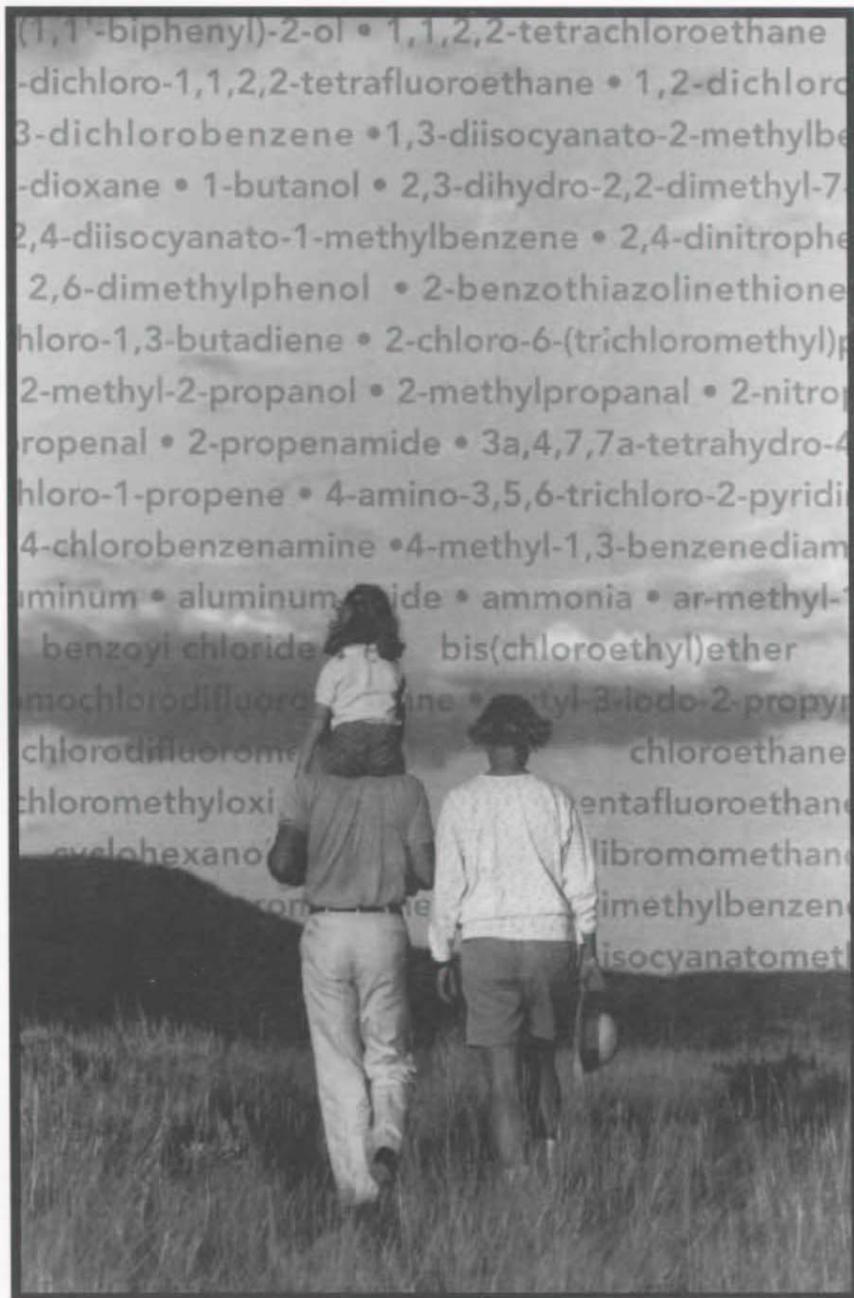


# TOXIC IGNORANCE



**The Continuing Absence of Basic  
Health Testing for Top-Selling  
Chemicals in the United States**

## **ACKNOWLEDGMENTS**

This report was produced by the Environmental Health Program of the Environmental Defense Fund, with the generous support of the Clarence E. Heller Charitable Foundation.

Dr. William Pease designed and directed the research reported in Chapter II, which was carried out by Dr. Pease, Ken Leiserson, Curtis Below, Jean Chang, and David Abercrombie. The report was written by David Roe, Dr. Pease, Karen Florini, and Dr. Ellen Silbergeld. David Roe served as general editor. Kristin Lawton served as production manager and associate editor.

EDF gratefully acknowledges the contributions of Professor John Dernbach, Dr. Tom McKone, Dr. Warren Muir, Dr. David Rall, and Dr. David Wallinga, who reviewed earlier drafts. Julia Bryson, Kristin Lawton, Nicole Nardone, and Dan Wright provided research assistance. Fryar Calhoun designed the text and layout. Curtis Below, Janice Caswell, Tim Connor, and Norma Watson designed the cover.

## **COVER**

The names of chemicals that appear on the cover are taken from the random sample of chemicals studied for this report, as described in Chapter II. They represent the group of sampled chemicals that are known to be emitted to the air from industrial facilities in the United States, as reported to the Toxics Release Inventory maintained by the U.S. Environmental Protection Agency.

## EXECUTIVE SUMMARY

After DDT, after lead, after PCBs and other unintended chemical catastrophes, our knowledge about the chemicals we allow in commerce must have gotten much better. So Congress wrote into law, and so the public has a right to assume.

Yet for most of the important chemicals in American commerce, the simplest safety facts still cannot be found. Environmental Defense Fund research indicates that, today, even the most basic toxicity testing results cannot be found in the public record for nearly 75% of the top-volume chemicals in commercial use.

In other words, the public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not — much less how serious the risks might be, or whether those chemicals are actually under control. These include chemicals that we are likely to breathe or drink, that build up in our bodies, that are in consumer products, and that are being released from industrial facilities into our backyards and streets and forests and streams.

In the early 1980s, the National Academy of Sciences' National Research Council completed a four-year study and found that 78% of the chemicals in highest-volume commercial use had not had even "minimal" toxicity testing. Thirteen years later, there has been no significant improvement.

What we don't know may not be hurting us — or it may. But guinea pig status is not what Congress promised the public more than twenty years ago. Instead, it established a national policy that the risks of toxic chemicals in our environment would be identified and controlled. Ignorance, pervasive and persistent over the course of twenty years, has made that promise meaningless.

Chemical safety can't be based on faith. It requires facts. Government policy and government regulation have been so ineffective in making progress against the chemical ignorance problem, for so long, that the chemical manufacturing industry itself must now take direct responsibility for solving it. It is high time for the facts to be delivered.

Step one toward a solution lies in simple screening tests, which manufacturers of chemicals can easily do. All chemicals in high-volume use in the United States should long since have been subjected to at least preliminary health-effects screening, with the results publicly available for verification. There is already international consensus on just what needs to be done as a first step. A model definition of what should be included in preliminary screening tests for high-volume chemicals was developed and agreed on in 1990 by the U.S. and the other member nations of the Organisation for Economic Cooperation and Development, with extensive participation from the U.S. chemical manufacturing industry. All that is missing is the industry's commitment to act, without waiting any longer.



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## I. Introduction — the Dominance of Ignorance

After DDT, after lead, after PCBs and other unintended chemical catastrophes, our knowledge about the chemicals we allow in commerce must have gotten much better. So Congress promised with major laws, and so the public has a right to assume.

Yet for most of the important chemicals in American commerce, the simplest safety facts still cannot be found. This report documents that, today, even the most basic toxicity testing results cannot be found in the public record for nearly 75% of the top-volume chemicals in commercial use.

In other words, the public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not — much less how serious the risks might be, or whether those chemicals are actually under control. These include chemicals that we are likely to breathe or drink, that build up in our bodies, that are in consumer products, and that are being released from industrial facilities into our backyards and streets and forests and streams.

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***The public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not.***

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Step one toward a solution lies in simple screening tests, which manufacturers of chemicals can easily do. All chemicals in high-volume use in the United States should long since have been subjected to at least preliminary health-effects screening, with the results publicly available for verification. There is already international consensus on just what needs to be done as a first step. A model definition of what should be included in preliminary screening tests for high-volume chemicals was developed and agreed on in 1990 by the U.S. and the other member nations of the Organisation for Economic Cooperation and Development, with extensive participation from the U.S. chemical manufacturing industry. All that is missing is the industry's commitment to act, without waiting any longer.

Chapter II of this report, "The Current State of Ignorance about Chemical Hazards," presents detailed results of the Environmental Defense Fund's research. It reveals the absence in the public record of basic health screening data for high-volume chemicals in general; for chemicals with recognized potential for significant human exposure; and for chemicals

actually being released from industrial facilities today.

Chapter III, "The Failure of Federal Testing Requirements," analyzes and explains why 20 years of federal law and regulation have failed to require necessary testing to be performed.

Chapter IV, "Hints of Progress," examines some promising developments outside conventional law and regulation that begin to suggest how much faster progress could be encouraged.

Chapter V, "Recommendations," provides recommendations for legal and policy changes to produce much faster progress, consistent with the principle of direct responsibility of the chemical manufacturing industry itself to satisfy the public's need for basic safety information about chemicals in widespread commercial use.

**TOXIC IGNORANCE**

## II. The Current State of Ignorance About Chemical Hazards

The starting point for safe use of a chemical is, of course, knowing whether the chemical is toxic. This is known as **hazard identification**. There are many chemicals in circulation, and by no means are all of them toxic. Step one is to screen them, usually with quick and relatively inexpensive toxicity tests, to get a preliminary idea of which ones might be toxic and what forms of toxicity are involved (for example, a potential to cause cancer; or a potential to disrupt normal development of the fetus or child).

Analysis of the extent of health-hazard information on chemicals is rare. In 1980, the National Academy of Sciences' National Research Council began an extensive study to determine what need there was for additional toxicity testing. It concluded in 1984 that 78% of the chemicals in U.S. commerce with production volume of greater than one million pounds per year lacked even "minimal toxicity information."<sup>1</sup> This report is the first public attempt to update the 1984 findings on the extent of toxicity testing for chemicals in U.S. commerce.

### A. Description of analysis and methods

Before presenting results, this section briefly describes the form of the analysis and the methods

used. A detailed description is presented in Appendix I.

### 1. Target category of chemicals

The chemicals addressed in this report do not include all, or even most, of the approximately 75,000 chemicals that the U.S. Environmental Protection Agency lists as being made in the U.S. in 1996.<sup>2</sup> This report covers only those chemicals that are produced in or imported into the U.S. in amounts greater than 1 million pounds per year (**high-production-volume chemicals**), as documented by the U.S. Environmental Protection Agency.<sup>3</sup> Because EPA's list does not include certain categories of chemicals, such as food additives, drugs, and pesticides, this study excludes those materials.

### 2. Analytical methods

This report uses the same approach as the 1984 National Research Council report, analyzing the availability of hazard identification data (i.e., toxicity testing results) by examining chemicals in a randomly selected representative sample<sup>4</sup> and then extrapolating the sample results to all high-production-volume chemicals.<sup>5</sup>

EDF drew its sample for this report from those chemicals that are *both* high-production-volume (more than 1,000,000 lbs./yr.), *and* have already been identified as subjects of regulatory attention under major environmental laws. Chemicals that turn up in both of these categories can fairly be considered to be **high-priority chemicals**, meaning chemicals with a high-priority need for hazard identification. Limiting the sample in this way makes it more likely to include chemicals that have been at least minimally tested, since a completely untested chemical is very unlikely to have been the subject of official regulatory focus. To the extent that this may introduce a bias in the results, it does so in favor of *overstating* the availability of information; i.e., the chemicals in the

sample are more likely to show adequate preliminary testing than chemicals in the entire high-production-volume group.

As in the 1984 report, the results from the sample are extrapolated to all 3,000 high-production-volume chemicals. This approach almost certainly overstates the degree of knowledge about hazard information for this larger group of chemicals, as explained above, and thus *understates* the actual degree of ignorance.

