inventory (in addition to the 62,000 pre-1979 chemicals on the Inventory). See OPPT Overview. However, EPA has made many chemicals exempt from the PMN requirement, including certain polymers (40 CFR section 723.250), as well as chemicals produced at less than 10,000 kg/yr and "low release and exposure" chemicals (40 CFR section 723.50). EPA received the required notice and documentation for over 9,000 such exemptions between 1979 and September 2002, which represent chemicals that have most likely reached the market without being listed on the TSCA Inventory. See OPPT Overview.

PMNs typically include little or no toxicity data because TSCA requires none. Although any test data the submitter has available must be submitted with a PMN, 67% of PMNs contain no test data at all, and 85% contain no data relating to human health. See OPPT Overview. For most chemicals, initial exposure and commercial use information need not be routinely updated after PMN's are processed and is unlikely to reflect subsequent commercial realities. Moreover, EPA has only ninety days to act on a PMN or extend the review period; after that market access is automatic. EPA performs an initial streamlined review of all PMNs, but is able to perform a more in-depth review for only a limited number. See GAO Report (2005); GAO Report (1994); OPPT Overview. Because EPA has so little actual test data, it relies instead on its own expertise, internal databases, searches and computer modeling (e.g., Structure-Activity Relationship ("SAR") analyses, which compare the structures of new chemicals to the structures of known toxic chemicals) in order to predict for new chemicals their physico-chemical properties, environmental fate and effects on human and the environment. See GAO Report (2005); GAO Report (1994), Chapter 3; OPPT Overview. At best, and though possibly improving with time, EPA's PMN program provides essentially preliminary screening reviews for new chemicals. Indeed, in a joint study of the effectiveness of new chemical screening programs, both the EPA and the European Commission concluded that they are deficient if based solely on

SAR analyses and would be more effective at detecting toxic chemicals if they included actual testing data. See U.S. EPA, *U.S. EPA/Joint EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships*, July 1993; Final Report (1994); Goldman (2002) at 11028 for discussion. The recent GAO report confirms that substantial shortcomings in this approach for evaluating chemicals persist. GAO Report (2005).

If EPA becomes concerned about a new chemical during a PMN review, it may require submission of additional test data. But before it can do so, TSCA requires that EPA first show that the chemical may present an unreasonable risk or significant exposure. Similarly, EPA may permanently control or ban a new chemical only if it first demonstrates an unreasonable risk to health and the environment. The lack of information included in the PMNs makes it difficult for EPA to establish such findings. EPA has very rarely imposed involuntary controls or testing requirements on a new chemical submission. In about 10% (3.500) of PMNs submitted between 1979 and September 2002, EPA has raised questions about chemical safety that have led to voluntary negotiated actions, including withdrawal of the PMN, or some type of control or testing agreement. See GAO Report (2005); OPPT Overview.

Concerns about the reliability of information as well as designation of chemical information as confidential also plague the new chemicals program. Even the identity of the chemical is claimed as confidential in about 90% of all PMN submissions and in about 65% of the PMN submissions for new chemicals that eventually enter commerce. See GAO Report (2005); OPPT Overview. This means that the public is unable to determine even the identity of most of the new chemicals that enter commerce through the PMN program.

Thus, despite the PMN program, many new chemicals enter the market with insufficient information made publicly available to evaluate their effects on human health and the environment. Many chemicals are exempt from the PMN requirement and many PMN's are not substantively reviewed by EPA. Even for chemicals that do receive a PMN review by EPA, the public is seldom able to obtain access to EPA's review, the underlying information or even the SAR analyses because of confidentiality restrictions. And once chemicals enter commerce, they become subject only to the sections of TSCA that govern marketed chemicals, so that there is little if any follow-up as commercial use matures. The public, including both industrial users and consumers of chemicals, is essentially unable to evaluate for itself the safety or even the identity of many new chemicals as they are introduced and disseminated into the marketplace.

