Strategies for Closing the Chemical Data Gap

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It is universally agreed that we know far too little about the long-term effects of low levels of exposure to most common toxic chemicals. The absence of such information, which is commonly called the "data gap," was a motivating factor behind the adoption of the Toxic Substances Control Act (TSCA) in 1976. In the intervening years, in study after study, researchers have empirically confirmed the data gap – from a 1984 National Academy of Sciences study, which found that only 22 percent of high production volume (HPV) chemicals had the minimum data set available,[1] to a 1998 U.S. Environmental Protection Agency (EPA) report, which found that there is no toxicity information available for 43 percent of such chemicals and that a full set of basic toxicity information is available for only 7 percent.[2] Indeed, we have made significantly less progress in closing this yawning data gap than we have in discovering new threats to public health. A study by the Center for Progressive Reform (CPR) found that EPA's central database for chemical information includes only a fraction of the chemicals identified as hazardous under EPA's principal statutes. The study, *Overcoming Environmental Data Gaps: Why What EPA Doesn't Know About Toxic Chemicals Can Hurt*, is available at CPR's website.[3]

The data gap did not happen by chance. Since at least the early 1980s,[4] risk assessment has been a central element of chemical regulation, and risk assessment demands a great deal of chemical information to generate ostensibly precise predictions of a chemical's toxicity and exposure profiles. Congress, courts, and regulatory agencies increasingly demand a high degree of quantified precision in predicting the long-term, low-dose effects of toxic chemicals on human and ecological receptors. Moreover, since the legal burden of proof is almost always on the regulatory agency to justify protective action, there is no incentive – actually, there is a strong *dis*incentive – for the makers of the chemicals to generate the needed data.[5] As a result, "[e]ach stage of the regulatory process produces a deficit between the amount of information needed for regulatory decision making and the amount that is available."[6] Put another way, there is a large gap between the legal system's demand for information about chemicals and the existing supply of available data. Since, when it comes to chemicals, what we don't know *can* hurt us, addressing the data gap needs to be a governmental priority.

Over the last eighteen months, CPR has been engaged in an ongoing project to define the extent of the data gap, to learn why the data gap has persisted over thirty years of environmental regulation, and to find solutions to the problem. CPR's Data Gap Project has two major components. The first is documentation of the extent of the data gap (*Evidence of the Data Gap*). A Data Gap Bibliography that is attached as an appendix to this report collects empirical studies of the data gap. The bibliography

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also includes a selective list of studies that analyze the data gap but do not report new empirical research. The other element of documentation is an assessment by CPR of EPA's Integrated Risk Information System (IRIS). IRIS is an internationally preeminent toxicological database, used by regulatory agencies throughout the world to evaluate the health effects of toxic chemicals. CPR's study revealed large gaps in the priority chemicals covered by IRIS' list of tolerance values (an estimate of the level of exposure that is likely to be toxic), and it determined that the federal planning and budget process facilitates data gaps by failing to coordinate government research either internally or externally. Again, the study is available on the CPR web site.

The second major component of the Data Gap Project, reported in the remainder of this white paper, is analysis of the underlying causes of the data gap and exploration of possible solutions. The analytical component builds on a forthcoming book written and edited by CPR scholars, *Rescuing Science from Politics*,[7] and it will be continued next year in a symposium comparing the data gap in the chemical and conservation areas of environmental law. The centerpiece of this component of the project is a CPR-sponsored workshop and subsequent conference with national experts designed to explore the data gaps dilemma. These meetings gathered evidence about the data gap, discussed frameworks for analyzing the evidence, and considered solutions.[8] This report synthesizes what CPR has learned through this process.

Evidence of the Data Gap

The "data gap" actually consists of several kinds of gaps in the data that underlie chemical regulation. Most of the studies cited in the attached bibliography focus on missing chemicals, that is, chemicals for which a basic battery of testing is not available, because the tests have not been performed at all or only incompletely. Other test data exist but are unreliable, having been performed badly or under outdated protocols. These two are the most obvious contributors to the overall data gap, and the remedy is the most obvious: do the testing. In the last decade, the concept of a standard battery of basic testing (for example, the Screening Information Data Set (SIDS)) has helped to quantify the extent to which available testing data fall short of completeness.

Other data gaps are less obvious. Much fundamental information is missing, some of it for lack of looking and some because of incomplete understanding of the relevant science.[9] The mechanism of action of chemical carcinogens, for example, is still only incompletely understood. Without this knowledge, statements of toxic potency are at most estimates based on phenomena that are inherently difficult to observe with precision. This gap can – and one day probably will – be filled through basic cancer research, but in the meantime its absence limits our ability to predict toxic effects. Similarly, "frontier" issues in toxicology – bioavailability, sensitive subpopulations, and endocrine disruption effects – require more basic research as well as straightforward testing. Our understanding of the effects of mixtures of chemicals and interactions between and among chemicals is extremely limited.

Finally, the data gap is also attributable to the sequestration of chemical information that would otherwise be useful to public decisionmaking. The importance of nondisclosure should not be underestimated; for most purposes, secret data might as well not exist. Such data gaps can arise for a variety of reasons, such as non-disclosure contracts[10] and overuse of the Confidential Business Information (CBI) claims. Further, some industry-produced data that are available could be better used if their reliability was increased, through, say, a certification process.