In measuring whether a chemical qualifies as having hazard identification data available, this report takes the internationally accepted definition of a minimum screening information data set that was created by the Organisation for Economic Cooperation and Development (OECD) Chemicals Program in 1990. It focuses only on the portion of the definition that covers screening for human health effects (“Toxicological Data”). These types of test data are shown in the accompanying box.

If enough data to meet this portion of the OECD minimum screening requirements were found to be available for a particular chemical, it was assumed that an informed preliminary judgment about that chemical’s potential human health hazards could be made.

There is international consensus that this data set represents the minimum amount of data required for a preliminary assessment of human health hazard of a chemical. However, it is important to note that the minimum screening information data set generally does *not* include enough data to conduct a comprehensive health risk assessment. It is only a starting point, and it is no substitute for the risk assessment that is called for under most major toxic chemical control laws. However, such a data set can be used to screen chemicals into different hazard categories with different priorities for next steps. Categories might include:

#### **Toxicological Data**

- Acute toxicity
- Repeated dose toxicity
- Genetic toxicity (*in vitro*)
- Genetic toxicity (*in vivo*)
- Reproductive toxicity
- Developmental toxicity/teratogenicity

***There is international consensus that this data set represents the minimum amount of data required.***

- no further action;
- recommendations for further testing or exposure assessment to characterize risks more accurately; or
- recommendations to adopt control measures to reduce probable hazards.

### **3. Limitation to publicly available data**

The analysis in this report uses only information from publicly available sources. For some chemicals there is undoubtedly private information as well: for example, tests on specific chemicals that major manufacturers have performed, or paid for, which to date have not been made available to the public. A specific example is discussed below at the end of this chapter. However, a report like this has no way to evaluate private data. More importantly, for purposes of assuring the public about the safety of specific chemicals, non-public data are of no real value. To rely on them is to ask the public to take chemical safety on faith — the exact opposite of the intent of modern toxic chemical control laws passed by Congress since 1970.

### **4. Limitation to high-production-volume chemicals**

Focusing on chemicals with the highest production volume is one way to set priorities. This is the approach now being used by the OECD program that is trying to generate information about chemicals in commercial use. By focusing on the approximately 3,000 high-production-volume chemicals in U.S. commerce, this report aims at the ignorance problem where it should be least prevalent. Any chemical currently produced or imported in quantities of more than one million pounds per year should not have escaped the notice of its manufacturer or of regulators. In the absence of solid information to the contrary, use in such volume is presumably likely to be leading to

significant human exposures and releases to the environment.

The actual facts are particularly hard to establish for chemicals with no hazard identification data because, almost inevitably, such chemicals are not tracked or monitored. Proving whether people are being exposed to such chemicals or not is therefore extremely difficult.

## B. Results

The results of EDF's analysis of the 100 chemicals in its random sample are illustrated in Figure 2-1. **Nearly three quarters (71%) of the sampled high-priority chemicals do not meet the minimum data requirements for health hazard screening set by the Organisation for Economic Cooperation and Development Chemicals Program.**

Thus, for the group of chemicals with the highest volume use in the United States, there is no basis for assurance that their use does not pose health risks to the American people, whether that assurance is offered by industry or by government.

Lack of meaningful assurance is not the same as proof of harm, of course. It is only proof of ignorance. But ignorance means that any conclusion about safety is unfounded. A system that relies on ignorance has no basis for inviting public confidence that chemical risks are under control — even from the chemicals being sold and used in the largest amounts. For approximately 75% of those chemicals, minimum critical information is lacking.

Of the potential health effects (“endpoints”) that would be covered by minimum screening tests, a majority of chemicals in the high-priority sample have

### Chemicals with minimum screening data

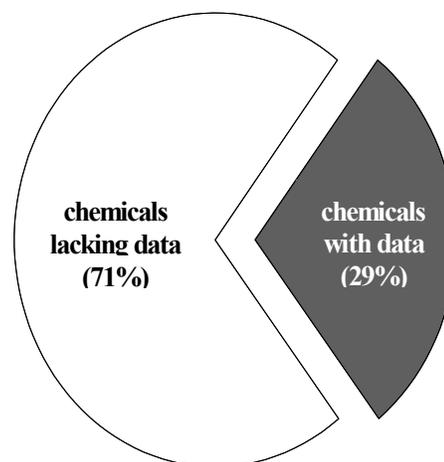


FIGURE 2-1

**Available toxicity studies by type of health risk**

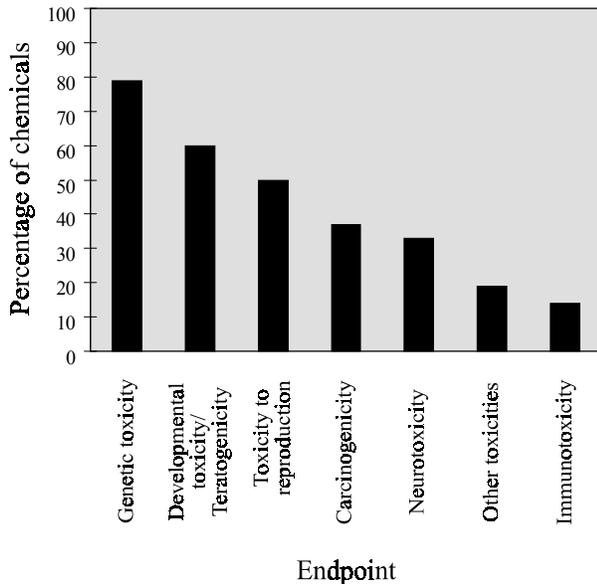


FIGURE 2-2

**Available toxicity studies by duration of exposure**

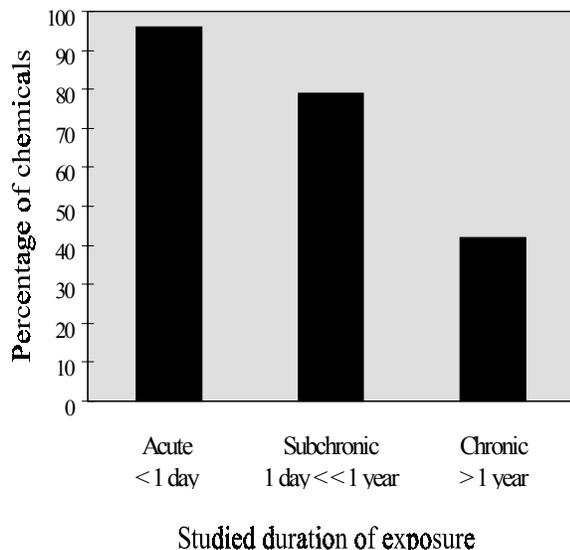


FIGURE 2-3

been tested for only two: genetic toxicity (i.e., ability to cause mutations) and developmental toxicity (e.g., ability to cause birth defects). Figure 2-2 illustrates.

Reproductive toxicity tests have not been conducted on 53% of high-priority chemicals. Carcinogenicity tests have not been conducted on 63% of high-priority chemicals. Neurotoxicity tests have not been conducted on 67%. Immunotoxicity tests have not been conducted on 86%. Endpoints of particular concern for evaluating impacts on children (such as postnatal performance and developmental neurotoxicity) have not been assessed for more than 90% of high-priority chemicals.

Exposure to these high-priority chemicals can occur from various sources, including from use of consumer products, from indoor or outdoor air, and in the workplace. In the workplace, use of chemicals can result in regular occupational exposures to production workers. Workplace use may also lead to ongoing exposures to the general public if these chemicals are released to the environment or are included in consumer products. To assess the safety of chemical use in such contexts, it is important to have data from chronic toxicity tests; i.e., tests investigating the effect of exposure to the chemical over substantial periods of time. Figure 2-3 illustrates that **more than half of the sampled high-priority**

**chemicals have not been tested for any form of chronic toxicity.**

For acute toxicity, by contrast, testing is much more likely to have occurred: over 90% of the sampled chemicals have been tested for some form of acute toxicity (usually death).

Most toxicity testing has not focused on the route of exposure that is most relevant for assessing human health risks. Both for the general public and for workers, the predominant route of exposure to many compounds is likely to involve breathing contaminated air (inhalation exposure). Yet more than two-thirds of high-priority chemicals have not been subjected to chronic inhalation tests that evaluate long-term air exposures to a toxicant.<sup>6</sup>

These results, for high-priority chemicals as a whole, are dismayingly meager. But an observer might raise the possibility that, despite their priority for regulators and their high volume of commercial use, the chemicals under study might not be representative of those actually out in the environment. Perhaps, for example, chemicals we are most likely to be exposed to outdoors have been tested, even if other high-volume chemicals have not. To test this possibility, EDF looked only at the chemicals in its sample that are reported on the national Toxics Release Inventory as being released by industry into the environment, a total of 47 chemicals.<sup>7</sup> The results are shown in Figure 2-4.

**Even of the sampled chemicals that are *known* to be released into the environment, 51% do not meet minimum screening requirements for health hazard identification.** This result is particularly

**TRI chemicals:  
proportion with minimum  
screening data**

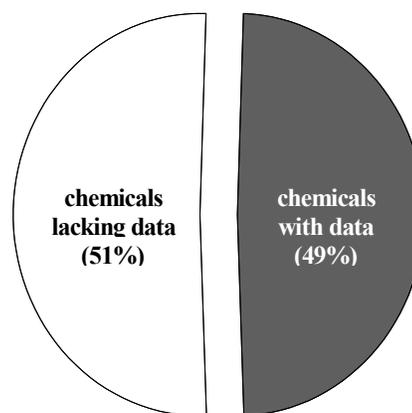


FIGURE 2-4

## Chemicals with medium/high potential human exposure: proportion with minimum screening data

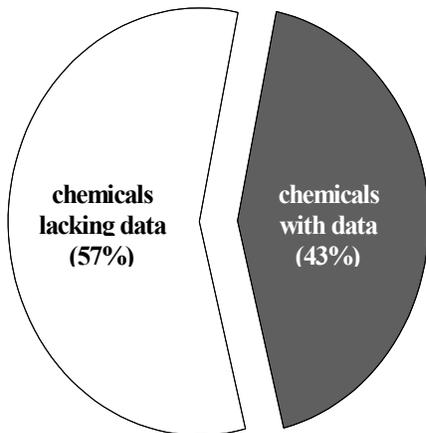


FIGURE 2-5

striking, since to be included on the Toxics Release Inventory a chemical must already have been found to be "toxic" on the basis of some evidence of harm. This finding illustrates an important point: that even with chemicals for which *one* health hazard may have been found, we are likely not to have even a preliminary idea whether *other* health hazards are also presented.

For the portion of the sampled chemicals for which we have especially strong reasons to anticipate human exposure, the results are similar. The U.S. EPA has established criteria for assessing the exposure potential of chemicals based on bioaccumulation and persistence; i.e., whether they are likely to build up in our bodies, and whether they are likely to last for a long time in the environment.<sup>8</sup>

Looking only at sampled chemicals with "high" and "medium" exposure potential, a total of 42 chemicals, 57% do not meet minimum screening requirements for health hazard identification. This finding means that **chemicals with special likelihood of exposure have not been tested to any**

**significantly greater degree than other chemicals.**

Just because regulators can identify chemicals with special likelihood of exposure does not mean that better testing for their potential health effects has yet occurred, or that the results of any such testing are publicly obtainable.

### C. Checking the accuracy of results

#### 1. Partial review by two chemical companies

Large chemical manufacturers are likely to be particularly knowledgeable about the state of testing

on their own chemicals. EDF therefore asked the two companies which appeared to have the greatest number of chemicals in the random sample, Dow Chemical Co. and DuPont, to review the scoring of those chemicals that EDF used in deriving the results shown in Section B above.