EPA must satisfy a Very Heavy Burden of Proof Before Regulating a Chemical in Commerce

Another pervasive feature of TSCA undermines EPA's incentives to require creation and dissemination of basic chemical safety data: EPA must generate very substantial evidence to meet its high burdens of proof before it can actually regulate the use of a chemical already in commerce. The changes needed in these legal burdens on government are directly addressed by the other elements of the Louisville Charter, but are relevant here to show just how much information EPA must be prepared to develop before attempting to regulate a chemical under TSCA.

As a threshold issue, TSCA is not a primary vehicle for controlling chemicals but rather is a "gap-filling" statute that EPA may use only as a last resort after considering whether other federal statutes or regulations are available to address the risk. See TSCA Sections 6(c) and 9; GAO Report (1994); Goldman (2002); OPPT Overview. This creates not only referrals of chemicals problems among groups within EPA, but also referrals to different federal agencies and deference to those agencies.

When EPA does use TSCA, EPA must impose controls on a chemical-by-chemical basis. In order to regulate a chemical, TSCA Section 6 requires EPA to provide "substantial evidence" that (1) the chemical presents or will present an "unreasonable" risk to health and the environment, (2) the benefits of regulation outweigh both the costs to industry of the regulation and the lost economic and social value of the product, and (3) EPA has chosen the least burdensome way to eliminate only the unreasonable risk. Both TSCA itself and the courts are clear that economic and social factors must be considered as well as environmental and human health effects when EPA determines whether a risk is unreasonable under TSCA. See TSCA Section 2(c); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). EPA's TSCA regulations can be challenged in court, and when they are, EPA is not entitled to the usual deferential Administrative Procedure Act "abuse of discretion" standard of review. This

means that EPA's TSCA regulations can be overturned in court more easily than many other federal agency actions. As a result, EPA has attempted to use Section 6 to impose controls on only five chemicals or groups of chemicals since 1979, the last time in 1990, and many of these have been unsuccessful. GAO Report (2005), pp. 18, 27. For example, EPA's comprehensive asbestos rule governing all aspects of asbestos use in the U.S., which had taken 10 years to develop and was based on a monumental public record, was challenged by industry and then struck down in large part by the Fifth Circuit Court of Appeals. The court concluded that EPA had not provided substantial evidence to support most of the regulation. See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). To this day, the U.S. has not fully banned asbestos despite such action in numerous countries around the world. See GAO Report (2005); GAO Report (1994), Chapters 2, 4; OPPT Overview.

The Information Gaps Undermine the Environmental and Liability Laws and Impede Innovation of Safer Chemicals

These data gaps undermine the existing efforts in the United States to reduce the use of toxic chemicals and their effects on human health and the environment. They diminish the effectiveness of the environmental and public health laws, which can control emission of chemicals into the environment and workplace only if their hazards are recognized. The pervasive data gaps effectively blind these laws to all intrinsically dangerous chemicals that are not recognized as hazardous, including laws relating to worker safety (OSHA), air pollution (Clean Air Act), water pollution (Clean Water Act), hazardous waste disposal (RCRA), hazardous waste clean-up (Superfund), toxic chemicals (TSCA), products (CPSC, California's Proposition 65) and many others. The damage to human health and the environment caused by unrecognized hazards remains externalized onto the public despite these laws. The legislative objective of disfavoring hazardous technology in order to stimulate innovation of new, safer technology is not fully realized. Moreover, regulators are unable systematically to assess or prioritize risks, must limit their targets to the relatively few chemicals that have been identified as hazards, and often must respond to political crises that the public must generate to get government to act at all.

The veil of ignorance also undermines the liability system and its important deterrent function. Under our common law liability system, plaintiffs must prove what hazards they have been exposed to and that their damages were caused by that exposure. This burden is of course impossible when people are exposed to chemicals that, unknown to everyone, are in fact toxic. The product liability laws, though they purport to be grounded in strict liability, nevertheless require proof that the product caused the damage, proof that cannot be provided when such information does not exist. Damage caused by unrecognized hazards simply lies where it falls.

