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Ready or Not: The Coming Wave of Toxic Chemicals

David Roe*

INTRODUCTION

Could the federal regulatory system for toxic chemicals cope with ten times as many chemicals as it has had to manage so far? We may be about to find out.

In an unprecedented public-private effort, intended to compensate for long neglect, thousands of high-volume industrial chemicals are now

* Former Senior Attorney, Environmental Defense. Roe was actively involved in generating the chemical testing program discussed below, see infra note 8 and text accompanying note 10, and in creating the state law discussed below. See infra Part III; see also infra notes 25 and 34.
being quickly screened for toxicity. Until the screening results are in, we can't know how many of those chemicals will show toxic effects needing regulatory control—but if even a modest fraction of them do, the burden on federal regulators will seem overwhelming. The supposed linchpin of public protection against toxic chemicals, under numerous federal laws, is the setting of chemical-by-chemical standards that take account of each separate chemical's degree of risk. That system is about to face a make-or-break challenge.

History suggests that the system is bound to break. Risk-based standard-setting for chemicals has moved very slowly over the last thirty years, falling far behind in its mandate even when the target group of chemicals was small. If the system lags behind much more dramatically, it would be tantamount to admitting bankruptcy for the chemical controls that government has been claiming are the public's primary guarantee of safety since modern regulation of toxic chemicals began.

This article reviews the basic premises of risk-based standard-setting for toxic chemicals and shows how those premises are undercut by the facts. It then explores several alternatives to a breakdown. Each alternative would take a conscious policy change. Discouraging as that might seem, particularly to seasoned observers of the policy process, some encouraging precedent at the state level makes optimism thinkable. The most promising alternatives are what might be called "ignorance-based"; in other words, policies that do not depend on a high level of scientific knowledge about each chemical's specific risks before they can begin to be applied.

I. THE PREMISES OF RISK-BASED STANDARD-SETTING

The basic federal policy formula for protecting the public against the hazards of toxic chemicals is straightforward. First, identify the chemicals that are toxic in any specific context (e.g., in air, water, consumer products, the workplace, or in special categories like pesticides, foods, drugs, etc.). Then, set control standards for each of those chemicals in that context. Different statutes such as the Clean Air Act, the Safe Drinking Water Act, and the Federal Hazardous Substances Act apply to different contexts. Under many of those laws, agencies must set standards on the basis of human health risk. In other words, enforcement of standards should guarantee that health risks from the regulated chemical in the particular context are kept within clear boundaries. Regulators use scientific risk assessment to determine where to draw the line for each chemical, in each context.

This process is logical and conceptually clear. However, its success depends on two premises, so obvious as to be largely unspoken: (1) the chemicals posing potential harm in a particular context will go through
THE COMING WAVE OF TOXIC CHEMICALS

the standard-setting process and become subject to necessary limits; and (2) the chemicals posing potential harm in each context have been identified. Not only does the regulatory system need to hit the target, but it also needs to know what the target is.

A. Setting Standards

As practitioners know, actually getting risk-based chemical standards determined and adopted is a slow process. The most obvious example is Section 112 of the Clean Air Act, covering hazardous air pollutants, which in twenty years managed to produce risk-based standards for a total of seven chemicals. In 1990, in effect conceding failure, Congress converted Section 112 to a technology-based standard-setting regime with only a token risk-based component.¹

The broader picture, represented in Table 1, is nearly as bleak. Regardless of the strengths or weaknesses of the standards under any particular statute, what stands out is how few standards have been put in place.² Table 1 presents a generous view of what constitutes a “standard” and shows the fruits of both risk-based and technology-based regimes. To put it mildly, risk-based standard-setting has not yet managed to cover a significant number of chemicals. One explanation might be that there are very few toxic chemicals to worry about, and therefore a handful of standards is enough. Again, Section 112 of the Clean Air Act provides the clearest evidence to the contrary, since its seven set standards exist in the context of a list of 188 chemicals identified by name as hazardous air pollutants and all known to be present in ambient air.³

B. Identifying Target Chemicals

The second assumption that the federal chemical regulatory system depends on is less visible. After all these years, including twenty-six years under the Toxic Substances Control Act (TSCA),⁴ we tend to take for granted that we know which chemicals are “toxic”—at least more or less,

1. 42 U.S.C. § 7412 (1990). Technology-based standards are meant to reflect the level of control, for example of air emissions of specific chemicals, which is capable of being achieved with current technology. Such standards have the advantage of being attainable by definition. They have the disadvantage that they may or may not reduce risk to the level that would meet health goals, for example a one-in-100,000 risk of cancer.
2. David Roe & William Pease, America’s Toxic Ignorance, ENVTL. F., May/June 1998, at 29, Table 1.
4. 15 U.S.C. §§ 2601 et seq. (2002); see also infra notes 6 and 7.
Actual Coverage of Selected Federal Laws (2)
(# of enacted standards for specific chemicals, as of 1998)

<table>
<thead>
<tr>
<th>Description</th>
<th># of Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAA National Emissions Standards for Hazardous Air Pollutants</td>
<td>7</td>
</tr>
<tr>
<td>CAA National Ambient Air Quality Standards</td>
<td>6</td>
</tr>
<tr>
<td>CAA New Source Performance Standards</td>
<td>6</td>
</tr>
<tr>
<td>CAA Prevention of Significant Deterioration</td>
<td>6</td>
</tr>
<tr>
<td>CAA Mobile Sources</td>
<td>4</td>
</tr>
<tr>
<td>CWA Toxic Pollutant Standards</td>
<td>6</td>
</tr>
<tr>
<td>CWA Effluent Limitation Guidelines</td>
<td>126</td>
</tr>
<tr>
<td>CWA Ambient Water Quality Criteria</td>
<td>88</td>
</tr>
<tr>
<td>Safe Drinking Water Maximum Contaminant Levels</td>
<td>75</td>
</tr>
</tbody>
</table>
and at least among major manufactured chemicals that have been in widespread commercial circulation for many years.