Early Studies

As early as 1971, the newly formed Council on Environmental Quality issued a report, *Toxic Substances*,[11] which made the case for a new statute to regulate industrial chemicals. The CEQ offered numerous reasons for such a statute, not the least of which was the lack of existing information on the toxic effects of industrial chemicals, *including those produced and used widely in commerce*. After much political debate, many of CEQ's recommendations were incorporated into the Toxic Substances Control Act of 1976. In the preamble to TSCA, Congress declared:

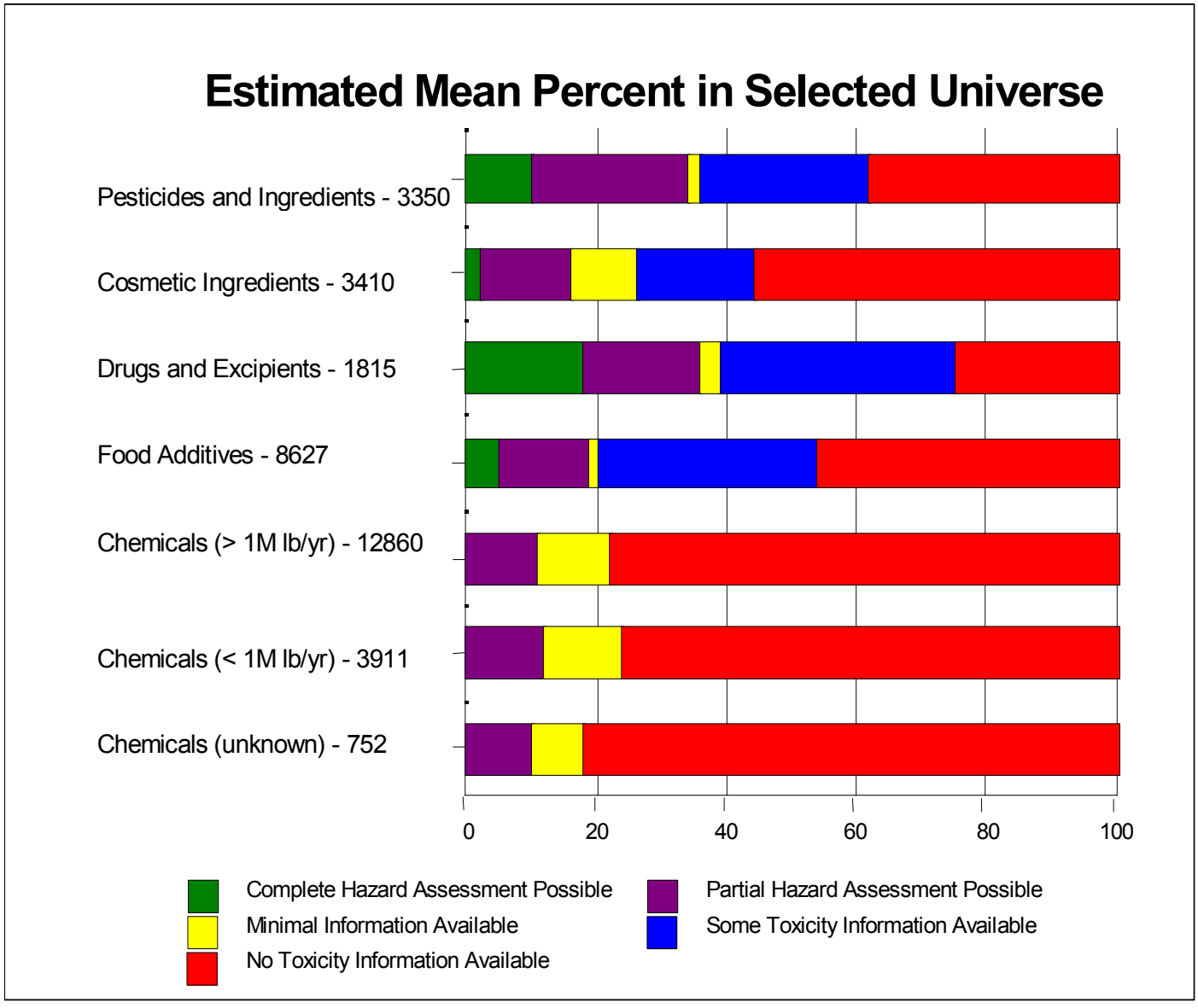
> It is the policy of the United States that . . . *adequate data should be developed* with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the *responsibility of those who manufacture* [such] chemicals [emphasis added].[12]

Substantively, TSCA included numerous regulatory techniques – including clearinghouses, adverse effect reporting, pre-market notification, and testing rules (§§ 4, 5, 8) – that were designed to gather the needed information.[13] Unfortunately, implementation of the statute has fallen far short of this goal.

The congressional finding that insufficient chemical information existed was confirmed in numerous empirical studies. The most frequently cited early study, *Toxicity Testing*, was undertaken by the National Academy of Sciences in 1984. Taking a sample of the universe of chemicals, including different uses and the range of production volumes, the NAS found that no toxicity testing was available for more than 80 percent of all toxic substances in commerce, and that only 22 percent of HPV chemicals had even a minimum data set available.[14] Its findings are summarized in Figure 1.