But also, and perhaps as importantly, the unavailability of chemical safety information for so many products is preventing the chemicals market from operating as a properly functioning free market ought to act. Over the last several decades, the field of information economics has demonstrated the crucial role of information in the proper operation of a market economy, and the serious economic consequences of "imperfect information" and "information asymmetries." For overview of information economics, see Stiglitz, J. E., "Information and the Change in the Paradigm in Economics, Part 1," 47 The American Economist 6-26 (Fall 2003); Stiglitz, J. E., "Information and the Change in the Paradigm in Economics, Part 2," 48 The American Economist 17-49 (Spring 2004) (available at *http://www2.gsb.columbia.edu/faculty/jstiglitz/papers.cfm*). See also Stiglitz, J.E., Globalization and Its Discontents, pp. 73-74, 261n.2, W.W. Norton & Company, Inc. (2003).

In the language of economists, an ideally functioning free market is one in which consumers are free to buy goods and services they desire, which are then produced by the market according to the laws of supply and demand. But for demand to reflect what consumers truly value, consumers must have access to all information that would affect their choices. Without this information, the prices people pay for goods and services will not reflect their true preferences, and people

will inadvertently buy goods and services they would not buy if they had more information. When this happens, the market is said to be "inefficient" because it is not producing goods and services according to the true desires of consumers. The lack of information in the market is causing what is called a "market failure" by preventing the laws of supply and demand from driving the market to produce what people really want.

Information economists have focused on the damaging economic effects of what they call "imperfect information," including both nonexistent information and information that is available to some, but not all market actors. They have shown that imperfect information and the resulting market failures and economic inefficiencies are pervasive in all economies, including the U.S. economy. They have shown that the market itself often does not provide appropriate incentives for creation and disclosure of information, and in fact can provide incentives for market actors to conceal information in order to gain market power and entrench themselves in the market. They also have shown that the market often simply cannot correct these market failures. This provides a rationale for government to intervene to correct the market failure in order to increase the efficiency of the market. Government can do many things to correct or adapt to information imperfections. One solution is to require industry to produce the needed information and make it widely available to the market. Well-known examples of such government action include the securities laws (requiring accurate financial disclosures by public corporations) and the drug laws (requiring pre-market proof that drugs are safe and effective). These laws were adopted after serious threats to the proper operation of the financial and drug industries arose, threats that the market alone was unable to redress. Though these laws impose burdens on the affected industries and are imperfect, they have plainly strengthened those industries by making them more "efficient" in the economist's sense of being more responsive to the desires of investors and consumers, thus enabling the economy to produce stronger companies and better drugs.

Turning to the chemicals market, many sectors of the public can be seen as market actors who are capable of using information about chemical safety in their choice of chemicals. For example, many industrial users of chemicals are technically sophisticated enough to choose the safest chemical that will suit their purposes, if they can get the information they need. Similarly situated are many other market actors, including:

- public health professionals trying to evaluate and prioritize risks to the public;
- purchasing organizations including those created by hospital groups;
- state and local governments and others attempting to purchase safer products;
- green building and other green standard setting bodies;
- consumer organizations, and indeed many consumers, attempting to identify safer consumer products;
- health-affected groups, citizens and community groups attempting to use information provided by the right-to-know laws to reduce pollution in their communities;
- workers attempting to ensure safe workplaces; and
- environmental and public health activists trying to motivate corporations to green their activities through market-based environmental and health protection campaigns.

The information these market actors are capable of using includes information about the hazardous properties of chemicals, how they are used in commerce and the workplace, the products they are incorporated into, and how they are disposed of. However, the lack of this information in a publicly-available, credible and reliable form for the majority of chemicals in commerce is impeding their efforts. While market actors can sometimes avoid chemicals and products known to be hazardous, the incompleteness of available information means they are unable to choose chemicals and products containing chemicals that they know to be safe. They risk failing to choose what is in fact the safest alternative or even unwittingly choosing a product that turns out later to be hazardous and no better or even worse than the chemical they avoided. Thus, the demand for safer products is not adequately expressed or realized in the market.