In 1984, the National Research Council of the National Academy of Sciences cautioned that toxicity testing data for chemicals in U.S. commerce was alarmingly sparse. But TSCA was relatively new at that time, with apparently omnibus testing authority and a seemingly reassuring policy that chemical manufacturers themselves should take responsibility for knowing the toxicity of their own products. Toxicity testing for industrial chemicals also soon began to get international attention via the Screening Information Data Set (SIDS) program developed under the auspices of the Organisation for Economic Cooperation and Development (OECD), with cooperation from the chemical industries in all major member nations including the U.S. The OECD began collecting a defined set of preliminary toxicity-screening data on high-volume chemicals in 1990. Thus, even if there were unknown hazards from major chemicals, there was reason to think they were being tracked down.

In 1997-98, however, the assumption that we have any real grasp of which chemicals are toxic was definitively shattered. First, a pilot study by the non-profit group Environmental Defense, and then extensive follow-up studies by both government (the U.S. Environmental

5. NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMY OF SCIENCES, TOXICITY TESTING (1984). For high-production-volume chemicals (defined as ones with a U.S. production or importation volume of over a million pounds per year), 78% were found to lack “minimal toxicity information” in the public record. Id. at 84, Table 7.
6. TSCA Sections 4 and 5 provide authority to order testing of existing and new chemicals respectively. But see infra note 59 for discussion of Catch-22 obstacle. 15 U.S.C. §§ 2603, 2604 (2002).
7. TSCA Section 2:
   It is the policy of the United States that:
   (1) 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 and those who process such chemical substances and mixtures.
9. The OECD definition of a high-volume chemical is one with at least 2.2 million lbs. per year of production in each of any two OECD member nations, compared with the U.S. definition. NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMY OF SCIENCES, supra note 5; Environment Directorate, Organisation for Economic Co-operation and Development: The 2000 List of High Production Volume Chemicals, Foreword, available at http://www.oecd.org/pdf/M00017000/M00017224.pdf (last visited Sept. 11, 2002).
10. ROE, supra note 8.
Protection Agency (EPA))\textsuperscript{11} and industry (the Chemical Manufacturers Association),\textsuperscript{12} found that the preliminary toxicity-screening data sets prescribed by the 1990 OECD program were not publicly available for over 90% of high-volume chemicals in U.S. commerce. Twenty years after TSCA, twelve years after the National Academy of Sciences study, and eight years after the startup of OECD's SIDS program, the holes in our knowledge of chemical hazards looked as gaping as ever. The close congruence\textsuperscript{13} of findings in separate studies performed by industry, government and environmentalists gave these findings high credibility.

The studies' implications were acutely unsettling: in a regulatory system that depends on identifying target chemicals before regulating them, less than 10% of the largest potential targets\textsuperscript{14} had been properly scanned\textsuperscript{15} for toxic effects. As far as the public could tell, the toxic properties, if any, of over 90%\textsuperscript{16} of those highest-volume chemicals were simply unknown, even though many of the chemicals had been in

\begin{itemize}
\item \textsuperscript{13} The original TOXIC IGNORANCE study found 71% of high-production-volume (HPV) chemicals lacking the basic SIDS results in the public record, based on a 100-chemical sample. EPA found 93% of HPV chemicals lacking the same data, and CMA found 94% lacking, after examining each of the approximately 3,000 HPV chemicals. The lower figure from the first study is explained by its authors' intentionally conservative bias in sample selection. See Roe, supra note 8, at 15; EPA's Office of Pollution Prevention And Toxics, supra note 11, at 2; CHEMICAL MANUFACTURERS ASSOCIATION, supra note 12.
\item \textsuperscript{14} The high-production-volume chemicals that all three studies addressed are the approximately 3,000 chemicals on EPA's TSCA Inventory Update for 1990 that show annual U.S. production and/or imports of greater than 1,000,000 lbs. The TSCA Inventory does not include pesticides; nuclear materials; ammunition; or foods, food additives, cosmetics, drugs and other chemicals regulated by the U.S. Food and Drug Administration. ROE, supra note 8, at 15; EPA's Office of Pollution Prevention and Toxics, supra note 11, at 2; CHEMICAL MANUFACTURERS ASSOCIATION, supra note 12.
\item \textsuperscript{15} It is important to emphasize that SIDS tests are screening tests only: relatively quick and inexpensive tests that are not intended to be definitive. They screen for a variety of health effects, both acute and chronic (e.g., genetic mutation, reproductive toxicity and cancer). ROE, supra note 8, at Appendix II. The SIDS requirements are met only if there are results for all of the basic SIDS tests, since the tests screen for different hazards. Thus, the percentages cited for chemicals lacking SIDS results, supra note 13, include chemicals that show results for one or more, but not all, of the basic SIDS tests. See infra note 22.
\item \textsuperscript{16} All three studies were necessarily limited to screening information available in publicly available data sources that could be searched electronically. The studies acknowledged that additional data might exist in private hands (e.g., chemical manufacturers) or in government files that could not be searched electronically. The studies also recognized that data the public could not see was not a desirable basis for assurances of public safety. ROE, supra note 8, at 15; EPA's Office of Pollution Prevention and Toxics, supra note 11, at 2; CHEMICAL MANUFACTURERS ASSOCIATION, supra note 12.
\end{itemize}
commerce for many years. No one knew whether they posed risks large enough to need regulation; and what a knowledge-dependent system does not know, it cannot protect against. Even assuming perfect regulatory control of each targeted chemical's every known hazard—a blithe assumption—the picket fence designated to protect the public against chemical harms was less than 10% pickets at best. The rest was either cardboard imitation, or open holes.