On 15 of the 17 chemicals which Dow and DuPont agreed to review,<sup>9</sup> EDF's overall score and that of the company was the same. Dow and DuPont both confirmed that the categories in EDF's scoring approach accurately matched the relevant categories of the OECD screening program. Each company differed with EDF on the overall scoring<sup>10</sup> of one chemical, for reasons discussed below.

Dow's difference with the overall score of one of its chemicals was based on the existence of private studies of the chemical that are not available in the public literature. If scoring is limited to publicly available studies — as EDF's scoring necessarily was — then Dow's and EDF's overall scores are the same. However, Dow did not concur that private studies should be excluded from consideration.

As a caveat, Dow also noted that it believed another of its chemicals in the sample should be considered to have been adequately screened, notwithstanding a negative score based on a lack of testing on the chemical itself, because the structure of the chemical is sufficiently similar to other well-tested chemicals that expert toxicologists could reasonably draw conclusions about its safety. As an additional caveat, Dow noted that tests outside the categories established in the OECD screening process should in some cases be considered superior to OECD-required tests, and thus that a chemical could in fact have been adequately tested for screening purposes notwithstanding a negative score based on the lack of an OECD-required test.

DuPont's difference with the overall score of one of its chemicals was based on a publicly available study that EDF's research did not locate. EDF confirmed that the study was appropriate and adequate to change the relevant score; i.e., that DuPont was correct. EDF did not locate the study because it lay outside the boundaries of the computer search methodology that EDF used. (This occurred in part because no abstract of the study existed on any of the relevant computer databases.) EDF's computer search methodology is discussed in detail in Appendix I.

Although incomplete (covering only 17 out of 100 chemicals), this review by Dow and DuPont provides additional confidence that the scoring of chemicals in EDF's random sample is accurate enough to be used as representative of high-production-volume chemicals in general for purposes of this report.<sup>11</sup>

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CHAPTER II NOTES

<sup>1</sup> National Research Council, Toxicity Testing (Washington, D.C.: National Academy Press, 1984), Table 7, p. 84. Findings for other categories of chemicals (e.g., chemicals with smaller production volume) are shown in the same table. The study's definition of "minimal toxicity information" appears in Table 3 on p. 47.

<sup>2</sup> As of October 1996, there were 75,857 chemicals in EPA's TSCA Inventory. The Inventory covers chemicals manufactured in the U.S., with certain important exceptions such as pesticides, food additives, and drugs. See discussion of TSCA in Chapter III.

<sup>3</sup> EPA's list can be obtained as digital media from the agency's Office of Pollution Prevention and Toxics. Pesticides and food additives are excluded from the listing as high-production-volume chemicals because of provisions in the Toxic Substances Control Act. Some chemicals are included in more than one of these categories.

<sup>4</sup> For analyzing the availability of hazard identification data, this report uses a sample of one hundred chemicals, the same size sample as used by the National Research Council in its 1984 study. See note 1 *supra*.

<sup>5</sup> The 1984 report presented results for other categories of chemicals as well. See note 1 *supra*.

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<sup>6</sup> 74% of high-priority compounds have been tested using at least one acute inhalation study; 50% have been examined using exposures lasting longer than 24 hours; and only 32% have been examined using lifetime inhalation exposures.

<sup>7</sup> The Toxics Release Inventory is discussed in more detail in Chapter IV below.

<sup>8</sup> U.S. Environmental Protection Agency, Office of Solid Waste and Office of Pollution Prevention and Toxics, Waste Minimization Prioritization Tool, Beta Test Version 1.0, User's Guide and System Documentation, Draft (Washington, D.C.: U.S. EPA, 1997), Exhibit B-1, p. B-1. Internet/WWW [address: <http://www.epa.gov/epaoswer/hazwaste/minimize/tool/tooldown.htm>].

<sup>9</sup> EDF initially identified 25 chemicals in its sample as Dow or DuPont chemicals, using the National Library of Medicine's Hazardous Substances Data Bank and the 1996 Directory of Chemical Producers: USA compiled by SRI International. However, for seven of the chemicals, the companies informed EDF that manufacturing of the chemical had either ceased or had been transferred to another entity (i.e., that the HSDB or SRI information was out of date). For one additional chemical, Dow informed EDF that it was inappropriate to consider Dow responsible for the chemical because it was manufactured on contract for a non-Dow business entity.

<sup>10</sup> Each chemical in the random sample first received yes-or-no scores for each of six categories of hazard identification testing. Those were then combined into an overall yes-or-no score for each chemical, indicating whether or not there had been sufficient testing to satisfy the OECD screening requirements. For the chemicals reviewed by Dow or DuPont, they agreed with EDF on 99 out of 108 scores for individual categories. Eliminating differences based on private studies or structural analogies to other chemicals (see text), which EDF intentionally excluded, there was agreement on 104 of 108 scores.

<sup>11</sup> Dow and DuPont each participated willingly and generously in this review. However, each company's participation was limited to reviewing the scoring of its own chemicals for purposes of satisfying the OECD screening requirements. Neither company should be understood to have made any judgment about the scoring of any chemicals other than its own, or about the significance of satisfying or not satisfying the OECD requirements. As indicated above, the companies believe that other forms of information, apart from the information scored by EDF, is also relevant to identification of chemical hazard.

**TOXIC IGNORANCE**

### III. The Failure of Federal Testing Requirements

Chemical safety is the opposite side of the same coin as chemical risk. Both require knowledge before they can be demonstrated. A system that is very slow in testing chemicals for their hazards is, necessarily, even slower in being able to establish their safety.

Yet assurance of safety is the purpose of toxic chemical control laws.<sup>12</sup> This is the public's understanding, and also the understanding of the chemical industry; "safe" is the term commonly used by the chemical industry to describe its products and activities.<sup>13</sup> Thus, the impossibility of giving any safety assurance for thousands of chemicals that we know are widely used and hundreds that we know are released to the environment is a fundamental failure. It is a failure not of degree but of kind. This chapter explains how a key federal law has led to that failure.

More than 20 years ago, Congress recognized that lack of data was a potential Achilles' heel for control and prevention of toxic chemical risks. In 1976, it 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 and those who

*More than 20 years ago, Congress recognized that lack of data was a potential Achilles' heel.*

process such chemical substances and mixtures.

15 U.S.C. § 2601(b).

*“The development of data should be the responsibility of those who manufacture and process chemical substances”*

*15 U.S.C. § 2601(b)*

The law that established this policy, and was intended to carry it out, was the Toxic Substances Control Act (TSCA), which created omnibus authority to require chemical testing and to impose controls as necessary.

Two decades later, this policy is largely defunct.<sup>14</sup> Chapter II has shown that even the first, minimal step of screening for toxicity has not been completed for most of the chemicals in the highest priority category, much less for commercial chemicals in general.

The primary cause of TSCA’s failure, notwithstanding its clear policy goal, is its self-defeating legal structure,<sup>15</sup> discussed below. In addition, the Environmental Protection Agency in the past has been less than aggressive in seeking to carry out the law’s provisions. A report from the General Accounting Office in 1984 concluded that EPA had been slow in implementing a chemical testing program under TSCA.<sup>16</sup> A followup report six years later found the same problem and noted the continuing absence of any “overall program objectives or strategy” on EPA’s part.<sup>17</sup> In the last few years, EPA has begun to show significant improvement in comparison to previous years,<sup>18</sup> but not in comparison to the size of the task that faces it, and the agency’s ability to improve is bound by the design of the statute itself. Yet as recently as 1996, the chemical manufacturing industry has reiterated its position that “[t]here are no fundamental flaws in TSCA” and that the law should not be revised.<sup>19</sup>

The Toxic Substances Control Act has several provisions that authorize EPA to compel production of data on potentially toxic chemicals. For chemicals already on the market, EPA may issue testing requirements to fill in the blanks when “there are

insufficient data and experience” to determine the effect of a chemical “on health or the environment”<sup>20</sup>; may direct chemical manufacturers to submit unpublished studies they know about; and may require chemical manufacturers and processors to provide certain basic information on request (e.g., fill out a two-page form on chemical quantities produced, use patterns, releases, and worker exposures).<sup>21</sup> Manufacturers and processors also have a duty to tell EPA if they have information “that supports the conclusion that [the chemical] presents a substantial risk of injury to health or the environment.”<sup>22</sup>

In addition to these data-oriented provisions, TSCA also allows EPA to regulate chemicals directly. EPA may prevent “unreasonable risks” from toxic chemicals, by applying measures ranging from labeling up to and including a partial or complete ban on the chemical’s sale.<sup>23</sup> Finally, for new chemicals not yet on the market, EPA reviews data that must be submitted 90 days before a new chemical is manufactured or processed. To fill data gaps, EPA may require additional testing before the chemical is allowed to be marketed, and EPA may limit production or use if the chemical poses an unreasonable risk.<sup>24</sup>

Together, these provisions of the Toxic Substances Control Act sound as though they would offer formidable protection against harm from toxic chemicals. It is worth a brief explanation to show why they work so poorly in practice, and why they were doomed from the start.

### **A. TSCA Section 4 — testing and review of existing chemicals**

Section 4 of TSCA is the key testing section, the one most directly aimed at curing the problem of lack of testing data about chemicals in commercial use. In theory it authorizes the Environmental Protection

Agency to issue so-called test rules, to require testing and reporting of information about almost any chemical.<sup>25</sup>

Unfortunately, the actual provisions of Section 4 put EPA into a Catch-22: the agency must already *have* data in order to show that it *needs* data. It must do so not only chemical by chemical, but even test by test for each chemical. Even though a testing law is obviously supposed to combat ignorance about chemicals, this one is written so that ignorance about chemicals can keep it from working.<sup>26</sup>

Using all Section 4 measures combined, EPA has developed testing actions on only 263 chemicals in the past 20 years,<sup>27</sup> most of them recently.<sup>28</sup> Using as an example EDF’s random sample of chemicals (discussed in Chapter II), only five of the 71 chemicals lacking minimum safety screening data have been subjected to any Section 4 testing requirement under TSCA. Of those five test rules, three fail to address major data gaps on specific human health impacts.<sup>29</sup> Even taking into account the recent upswing in activity to about 65 actions per year,<sup>30</sup> testing of existing chemicals under TSCA is making only a modest dent in the backlog of untested chemicals. EPA has now developed a Master Testing list that identifies the highest priorities for testing, which covers approximately 500 chemicals.<sup>31</sup>

*Only five of the 71 sample chemicals lacking minimum safety screening data have been subjected to any TSCA Section 4 testing requirement.*

## **B. TSCA Section 5 — screening new chemicals before they are manufactured**

For new chemicals, as opposed to existing ones, Section 5 of TSCA appears to give the Environmental Protection Agency stronger tools. It allows EPA to pre-screen any new chemical before it is manufactured, and it requires a “pre-manufacture notification” (PMN) that must include certain information on the new chemical.

However, as with Section 4, the requirements of Section 5 were written in such a way that the law's theory can easily be defeated in practice. First and most obvious, under the regulations adopted to implement Section 5, **it is only optional and not mandatory for a pre-manufacture notice to include any actual data on a chemical's toxicity.**<sup>32</sup> Over half of pre-manufacture notifications are submitted with no toxicity data at all.<sup>33</sup> By contrast, European nations require a defined set of actual test results for new chemicals.<sup>34</sup>

In addition, the contents of a pre-manufacture notification are not binding, and thus there is no incentive for a manufacturer to insure that its original submission is accurate and reliable. Once the Environmental Protection Agency has reviewed a chemical based on its pre-manufacture notification, the manufacturer does not need to limit uses or production levels to those described in the notification.<sup>35</sup> Manufacturers can even change the contents of the document while it is being reviewed.