Moreover, the imperfections in information impede innovation by members of industry that could respond to the preference for safer products. Innovation cannot occur unless a firm has the willingness, opportunity and capacity to change its technology, and information about technological alternatives is fundamental to these preconditions for innovation. See Ashford, N.A, "An Innovation Based Strategy for a Sustainable Environment," in Hemmelskamp et al. (eds.), *Inno-*

vation-oriented Environmental Regulation: Theoretical Approaches and Empirical Analysis, pp. 67-107 (2000). Thus, industry cannot switch to safer chemical alternatives if they are not identified as such. Manufacturers who do sell safer chemicals often lack the comparative information they would need to claim an advantage in the marketplace, and indeed may not even know they have such an advantage. Manufacturers of chemicals have reduced commercial incentive to develop safer chemical products when they cannot gain their deserved reward in the marketplace, and this results in lowered investment in green chemistry and in the design of safer chemicals. Perhaps most importantly, the information about which chemicals are toxic is the fundamental technological knowledge that designers of safer chemicals must have in order to design safer chemicals—without it they cannot succeed.

There is an asymmetry between pre-1979 and post-1979 chemicals that would seem to be causing even further distortion of the market. Though imperfect, TSCA information requirements and scrutiny are greater for new chemicals than for pre-1979 chemicals. This unequal playing field constitutes an additional incentive for industry to continue to market older chemicals rather than replace them with new chemicals, even if the new chemicals are comparatively safer.

Some chemical safety information is possessed by individual companies and EPA, but is not publicly available. But the mere existence of such information does the broader market forces no good. For them such information may as well not exist at all.

In sum, the lack of credible and reliable publicly-available chemical safety information is dampening the influence on the market of the many social forces attempting to drive the innovation of the safer chemicals, and it is undermining the ability of industry to innovate those products.

Maintaining this system are powerful commercial interests that seek the continued sale of their particular chemicals, especially those that were on the market before 1979 and still comprise by weight most of the chemicals used in the U.S. today. The chemicals market is a classic example of a market dominated by mature firms that seek to block changes that will encourage innovation and entry into the market of new competitors. See Ashford (2000). Fear of liability and regulation gives these firms substantial incentives to perpetuate the information imperfections, and to use these information gaps to protect their products and entrench themselves in the market. Thus, acting rationally in their self-interest, they resist studying the environmental health effects of their products, produce studies that all too often are designed to exonerate their products, resist independent study of their products and oppose measures that would encourage more information disclosure and foster innovation of safer substitutes by competitors. As a result, threats to human health and the environment can only be discovered too late, once chemicals become widespread throughout industry and the environment, and after the impacts have grown large, obvious, distinct and undeniable. We seem condemned to struggle endlessly to protect environmental and human health by belatedly confronting substantial threats caused by entrenched and powerful industries.

"No Data, No Market" Must Be Established

As we have seen, inadequate publicly-available information about chemical safety is seriously undermining management of chemicals in the U.S. The existing market is incapable of providing incentives for production and dissemination of the needed information, and in fact provides disincentives. Under these circumstances, it is appropriate for government to take steps to address this problem. The government's goal should be to create the conditions that are necessary for the proper operation of our existing institutions for controlling chemicals: the environmental and public health laws, the liability system and the markets.

To do this, government should require the chemical industry to provide to the public and government a basic level of health and safety information about its products as a condition of entering and remaining in the public marketplace. The information must be reliable and it must be comprehensive, that is, sufficient to permit the reasonable evaluation of the safety of chemicals for human health and the environment. The requirement must apply to substantially all marketed

chemicals, with a date certain by which such information should be made available for chemicals already on the market.