The data also demonstrated that different regulatory regimes have different effects on chemical

Figure 1: Summary of *Toxicity Testing* study findings.[15]



information. Licensing programs like pesticides and prescription drugs, for example, produce far more data than after-the-fact information gathering.

OECD's Screening Information Data Set

In 1989, the international Organisation for Economic Cooperation and Development (OECD), developed a Screening Information Data Set (SIDS) for chemicals. SIDS is a battery of risk-related testing that would enable a basic analysis of a chemical's toxic potential. The endpoints include acute toxicity, chronic toxicity, developmental and reproductive toxicity, mutagenicity (a key indicator of carcinogenicity), ecotoxicity, and environmental fate.[16] The purpose of the SIDS project was to encourage the chemical industry voluntarily to develop "base level test information on approximately 600 poorly characterized international HPV chemicals," and not (at least in the U.S.) to regulate the chemicals.[17] While the focus was generation of new chemical data, its main utility was to allow the quantification of the data gap by establishing a clear baseline expectation for data. OECD's program provided the basis for numerous subsequent studies of the data gap.

The Toxic Ignorance Studies

In 1997, the Environmental Defense Fund (now Environmental Defense (ED)), published *Toxic Ignorance*,[18] an indictment of the chemical industry and its regulators for failing to develop adequate chemical information. The authors reviewed publicly available data for 100 regulated HPV chemicals (>1 million lbs/year) – the chemicals that are or should be most likely to be best documented – and found that full SIDS data were available for only 29 percent of them. Conversely, for 71 percent of this sample, none or only part of SIDS mammalian toxicity dataset was publicly available. The gap is particularly striking because, as noted above, the SIDS data focus on hazard identification only and so are adequate for screening and priority setting, but not for the kind of full risk assessment that industry demands as the basis for actual regulation. A complete quantitative risk assessment, in other words, is even farther out of reach.

In response to *Toxic Ignorance*, the Chemical Manufacturers Association (CMA, now American Chemistry Council (ACC)) did its own study, and the truly remarkable thing about it was how close its results were to ED's. The results are subject to some interpretation, and CMA concluded that full SIDS data existed for 47 percent of chemicals. Others read it to show that 91 percent of high-volume chemicals lacked publicly available SIDS data set for all elements of the battery.[19]

EPA also undertook a study in response to *Toxic Ignorance*, and its findings were somewhere in between. As David Roe (of ED) summarized it, of approximately 3000 HPV chemicals, "No basic toxicity information . . . is publicly available for 43 percent of the high volume chemicals manufactured in the US and a full set of basic toxicity information is available for only 7 percent of these chemicals."[20] EPA summed up: "Although HPV chemicals are produced or imported in large quantities in the United States, there is little or no publicly available information regarding the potential hazards associated with most HPV chemicals."[21]

European Chemical Policy Studies

In the late 1990s, the European Union was also beginning to consider a major overhaul of its chemical regulations, to bring together a number of disparate regulatory regimes and to fill regulatory gaps in a single legislative proposal called REACH (for Registration, Evaluation, and Assessment of CHemicals). In connection with the proposal, and as part of the White Paper that supported it,[22] the European Commission commissioned several studies of the extent of the data gap.

A 1999 study by Allanou and others concluded that a publicly available base set existed for only 14 percent of HPV chemicals studied, less than a base set for 65 percent, and no data for 21 percent.[23] Another study found a similar pattern (17 percent - 22 percent) across a whole range of production amounts, from 10 to over 1000 metric tons per year,[24] and yet another came to conclusions similar to the EPA study.[25] These results and others were collected in a general assessment of testing needs[26] and form a critical part of the basis for the Commission's REACH proposal.

CPR's IRIS Study

Finally, CPR's own review of EPA's IRIS database shows that there are many toxic chemicals lacking assessments and tolerance values.[27] The IRIS database is one of the world's most important sources of chemical toxicity information, garnering thousands of "hits" daily on the worldwide web. While IRIS contains toxicological profiles for 544 chemicals, this number is woefully inadequate compared to almost any other list of environmentally significant chemicals. IRIS assessments are unavailable for many of the chemicals that EPA regulates under the Clean Air, Safe Drinking Water, and Emergency Planning and Community Right-to-Know acts. Remarkably, over one-fifth of the Hazardous Air Pollutants (HAPs) regulated under the CAA are missing from IRIS, and the data for those HAPs included in IRIS is on average almost 12 years old.[28] Despite this alarming lack of information, federal funding for research and development (R&D) are declining. EPA's R&D budget, for instance, has declined from $743 million in 1976 to $591 million in 2005 in constant FY 2004 dollars leaving the future of federal toxics research uncertain at best.[29]

Conclusion: A Castle Built on Sand

The picture of the knowledge base for toxic chemicals portrayed in these studies contrasts dramatically with the legal and political rhetoric of toxics regulation. The rhetoric emphasizes a scientific analysis of risk, and it demands regulation justified by and tailored to the results of the analysis. Yet there is astoundingly little information to analyze. Even more remarkably, the risk profession (peruse, for example, the pages of *Risk Analysis*, the journal of the Society for Risk Analysis) continues to construct elaborate risk assessment methodologies, either unaware of or unwilling to acknowledge the absence of underlying data to support them. This regulatory system, based on information-hungry risk assessment, is a castle built on sand. One may admire the high towers, the luxurious royal quarters, the colorful flags and banners, and the looming battlements, but beneath it all is a foundation that cannot support it.