II. 
RESPONSE TO LACK OF INFORMATION ABOUT MAJOR INDUSTRIAL CHEMICALS

As a direct result of the three studies, an unprecedented chemical screening program was born. The chemical industry, government, and environmentalists worked together to design a unique, quasi-voluntary initiative. The HPV Challenge Program called for individual chemical manufacturers (or consortia of manufacturers) to sponsor individual high-production-volume (HPV) chemicals and provide data from screening tests, under agreed protocols and definitions, based largely on the OECD SIDS program. The program, announced in late 1998, had by early 2000 received commitments from over 400 companies to test more than 2,000 chemicals, at a cost to the participating chemical manufacturers that the industry initially estimated at $500 million. All data are to be submitted by the end of 2004, with deadlines for individual chemicals spread out over the intervening years.

Despite some variations and delays, the HPV Challenge Program appears to be on track to deliver screening-test results for chemicals in substantial numbers over the next two years. Test plans, which include "robust study summaries" of all existing data and evaluation of data gaps, have been posted online for 801 HPV chemicals as of mid-2002, with an

17. See, e.g., Table 1.
18. EPA's Office of Pollution Prevention and Toxics, ChemRTK HPV Challenge Program, at http://www.epa.gov/opptintr/chemrtk/volchall.htm (last visited June 21, 2002). Although often thought of as a “testing” program, the HPV Challenge Program focuses specifically on the availability of necessary information for toxicity screening and calls for use of existing data wherever available and scientifically adequate. Identification of existing data and data gaps is therefore the first step, performed in the course of developing the test plan for each chemical. The program also encourages use of analytic techniques such as structure-activity relationship analysis in lieu of traditional laboratory-animal tests where scientifically appropriate, to minimize both cost and animal testing. Id.
20. U.S. Environmental Protection Agency, Robust Summaries and Test Plans, at http://www.epa.gov/chemrtk/viewsrch.htm (last visited July 30, 2002); see also U.S.
additional 368 due by the end of 2002 and 263 more due at the end of 2003. A parallel and intentionally similar program set up by the global chemical industry is handling approximately 650 of the HPV chemicals committed for screening in order to spread costs more equitably among global producers. A parallel and intentionally similar program set up by the global chemical industry is handling approximately 650 of the HPV chemicals committed for screening in order to spread costs more equitably among global producers.\textsuperscript{21} Screening-test results to cover the gaps identified through chemical-by-chemical evaluation are due within 24 months of test plan submission, with all results due by the end of 2004. All this new information, by definition, represents potential chemical hazards that the regulatory system has not previously addressed.\textsuperscript{22} A new group of chemicals identified at least provisionally as "toxic" is on the way.

How large will this group be? Not as large as the total number of new test results, of course. For risk-control purposes, only the chemicals that show toxicity at the screening level will matter, and perhaps at first, only those with strongly positive results for high-profile kinds of toxicity, such as reproductive toxicity and carcinogenicity. All participants recognize that screening results will not be definitive by themselves and that further investigations of toxicity will be appropriate. If, hypothetically, 25% of the newly screened chemicals show results of preliminary concern, some 500 chemicals not previously recognized as toxic\textsuperscript{23} could be added to the regulators' plates for additional attention. The actual number could be much lower\textsuperscript{24} or higher. But each new target

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\textsuperscript{21} The International Council of Chemical Associations (ICCA) formed a working group to pursue its own HPV Chemicals Initiative in coordination with the U.S. program, two months after the U.S. program was announced. International Council of Chemical Association, Website of the Global Initiative on High Production Volume (HPV) Chemicals, at http://www.cefic.org/activities/hse/mgt/hpv/hpvinit.htm (last visited June 6, 2002).

\textsuperscript{22} A substantial number of chemicals in the HPV Challenge Program have already had incomplete screening, i.e., some but not all the minimum preliminary hazard assessments, and some are already being regulated for specific hazards. Even those chemicals pose potential unregulated risks. For example, a chemical may be regulated for carcinogenicity, but not have been screened for reproductive toxicity, which may be greater than its carcinogenicity potential; i.e., significant at lower exposure levels. If so, standards set to control the former—even if fully obeyed—are inadequate to protect against the latter. Lead (Pb) is a well-known example of a toxic substance that poses significant non-cancer risks at much lower levels than its cancer risk. Compare CAL. CODE REGS. tit. 22, § 12805(b) (1986) (setting "safe harbor" exposure levels for reproductively toxic chemicals under California's Proposition 65), with CAL. CODE REGS. tit. 22, § 12705(b) (1986) setting "safe harbor" exposure levels under the same law for carcinogenic chemicals), and note that the "safe harbor" exposure for lead considered as a reproductively toxic chemical is 30 times lower than the "safe harbor" level for the same chemical considered as a carcinogen (0.5 ug/day as compared to 15 ug/day). See also infra notes 26 and 27.

\textsuperscript{23} Or with toxic properties not previously recognized. See supra note 22.

\textsuperscript{24} It is reasonable to expect that at least the earliest results from the HPV Challenge Program will be biased toward chemicals with low-concern results. If true, however, this
THE COMING WAVE OF TOXIC CHEMICALS

will be a high-volume, industrial chemical, and thus hard to dismiss or ignore.