The cost of such a program would constitute a minimal percentage of product prices, and would not be unduly burdensome, especially considering the great benefits to be gained. For example, a recent estimate of the direct and indirect costs of compliance with the October 2003 REACH proposal is less than 10 billion euros over an 11 year period, which is less than 0.15% of the chemical industry's sales revenue over that period. Ackerman and Massey, *The True Costs of REACH*, Global Development and Environment Institute, Tufts University (2004). More importantly, each dangerous chemical that is replaced or prevented from ever reaching the market will not damage human health or the environment or need to be cleaned up, benefits that will be substantial. The European Commission has determined that the costs of its chemical information requirements for 30,000 chemicals under its REACH proposal are far outweighed by the benefits expected from reducing human disease. EC Extended Impact Assessment, pp. 24-29. Moreover, the advent of REACH signals the EU's intent to stimulate creation of the safest products in the world and to gain the competitive advantage that comes from being the first to move toward safer chemicals. The United States should choose this same path, and take steps to encourage and capitalize on its substantial capacity for innovation. A chemical information requirement underpinning a marketplace that rewards innovation of safer chemicals will encourage, not discourage, creation of a sustainable, safer chemical industry in the United States.

Several elements must be incorporated into a "no data, no market" information requirement if its objectives are to be fully realized.

1. The information requirement must not delay taking appropriate precautionary action. Precautionary action in accord with the other principles of the Louisville Charter may be appropriate based on less than all required information.

2. The information requirement should identify specific information that must be provided as an unalterable condition of gaining the right for a chemical to enter or remain on the market. This information may be required before significant quantities of a chemical are manufactured, and not just at the pre-marketing stage, to assist in protection of workers. New additional information on health and environmental effects must be provided promptly.

3. The required information must be "comprehensive," that is, it must constitute enough information about the hazards, exposure (to workers, consumers, the general public and the environment), uses in commerce, products a chemical is incorporated into and disposal of a chemical to support a reasonable evaluation of its safety for human health and the environment. Government must be able to require additional information if necessary to evaluate a particular chemical or class of chemicals.

It may be desirable to prioritize chemicals, such as by tonnage manufactured per year, so that higher priority chemicals have greater information requirements. It may be desirable to require different information for different classes of chemicals, such as persistent or bioaccumulative chemicals.

Where possible, harmonization with existing data sets and protocols is desirable to the extent it would avoid unnecessary duplication in government requirements. Existing data sets include the OECD SIDS data set, and the three tiered data sets required by the October 29, 2003 draft of REACH. These are set forth and compared in the attached chart. It is doubtful that the SIDS data set or the data requirements for the lowest tiers in REACH are sufficient to allow a reasonable evaluation of the safety of chemicals for human health and the environment.

4. The information must be disseminated into the stream of commerce. Human health and environmental effects information must be communicated down the stream of commerce so that users of chemicals and products containing chemicals know the hazards of the chemicals and products they use. Also, information about the uses of chemicals must be distributed upstream to manufacturers so that they know how their chemicals will be used.

5. The chemical information must be reliable if society is to properly manage chemicals. Some prefer that industry itself produce the information. This would be intended to encourage industry to incorporate safety testing into early stages of its R&D programs, and would result in disclosure only once chemicals appear commercially significant. Others place greater trust in generation of the information by government or by independent labs, at industry expense. While this may be more reliable and credible, it may also necessitate greater intrusion into the industry R&D process.

For any of these approaches to generate credible and reliable information, however, they must include establishment of data quality standards and thorough expert review; legal penalties sufficient to motivate full, complete and accurate disclosures, possibly including criminal penalties; and mechanisms for auditing, oversight, and public disclosure of underlying data. Several laws exist requiring generation and public disclosure of valuable corporate information, such as the securities laws, and these may be appropriate models.

Industry should bear the cost of the generation of information. Manufacturers of chemicals appear to be best positioned to bear the burden of producing chemical safety information. They are best positioned to minimize the costs of producing the information and to allocate those costs to all users of the chemicals. Appropriate data sharing mechanisms may help to avoid duplication of work, thereby reducing costs and unnecessary animal testing.