But this is not merely a tale of dysfunction. The disjunction between the available information and the information demands of the system can be – and is being – exploited by opponents of protective regulation, because the burden of providing information rests with the regulators. In its decade-old "sound science" campaign, for example, industry (through groups like the ACC) in litigation, legislation, and political rhetoric charges that current regulation lacks a strong scientific basis and demands even more data to support it. Of course, those data do not exist, as the foregoing studies show, and that makes regulation impossible – which, of course, is the whole point.

Filling the Data Gap

The description of the lack of toxics information as a data *gap* conjures up the picture of a pit of ignorance that lies between our present state of knowledge and the knowledge that we need to be able to regulate chemicals to protect human health and the environment. The gap is not a bad metaphor, and indeed it suggests that there are two ways to reach a sufficient amount of data to justify regulation: by filling the gap or by bridging it.[30] The first approach – filling – would get us to the other side by producing new research on unstudied or under-studied chemicals. Filling data gaps has the advantage of generating badly needed data regarding toxicity characteristics and the mechanisms by which exposure can cause disease. The second approach, bridging, would take us to the other side of the gap by adopting regulatory systems or standards that do not require the massive data of a risk-based system. Our risk-based system, especially as it has come to be interpreted by courts and aided by legislation like the Data Quality Act, requires vast amounts of information on a wide variety of topics to sustain regulatory action. Other systems (for example, those built on technology-based standards) require less information, and so they bridge the gap.

The foregoing suggests an overall strategy for crossing the data gap. Given the existing risk-based regulatory system, the basic effort must be to fill in. However, this approach is limited by the high cost of testing in an era when public funding for federal research has been cut repeatedly. One strategy to make progress during an era of funding shortfalls is to focus on

increasing availability and reliability of existing information, resulting in faster and less expensive analysis. This focus will also improve understanding of the immediate environmental and public health effects of toxic chemicals. Even so, it is highly unlikely that a gap this wide can be filled in any reasonable amount of time. Moreover, if the past is any portent for the future, regulated industries will resist requirements that they disclose what they know about their products. Consequently, the basic strategy must also adopt regulatory policies that *bridge* the gap, to allow us to find ways to control dangerous chemicals without requiring vast information. CPR's Data Gaps Project focuses on the filling approach, because that has been less studied and so the need for understanding and action is greater, but this report will return to bridging briefly on page 11, *infra*.

Public and Private Funding

Filling the data gap raises an important public policy issue: how do we develop more comprehensive and up-to-date information about the thousands of chemicals to which individuals and the environment are exposed? CPR believes that the country must increase *both* publicly and privately funded data generation and that these sources must be used in a complementary manner. First, the generation of information using public funds should be reformed by increasing funding, improving IRIS, encouraging emerging technologies appropriately, and, on a longer time scale, changing the institutional design of federal research and testing. CPR's suggestions for filling the data gap span a variety of approaches. In the short-term, CPR recommends methods to combat excessive secrecy, such as prohibiting non-disclosure contracts, extending controls on public research to private research used in public processes, and decreasing overuse of unwarranted CBI claims. Longer-term strategies endorsed by CPR include creating a registry of results and promulgating rules under TSCA and the Sarbanes-Oxley anti-corporate-fraud legislation to increase information availability. Second, CPR recommends privately-funded strategies such as establishing incentives for information production through burden shifting, reforming tort standards, and establishing penalty defaults. On a longer time scale, CPR endorses proposals to amend TSCA.

Before making specific suggestions for filling data gaps, it will be useful to apply some sorting principles to determine when new research to fill data gaps should be publicly funded and when it is appropriate to rely on privately generated data (*i.e.,* generated by the chemical industry). Generally speaking, the government should be responsible for information production when (1) there is an informational market failure, (2) government has an inherent comparative advantage, and (3) industry funded data lack the requisite credibility:[31]

1) *Market Failure*. In an efficiently functioning market, consumers would have adequate information about the qualities of the products they buy, including information about the risks that such products pose to them and the environment. In the real world, however, sellers often fail to make such information available to consumers because the development and release of such information is likely to decrease sales, to incur legal liability for injury, or to have other adverse financial consequences. This informational market failure is common for toxic substances, because toxicology information is expensive and difficult to obtain. Also, causal connections between the chemical and the plaintiff's disease are often unclear, so there is no incentive for producers to complete basic research.[32]

2) *Governmental Advantage*. Even in the absence of market failure, government is uniquely positioned to produce certain *types* of toxicity information, especially those that involve collection, interaction, and dissemination of data from many sources. Only government has the resources to reach out broadly to gather and analyze information with no economic return. Moreover, the large amounts of data required to evaluate environmental pollutants confers a comparative advantage on the government because of economies of scale.