III.
STATE-LEVEL PRECEDENT

At the state level, there is precedent for the sudden arrival of a large group of chemicals needing new risk-based regulatory attention. How this arrival was successfully handled at the state level may provide guidance for the looming federal problem. The state precedent was arguably more urgent than the results of the HPV Challenge Program will be, since every chemical in the state example was determined to be toxic based on definitive evidence rather than mere preliminary screening.

In 1986 California enacted the Safe Drinking Water and Toxic Enforcement Act, commonly known as Proposition 65. This law requires publication of an official list of chemicals "known to the State" to cause either cancer or reproductive toxicity. One year after the list is published, businesses that intentionally create exposures to any of the listed chemicals are responsible for issuing warnings to the people exposed. Selling products that then expose consumers through intended use of the product is sufficient to trigger the warning responsibility (for example, selling a food product with a carcinogen in it, which exposes consumers when they eat the food; or selling a paint stripper product, which exposes users to a carcinogen in the fumes).

Risk-based standards for the listed chemicals are not required, but risk-based calculations are highly desirable to the regulated community because they offer the surest way for a business to qualify for exemption. Exposures that pose only trivial risk are exempted, and regulators applying the law's generic exemption provisions to a particular chemical are allowed to determine, in specific quantitative terms, the level of exposure to that chemical below which a warning does not have to be

phenomenon may represent at most a year's delay in the appearance of substantial numbers of potentially high-concern test results.

25. CAL. HEALTH & SAFETY § 25249.5 (1986). For history, documents, and controversies see David Roe, A Quick Reference Guide to California's Proposition 65, Prop. 65 Kit, at http://www.prop65kit.org (last visited June 21, 2002). The author of this article was the principal author of the Proposition 65 ballot measure and an original co-sponsor of it.

26. CAL. HEALTH & SAFETY § 25249.10(c) (1986). Defendants in enforcement actions bear the burden of proof on whether challenged exposures pose "no significant risk" (for carcinogens) or are sufficiently below the no observable effect level (for reproductive toxins). Id. Unless there is a clear numerical definition of the level of exposure that qualifies for exemption (e.g., 7 micrograms per day of benzene exposure is defined as the level of "no significant risk" for benzene; CAL. CODE REGS. TIT. 22 § 12705(b) (1986)), nearly all potential defendants see prohibitive risks in litigation. The law includes a provision for enforcement by citizen suit, CAL. HEALTH & SAFETY § 25249.7(d), which creates an ever-present threat of enforcement litigation over violations.
given. These sought-after determinations—informally known as risk-based "safe harbor numbers" (SHNs)—become, in practical effect, risk-based standards.  

More than 200 chemicals were officially listed under Proposition 65 by 1989 and more than 400 by 1992, with the demand for calculation of safe harbor numbers rising commensurately. By early 1992, the lead regulatory agency was informally circulating SHNs for well over 200 chemicals, which regulated entities were able to rely on. In April 1992, using an “expedited” calculation method, the lead agency published its findings in support of proposed regulatory SHNs for 140 individual carcinogenic chemicals on the Proposition 65 list. In January 1994, the lead agency formally published a list of SHNs for 282 listed chemicals, essentially the same list that had been in informal circulation for over a year.

In short, one state agency, in response to a group of hundreds of chemicals needing scientific risk assessment, managed to produce nearly

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27. CAL. CODE REGS. TIT. 22 §§ 12705(b), 12805(b) (1986); see also REPRODUCTIVE AND CANCER HAZARD ASSESSMENT SECTION, OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY, PROPOSITION 65 STATUS REPORT: NO SIGNIFICANT RISK LEVELS FOR CARCINOGENS AND MAXIMUM ALLOWABLE DAILY LEVELS FOR CHEMICALS Causing REPRODUCTIVE TOXICITY, (March 2002), available at http://www.oehha.ca.gov/prop65/pdf/Mar2002StatusReport.pdf (last visited June 21, 2002) [hereinafter STATUS REPORT]. Interestingly, once SHNs are published by the regulatory agency, they have taken effect in practice even without being formally enacted as regulations. Cf regulatory standards § 12705 (b) and § 12805 (b) with the "informal" SHN list. Id.; see also infra note 28.

28. Although the law required publication of the official list of covered chemicals in early 1987, less than four months after the law’s passage, legal maneuvering in effect delayed full listing for approximately two years. See AFL-CIO v. Deukmejian, 260 Cal. Rptr. 479 (1989). Thus, the need for SHNs occurred in phases over a multi-year time period, rather than all at once. See CAL. CODE REGS. TIT. 22 § 12000 (1986) (showing official listing date for each listed chemical).

29. The incentive mechanism in Proposition 65 for the setting of safe harbor numbers is a shift in the burden of proof on establishing a safe-harbor exemption. See CAL. HEALTH & SAFETY § 25249.10(c) (1986); see also infra note 34. A calculation of the “no significant risk” level for a specific carcinogen, performed by the lead regulatory agency, was effectively good enough to meet that burden of proof in practical terms, whether or not the agency’s number was formally enacted as a regulation. Although never tested in appellate litigation, this concept exerted a definitive influence on the behavior of both potential plaintiffs and potential defendants in Proposition 65 enforcement cases. See also supra notes 26 and 27.


300 chemical-specific, risk-based, quantitative limits in less than five years. Even though the commercial implications have been significant in a number of cases, and even though California law offers at least as broad an avenue for judicial review of regulatory standard-setting as federal law, not a single one of those numbers has yet been challenged in any court, on any ground, by any affected entity.