Within these severe restrictions, imposed by Congress in the structure of the Toxic Substances Control Act, EPA has tried to make the best of what little information on new chemicals that it does have the right to receive. In the absence of testing data, it has become a leader in the use of Structure-Activity Relationship (SAR) analysis, which tries to predict a chemical's likely toxicity based on its chemical structure. Limited experience to date suggests that the usefulness of SAR analysis varies considerably depending on the particular chemical characteristic sought to be predicted. One study, jointly sponsored by the U.S. Environmental Protection Agency and the European Community, showed very poor correlations between SAR predictions and actual test results for certain health effects and other chemical characteristics, relatively good correlation for at least

one health effect, and did not examine some other important health effects.<sup>36</sup>

Thus, the apparently comprehensive power under Section 5 for EPA (a) to obtain information on new chemicals before they are manufactured, and (b) to impose any needed controls on them as a condition of their being allowed to be manufactured, has been effectively given back to the manufacturers themselves. Conscientious manufacturers of new chemicals may submit full screening data in their pre-manufacture notifications, but they are currently not required to meet any minimum testing requirements similar to the requirements adopted by the OECD Chemicals Program.

### **C. TSCA Section 6 — catch-all authority for controls**

In addition to testing and screening for existing and new chemicals, the Toxic Substances Control Act includes a section explicitly authorizing the Environmental Protection Agency to take action to control risks from toxic chemicals, ranging from labeling to outright ban. Section 6 allows EPA to proceed against any chemical that presents an “unreasonable risk of injury to health or the environment.”<sup>37</sup>

Nevertheless, the need to have enough information to show “unreasonable risk” has been enough to stymie EPA’s use of Section 6 almost completely. In the law’s 20-year history, regulatory actions under Section 6 have been taken against only five chemicals or chemical classes.<sup>38</sup> The chemical industry itself describes the number of Section 6 actions as “very few.”<sup>39</sup> The way the law was written virtually guaranteed that it would be only rarely applied.

*In the law’s 20-year history, regulatory actions under TSCA Section 6 have been taken against only five chemicals.*

## CHAPTER III NOTES

<sup>12</sup> See, e.g., the title of the *Safe Drinking Water Act* [emphasis added], 42 U.S.C. Sec. 300f *et seq.* (West 1991 & Supp. 1997). Different laws use different legal language to express the idea of safety. Most recently, in the Food Quality Protection Act of 1996, Congress defined it as a "reasonable certainty [of] no harm." 21 U.S.C. 346a, (b)(2)(A)(ii), amending Sec. 408(b)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act. This definition clearly reflects that the goal is not perfect safety or total absence of any possible harm, but rather a high degree of reasonable assurance.

<sup>13</sup> See, e.g., the 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 (Arlington, VA: Chemical Manufacturers Association, 1996), p. 8. 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 (1995), p. 2. 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, Internet/WWW [address: <http://www.ciit.org/AnnualReports/AR96.html>].

<sup>14</sup> 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). See also following footnotes.

<sup>15</sup> See generally GAO, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (GAO/RCED-94-103, September 1994). Throughout TSCA's history, chemical manufacturers have used the weaknesses of the law to sue EPA and delay its efforts to require chemical testing. Two appellate courts noted that EPA bears a higher burden of justifying regulatory action under TSCA than under the traditional "arbitrary and capricious" standard that applies to federal agency actions

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generally. Shell Chemical v. EPA, 826 F.2d 295, 297 (5th Cir. 1987); Auismont U.S.A. Co. v. EPA, 838 F.2d 93, 96 (3rd Cir. 1988). See also Chemical Manufacturers Association v. EPA, 859 F.2d 977 (D.C. Cir. 1988).

<sup>16</sup> GAO, EPA's Efforts to Identify and Control Harmful Chemicals in Use (GAO/RCED-84-100, June 13, 1984).

<sup>17</sup> GAO, EPA's Chemical Testing Program Has Made Little Progress (GAO/RCED-90-112, April 25, 1990), p.3.

<sup>18</sup> See discussion below regarding test rules. In addition, during 1997, EPA is developing a specific Toxics Agenda to "systematically address[ ]" chemicals covered by TSCA. Presentation of William Sanders, Director, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, at TSCA 20th Anniversary Conference, November 12, 1996, Arlington, VA.

<sup>19</sup> Comments of Chemical Manufacturers Association on the Report of the Risk Assessment and Risk Management Commission, August 13, 1996, pp. 41-42: "CMA does not agree that Congress needs to rewrite or revise TSCA. TSCA is a risk-based statute and provides EPA with all of the authority and flexibility necessary for EPA to protect human health and the environment from unreasonable risks posed by new and existing chemicals."

<sup>20</sup> TSCA Section 4, 15 U.S.C. Section 2603 (West 1982), P.L. 94-469, 90 Stat. 2003.

<sup>21</sup> TSCA Section 8, 15 U.S.C. Section 2607 (West 1982).

<sup>22</sup> *Id.*

<sup>23</sup> TSCA Section 6, 15 U.S.C. Section 2605 (West 1982).

<sup>24</sup> TSCA Section 5, 15 U.S.C. Section 2604 (West 1982).

<sup>25</sup> TSCA's jurisdiction does not include some important categories of chemicals that Congress viewed as adequately addressed by other statutes, namely pesticides; tobacco products; certain nuclear materials; ammunition; and foods, food additives, cosmetics, drugs, and medical devices regulated by the Food and Drug Administration. TSCA Section 3(2)(B), 15 U.S.C. 2602(2)(B) (West 1982).

<sup>26</sup> Before EPA can issue a test rule (i.e., ask for testing) on a specific chemical, the agency must first show either (i) that the chemical may present an "unreasonable risk" or (ii) both that it is produced in major quantities and that either "substantial" exposures are occurring in quantitative terms (e.g., numbers of people exposed, or pounds being released) or that "significant" exposures are occurring in qualitative terms (a case-by-case

determination of the impact of exposures). Obviously, “substantial” exposures cannot be proven if quantitative information on releases of the chemical or exposures to the chemical is lacking. And “significant” exposures cannot be proven without information on the chemical’s toxicity. When EPA does have a basis for worrying about a specific chemical’s risk to health or the environment, but a factual question like the amount of exposure to that chemical remains in doubt, EPA can proceed only “where there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic at that level of exposure to present ‘an unreasonable risk to health.’” Chemical Manufacturers Association v. EPA, 859 F.2d 977, 984 (D.C. Cir., 1988). In addition, before issuing a test rule, EPA must also show that existing data are insufficient, and that testing is “necessary.” Industry can trip EPA in court on either of these hurdles as well.

<sup>27</sup> Environmental Protection Agency, Chemicals On Reporting Rules Database (CORR) (1996), Internet/WWW [address: <http://www.epa.gov/docs/CORR>].

<sup>28</sup> Presentation by Lynn R. Goldman, M.D., Assistant Administrator, EPA Office of Prevention, Pesticides, and Toxic Substances, “Successes and Lessons Learned During 20 Years of the Toxic Substances Control Act,” p. 3. TSCA 20th Anniversary Conference, Arlington, VA, November 12, 1996. Dr. Goldman’s talk indicates testing actions on 550 chemicals; the discrepancy with EPA’s database (see previous footnote) is unclear.

<sup>29</sup> For example, EPA’s test rule for 1,3-dichlorobenzene requests voluntary provision of biodegradation test results, but it does not address the complete lack of data on reproductive and developmental toxicity for 1,3-dichlorobenzene.

<sup>30</sup> Goldman, *supra* note 28.

<sup>31</sup> 61 Fed. Reg. 65936 (December 13, 1996).

<sup>32</sup> The U.S. Pre-Manufacture Notification (PMN) requires only the following information:

- the substance’s chemical identity and structure, and impurities “anticipated to be present”;
- byproducts from the manufacturing, processing, use, and disposal of the new substance;
- estimated maximum amount to be manufactured or imported during each of the first three years of production; and
- to the extent known, worker exposure and environmental release information, intended uses, and locations where the new substance will be handled.

40 CFR 720.45

<sup>33</sup> GAO 94-103, p. 34.

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<sup>34</sup> Union Directive 79/831/EEC (1979, amending 67/548/EEC) requires any manufacturer or importer who markets more than one metric ton of a “new” substance to submit a notification dossier that includes results of the “Base Set” of tests, including physical and chemical properties; acute toxicity; sub-chronic toxicity (28-day study); mutagenicity; ecotoxicity; and environmental degradation. When the marketing levels for a substance exceed 10 metric tons annually, authorities may require additional data; at levels above 100 and 1000 metric tons annually, additional data requirements automatically apply (known as Level 1 and Level 2 testing packages). U.S. Environmental Protection Agency, Office of Pollution Prevention, Pesticides, and Toxic Substances, U.S. EPA/E.C. Joint Report on the Evaluation of (Quantitative) Structure Activity Relationships, Doc. No. EPA 743-94-001, Washington, D.C., 1994.

<sup>35</sup> GAO 94-103, *supra* note 15, p. 32. On occasion, when learning that EPA was considering controls on a chemical, manufacturers have reportedly gone back and lowered the exposure estimate for the chemical in the PMN to avoid EPA action. They have also revised PMNs to show lower releases than previously estimated, and added claims that the chemical will be used in a zero-release system. GAO 94-103, p. 37.

<sup>36</sup> U.S. EPA, Doc. No. EPA 743-94-001, *supra* note 34. As the report noted, “the project is not, and was not designed to be, an evaluation of [SAR] techniques in general.” *Id.*, p. 3. Because the European Union’s base data set does not include studies on most types of chronic toxicity, some critically important endpoints were not assessed at all.

<sup>37</sup> TSCA Section 6(a), 15 U.S.C. Section 2605(a) (West 1982).

<sup>38</sup> Final rules have been issued for: dioxin waste disposal; hexavalent chromium use in cooling towers; polychlorinated biphenyl manufacturer prohibitions (rule mandated by statute); metal fluids; and lead paint disclosures. In addition, two proposed rules have been issued: banning acrylamide grouts; and banning lead fishing sinkers.

<sup>39</sup> CMA, Overview, *supra* n. 13, at 3.

## IV. Hints of Progress

The failure to obtain necessary minimum data on commercially important chemicals has been no secret to those directly involved. To try to fill in for the failures of regulatory government in this area, there have been various attempts to deal with the lack of data on chemicals through other means.

Voluntary efforts by the chemical industry to address the problem have generally been disappointing, at least to the extent of generating data that are publicly available.<sup>40</sup> The analysis in Chapter II above has covered virtually all reliable testing data that are available through public sources<sup>41</sup>, whether voluntary or mandated, and it has shown how unsatisfactory the results have been.

However, one international effort has gone far toward recognizing and defining the problem of lack of preliminary screening data. At the same time, one federal law with a new approach has shown how to stimulate much faster progress than would seem possible from experience with the Toxic Substances Control Act.

### **A. The SIDS Program — Recognizing the Problem**

In 1990, with extensive participation from industry, the Organisation for Economic Cooperation and Development took a major step by creating an international program to obtain basic information on high-volume chemicals.<sup>42</sup> The very name given to this

effort is itself a significant contribution. The Screening Information Data Set (SIDS) program emphasizes the idea of screening chemicals on the basis of a minimum or preliminary set of basic data about them (see accompanying chart). The OECD program helps to clarify and define the problem of lack of chemical information, and it undertakes to address the problem directly.