3) *Credibility*. The government should also take a lead role when privately generated information lacks credibility.[33]

In contrast, the use of private data generation is preferable when these overlapping conditions are absent. Indeed, industry generation of chemical information should generally be preferred. The size of the data gap in absolute terms means that substantial new resources for generating chemical information will have to come from industry rather than from a deficit-plagued government. Furthermore, this information relates to the safety of privately produced goods whose production has primarily private benefits. Industry can produce information early in the product development process to prevent harm, and familiarity with its own products can also improve the quality of the information generated. Politically, too, one might want to take the advocates of "sound science" at their word – if they want the information so much, then they should provide it.

In light of these principles, we next address ways in which data gaps can be filled by both government and industry.

Overall, non-defense R&D (excluding National Institutes of Health) has remained stagnant for the last fifteen years, and it is slated for a cut under the President's proposed FY 2006 budget. EPA's R&D budget, in particular, has declined from $743 million in 1976 to $591 million in 2005 in constant FY 2004 dollars. For the federal government to play its much needed role in filling data gaps, these declining funding trends must be reversed.

Publicly Funded Data Generation

CPR offers the following recommendations for improving the contribution of publicly funded research to fill the data gap:

1) *Research Funding.* CPR's most basic recommendation for publicly funded data generation is that there needs to be more of it. The federal portion of chemical research and development (R&D) has been declining steadily since the 1980s, when the federal government funded the majority of the nation's research.[34] Although federal spending on R&D will reach an all time high of $132.2 billion in FY 2005, the majority is allocated to defense, including spending in the Departments of Defense, Energy, and Homeland Security.[35] Overall, non-defense R&D (excluding National Institutes of Health) has remained stagnant for the last fifteen years, and it is slated for a cut under the President's proposed FY 2006 budget.[36] EPA's R&D budget, in particular, has declined from $743 million in 1976 to $591 million in 2005 in constant FY 2004 dollars.[37] For the federal government to play its much needed role in filling data gaps, these declining funding trends must be reversed.

   In addition to increased federal R&D funding allocated to chemical testing, it is essential get the most out of what is available. Thus, the federal government should also improve the coordination and prioritization of research between and among agencies. CPR's study on data gaps illustrated problems in the planning process within EPA's Office of Research and Development, including a lack of inter- and cross-agency planning that facilitated ongoing data gaps.[38]

   Finally, in order to increase the funds available for research, the federal government should establish a program in which industry would pay into a fund to pay for federal testing of potentially toxic chemicals, providing money for screening for health and environmental effects. Any such arrangement should be carefully designed to avoid the problems experienced with drug testing under the Prescription Drug User Fee Act (PDUFA), where increased user fees were accompanied by decreasing federal dollars. Because the law required a consistent level of federal funding, money has been diverted from other core Food and Drug Administration functions to pay for testing of new drugs, while critical research areas, such as post-approval drug monitoring, have suffered.[39]

2) *Reinvigorate IRIS.*[40] IRIS provides health effects information and tolerance values for over 500 chemicals. As a reflection of its prominence, in February 2005 alone the IRIS web site received 626,591 requests.[41] Moreover, internet domains requesting IRIS information range across the

globe, from Nepal, to Guatemala, to the United Kingdom.[42] Unfortunately, IRIS is missing values for many chemicals, and the addition of new values is slowed by an ossified peer review process, lack of resources, increasing political meddling, and a priority list that omits many statutory needs (the HAPs, for example). Although the IRIS process generates synthesis assessments and not raw toxicological data, the program should be coordinated with other federal testing programs and used to generate research priorities to simultaneously close the gaps in basic data and IRIS chemical assessments.

3) *Encourage Development of Emerging Technologies*. Emerging technologies such as toxicogenomics (changes in expression of genes in cells or tissues in response to toxic exposure) should continue to be developed as a potential method to understand a chemical's health effects.[43] However, new technologies should not be relied upon as a silver bullet to close all data gaps, and traditional toxicological and mechanistic testing should remain the focus for research and funding until such new methods are proven effective.[44]

4) *Improve Institutional Design*. Research on toxic substances currently occurs in many parts of the federal government. The National Toxicology Program (NTP), EPA, and others perform toxics testing, but there is little government-wide coordination. There are several ways to remedy this situation:

   - A National Agency for Toxicity Testing could track and coordinate all federal testing and serve as a repository of results. Additionally, such an agency could coordinate testing and analysis priorities and establish an agenda to close data gaps that agencies individually are unable to achieve. It could also develop quality assurance protocols and standard test batteries. All agency R&D plans targeting toxic substances could be coordinated through this program to ensure the most effective use of federal resources. The new agency or program could be housed in an existing agency, preferably in a non-regulatory agency like the Agency for Toxic Substances and Disease Registry or NTP.
   - As a variant, a National Registry of Results could allow the federal government to coordinate a "super study" program, in which the government would establish a study plan to close data gaps, funded by the industries that make and use the chemicals.[45] Testing would be done by public and private sources according to specific testing protocols, and, importantly, results would have to be registered to ensure their availability. As a part of this research initiative, the government should require a lab certification and accreditation process for testing laboratories.[46]
   - An Information Gap Analysis, performed as part of the regulatory process (by analogy to the Paperwork Reduction Act and other regulatory analytic steps required of agencies), would allow the government to identify what information is necessary and missing for a rulemaking, who should produce this information, and how to ensure that the information is produced properly.[47] Ideally, such a process would occur prior to rulemaking, to allow information to be produced in time for its use in the decision.