The incentives for making risk-based determinations are very different under Proposition 65 than they are under federal laws that apply in the same contexts. Under conventional federal law, delay and extended disputes about standard-setting are to the legal advantage of regulated industry, because no regulatory consequences can occur until a standard has been set. Under the state law, delay puts industry at a disadvantage; instead, industry benefits from timeliness, decisiveness, and clarity in the risk assessment process. The difference in incentives appears to be the sole cause of the difference in regulatory track record. California's regulators had much smaller scientific and budgetary resources than the federal government in performing the necessary risk assessment tasks, and there was no special political support or leadership for their efforts from the state executive. Conventional wisdom tends to assume that the slowness of federal standard-setting is caused by constraints of scientific knowledge, budgetary resources, or lack of political leadership, which are viewed as more or less inevitable. California's experience under Proposition 65 stands as clear disproof of those widely shared assumptions.

33. CAL. GOVT §§ 11346 et seq. (2002).
34. See generally David Roe, An Incentive-Conscious Approach to Toxic Chemical Controls, 3 ECON. DEV. Q. 179 (1989).
35. See infra Part III (B).
37. U.S. EPA spent approximately 15 times as much money on risk assessment activities as California's relevant agency during the period in question, conservatively estimated. Personal communication with Dr. Steven Book, California Health and Welfare Agency (June 1992) (estimating OEHHA annual expenditures for all Proposition 65-related activities including risk assessment); personal communication with Dr. Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency (April 1993) (estimating OPPTS annual expenditures in 1988–92 solely for chemical risk assessment activity, following internal staff research).
38. Indeed, Governor George Deukmejian opposed Proposition 65 when it was on the statewide ballot in 1986, and tried unsuccessfully to limit its scope by listing only a handful of chemicals on the first official list of chemicals to be covered by the law. See infra note 47.
IV. POSSIBLE FEDERAL POLICY RESPONSES

Federal regulators and Congress could respond to a large new group of chemicals needing risk-based standards in a number of ways, from doing nothing to undertaking a wholesale revamping of the regulatory system, using changed incentives to make it work much more quickly. The remainder of this article outlines the major choices. The last group of choices appears to be the most promising. These are called "ignorance-based" regulation, to distinguish them from approaches that depend on scientific knowledge and are stymied by its absence.

A. Stand Still

As test results from the HPV Challenge Program start to accumulate, one possible policy response is no response at all. Hundreds of additional chemicals with suggestive but not definitive evidence of toxicity simply may get added to the existing backlog, under each of the relevant federal statutes. After all, one lesson from the Toxics Release Inventory (TRI), for which Congress-designated hundreds of chemicals as "toxic" in 1986, is that officially identifying chemicals as "toxic" does not automatically lead to regulatory standard-setting, even when there is the clearest possible evidence that the chemicals are present where they could pose risks (e.g., in ambient air), and there is significant public disclosure of their presence. Absent new law, federal regulators will face no legal duty to act on the toxicity screening results, particularly since no exposure studies will accompany them. Even when agencies have all the knowledge they need to impose regulatory controls, they know from experience that their critics have a much easier time going to court to stop them from taking action than in getting the courts to force them to act.

However, as a political matter, neither government nor chemical-using industries will be able to offer the public any credible assurance that this newly identified group of chemicals is safe, and manufacturers' own tests will provide at least suggestive evidence of potential harm. The chemical manufacturing industry will be particularly vulnerable to public opinion, having long since committed itself to the concept of "chemical

39. Although Section 112 of the Clean Air Act lists a table of 188 hazardous air pollutants, 469 "toxic chemicals" were reported as being emitted into ambient air in the U.S. in 1999 under the Toxics Release Inventory. See Environmental Defense, Ranking of Air Releases for Entire U.S., Scorecard website, at http://www.scorecard.org/chemical-profiles/rank-chemicals.tcl?how_many=500&drop_down_name=Air+releases&fips_state_code=Entire+United+States (last visited June 21, 2002).
40. See infra note 44.
41. See infra note 59.
safety" and having shown extreme reluctance to admit publicly that gaps exist in that comforting concept. There is likely to be a political need to show that something is being done to cope with this wave of newly uncovered chemical hazards, some of which will undoubtedly be not only high-volume, but also high-exposure. Therefore, a no-action alternative will be unattractive in political as well as in policy terms.

42. See, e.g., 1996 policy statement of the Chemical Manufacturers Association describing its view of chemical risk management: "Generally speaking, the philosophy of risk-based . . . management of chemicals . . . allows for the continued safe use of chemicals . . . . Through [this] approach, we can ensure that chemicals are used safely" (emphasis added). CHEMICAL MANUFACTURERS ASSOCIATION, OVERVIEW, PRODUCT RISK MANAGEMENT STRATEGY (1996); see also the same organization's much-publicized Responsible Care® Program, required for all member companies, which commits members to "develop and produce chemicals that can be manufactured, transported, used and disposed of safely," and to "counsel customers on the safe use, transportation, and disposal of chemical products" (emphasis added). CHEMICAL MANUFACTURERS ASSOCIATION, 10 ELEMENTS OF RESPONSIBLE CARE: 1994–95 RESPONSIBLE CARE PROGRESS REPORT 2 (1995) (on file with Environmental Defense). The Chemical Industry Institute of Toxicology, a private research institution largely funded by industry, takes the position, "We all want a healthy society . . . . We want safe chemical products. On that we can all agree." (emphasis added). Chemical Industry Institute of Technology, Annual Report 1995 (on file with Environmental Defense). For the industry's most current statements, see the section entitled American Chemistry Council Responsible Care® and the American Chemistry Council (formerly Chemical Manufacturers Association) website, at http://www.americanchemistry.com/ (last visited June 21, 2002).