One important attribute of the OECD program is the sharing of the costs of testing among countries and among industries. Depending on how much testing had already been performed for a specific chemical, completing the screening information data set can cost between \$20,000 to \$150,000 per chemical, according to OECD estimates.<sup>43</sup>

### OECD SCREENING INFORMATION DATA SET ELEMENTS<sup>44</sup>

1. General Information
  - Substance information
  - CAS-number
  - Name (OECD name)
  - CAS descriptor
  - Structural formula
  - Quantity (production ranges)
  - Use pattern (categories and types of use)
  - Sources of exposure
2. Physical-Chemical Data
  - Melting point
  - Boiling point
  - Relative density
  - Vapor pressure
  - Partition coefficient: n-Octanol/water
  - Water solubility
  - Dissociation constant
  - Oxidation-reduction potential
3. Environmental Fate and Pathways
  - Photodegradation (by estimation)
  - Stability in water (by estimation)
  - Monitoring data (environmental)
  - Transport and distribution between environmental compartments
  - Aerobic biodegradability
4. Ecotoxicological Data
  - Acute toxicity to fish
  - Acute toxicity to daphnids (chronic toxicity if there is concern for possible long-term effects)
  - Toxicity to algae
  - Appropriate terrestrial toxicity tests (if significant exposure is expected in the terrestrial environmental compartment or aquatic testing is not possible)
5. Toxicological Data
  - Acute toxicity
  - Repeated dose toxicity
  - Genetic toxicity (in vitro)
  - Genetic toxicity (in vivo)
  - Reproductive toxicity
  - Developmental toxicity/teratogenicity

Unfortunately, the program has been very slow in actually producing the information it seeks, as even some industry participants have noted.<sup>45</sup> To date, work has begun on 322 chemicals.<sup>46</sup> As of mid-1996, screening had been completed for 99 chemicals, with another 223 chemicals still in the pipeline at various stages.<sup>47</sup> Each year approximately 80 additional chemicals are added to the process. At the program's current pace, assessments of the currently targeted 2,500 chemicals would take another 25 to 30 years to complete, although some may be addressed by other international organizations.<sup>48</sup> Meanwhile, with the expansion of the global economy and with changes in materials production and use, the number of chemicals in the targeted category can be expected to grow.

Of course, collecting the necessary screening data for hazard identification is only a first step. It provides enough preliminary data and toxicity test results to allow a reasonable judgment on whether further testing is needed. Some chemicals will require more extensive and detailed information to determine health hazards. For others, preliminary data may be enough to conclude that they probably pose minimal risk. However, under the OECD program, there is no international obligation on government or industry to take any action in response to the screening data, whether this involves more testing or reducing exposures. These activities are beyond the program's scope and are up to individual nations. As far as the OECD program is concerned, "[T]he overall responsibility for initiating and undertaking any [post-SIDS] work rests with industry."<sup>49</sup> There are no incentives or requirements<sup>50</sup> for doing so.<sup>51</sup>

*At the current pace, SIDS assessments would take another 25 to 30 years to complete.*

## **B. The Toxics Release Inventory — Mandated Reporting and Public Disclosure**

Eleven years ago, acknowledging the public's right to know about toxic chemicals, Congress required certain industrial facilities to report annually to the U.S. Environmental Protection Agency on the amounts of each of 329 specific chemicals that they release into the environment, creating what is known as the Toxics Release Inventory (TRI). The agency then makes that information available to the general public.<sup>52</sup> The listing criteria reflect some preliminary judgment as to a chemical's potential harm,<sup>53</sup> and the number of chemicals or chemical classes subject to the reporting requirements has since risen to 654.<sup>54</sup>

Getting this information and making it public has had a well-recognized effect. According to the Environmental Protection Agency, between 1988 and 1994, facilities covered by the law reduced their reported releases of chemicals on the TRI list by 44 percent, or 1.6 billion pounds.<sup>55</sup> Chemical company executives have acknowledged that the Toxics Release Inventory made them aware — in many instances for the first time — just how much pollution they were emitting and had a major impact in stimulating them to cut back on those emissions.<sup>56</sup>

It is important to note, as many observers have, that the success of the Toxics Release Inventory comes purely from the power of information. Nothing in the law that created it imposed any new controls on chemicals. Companies acted to reduce their releases of chemicals after those releases were (or were about to be) announced to the public. The chemical manufacturing industry's reaction to the law has been erratic. Although its lead trade association publicly praises the law,<sup>57</sup> the same trade association recently sued to try to prevent the Environmental Protection

*The success of the Toxics Release Inventory comes purely from the power of information.*

Agency from expanding the number of chemicals on the Toxics Release Inventory list.<sup>58</sup>

What the Toxics Release Inventory has accomplished is to show that disclosure can work as a strong incentive to improved industrial behavior with chemicals, even when information is lacking about the degree of hazard those chemicals may pose. TRI proved that a disclosure system by itself could offer important rewards for early, non-compulsory action, and that those rewards would work. By inviting public comparisons between individual companies, it can have the effect of stimulating competition among those companies for improvement.

However effective once mobilized, TRI's incentive depends on the existence of at least a partial preliminary hazard identification, for each chemical in question, sufficient to support its being placed on the TRI list. TRI does *not* address the problem of complete lack of hazard identification, as the OECD minimum screening information data set program does. For chemicals not included on the TRI list, there are no incentives or rewards for manufacturers to conduct tests or otherwise improve the knowledge base. But the incentive strategy embodied in TRI can also be used to stimulate hazard identification activity by spotlighting those chemicals for which data are lacking. The next chapter describes how.

*Disclosure can work as a strong incentive to improve industrial behavior with chemicals, even when information is lacking.*

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#### CHAPTER IV NOTES

<sup>40</sup> There is, of course, no way to quantify the testing and other data on specific chemicals that may be in private hands.

<sup>41</sup> The methodology used to search publicly available databases, with the identity of the databases, is explained in Appendix I.

<sup>42</sup> Organisation for Economic Cooperation and Development Secretariat, SIDS Manual (Second Revision): Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals, (Paris, France: May 1996), Ch. 1, p. 3. OECD defines "High Production Volume" chemicals as those produced in quantities above 1,000 metric tons (2,200,000 lbs.) annually in each of any

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two OECD member nations, or more than 10,000 metric tons (22,000,000 lbs.) annually in any one member nation. Currently, there are about 2,500 compounds on OECD's High Production Volume list, which was last updated in 1995.

<sup>43</sup> Turnheim, "Evaluating Chemical Risks," The OECD Observer, No. 189, August/September 1994, pp. 12-15.

<sup>44</sup> SIDS Manual, *supra* note 42, Ch. 2, pp. 2-3. Some elements of the box have been rephrased slightly for brevity. Exposure data are also requested as part of the minimum data set.

<sup>45</sup> Chemical Manufacturers Association, Environment, Health, Safety, and Operations Committee, Chemicals Testing Task Group, "The OECD Cooperative Investigation of High Production Volume Chemicals: Review of Program Status, 1996," (May 1997), p. 14 (noting that "a number of companies that have [participated in SIDS] . . . have expressed concern about the slow pace of movement through the SIDS process").

<sup>46</sup> Personal communication, Dian Turnheim, Principal Administrator, OECD Environmental Health and Safety Division, to Karen Florini, EDF, March 3, 1997.

<sup>47</sup> Testing is not conducted directly by the OECD; actual testing is carried out under the sponsorship of an OECD member nation, generally by a chemical manufacturer. Turnheim, *supra* note 44.

<sup>48</sup> SIDS dossiers on individual chemicals are provided to the International Program on Chemical Safety, a joint project of the United Nations Environment Program, the World Health Organization, and the International Labor Organization. IPCS in turn may use them in preparing Health and Safety Guides, or Environmental Health Criteria documents. SIDS Manual, *supra* note 42, Ch. 1, p. 9. However, there is no mechanism to enforce the guides or the criteria documents, unless and until they are used as the basis for regulatory action by individual governments.

<sup>49</sup> SIDS Manual, *supra* note 42, Ch. 1, p. 8.

<sup>50</sup> See discussion *supra* note 48.

<sup>51</sup> The OECD has recently established an Advisory Group on Risk Management that is charged with "accelerating priority risk reduction," but no specific measures have been adopted as of July 1997.

<sup>52</sup> Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. Sec. 11001-11050 (West 1995), P.L. 99-479, 100 Stat. 1613.

<sup>53</sup> The 329 chemicals which Congress placed on the TRI list at the outset came from preexisting lists developed by the States of Maryland and New Jersey. EPA was authorized to delete

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chemicals which turn out not to meet the law's specified criteria for listing, as well as to add chemicals which do. A chemical may be listed if it is known or anticipated to cause significant acute effects beyond the facility boundary; to cause chronic effects such as cancer, neurological disorders, or other chronic effects; or to cause adverse effects on the environment.

<sup>54</sup> 40 CFR 372.65. In addition to manufacturing facilities covered by the program to date, seven additional industry sectors will also have to report, beginning in 1997, under a final rule announced by President Clinton on April 22, 1997 (Earth Day).

<sup>55</sup> 61 Fed. Reg. 51322 (Oct. 1, 1996). Because of concerns about the accuracy of reports filed in the program's first year (1987), EPA generally uses the year 1988 as the baseline. Between 1987 and 1992, production of basic industrial chemicals increased by 18%. Chemical Manufacturers Association, "Responsible Care Communication," March 10, 1995, Internet/WWW [address: <http://es.inel.gov/techinfo/facts/cma/cmacommo.html>].

<sup>56</sup> Examples:

- "In the long history of legislation in the United States, passage of Title III in 1986 was the most important for Monsanto Company." — Earl Beaver, Monsanto; Proceedings, International Conference on Reporting Releases of Toxic Chemicals, November, 1991.
- "[The first TRI data] shocked a lot of the industry folks, the magnitude of these releases. It really hit home. People from boardrooms all the way down to plants recognized they had to get aggressive to try to find ways to reduce these emissions." — Dan Borne, Louisiana Chemical Association; The Times-Picayune, February 17, 1991.
- "[TRI] really forced us to look at the numbers in a condensed way, and it dawned on us that these were some big numbers. Maybe it's just a big number, but people don't like that." — Randy Emery, Amoco; Houston Chronicle, July 24, 1989.
- "It's not necessarily that we didn't want to [reduce emissions] before. We never had the information we needed to know if progress was being made." — Steven Schoger, BP Chemicals (Cleveland, Ohio); Occupational Hazards, July 1991.

See generally Working Group on Community Right-to-Know, "What Industry Has Said About TRI," July 1995.

<sup>57</sup> "We continue to believe that T.R.I. has been a very successful venture. Our members have gotten behind it and witnessed a 50 percent reduction in pollution." — Mort Mullins, Chemical Manufacturers Association; quoted in The New York Times, June 28, 1995.

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<sup>58</sup>National Oilseed Processors Association, Chemical Manufacturers Association, et al., v. EPA, 924 F. Supp. 1193 (D.D.C. 1996), appeal docketed *sub nom.* Troy Corporation, et al. v. Browner, No. 96-5188 (D.C. Cir. 1996). The trial court in the case concluded that “EPA went to great lengths to separately evaluate each and every chemical on the basis of the relevant data,” 924 F. Supp. at 1217.

## V. Recommendations

In a world of chemicals, the most basic policy question is what to do in the face of lack of information.

The steps that are suggested in this chapter are intended to shift incentives away from the status quo, in order to begin to discourage commercial use of massive quantities of chemicals that have not at least been screened for basic toxicity. To be effective, incentives should stimulate both (a) the gathering and disclosure of screening information about major chemicals and (b) early actions to reduce the use of and prevent exposures to chemicals that have been identified as hazardous or that have not been screened.

Considering incentives does not mean ignoring or abandoning direct requirements on manufacturers to test their chemicals. The 20-year failure of the Toxic Substances Control Act does not mean that testing requirements are necessarily futile; it means only that, to work, they need to be much better designed. Merely adding agency staff and laboratory resources or enforcement authority to existing TSCA requirements will *not* significantly improve performance in getting the necessary tests performed and the necessary information to the public. The law itself will have to be rewritten to get the necessary design changes.