Privately Funded Data Generation

Private generation of chemical information will also be essential for any meaningful filling of the data gap. CPR recommends the following:

1) *Establish incentives for information production*. As discussed above, there are systematic disincentives for industry to generate chemical information. It is expensive and may result in negative information that will hurt sales or support tort liability. If there is no reason to generate such expensive, potentially negative information, no company will do it. Several mechanisms are available to create incentives to generate such information.

   - The most powerful mechanism is shifting the burden of proof. In the United States, with few exceptions the burden of proving a

chemical's *un*safety rests with the regulator. As Figure 1 demonstrates so dramatically, a regulatory system based on licensing or pre-clearance of chemical substances is far more effective in generating toxicity information than a retrospective control system. Such a "penalty default" prohibits new products from entering the market until their makers demonstrate their safety.[48] This prohibition creates an incentive for those in the best position to provide information to do so.[49]

Several options exist to shift the burden of information generation to chemical producers. Under a licensing process, companies must have their products certified as safe by the government prior to approval for sale and use.[50] California's Proposition 65 provides another model of burden shifting. Under this law, companies cannot knowingly expose citizens to any of the chemicals placed on a state list of known carcinogens or reproductive toxins without clear warning.[51] While this approach could create a strong incentive to produce information about products to avoid the duty to warn, it appears to have produced primarily an incentive to develop regulatory standards with less information, like a bridging strategy, discussed below. The European Union's proposed REACH program, which recently received the initial approval of the European Parliament, is aimed directly at information generation. It would require pre-market testing by companies producing chemicals that have certain potentially dangerous qualities (*e.g.*, persistence) or are used in high volumes or else face a ban on sales.[52] Negotiations between regulators and the chemical industry continue regarding the nature and scope of testing requirements, however, and it remains to be seen how stringent REACH protocols will be in their final form.

- Legislation, or possibly judicial decisions, could reform tort standards. The traditional common law of torts places the burden on plaintiffs to prove causation, thus creating a perverse incentive system that makes ignorance the rational choice for producers. Causation requirements should be reformed to shift the burden of information production to the chemical makers by allowing plaintiffs to establish a prima facie case against defendants when the defendant cannot show that minimal safety data are available.[53]

2) *Reinvent TSCA.* Despite initially high hopes,[54] TSCA has been a disappointing vehicle for regulating toxic chemicals. The two provisions (sections 4 and 8) that EPA could use to require companies to test their chemicals and submit environmental and health effects data have had minimal effect for the testing of existing chemicals.[55] For example, while EPA has the authority to require testing on existing chemicals by chemical producers, EPA must first show that the chemical presents some health risk. This requirement creates a Catch-22: EPA must have chemical information in order to prove that it needs it, but it needs the information because it doesn't have the information.[56] As a result, less than one percent of all chemicals in the TSCA inventory have rules requiring testing.[57]

- As a first step, Congress should amend TSCA to facilitate EPA's ability to require testing of existing chemicals. Section 4 should be amended to change the threshold that EPA must meet before it can require testing. For example, instead of requiring a de facto risk assessment, the trigger in section 4 for mandatory testing should be based on production volume or certain structure activity relationship groups for which basic toxicity data are lacking.[58]

- The European chemicals legislation, REACH, provides a starting point for revising TSCA. It is an appropriate model, first and foremost, because one of its principal objectives is generating chemical information; it is specifically designed to fill the data gap. Thus, it develops a comprehensive system of chemical regulation that not only requires members of the European Union to develop controls on chemicals, but more importantly

it provides incentives for the chemical industry to generate the data needed to establish controls. (However, whether as a substantive matter the regulatory controls are sufficiently stringent is a matter of considerable debate.) To accomplish this goal, REACH deploys several sensible information strategies, such as: establishing a basic test battery; tiering of test requirements by production volume (HPV chemicals require more data); priority setting by inherent characteristics like persistence and bioaccumulation; and creation of a central, accessible data repository. It also allocates testing responsibilities appropriately, giving government the job of establishing guidelines for testing and collecting data, and industry the job of individual testing.

Increasing Availability and Reliability of Information

Actually generating information, no matter who does it, is an expensive and time-consuming proposition, and it will not yield quick results. Nearer term results can be achieved by increasing the availability and reliability of existing information. CPR recommends the following reforms:

1) *Prohibit non-disclosure contracts between industry and university scientists as a criterion for federal aid eligibility*. Currently, some industry-funded studies include non-disclosure contracts preventing academic scientists from publishing their results if the results are unsatisfactory to the sponsor.[59] Such contracts should be prohibited as a way to ensure that more data is available by refusing federal aid to schools who agree to such conditions.

2) *Extend disclosure requirements for publicly funded research to private research used in regulatory processes.* Congress has passed two pieces of legislation that are designed to restrict the information available to support environmental regulation, by creating opportunities, not available in other contexts, to challenge the data underlying the decision.[60] The government should be able to see and review industry data if it is to be used in any regulatory process or government database, including the data that underlies forms and other industry submissions. For example, because EPA cannot demand industry data, the IRIS program has relied on industry models and tolerance values without being able to evaluate or reanalyze the data. The Data Access Act, which requires all data from federally-funded studies to be made available through the FOIA process, should be extended to apply to privately-funded data used in government processes.[61]

3) *Decrease and penalize overuse of confidential business information (CBI) claims.* The widespread industry practice of submitting scientific data to the government, but stamping it "Confidential Business Information" prevents agencies from releasing information to the public and fellow scientists. Many data sets are gratuitously stamped CBI because the firms that provide them have a strong incentive to assert such claims without going to the effort of determining whether the data are truly confidential. In fact, CBI claims drop substantially – by as much as 50-60 percent – when EPA requires upfront substantiation of the nature of the trade secret protections.[62] Decreasing overbroad CBI use would make information available to help close data gaps.