43. In response to severe criticism in a March 26, 2001 PBS Documentary "Trade Secrets" by Bill Moyers, an official spokesman for the American Chemistry Council (formerly the Chemical Manufacturers Association) appeared on camera immediately after the documentary and forcefully asserted that industrial chemicals are safe because "they have been tested" and "have been carefully scrutinized." The head of the Council, who had personally helped launch the HPV Challenge Program in 1998 in recognition that chemicals had not been tested (see supra note 18), declined to issue a retraction despite being reminded of the facts in pointed fashion. Press Release, ENVIRONMENTAL DEFENSE FUND, ENVIRONMENTAL DEFENSE Rebukes AMERICAN CHEMISTRY COUNCIL Strongly Worded Letter Criticizes Industry Group's Appearance on PBS TOXICS SAFETY PROGRAM (March 27, 2001), at http://www.environmentaldefence.org/article.cfm?contentid=1021 (last visited June 21, 2002).

44. The HPV Challenge Program will not yield information about exposure, even though exposure information is as important in determining chemical safety as toxicity information. In general, exposure information is not sought until after toxicity determinations have been made (why check for exposures to a chemical you don't suspect of being toxic?). In other words, it is an appropriate working assumption that there will be not be existing exposure information for any chemical in the program that shows previously undisclosed toxicity potential. Anticipating the screening results for toxicity from the HPV Challenge Program, a business group called the Alliance for Chemical Awareness (ACA) has launched an effort to define the elements of a basic set of exposure information (analogous to SIDS for toxicity information) for the purpose of putting toxicity information into "an appropriate risk communication context." See Alliance for Chemical Awareness website, at http://www.chemicalawareness.org/background.html (last visited 6/21/02).

A small advisory committee drawn from academia and public-interest groups has provided comments on initial ACA drafts.
B. Accelerate Conventional Risk Assessment

For the chemicals that emerge from the HPV Challenge Program evaluation as clear hazards, U.S. EPA and other affected regulatory agencies could try to increase their output of conventional risk assessments to support an increased number of standard-settings under existing federal law. More budgetary support from Congress and a higher executive priority could help. However, as discussed supra, California made "a hundred years of progress"\(^45\) by federal standards using only a fraction of the federal budget for risk assessment\(^46\) and despite executive hostility. California's experience with Proposition 65 therefore demonstrates that the important constraint on regulatory risk determinations is neither budgetary nor executive.\(^47\) (Proposition 65 was consciously designed to reverse structured disincentives built into federal laws and to find out what difference the change would make.\(^48\)) Ironically, California's experience suggests that even a dramatic increase in budget and priority would probably not speed up the current evaluation process significantly, unless the underlying disincentives were also addressed.

C. Abandon Risk-Based Standard-Setting

As it did in the 1990 amendments to Section 112 of the Clean Air Act, Congress could abandon risk-based standard-setting as the primary means for protecting the public against harm from toxic chemicals. As with the 1990 amendments, Congress could buy time by installing a substitute regime.

A new regime, however, would need a plausible basis for success. One possibility is to implement performance-based standards, like those that Congress imposed in the 1990 Clean Air Act amendments. After twelve years of experience with the amended Clean Air Act, however,


\(^{46}\) See supra note 37.

\(^{47}\) In issuing the required first list of chemicals "known to cause cancer or reproductive toxicity," Governor Deukmejian issued a list with only 29 chemicals, notwithstanding clear reference in the statute to minimum lists of approximately 200 chemicals. The courts quickly disallowed the Governor's restrictive interpretation, first in a preliminary injunction issued against the Governor and then, eventually, on appeal. AFL-CIO v. Deukmejian ["Duke I"], 260 Cal.Rptr. 479 (1989). California courts also quickly blocked two other restrictive interpretations of Proposition 65 by the Deukmejian Administration. AFL-CIO v. Deukmejian ["Duke II"], No. 502541 (Sacramento Super. Ct. May 31, 1988) (order granting a preliminary injunction); AFL-CIO v. Deukmejian ["Duke III"], No. 359223 (Sacramento Super. Ct. June 22, 1988) (granting summary judgment).

\(^{48}\) ROE, supra note 34.
performance-based standards must be judged by their track record, which is not very reassuring in terms of speed or comprehensiveness of coverage.

D. Use Wholesale Regulation

If the means to regulate hundreds of new chemicals one-by-one is not available, it might be possible to regulate them in groups, based on generic rather than individual characteristics. Group classification with regulatory consequences is by no means a new concept in toxic chemical law. One current version of this approach is the Globally Harmonized System (GHS) that was endorsed in principle at the 1992 Rio Summit conference and is currently used by the European Union. Under GHS, industrial chemicals in commerce are classified and required to be labeled according to the type of hazard they present. The U.S. is participating in GHS development activities while noting that any U.S. participation in the system, once developed, is voluntary.

On first blush, GHS would seem to be a good fit with the HPV Challenge Program, which will produce test results that could be translated into GHS classifications for numerous chemicals. However, although the OECD formed an advisory group to develop health and environmental hazard classification criteria, which is led by U.S. EPA, there is, as yet, no formula or common understanding for translating SIDS test results into GHS classifications. The theoretical advantage of speed that a classification-based regime offers is, in this case, unavailable in practice.