6. For chemicals already on the market, there must be a fixed deadline for provision of the required information. It will probably be necessary to prioritize chemicals, such as by tonnage, so that some chemicals will have earlier deadlines than others.

7. The information must be made available in complete as well as in readily useable form to the public, government and industry. No information that is material to the evaluation of the safety for human health and the environment of a chemical actually on the market may be maintained as confidential. Material information includes the identity of the chemical and experimental data and other forms of information that are relevant to evaluation of a chemical by an environmental health professional, including hazard, exposure and use information.

Since such information has commercial value, some methods of preserving that value to those who disclose it for public use may be appropriate, including mechanisms for sharing costs with other commercial users of the information, limited grants of exclusive use of the information for regulatory purposes, etc.

8. Substantially all chemicals must be subject to the information requirements. An exemption for chemicals used for R&D or for very low volume chemicals may be considered, although given the advent of nanotechnology any low volume exemption must be carefully structured. Chemicals controlled by other laws, such as pesticides, food additives, cosmetics and pharmaceuticals, should only be excluded from a broad law if separate statutes provide equivalent or better information requirements for those chemicals.

9. Government must review and attest to the quality and completeness of the required information, and independently evaluate all submissions, within fixed time periods. Government must be able to request any information it deems necessary to reasonably evaluate a chemical before granting new or continued market approval. Adequate government resources must be provided to carry out these tasks, principally from fees paid by persons seeking to place chemicals on the market. Industry evaluation of the data in the first instance, as is required under the October 29, 2003 REACH draft, may or may not be desirable. On the one hand, flawed and biased industry arguments would create a burden of rebuttal on government and on the public. On the other hand, it would be desirable to create a system that to the extent possible enables and motivates responsible stewardship by industry.

ENDNOTES

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SUMMARY OF REACH INFORMATION REQUIREMENTS
By Production Volume; Comparison to US HPV/OCED SIDS Requirements

Prepared by Richard A. Denison, Environmental Defense, November 2004

Based on the REACH Annexes V-VIII, October 2003

NOTES: Most information requirements are heavily caveated and conditional on many factors, such as the type or properties of the chemical, the results of preceding tests in the production volume-based hierarchy, etc. (See REACH Annexes V-VIII). At Registration, all relevant data required under Annexes V-VI are to be submitted, but only test proposals are required for any additional tests (based on production volume) under Annexes VII-VIII. Determination of which of those tests are to be done is made by the member state assigned the dossier as part of Evaluation.
In addition, numerous alternatives to direct testing are allowed, including use of estimation techniques, category-based extrapolation, etc. (See REACH Annex IX).

Grey highlights indicate tests that can be waived if exposure potential is considered low.