4) *Create a registry of studies and study results.* Existing studies should be added to a registry of studies to increase the availability of existing information. Registration could be required as a condition of using the information in rulemakings or other government functions. Furthermore, notification of the start of the study should be required for inclusion in the registry and use in decisionmaking, to ensure that the public receives all studies, not just ones favorable to the proponent of the chemical.

5) *Require corporate data disclosure requirements.* Under Sarbanes-Oxley,[63] the recent federal legislation designed to combat corporate accounting fraud, CEOs can be held personally liable for errors in disclosure and reporting, and they must certify accuracy before submission to the Securities and Exchange Commission. Reporting requirements should be expanded to include information and data regarding any

previously undisclosed health or environmental effects of chemicals.

6) *Reinventing TSCA.* EPA should promulgate a rule under TSCA to require chemical producers to provide to EPA environmental and health effects data that have been submitted to foreign governments. (This approach will be particularly effective when REACH is enacted.) Unless this change is made, U.S. chemical producers may be required to provide health and safety information to foreign countries in order to export to or manufacture in those countries, but they do not have to make it available domestically.[64]

Bridging the Data Gap: Decreasing Demand for Information

The CPR Data Gap Project focused on legal and regulatory approaches that would help to fill the chemical data gap. However, since a complete strategy for remedying the data gap requires both filling and bridging, this report concludes with a brief discussion of bridging, that is, adopting regulatory systems or standards that require fewer data than a risk-based system. Our current regulatory system for chemicals, especially as it has come to be interpreted by courts and aided by legislation like the Data Quality Act, requires vast amounts of information on a wide variety of topics to sustain regulatory action. Other systems, for example, technology-based ones, require far less.

There are several reasons that bridging the gap makes sense as an alternative or complement to filling. First, filling takes too long and costs too much. Second, many observers are justly concerned that the data gap is in fact a bottomless pit. In science, there is always more to be known, and if science is to be the standard of regulatory justification, it will never be enough.[65] This characteristic is especially true of toxicology information, which is frequently uncertain in its own right. Moreover, even when solid toxicology information appears, it is met with an opposing reaction in the form of new, supposedly exculpatory studies that keep the controversy alive[66] and in the form of attacks on the original science and scientists.[67] Filling the data gap, in this view, is a Sisyphean task. Finally, because filling is a long-term and expensive strategy, the *value* of the additional information relative to the cost of inaccuracy in regulating (*e.g.*, overly stringent standards) may not justify the investment. This is especially true if the information obtained is not likely to be definitive. It is not at all clear that the regulatory enterprise gains much from this investment.

Turning from the reasons for bridging the gap to strategies for accomplishing this result, bridging can be analyzed conceptually as a way to moderate the demand for chemical information. As we have already seen, certain legal mechanisms increase the *supply* of available data and others decrease it. These form the basis of the above recommendations for the gap-filling strategy. Other legal mechanisms increase or decrease

Figure 2: Mechanisms affecting supply of and demand for chemical information.

	Filling Mechanisms: SUPPLY	**Bridging Mechanisms: DEMAND**
Closes Data Gap	• Licensing, burden of proof on polluters • Test rules and testing requirements	• Technology-based standards • Burden of proof on polluters • Hazard-based regulation (Prop. 65) • Legislative listing of chemicals
Widens Data Gap	• Legal incentives for ignorance • "Sound science" demands • Data Quality Act • Redundant peer review	• Risk-based regulation • Aggressively skeptical judicial review • Burden of proof on government • OMB intervention

the *demand* for information, and they are the basis for a bridging strategy.[68] These mechanisms are categorized in Figure 2.

The best known and most frequently deployed legal strategy to reduce the demand for chemical information is technology-based regulation, that is, regulatory standards based on the best available control technologies rather than the risk-based levels of chemicals allowed to be released. Risk-based standards "eat up heroic amounts of money, remain information-starved, feature shameless manipulation of the data, face crippling political pressure, and produce little abatement."[69] While setting technology-based standards is far from simple, they only require basic knowledge of the toxic properties of the chemical – the SIDS battery or less – for the purpose of identifying chemicals subject to regulation.[70] Technology-based regulation was famously adopted by Congress in the 1990 amendments to the Clean Air Act's HAPs provision[71] as a way to re-energize a completely stalled program based on health-based standards. The success of the air toxics program has encouraged new interest in technology-based standards.[72] Another, more drastic approach is to forgo fine-tuned regulation altogether and to focus instead on the lead time required to allow an industrial sector to phase out a toxic chemical.[73]

Another strategy requiring less information, ironically, is what might be called information-based regulation. By publicizing the toxic properties of particular chemicals and pollutants, regulation can make their use and release highly unattractive. California's Proposition 65 relies on hazard identification – is the chemical a carcinogen? – to require warnings and to ban releases to drinking water, unless the producer or discharger can demonstrate that the levels pose an acceptable risk. As David Roe has demonstrated, this burden-shifting mechanism has permitted controls to be imposed with far less testing and far less controversy, and hence far more quickly, than other regulatory strategies.[74] Burden shifting, which was recommended above as a way of generating chemical information, both bridges and fills – and thus it represents the single most effective step that can be taken to address the chemical information data gap.