*The most basic policy question is what to do in the face of lack of information.*

## A. A right to know what we *don't* know

Thanks to the Toxics Release Inventory, members of the public now have the right to know about some potential sources of exposure to a few hundred chemicals with partially known risks. It is a right they appreciate and have come to expect. In just the same way, they should have the right to know about possible sources of exposure to important chemicals that have *unknown* risks.

*Labeling ignorance as ignorance, rather than safety, is an important first step.*

### 1. Disclose the status of knowledge about individual chemicals

Labeling ignorance as ignorance, rather than safety, is an important first step. Either government or private parties can publicize the state of scientific knowledge (and ignorance) about individual chemicals. Much specific information, or the fact that such information is absent, can now be compiled on a chemical-by-chemical basis; the database described in Appendix I and used in this report is an example. With modest additional resources, such databases can be made readily searchable by any member of the public and can be made available to the public on the Internet. This information can and should become a basic element of right-to-know policy about chemicals in substantial circulation in commerce.

### 2. Define the criteria for minimum necessary screening information

Apart from creating effective public access to what is and is not already known, government can take an important definitional step. Using current science, it can determine what constitutes a minimum necessary set of scientific data for a given chemical that makes it possible to screen that chemical for safety, on a preliminary basis.

The advantage of a clear definition is simplicity. A chemical either would, or would not, meet the defined criteria for minimum screening information.

Once determined, this kind of status is easy to communicate to a wide audience.

The OECD minimum screening information data set, discussed above in Chapter IV, is one example of such a definition. The OECD criteria can be used immediately as an interim definition, to be replaced when U.S. EPA or another designated independent agency completes its own. An existing definition that takes effect in the interim is critical, in order to act as a disincentive to prolonged delay.

It is important to use criteria that are appropriate for early screening, as OECD has done, rather than making the criteria so comprehensive that meeting them in the near future is not feasible. It is equally critical that the definition be able to be updated easily whenever there are significant advances in scientific techniques or awareness of hazards (e.g., the emerging problem of environmental endocrine disruptors). For example, it has been predicted that advances in molecular toxicology will make animal testing and other current screening methods obsolete.<sup>59</sup> If so, a definition that required specific tests as screening requirements would need to be promptly revised.

### **3. Identify Toxics Release Inventory chemicals that have not been screened for safety**

If any chemical on the Toxics Release Inventory does not have available the minimum information necessary for health safety screening, the public's right to know should include that fact as part of all reports of the chemical's release. This would accurately convey to the public the unknown nature of the risk represented by releases of such a chemical. It would also create a useful incentive for manufacturers or users of TRI-listed chemicals to acquire the necessary data to avoid such a designation.<sup>60</sup>

**4. Report on releases of unscreened chemicals — an “Unknowns Release Inventory” (URI)**

A reporting system parallel to the Toxics Release Inventory should be established for releases of major chemicals that do *not* have available the minimum information necessary for safety screening. Such an Unknowns Release Inventory, a “URI,” would give force and effect to the public’s right to know about all major *unscreened* chemicals to which the public is being exposed. The number of chemicals involved would depend on how quickly the manufacturers or releasers of the chemicals in question choose to generate and disclose the necessary data.

*An Unknowns Release Inventory would give force and effect to the public’s right to know about all major unscreened chemicals to which the public is being exposed.*

This step should take effect only after a reasonable grace period expires, in order to give responsible industries a reasonable time to produce the necessary data and thus avoid URI listing for their chemicals by demonstrating — through screening data — that the chemicals pose low enough risks that reports are unnecessary. Avoiding URI reporting requirements would presumably be a substantial incentive for a chemical’s manufacturer or user to produce the data. For those that choose not to, the public will at least have useful information on the location and quantity of some of the major industrial sources of the chemicals in question.

The coverage of a URI should also be phased in over time, beginning with chemicals in the largest-volume category (e.g., over 1,000,000 lbs./yr.) and eventually reaching all chemicals within the TRI “high volume” category (e.g., over 10,000/lbs.yr.). An appropriate phase-in, with three steps, might provide a one- or two-year grace period for chemicals in the 1,000,000 lbs./yr. category; another two years for chemicals between 100,000 lbs./yr. and 1,000,000 lbs./yr.; and additional years for chemicals between 10,000 lbs./yr. and 100,000 lbs./yr.

Other chemicals of special importance — for example, those with high worker exposure or particular health or environmental dangers identified in the course of existing regulatory programs — could also be placed in Phase I, II, or III, independent of volume criteria. For example, for a hazardous air pollutant already identified by Congress but not yet screenable due to lack of testing data, it would make no sense to wait several additional years before adding it to a URI list simply because its total production volume is less than 1,000,000 lbs./yr.

A URI should also have an automatic exclusion for one set of chemicals that, as a class, is very unlikely to present health hazards — i.e., high-molecular-weight polymers — and authority for EPA to exclude other individual chemicals or chemical classes on similar grounds after a sufficient scientific showing as defined in the law.

## **B. Alterations in legal status for chemicals that cannot be screened for safety**

Chemicals in substantial commercial use in the U.S. hold legal status and thereby enjoy certain legal privileges, some more widely recognized than others. Their status and their privileges depend, in large part, on an assumption that the chemicals are not posing unacceptable harms to human health or to the environment. If they were, then the regulatory system should — in theory — have already banned or restricted their use. As this report documents, this presumption of safety is most often based on ignorance rather than on any reliable scientific information.

Once it is recognized that a chemical's status and privileges depend on a presumption of safety, it is obvious that a failure to justify that presumption should result in progressive withdrawal of legal

*A failure to provide test results should cause progressive withdrawal of legal privileges over time.*

privileges over time. The examples below are illustrative rather than comprehensive.

**1. Lower the threshold for TSCA testing**

As discussed in Chapter III, Section 4 of the Toxic Substances Control Act requires the Environmental Protection Agency to have substantial data in hand before it can require testing on existing chemicals. If a high-production-volume chemical cannot meet minimum screening data requirements after a defined grace period expires, the burden should be reversed: testing should automatically be required unless EPA affirmatively determines that it is not needed. In other words, ignorance should make a chemical *more* of a priority for government-imposed testing obligations, not less.

**2. Reclassify as “new” chemical under Toxic Substances Control Act**

If a chemical in current or long-standing use continues without meeting minimum screening data requirements for a substantial period of time, i.e., after a multi-year grace period expires, there is no logical reason that it should enjoy grandfathered status under the law. As an unknown risk, it becomes much more akin to a “new” chemical than an “old” one. Under the Toxic Substances Control Act, it would therefore be appropriate for such chemicals to be automatically reclassified as “new” chemicals for purposes of Section 5. In other words, such chemicals would forfeit their “grandfather” privileges. The mechanics of Section 5 would need to be slightly adjusted to accommodate this reclassification.

*Untested chemicals would forfeit their “grandfather” privileges.*

**3. Invalidate trade-secret claims**

Current law offers protection of some information on chemicals that manufacturers, importers, or users deem confidential. Once again, if a high-production-volume chemical persists in commercial use for a substantial period of time without being able to meet

minimum data requirements, the rationale for allowing protection of confidential business information is seriously weakened. The price of maintaining trade secrets about a chemical should be public disclosure of at least the minimum scientific information necessary for safety screening. Thus, after an appropriate time interval, trade-secret protection should be invalidated as a matter of law for any information about a high-production-volume chemical that has not met the minimum screening data requirements. The invalidation should apply in all legal contexts, not just TSCA or TRI.<sup>61</sup>

#### **4. Add lower-production-volume chemicals over time**

Alterations of legal status can be phased in over time for other categories of chemicals as well, such as lower-production-volume chemicals or other priority classes of chemicals.

Each of the four steps discussed above is relatively easy to implement and relatively inexpensive. For government, the burden consists primarily of additional data management, which would be difficult only if the minor funding required were unavailable. A decade's experience with TRI data management provides a basis for confidence that the tasks are manageable.

For private business, the maximum cost for each chemical is the cost of generating and making available a defined set of necessary safety screening data, estimated (in the context of the OECD minimum screening information data set) as approximately \$20,000 to \$150,000.<sup>62</sup> For a chemical being sold in quantities exceeding 1,000,000 lbs./year, this should be a very modest cost in comparison to revenues. The cost of making disclosures for the same chemical would presumably be even less, since otherwise, the manufacturer or other responsible entity would pay to test.

*After an appropriate time interval, trade-secret protection should be invalidated as a matter of law.*

Moreover, the testing and disclosure costs for a chemical need to be incurred only once. They do not fall on every business responsible for a chemical, or even on every manufacturer of the chemical. It is reasonable to expect that the largest producers or users will shoulder those costs jointly.

### **C. More effective mandatory testing for both new and existing chemicals**

Although perhaps politically difficult, it would be conceptually easy to strengthen the testing authority of the Toxic Substances Control Act for both new and existing chemicals. Congress could easily direct industry to develop basic data (e.g., such as that required by the OECD Screening Information Data Set) for new and existing chemicals, using a phased timetable for existing chemicals and for new chemicals as they are developed. A key element for success — one that is currently missing — would be an automatic sanction for failure to produce timely data. This sanction must *not* depend on agency initiative before it is invoked. For example, the law could provide that no chemical in a specified class which does not have specified data publicly available by a fixed deadline may be released; or be the subject of a permit; or be manufactured; or be sold; etc.

As with the URI proposal discussed above, such a mandate could include both automatic and discretionary exclusions for individual chemicals or classes of chemicals where the information is demonstrably not needed to assure safety.

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#### CHAPTER V NOTES

<sup>59</sup> Farr, “Molecular Assays for Environmental Endpoints,” Screening and Testing Chemicals in Commerce, U.S. Congress, Office of Technology Assessment (Washington, D.C.: 1995), pp. 79-84. Doc. No. OTA-BP-ENV-166.

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<sup>60</sup> At first thought it might seem that TRI-listed chemicals must already have sufficient minimum data available, since evidence of some form of risk was necessary to get them listed in the first place. However, few TRI-listed chemicals have actually been studied beyond the feature that cause them to be included on the list. A known carcinogen, for example, may never have been studied for its effects on reproduction, or on the environment.

<sup>61</sup> At present, confidentiality claims under the Toxic Substances Control Act continue in perpetuity, regardless of whether a chemical is on the market. TSCA Sec. 14, 15 U.S.C. 2013 (West 1982). Among other problems, this “limit[s] the ability of outside parties to independently scrutinize, validate, and improve upon EPA [Structure-Activity Relationship] models,” because a significant portion of the underlying data have been claimed as confidential. Ann M. Richard, Pauline Wagner, Richard Purdy, and Gilman Veith, “SAR and Modeling,” Screening and Testing Chemicals in Commerce, Doc. No. OTA-BP-ENV-166, U.S. Congress, Office of Technology Assessment (Washington, D.C.: 1995), pp. 101-115.

<sup>62</sup> Turnheim, “Evaluating Chemical Risks,” The OECD Observer, No. 189, August/September 1994, pp. 12-15.

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## Conclusion

Taken together, the measures recommended above are relatively easy to implement and inexpensive for all parties to comply with. They could go far toward reducing our current massive ignorance about the basic toxicity of the major chemicals in U.S. commerce.

These measures are only the beginning of a solution to the problem documented in this report. Once necessary screening data are available (or once the use of major chemicals lacking such data is being seriously reduced), then the chemicals in question must actually be evaluated, and regulators must take the appropriate actions in response to screening results. Further testing and data gathering in some cases will be required. Control actions in some cases will be essential. The job of assuring public safety from chemicals is not over until all of these tasks are completed, for all chemicals that potentially pose a risk.

Fortunately, experience suggests that as information becomes more available, responsible industry can and does practice a greater and greater degree of self-control. Public knowledge is a powerful motivator. Once there is an expectation that the public will learn about potentially unsettling information (including *both* risks *and* uncertainties), companies have shown a desire to act in advance to minimize the unsettling elements and to reduce uncertainties. The system becomes self-enforcing rather than self-defeating. That is the direction we must take.