REACH section ID	*Required for HPV/ SIDS?*	*Endpoint*	Annex V >1 t/yr	Annex VI >10 t/yr	Annex VII >100 t/yr	Annex VIII >1000 t/yr
6.		**Mammalian Toxicological Data**				
6.1		Skin Irritation or Skin Corrosion in vitro	√			
6.1.1		Skin Irritation or Skin Corrosion in vivo		√	√	√
6.2		Eye Irritation in vitro	√			
6.2.1		Eye Irritation in vivo		√	√	√
6.3		Skin Sensitization	√	√	√	√
6.4		Genetic Toxicity				
6.4.1	y	in vitro (Gene Mutation)	√	√	√	√
6.4.2	y	in vitro (Cytogenicity)		√	√	√
6.4.3		in vitro in mammalian cells		√	√	√
6.4.X		Further Mutagenicity Studies				√
6.5	y	Acute Toxicity		√	√	√
6.5.1		by oral route				
6.5.2		by inhalation route				
6.5.3		by dermal route				
6.6		Repeated Dose Toxicity				
6.6.1	y	short-term (28 days)		√	√	√
6.6.2		sub-chronic (90 days)			√	√
6.6.3		long-term (≥12 months)				√
6.7		Reproductive Toxicity				
6.7.1	y	Screening Reproductive/Development Toxicity		√		
6.7.2	y	Developmental Toxicity		√	√	√
6.7.3/4		Two-Generation Reproductive Toxicity			√	√
6.8		Toxicokinetics (if already available)		√	√	√
6.9		Carcinogenicity				√
7.		**Ecotoxicological Data**				
7.1		Aquatic Toxicity				
7.1.1	y	Aquatic Invertebrates (Daphnia) Acute Toxicity	√	√	√	√
7.1.2	y	Aquatic Plants (Algae) Toxicity		√	√	√
7.1.3	y	Fish Acute Toxicity		√	√	√
7.1.4		Activated Sludge Respiration Inhibition		√	√	√
7.1.5	(y)*	Aquatic Invertebrates (Daphnia) Chronic Toxicity			√	√
7.1.6		Fish Chronic Toxicity			√	√
7.1.6.1		Fish Early-Life Stage Toxicity			√	√
7.1.6.2		Fish Short-term Embryo/Sac-Fry Stage Toxicity			√	√
7.1.6.3		Fish Juvenile Growth			√	√

* Under HPV/SIDS, for chemicals with low water solubility or certain other properties, chronic ecotoxicity testing may be required as well or instead

REACH section	*required for HPV/ SIDS?*	*Endpoint*	**Annex V >1 t/yr**	**Annex VI >10 t/yr**	**Annex VII >100 t/yr**	**Annex VIII >1000 t/yr**
7.2		Degradation				
7.2.1		Biotic Degradation				
7.2.1.1	y	Ready Biodegradability		√	√	√
7.2.1.2		Surface Water Simulation			√	√
7.2.1.3		Soil Simulation			√	√
7.2.1.4		Sediment Simulation			√	√
7.2.1.5		Further Studies				√
7.2.2		Abiotic Degradation				
7.2.2.1	y	Stability in Water/Hydrolysis		√	√	√
7.2.3		Identification of Degradation Products			√	√
7.3		**Fate and Behavior in the Environment**				
7.3.1		Adsorption/Desorption Screening		√	√	√
7.3.2		Bioconcentration			√	√
7.3.3		Further Studies			√	√
7.3.4		Further Environmental Fate and Behavior Studies				√
7.4		Terrestrial Organisms				
7.4.1		Earthworms Short-Term Toxicity			√	√
7.4.2		Soil Micro-Organisms Effects			√	√
7.4.3		Plants Short-Term Toxicity			√	√
7.4.4		Earthworms Long-Term Toxicity				√
7.4.5		Soil Inveterbrates Long-Term Toxicity				√
7.4.6		Plants Long-Term Toxicity				√
7.5		Sediment Organisms Long-Term Toxicity				√
7.6		Birds Long-Term or Reproductive Toxicity				√
--	y	Photodegradation				
--	y	Transport/Distribution between Compartments (Fugacity)				
5.		**Physical-Chemical Data**				
5.1		State of the substance at standard temperature and pressure	√	√	√	√
5.2	y	Melting/Freezing Point	√	√	√	√
5.3	y	Boiling Point	√	√	√	√
5.4		Relative Density	√	√	√	√
5.5	y	Vapor Pressure	√	√	√	√
5.6		Surface Tension	√	√	√	√
5.7	y	Water Solubility	√	√	√	√
5.8	y	Partition Coefficient (n-octanol/water)	√	√	√	√
5.9		Flash Point	√	√	√	√
5.10		Flammability	√	√	√	√
5.11		Explosive Properties	√	√	√	√
5.12		Self-ignition Temperature	√	√	√	√
5.13		Oxidizing Properties	√	√	√	√
5.14		Granulometry	√	√	√	√
5.18		Stability in Organic Solvents/Identif. of Breakdown Products			√	√
5.19		Dissociation Constant			√	√
5.20		Viscosity			√	√