Next Steps

CPR is planning to extend the work of the Data Gap Project to explore the disjunction between the needs for scientific information in the regulatory systems for the chemical and conservation areas of environmental law. The conservation aspects of environmental law (endangered species, ecosystem impact, and land management) and the chemical aspects (air and water pollution, toxic substances and hazardous wastes) each present their own data gaps, but they have surprisingly few points of intersection and are analytically very separate.[75] The most obvious difference is scale: conservation regulation generally concerns itself with ecosystems and the macro-scale organisms within them; chemical regulation concerns itself primarily with health and the threats posed to it, often at the cellular and molecular level, by chemical agents of various kinds. A further difference is the object of concern. For conservation regulation, it is primarily non-human species, and even inanimate objects like land forms; for chemical regulation, it is overwhelmingly *human* health. Moreover, in thinking about information needs, we need to distinguish not only between supply and demand, and scientific and regulatory-legal norms, but also between chemical and ecosystem issues, and regulatory regimes whose object is regulation (primarily negative commands) and management (primarily positive commands).

To explore these issues, CPR will co-sponsor a conference, to be held in March 2006 at the Indiana University School of Law – Bloomington, to bring together established experts in the conservation and chemical areas of environmental regulation. The purpose of the conference is to evaluate the status of the data gaps in each field and to determine which of the above differences (scale, regulation, management) is most effective in addressing data gaps.

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Katherine Baer, a Policy Analyst with CPR from 2004-05, now works as Director of River Advocacy at American Rivers.

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APPENDIX A

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57 GAO: Options Exist, *supra* note 55.

[58] *Id.* at 37, 52; *see also* Applegate, *Perils, supra* note 5. Structure activity relationship (SAR) analysis uses models to compare chemicals with similar molecular structure to predict environmental and health effects.

[59] Katherine S. Squibb, *Scientific Independence in Environmental Health Science Research*, in Rescuing Science from Politics, *supra* note 7.

[60] *E.g.,* Data Access Act, Pub. L. No. 105-277, 112 Stat. 2681 (1998) (also known as the Shelby Amendment); Information Quality Act, Pub. L. No. 106-554, § 515, 144 Stat. 2763 (2001).

[61] Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 Am. J. Law & Med. 119, 138 (2004).

[62] *Id.* at 134.

[63] Sarbanes-Oxley Act of 2002 (Public Company Accounting Reform and Investor Protection Act) (Pub.L. 107-204, July 30, 2002, 116 Stat. 745).

[64] GAO: Options Exist, *supra* note 55 at 30, 37.

[65] Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 Yale J. on Reg. 89 (1988).

[66] *See, e.g.,* David Michaels, *Doubt is Their Product*, Scientific American, 96 (June 2005); David Michaels & Celeste Monforton, *Scientific Evidence in the Regulatory System: Manufacturing Uncertainty and the Demise of the Formal Regulatory System*, 13 J.L. & Pol'y 17 (2005).

[67] *See, e.g.,* Robert R. Kuehn, *Suppression of Environmental Science*, 30 Am. J. L. & Med. 333 (2004); Melanie Warner,

Striking Back at the Food Police, N.Y. TIMES, § 3, p. 1, June 12, 2005.

[68] This table is adapted from Applegate, *The Government Role*, *supra* note 31.

[69] Oliver A. Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 17 TUL. ENVTL. L.J. 163, 169-70 (2003).

[70] In risk assessment terms, it requires the "hazard identification" phase of the assessment process, and not the "dose-response" and "exposure assessment" phases.

[71] 42 U.S.C. § 7412.

[72] *See, e.g.,* David M. Driesen, *Distributing the Costs of Environmental, Health, and Safety Protection: The Feasibility Principle, Cost-Benefit Analysis, and Regulatory Reform*, 32 B.C. ENVTL. AFF. L. REV. 1 (2005); SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH (2003); Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 U. ILL. L. REV. 83.

[73] *See* Oliver A. Houck, *The Regulation Of Toxic Pollutants Under The Clean Water Act*, 21 ENVTL. L. REP. 10528, 10554 (1991).

[74] Roe, *Toxic Chemical Control Policy, supra* note 4.

[75] *See, e.g.*, Robert L. Fischman, *The Problem of Statutory Detail in National Park Establishment Legislation and its Relationship to Pollution Control Law*, 74 DENV. U. L. REV. 779 (1997); Robert L. Glicksman, *Pollution on the Federal Lands I: Air Pollution Law*, 12 UCLA J. ENVTL. L. & POL'Y 1 (1993); *But see* Richard J. Lazarus, *Restoring What's Environmental About Environmental Law in the Supreme Court*, 47 UCLA L. REV. 703 (2000) (describing characteristics common to all of environmental law).

[76] Compiled by John S. Applegate.

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