*The system can become self-enforcing rather than self-defeating.*



## Appendix I. Data Sources and Methods

This appendix presents the data sources and methods used by EDF in this report to evaluate whether the preliminary screening data needed to assess the human health impacts of a given chemical are available. Part A describes EDF's database of chemical information and defines how the chemicals that are analyzed in this report were selected. Part B explains the analytical methods EDF used to make the major findings of the report. Part C describes how EDF identified chemicals known to be released to the environment or expected to have significant exposure potential.

### A. Selection of chemicals analyzed in this report

U. S. EPA currently estimates that there are over 75,000 chemicals in commercial use.<sup>1</sup> A detailed evaluation of the availability of environmental information for chemicals is feasible only if it focuses on smaller categories of chemicals of concern. EDF selected the chemicals it evaluated in this report from the universe of substances included in a database of chemical information that EDF has created as part of a public information effort. This database includes all chemicals that are produced or imported in high volume and all chemicals that are the subject of regulatory attention under major U.S. or California environmental statutes.

U.S. EPA defines "high production volume" (HPV) chemicals as substances with annual import or production exceeding one million pounds. These chemicals can be feedstock or intermediates in manufacturing processes (e.g., hydrofluoric acid), constituents of consumer products (e.g., octane), or products in their own right (e.g., kerosene). EPA's 1990 list of HPV chemicals includes 2,971 compounds.<sup>2</sup> To identify chemicals that are the subject of regulatory attention, EDF included all chemicals regulated under any of the following federal and state environmental statutes:<sup>3</sup>

## TOXIC IGNORANCE

### Federal

- Clean Air Act;
- Clean Water Act;
- Comprehensive Emergency Response, Compensation and Liability Act (Superfund);
- Emergency Planning and Community Right to Know Act (TRI);
- Federal Insecticide, Fungicide and Rodenticide Act;
- Occupational Safety and Health Act; and
- Safe Drinking Water Act.

### California

- Air Toxics “Hot Spots” Information and Assessment Act;
- California Occupational Safety and Health Act;
- California Safe Drinking Water Act; and
- Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

This report focuses on a random sample drawn from what are described in the text as **high-priority chemicals**. High-priority chemicals are defined as substances that are *both* used in high volume *and* are subject to current regulatory attention. EDF merged various lists of chemicals subject to state and federal regulatory attention with EPA’s list of high-production-volume chemicals and identified 486 chemicals as high-priority chemicals. Priority consideration is justified for such chemicals because they are used in substantial quantities (increasing the likelihood of environmental release and exposure) and because they have been identified as a potential hazard by at least one regulatory program.

EDF randomly selected 100 chemicals from this set of high priority chemicals for its analysis of the availability of basic hazard identification data. This sample is statistically representative of chemicals in wide commercial use that have come to regulatory attention.<sup>4</sup>

## **B. Methodology for assessing availability of basic hazard identification data for high-priority chemicals**

### **1. Adopting an internationally accepted minimum data set for identifying human health hazards**

To evaluate the extent of hazard identification data available on each randomly selected high priority chemical, EDF relied on an internationally accepted definition of the minimum data set required for hazard identification. The Organisation for Economic Cooperation and

Development has defined the minimum data elements that are required to make a preliminary informed judgment regarding a range of potential hazards of chemicals, including but not limited to human health effects. The elements of this Screening Information Data Set<sup>5</sup> (SIDS) are shown in Chapter IV of the report. The human health component of this minimum screening data set includes toxicity test results in each of six broad categories of adverse health impacts:

- acute toxicity;
- repeated dose toxicity;
- *in vitro* genetic toxicity;
- *in vivo* genetic toxicity;
- toxicity to reproduction; and
- developmental toxicity (including teratogenicity).

For each chemical in the random sample, EDF examined whether any data are publicly available on each of these six essential elements of a minimum human health data set. It is important to note that chemicals found to possess these six data elements may still lack other essential data on environmental fate or ecotoxicity which are required to meet the requirements of the OECD program's minimum data set. A comprehensive approach to hazard identification would examine not only health effects but also the fate of a chemical in the environment and whether the chemical poses potential harm to ecosystems. For this report, EDF focuses only on the minimum data required to screen a chemical for its potential hazard to human health.<sup>6</sup>

## 2. Searching and scoring available toxicity data

To assess whether the defined minimum set of data exists, in public form, for each of the 100 chemicals in the random sample, EDF searched four major electronic databases for toxicity data relevant to human health impacts:

- the Registry of Toxic Effects of Chemical Substances (RTECS);<sup>7</sup>
- the Hazardous Substances Data Bank (HSDB);<sup>8</sup>
- Toxline;<sup>9</sup> and
- Medline/Medlars.<sup>10</sup>

The HSDB was also used to identify the major producers of chemicals in the random sample.<sup>11</sup> EDF identified several additional sources of toxicity data that it considered for inclusion in this analysis but rejected because of database quality or access problems.<sup>12</sup> The results of these searches were compiled in a Microsoft Access database for analysis.

## TOXIC IGNORANCE

In each of the six areas of human health effects covered by the OECD program's defined minimum data set, any one of a variety of specific toxicity tests could provide the needed information. EDF identified 72 specific toxicity tests which are generally used to assess human health impacts and which might be conducted to meet the defined requirements.<sup>13</sup> The "Toxicity Data Availability Scoring Sheet" shown in Appendix II identifies the specific toxicity tests that might satisfy each broad category in the screening information data set. For example, there are nine specific toxicity tests that are frequently used to assess a compound's acute toxicity (involving different test species, routes of exposure, etc.).

EDF analyzed the publicly available toxicity data on each chemical in the random sample to determine which of the 72 types of toxicity tests had reported for that chemical, and then ascertained whether at least one qualifying test had been done in each of the six defined categories. If a chemical's data set included results for any one of the specific tests within a given category, it was considered to have satisfied the screening information requirement for that category. Chemicals with at least one test in all six health categories were considered to have a complete minimum screening information data set. Chemicals without test results in one or more of the six categories were considered to lack a minimum data set.

This scoring method probably overstates the availability of data from well-conducted toxicity tests. If the data sources indicated that a relevant study had been conducted, it was scored as sufficient. EDF did not review specific studies to determine whether they comply with OECD or EPA guidelines for conducting specific tests. The National Research Council's detailed evaluation of toxicity testing in 1984 found that only one-quarter of published toxicity tests met the standards of reference protocol guidelines or were judged adequate by expert committees.<sup>14</sup> EDF's analysis is therefore likely to overstate the number of chemicals for which minimum health hazard screening data are available.

### **C. Identifying high-priority chemicals that are known to be released to the environment or are expected to have significant potential for human exposure**

To identify whether people are likely to come into contact with the chemicals in its random sample of high-priority chemicals, EDF ascertained which chemicals in the sample are known to be released to the environment or are expected to have significant potential for human exposure.

Chemicals were considered "known to be released to the environment" if reports to the 1995 Toxic Release Inventory (TRI) indicate they were released to air, water, or land.<sup>15</sup> TRI's reporting requirements were established by the Emergency Planning and Community Right-to-Know Act of 1986. However, reported releases under TRI are likely to be a substantial

underestimate of total environmental releases, because the requirements apply only to certain manufacturing facilities.<sup>16</sup> It is inappropriate to conclude that the absence of TRI data means that a chemical is not released to the environment.

Chemicals were considered to have a significant potential for human exposure if they scored "medium" to "high" in human exposure potential according to EPA's Waste Minimization Prioritization Tool.<sup>17</sup> This tool ranks over 800 chemicals by their human exposure potential, based on each chemical's persistence in the environment and its tendency to bioaccumulate. If a chemical persists in the environment (because it is resistant to biodegradation or other destruction pathways), its long-term human exposure potential is increased. If a chemical bioaccumulates in the environment (increasing in concentration as it moves up food chains), there is increased exposure potential for humans via food pathways.

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#### APPENDIX I NOTES

<sup>1</sup> As of October 1996, there were 75,857 chemicals in EPA's TSCA Inventory.

<sup>2</sup> EPA's list of High Production Volume (HPV) chemicals can be obtained as digital media from the agency's Office of Prevention, Pesticides, and Toxic Substances. Pesticides and food additives are excluded from listing as high-production-volume chemicals because of provisions in the Toxic Substances Control Act. Some chemicals are included in more than one of these categories.

<sup>3</sup> Most regulatory lists utilized by EDF are included on a chemical cross-index compiled by CalEPA (1996) entitled "List of Lists," which can be obtained from the Hazardous Materials Data Management Program, Department of Toxic Substances Control, CalEPA, Sacramento, CA, Internet/WWW [address: <http://www.calepa/cahwnet.gov/cci.htm>]. Additional regulatory lists were obtained directly from the Code of Federal Regulations, as summarized in the Book of Lists for Regulated Hazardous Substances, published in CD-ROM format by Government Institutes, Inc., Rockville, MD.

<sup>4</sup> The manufacturers of high production volume chemicals included in EDF's random sample can be identified using data from the Hazardous Substances Data Bank and SRI International's Directory of Chemical Producers. SRI International, Directory of Chemical Producers: United States of America, (Menlo Park, CA: Chemical Industries Division, SRI International, 1996).

<sup>5</sup> The Screening Information Data Set is based on characterization and effects elements similar to those found in the Minimum Premarketing set of Data (MPD) adopted by OECD in 1982. The MPD was designed for the purposes of making an initial assessment of the hazards of newly marketed chemicals. Turnheim, "Evaluating Chemical Risks," The OECD Observer, No. 189, August/September 1994.

<sup>6</sup> This focus on the availability of human health data was necessary because of resource constraints: evaluating the availability of the minimum data required to identify hazards based on environmental fate, ecotoxicity or use, release, and exposure would have tripled the research required to produce this report.

<sup>7</sup> The Registry of Toxic Effects of Chemical Substances (RTECS) is a non-bibliographic database of toxicological information on some 130,000 chemicals maintained by the National Institute for Occupational Safety and Health (NIOSH). In addition to regulatory standards and updates on governmental agency activities, RTECS contains

information on six main toxicity areas: primary irritation, mutagenic effects, reproductive effects, tumorigenic effects, acute toxicity, and other multiple dose toxicity.

RTECS records the quantitative findings of toxicity tests (e.g., LD<sub>50</sub>s) with references, drawing its data from a core set of about 200 technical journals, as well as abstracts, government reports, textbooks, proceedings of scientific meetings, compendia, industry reports and letters, professional society reports, reports by research institutions, personal communications, and publications from a large number of non-English language journals.

EDF retrieved all data indexed under the six main toxicity areas from a version of RTECS that was current through April 1996, contained on a CHEM-BANK CD-ROM at the University of California at Berkeley Public Health Library. RTECS had records for all 100 chemicals in the random sample.

<sup>8</sup> The Hazardous Substances Data Bank is a non-bibliographic, peer-reviewed database, created and maintained by the National Library of Medicine (NLM) and containing information on some 4,500 potentially hazardous chemicals. Focusing primarily on chemical toxicology, HSDB is further enhanced with data from such related areas as emergency handling procedures, environmental fate, human exposure, detection methods, and regulatory requirements. Data are derived from a core set of standard texts and monographs, government documents, technical reports, and the primary journal literature.

EDF retrieved entire chemical records from a version of HSDB that was current through April 1996, contained on a CHEM-BANK CD-ROM at the University of California at Berkeley Public Health Library. HSDB had records for 95 chemicals in the random sample.