GHS also goes no further than to label chemicals for hazard. To control chemical risks, it relies on voluntary behavior changes by individuals in response to label information (and, presumably, by companies in response to having to provide label information). To adapt it for any regulatory consequences beyond labeling, the U.S. would have

49. For example, halogenated solvents are a well-recognized family of industrially significant chemicals that share physical and chemical similarities. They include TCE, TCA, perchloroethylene, methylene chloride, and CHCs. However, this well-studied group illustrates the potential difficulties in wholesale treatment, since the toxicity of its main members varies substantially. SOURCE REDUCTION RESEARCH PARTNERSHIP, METRO. WATER DIST. & ENVTL. DEF. FUND, POTENTIAL FOR SOURCE REDUCTION AND RECYCLING OF HALOGENATED SOLVENTS, SUMMARY REPORT 16–18, Table 2.2 (1992).


51. Id.
to create its own regime. The next two subsections describe possibilities that could be applied to GHS-classified chemicals or to other groups of chemicals identified as priorities, such as chemicals that emerge from the HPV Challenge Program showing high-priority forms of toxicity based on screening tests.

E. Authorize Risk Assessment Shortcuts To Support Interim Control Measures

California regulators were able to generate chemical-specific standards quickly and in large numbers because they used scientific shortcuts in risk assessment, rather than following the laborious risk assessment model of federal practice. Scientists in the state’s Office of Environmental Health Hazard Assessment (OEHHA) generated 140 “expedited” cancer potency values for “previously unassessed agents” in a matter of months, based on data from acute-toxicity tests and a uniform set of extrapolation assumptions that were openly acknowledged to differ from “usual practice.” OEHHA compared potency estimates derived through its expedited method with conventional potency estimates, to the extent feasible, and concluded that “reliable potency values can be derived using the expedited procedure.” It also carefully noted that “more extensive analyses may result in improved potency estimates and that some of the values presented here may require revision.” Nevertheless, the 140 calculations were immediately converted to “proposed” regulatory levels that took immediate practical effect.

Although not one of the regulatory levels devised from this expedited procedure in California has been challenged in any California court, it seems likely that federal use of an analogous procedure to set binding standards would be challenged in court, and that it would lose. A change of law would therefore be necessary to authorize such shortcuts. Because it has a proven track record, both in science and in practical effect throughout the regulated community for a decade, OEHHA’s expedited method would be one early candidate for consideration as a “first-cut” mechanism to support interim measures in appropriate cases. For example, chemicals screened in the HPV Challenge Program that show specific results of concern (such as reproductive toxicity) could be subjected to interim controls, pending further findings.

52. Potency Values, supra note 30, at 1.
53. Id. at 5.
54. Id. at 5–6.
55. See supra note 30.
F. Adopt "Ignorance-Based" Control Measures

The familiar knowledge-based systems of federal toxics law create a perverse incentive: the incentive to resist knowledge. For the rational member of the regulated community, there are no negative consequences to resisting scientific consensus and mounting elaborate arguments to each piece of each risk assessment for each new chemical, other than the cost of hiring shock troops. Delay postpones any potential regulatory burden; cooperation merely brings it closer.

The incentive against knowledge in hazard screening is even stronger. Without screening information, not only is the federal regulatory process stymied, but there is no public perception of possible risk. A chemical manufacturer bringing forward a set of screening data is like a taxpayer volunteering for an IRS audit—there is no possible advantage from a legal point of view.\(^\text{56}\)

The most constructive policy response, therefore, is to shift the incentives so that they reward knowledge rather than ignorance and reward consensus rather than drawn-out haggling on scientific and technical issues. The Proposition 65 experiment shows that changed incentives for standard-setting can be remarkably successful, but Proposition 65 is limited to chemicals already well known to be hazardous. There is no equivalent body of experience to consult in shifting the incentives in favor of identifying hazard in the first place.

However, once the perverse incentives of a knowledge-dependent system are recognized, it is possible to imagine alternatives. Shaping the consequences of ignorance, rather than allowing it to be the most comfortable default, is the common thread in what might be termed an "ignorance-based" approach.

Three types of ignorance-based policies could be applied in the context of hazard identification:\(^\text{57}\)

1. **Disclosures.** Ignorance is itself a fact that can be disclosed about individual chemicals. For example, the public can be informed whether any particular chemical has been screened, either to SIDS specifications or to other minimum hazard screening criteria prescribed by regulation. (For HPV chemicals, a version of such disclosure is already occurring through the

\(56\) TSCA's attempt to urge the companies forward with hortatory language alone, *see supra* note 7, was bound to be futile.

\(57\) *See ROE, supra* note 8, at Chapter V "Recommendations" section.
public-private Challenge Program.) In particular contexts, regulators could disclose the testing status of certain sets of chemicals of particular interest, one obvious candidate being TRI chemicals released into air or water. A “status of hazard screening” element could be required to be included for each chemical in every facility report under TRI, or for each chemical in a material data safety sheet (MSDS), or in other chemical reporting contexts. Alternatively, any reporting requirement imposed on a private party could require the party to identify the releases, exposures, or other chemical-related events for which the reporting party itself did not have specified screening or other hazard-related data in hand (e.g., an asterisk on chemicals with releases to the environment reported under TRI, indicating “health hazards not yet researched”). This requirement would be likely to spur demand within the private sector for such data.

2. Reductions In Legal Status. Chemicals in commercial use in the U.S. enjoy legal privileges, some more widely recognized than others. These include being allowed to be manufactured, sold, patented, etc. Those privileges arguably depend on an assumption that the chemicals are not posing unacceptable harms to human health or to the environment. If they were, the regulatory system should, in theory, have already restricted or banned their use.

If a commercial chemical’s privileges depend on a presumption of safety, then failure to justify that presumption could result in progressive withdrawal of legal privileges over time. Each step would represent an incentive to make good on the safety presumption (e.g., by curing data gaps, conducting tests, restricting exposures, etc.). A sequence of progressively more burdensome steps would presumably work better than a single, all-or-nothing consequence that might be either too mild or too draconian for particular chemicals in specific contexts.

Examples of progressive steps might include the following:

58. The Scorecard website, managed by Environmental Defense, includes (among many other disclosure elements) the current testing status of each of the approximately 3,000 HPV chemicals, specifying which of the SIDS suite of screening tests has and has not been completed according to public records. See, e.g., the “Basic Testing to Identify Chemical Hazards” heading in any individual chemical profile, reached from Scorecard’s “About the Chemicals” feature, at http://www.scorecard.org/chemical-profiles/ (last visited June 21, 2002). The data is derived from U.S. EPA’s 1998 follow-up study to the Toxic Ignorance study. Roe, supra note 11.
A requirement to be tested under TSCA Section 4 (i.e., the issuance of a Section 4 test rule) could be triggered automatically by the failure of EPA to receive specified minimum data within a specified time frame (current impediments\textsuperscript{59} to Section 4 authority would have to be fixed).

After an additional period without minimum data (or increased data), a chemical could automatically be reclassified as a "new" chemical under TSCA, thereby forfeiting its status as a grandfathered "existing" chemical and making it subject to the stricter provisions that apply to new chemicals under TSCA Section 5.

Confidentiality claims related to a chemical, such as the claim that formulation or sales data should be protected as "confidential business information," could also be automatically forfeited after a fixed period, if specified data is not forthcoming.

Status-changing measures like these could be applied first to high-priority groups of chemicals (e.g., HPV chemicals) and then extended to other groups over time. Progressively harsher sanctions, up to and including a ban after extended failure to meet other deadlines, are also possible.

c. More Effective Mandatory Testing. TSCA testing authority for new and existing chemicals could be strengthened and the current Catch-22 eliminated.\textsuperscript{60} Minimum screening could also be made mandatory for different groups of chemicals on different timetables. Both the SIDS program and the HPV Challenge Program offer useful precedents for technical issues, such as identification of particular screening requirements;

\textsuperscript{59} In practice, TSCA Section 4 authority has been undermined by an apparent legal Catch-22. The courts have held, in effect, that EPA cannot order Section 4 testing to find out whether a chemical is toxic unless it already has either some evidence of toxicity or data showing extensive potential exposure. Chemical Manufacturers Association v. EPA, 859 F.2d 977, 984 (D.C. Cir. 1988). Total lack of information thus puts a chemical effectively beyond Section 4's reach. See generally ROE, supra note 8, at 26; supra note 26. TSCA's failings have been repeatedly documented in both government and private reports. See GAO, TOXIC SUBSTANCES: EPA'S CHEMICAL TESTING PROGRAM HAS NOT RESOLVED SAFETY CONCERNS (GAO/RCED-91-136, June 19, 1991); GAO, TOXIC SUBSTANCES: STATUS OF EPA'S REVIEWS OF CHEMICALS UNDER THE CHEMICAL TESTING PROGRAM (GAO/RCED-92-31FS, October 31, 1991); GAO, TOXIC SUBSTANCES CONTROL ACT: EPA'S LIMITED PROGRESS IN REGULATING TOXIC CHEMICALS (GAO/T-RCED-94-212, May 17, 1994).

\textsuperscript{60} Id.
reporting formats; realistic timetables, etc. For any mandatory approach, it is important that sanctions occur automatically when fixed time limits expire, rather than at the discretion of agency initiative. Otherwise the incentive shifts back in favor of extended administrative dispute and administrative review litigation.

CONCLUSION

The success of any policy response to the coming wave of chemicals will depend on counterbalancing and reversing the disincentives to knowledge and productivity that the current federal system enforces. Those disincentives are deeply imbedded in intellectual habit, institutional reflex, and case law. But there is good news in the fact that they are artificial rather than inevitable. As merely legal structures, they can be changed, and state-level experience suggests that altering them can be effective in accelerating the same machinery that now groans at the prospect of any additional load.

In this light, there is even a potentially rosy scenario. Seeing the handwriting on the wall, the chemical manufacturing industry might react in advance of significant policy changes. As the sponsors of a chemical's test plan under the HPV Challenge Program, its manufacturers will be able to anticipate adverse results before tests are complete. In response, they may begin imposing voluntary restrictions, issuing private cautions to customers, or marketing substitutes. In an ideally responsive world, by the time regulators and the public understand test results of serious concern, what would have been the highest-priority chemicals for action may have already begun being phased out.

This scenario is not as unlikely as it sounds. The chemical manufacturing industry cooperated in developing the HPV Challenge Program, at least in part because it perceived an acute risk in not testing. As test results start to flow, there may be a similar perceived risk in not acting in response to what the tests show. Ironically, the more attention the industry pays to the coming crisis, and the more widespread and active its exploration of policy options to address it, the more likely a self-healing response becomes.

61. For example, after the 3M company discovered information in 2000 showing widespread public exposure to its chemical product perfluorooctane sulfonate (PFOS), along with suggestive results from toxicity tests on PFOS (not via the HPV Challenge Program), the company made plans to withdraw PFOS from the marketplace and quickly introduced non-PFOS alternatives. See 3M press release on Non-PFOS Photo-acid Generators (July 16, 2001), at http://www.3m.com/profile/pressbox/semicon071601.html (last visited September 12, 2002).