<sup>9</sup> TOXLINE is a bibliographic, on-line database, maintained by the NLM and covering toxicological, pharmacological, biochemical, and physiological effects of drugs and other chemicals. Approximately 75% of the articles have English abstracts. TOXLINE takes its information from 18 secondary database sources: Aneuploidy, Chemical-Biological Activities, Developmental and Reproductive Toxicology (DART), Environmental Mutagen Information Center File (EMIC), Environmental Teratology Information Center File, Epidemiology Information System, Federal Research in Progress, Hazardous Materials Technical Center, International Labour Office (CIS), International Pharmaceutical Abstracts, NIOSHTIC, Pesticides Abstracts, Poisonous Plants Bibliography, Toxic Substances Control Act Test Submissions (TSCATS), Toxicity Bibliography, Toxicological Aspects of Environmental Health (BIOSIS), National Technical Information Service Toxicology Document and Data Depository, and Toxicology Research Projects (CRISP).

TOXLINE provides access to several important data sources that are not covered by the preceding databases. DART and EMIC cover reproductive and developmental studies which the other databases may slight. In addition, TSCATS contains summaries of the data being generated in response to TSCA toxicity testing and reporting rules that are conducted by private firms and rarely published in the scientific literature. TOXLINE also contains summaries of regulatory agency chemical assessments (e.g., by EPA or WHO) with extensive abstracts describing toxicity data available for a specific chemical. Toxicity tests summarized in these summary secondary sources were also included in EDF's scoring.

EDF obtained a MEDLARS account and accessed TOXLINE using the GRATEFUL MED software package. Because of the variety of secondary sources, keyword (KW) searches are highly unreliable. Both UC Berkeley reference librarians and the NLM suggest searching TOXLINE using the text word index, TW. Using GRATEFUL MED's Medical Subject Heading (MeSH) Thesaurus, keywords which GRATEFUL MED interprets as TWs were selected. The standard search was for CAS number and TW "*toxicity tests*" or "*pharmacokinetics*" or "*reproduction*" or "*growth and development*"; was limited to English entries; excluded Medline references; and retrieved abstracts if available. The search routine was applied to TOXLINE's current on-line database, covering 1981-present, and produced records for 93 chemicals.

<sup>10</sup> MEDLINE is a bibliographic database, maintained by the NLM. MEDLINE contains articles from some 3,700 international biomedical journals, covering the fields of medicine, nursing, dentistry, veterinary medicine, and the preclinical sciences. Approximately 75% of the articles have English abstracts. With the assistance of UC Berkeley research librarians, EDF created a template for conducting a keyword (KW) search of this database. The standard search was for CAS number and KW toxic# or adverse or pharma#, was limited to English entries; and retrieved abstracts if available. (Using the # sign after "toxic" searches for the letter string "toxic" in any word or phrase.) Note that the key words did not include terms such as carcinogen, mutagen,

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or teratogen in order to avoid introducing too much specificity into the search. The KW search in MEDLINE not only searches article titles and abstracts, but also subject headings. Particular toxicities (such as teratogenicity) fall within the general subject headings of toxicology, adverse effects, etc.

The search routine was applied to MEDLINE's current on-line database, covering 1992-present, and produced records for 74 chemicals. Searching the MEDLINE database for records prior to 1992 would have required repeating the entire search effort, as the database is broken into several covered time periods. The marginal gain in coverage from searching earlier database periods was judged to be small, as substantially more toxicity data over longer time periods were available through RTECS and HSDB.

<sup>11</sup> HSDB identifies the major producers of a chemical (including parent company and production site locations). Because HSDB incorporates data from a variety of sources that can become outdated (e.g., as companies merge or change their product line), EDF verified that companies were recorded as producers of a random sample chemical in SRI's 1996 survey of chemical producers. See note 4 *supra*.

<sup>12</sup> The most significant of these potential sources was EPA's TSCA Triage Database, available in electronic form from EPA's Office of Prevention, Pesticides and Toxic Substances. U.S. EPA, Office of Prevention, Pesticides and Toxic Substances, TSCA 8(e) Triage Database, version 2.0 of 8(e), (Washington, D.C.: U.S. EPA, 1996), Internet/WWW [address: [http://www.epa.gov/docs/8e\\_triage/](http://www.epa.gov/docs/8e_triage/)]. TSCA Section 8(e) requires industry to report "substantial risk" information to EPA, excluding studies published in the open scientific literature or studies already reported to EPA as a result of other regulatory requirements. Since 1977, over 10,000 notices covering a wide range of chemical substances and mixtures and a variety of toxic effects and exposures have been submitted to EPA. Unfortunately, the Triage Database has substantial design and quality problems: chemicals are frequently identified with incorrect CAS numbers; study records are often inadequate to assess what type of test is being reported; many studies involve mixtures and not distinct chemicals; and cross-referencing within database files do not retain referential integrity. EDF was able to ascertain that including toxicity test reports in the Triage database in its assessment of toxicity data availability does not change the number of compounds that lack minimum datasets. It was not possible to include the Triage database results in our scoring of the availability of the 72 tests included in our comprehensive human health data set.

EDF also evaluated several electronic compilations of Manufacturer's Safety Data Sheets as a source of toxicity data. An MSDS summarizes available health and safety data on a chemical and must be provided by chemical producers and marketers to end users to comply with OSHA's Hazard Communication Standard. Unfortunately, substantial data quality and public access problems convinced EDF that these documents are not a useful source for evaluating data availability. Different manufacturers produce a different MSDS for the same chemical, with inconsistent descriptions of toxicity data and without citation to original data sources. Moreover, only some manufacturers allow MSDSs to be included in publicly accessible databases. The Chemical Manufacturers Association's CHEMTREC database, for example, allows only emergency response services to access all of its MSDS files. Some companies registered with CHEMTREC allow public access to their MSDS files on a non-emergency basis (although they charge a fee for providing the MSDS).

<sup>13</sup> These tests comprise all toxicity tests with official OECD (1996) guidelines or EPA (1996) guidelines. Organisation for Economic Cooperation and Development Secretariat, SIDS Manual (Second Revision): Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals, (Paris, France: May 1996). U.S. EPA, Office of Prevention, Pesticides and Toxic Substances, OPPTS Test Guidelines: Series 870, Health Effects, Volume I (Washington, D.C.: U.S. EPA, 1996), Internet/WWW [address: [http://www.epa.gov/docs/OPPTS\\_Harmonized/](http://www.epa.gov/docs/OPPTS_Harmonized/)]. They also include additional tests identified in the National Research Council's 1984 report on toxicity testing as components of a comprehensive human health data set. National Research Council, Toxicity Testing (Washington, D.C.: National Academy Press, 1984).

In order not to exclude potential toxicity information, the following test types were expanded to include virtually any relevant study: reproduction and fertility effects, preliminary developmental toxicity screen, prenatal developmental toxicity study/teratology study, neurotoxicity screening battery, metabolism and pharmacokinetics.

<sup>14</sup> *Id.*

## TOXIC IGNORANCE

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<sup>15</sup> EDF used 1995 TRI data, the latest available, obtained from EPA's TRI web site in June 1997, Internet/WWW [address: <http://www.epa.gov/opptintr/tri/disks.htm>]. TRI point and nonpoint release categories were summed to calculate total reported releases to air. Any reported air, water, publicly owned treatment work, land, underground injection, or accidental release was considered an environmental release.

<sup>16</sup> The TRI list for 1995 included 578 chemicals and 28 chemical categories. Reporting requirements do not apply to all sources of a listed chemical, but only to manufacturing facilities in specific industrial sectors (SIC codes 20-39) with more than 10 employees. Over 50% of facilities involved in chemical manufacturing and processing have fewer than 10 employees and are not required to report under TRI.

<sup>17</sup> U.S. EPA, Office of Solid Waste and Office of Pollution Prevention and Toxics, Waste Minimization and Prioritization Tool: Software and User's Guide and System Documentation, Draft (Washington, D.C.: U.S. EPA, 1997), Internet/WWW [address: <http://www.epa.gov/epaoswer/hazwaste/minimize/tool/tooldown.htm>].

## Appendix II. Toxicity Scoring Sheet

This appendix shows the scoring sheet used by EDF to record the availability or unavailability of toxicity test data for each chemical studied.

As explained in Chapter II and in Appendix I, these tests comprise all toxicity tests with official OECD (1996) guidelines or EPA (1996) guidelines. See Appendix I, note 13. The tests are organized by the categories in the OECD Screening Information Data Set initiative.

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## *SIDS Checklist*

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**CAS Number:** \_\_\_\_\_

**Chemical Name:** \_\_\_\_\_

### Acute Toxicity

Acute oral toxicity: \_\_\_\_\_

Rodent:

Nonrodent:

Acute inhalation toxicity:

Acute dermal toxicity:

Acute toxicity-Other routes: \_\_\_\_\_

Parenteral:

Other:

Skin irritation/corrosion:

Eye irritation/corrosion:

Skin sensitization:

### Repeated Dose Toxicity

Subchronic Toxicity: \_\_\_\_\_

Oral:

14-28 day:

Rodent:

Nonrodent:

90 day:

Rodent:

Nonrodent:

6-12 month:

Nonrodent:

Subchronic Toxicity: \_\_\_\_\_

Inhalation:

90 day:

Other: \_\_\_\_\_

Dermal:

21-28 day:

90 day:

Other:

Other:

Chronic Toxicity: \_\_\_\_\_

Chronic:

Carcinogenicity: \_\_\_\_\_

Chronic toxicity-Carcinogenicity combined:

## Genetic Toxicity-In Vitro

### *In Vitro:*

#### Bacterial:

- Salmonella typhimurium reverse mutation assay:
- Escherichia coli WP2 WP2 uvrA reverse mutation assays:
- Bacterial DNA damage or repair tests:

#### Non-Bacterial:

- Gene mutation in Aspergillus nidulans:
- Gene mutation in Neurospora crassa:
- Detection of gene mutations in somatic cells in culture:
- Mitotic gene conversion in Saccharomyces cerevisiae:
- In vitro sister chromatid exchange assay:
- In vitro mammalian cytogenetics:
- Unscheduled DNA synthesis in mammalian cells in culture:

## Genetic Toxicity- In Vivo

### *In Vivo:*

- Sex-linked recessive lethal test in Drosophila melanoqaster:
- Rodent heritable translocation assays:
- Rodent dominant lethal assay:
- Mouse specific locus test:
- In vivo sister chromatid exchange assay:
- In vivo mammalian cytogenetics test: Erythrocyte micronucleus assay:
- In vivo mammalian cytogenetics test: Bone marrow chromosomal analysis:
- In vivo mammal cytogenetics test: spermatogonial chromosomal aberrations:

## Toxicity to Reproduction

- Multigeneration reproduction study-rodent:
- Segment I: Fertility and reproductive performance:
- Reproduction and fertility effects:

## Developmental Toxicity/Teratogenicity

- Preliminary developmental toxicity screen:
- Prenatal developmental toxicity study/Teratology study:
- Inhalation developmental toxicity study:
- Segment III: Perinatal and postnatal performance:
- Developmental neurotoxicity screen:
- Developmental neurotoxicity study:

## Other Specific Toxicities

### Neurotoxicity:

- Neurotoxicity screening battery:
- Schedule-controlled operant behavior:
- Peripheral nerve function:
- Neurophysiology: Sensory evoked potentials:
- Subchronic neurotoxicity - 90 day:
- Acute delayed neurotoxicity/Delayed neurotoxicity:

### Human Toxicity:

- Acute toxicity:
- Subchronic toxicity:
- Chronic toxicity:
- Sensitization studies:
- Immunotoxicity:
- Other:

## Other Relevant Information

### Toxicokinetics:

- Metabolism and pharmacokinetics:
- Pharmacokinetics:
- Oral/dermal pharmacokinetics:
- Oral and inhalation pharmacokinetic test:
- Toxicokinetics:

### Other:

- Implantation studies:
- Dermal penetration studies:
- Domestic animal safety:
- Morphologic transformation of cells in culture:
- Subchronic eye toxicity:
- Skin painting-chronic: