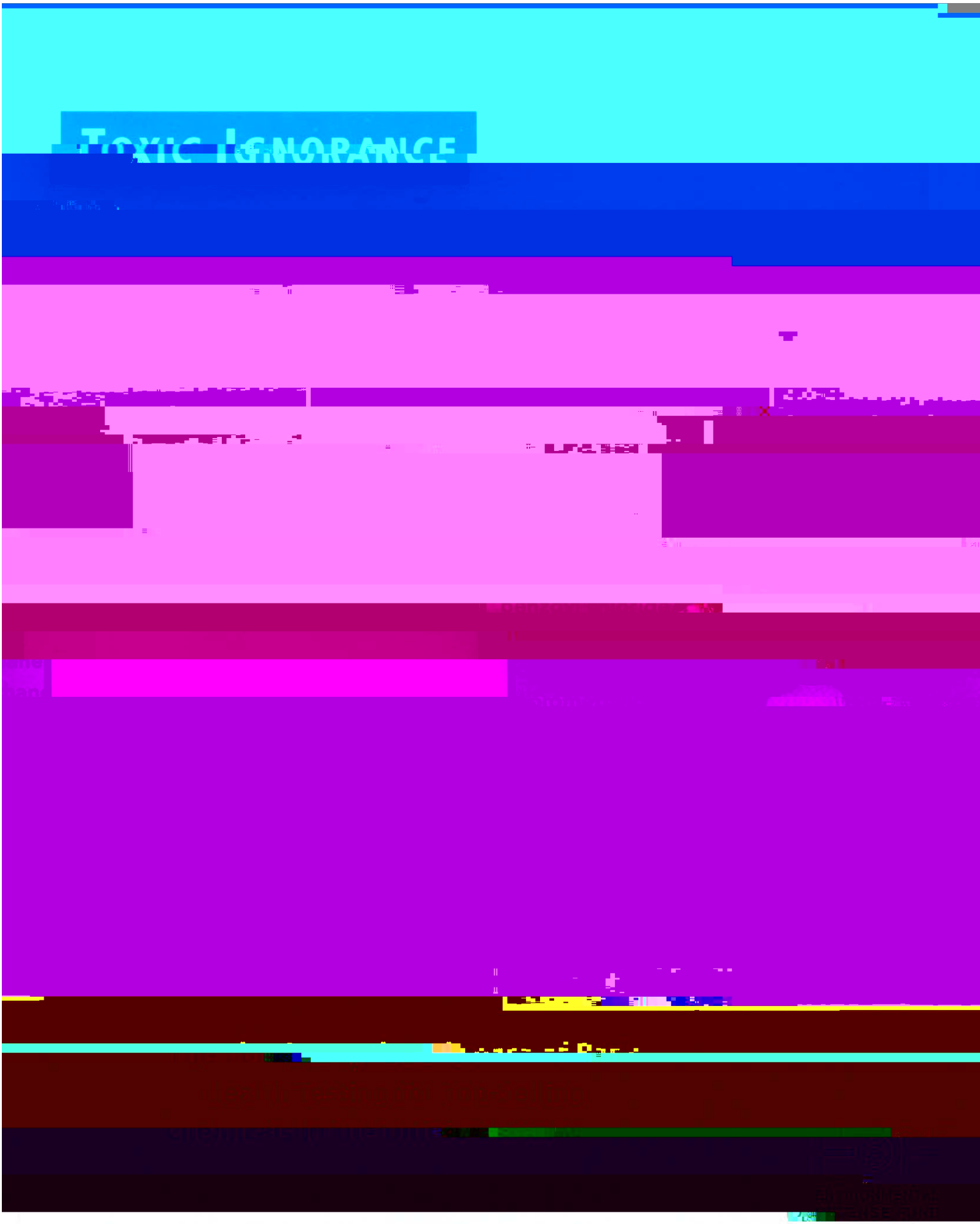
Toxic Ignorance

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.

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.

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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

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."[1] 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.[2] 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.[3] 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[4] and then extrapolating the sample results to all high-production-volume chemicals.[5]

EDF drew its sample for this report from those chemicals that are high-production-volume (more than 1,000,000 lbs./yr.), 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 the availability of information; i.e., the chemicals in the

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

Chemicals with minimum screening data

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

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-

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

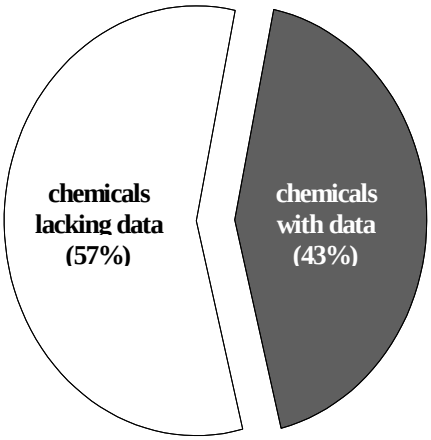

FIGURE 2-5

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 health hazard may have been found, we are likely not to have even a preliminary idea whether 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.[8] 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,[9] 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[10] 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.[11]

CHAPTER II NOTES

[1] 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.

[2] 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.

[3] 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

[6] 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.

[7] The Toxics Release Inventory is discussed in more detail in Chapter IV below.

[8] 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].

[9] 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.

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.[14] 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,[15] 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.[16] 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.[17] In the last few years, EPA has begun to show significant improvement in comparison to previous years,[18] 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.[19]

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"[20]; 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).[21] 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."[22]

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.[23] 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.[24]

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.[25]

Unfortunately, the actual provisions of Section 4 put EPA into a Catch-22: the agency must already data in order to show that it 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.[26]

Using all Section 4 measures combined, EPA has developed testing actions on only 263 chemicals in the past 20 years,[27] most of them recently.[28] 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.[29] Even taking into account the recent upswing in activity to about 65 actions per year,[30] 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.[31]

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

For new chemicals, as opposed to existing ones,

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**.[32] Over half of pre-manufacture notifications are submitted with no toxicity data at all.[33] By contrast, European nations require a defined set of actual test results for new chemicals.[34]

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

one health effect, and did not examine some other important health effects.[36]

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."[37]

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

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.[38] The chemical industry itself describes the number of Section 6 actions as "very few."[39] The way the law was written virtually guaranteed that it would be only rarely applied.

CHAPTER III NOTES

[12] See, e.g., the title of the Drinking Water Act [emphasis added], 42 U.S.C. Sec. 300f . (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

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).

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

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

[18] 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.

[19] Comments of Chemical Manufacturers Association on the Report of the Risk Assessment and Risk Management

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.

[27] Environmental Protection Agency, Chemicals On Reporting

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[34] 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.

[35] GAO 94-103, 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.

[36] U.S. EPA, Doc. No. EPA 743-94-001, note 34. As the report noted, "the project is not, and was not designed to be, an evaluation of [SAR] techniques in general." , 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.

[37] TSCA Section 6(a), 15 U.S.C. Section 2605(a) (West 1982).

[38] 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.

[39] CMA, Overview, n. 13, at 3.

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Unfortunately, the program has been very slow in actually producing the information it seeks, as even some industry participants have noted.[45] To date, work has begun on 322 chemicals.[46] As of mid-1996, screening had been completed for 99 chemicals, with another 223 chemicals still in the pipeline at various stages.[47] 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.[48] Meanwhile, with the expansion of the global economy and with changes in

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.[52] The listing criteria reflect some preliminary judgment as to a chemical's potential harm,[53] and the number of chemicals or chemical classes subject to the reporting requirements has since risen to 654.[54]

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.[55] 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.[56]

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

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,[57] the same trade association recently sued to try to prevent the Environmental Protection

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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.

[54] 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).

[55] 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].

[56] 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.
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> "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 mfr [(C)5.3.8(t)3.bi 8yP2t6-0.0004 7(t)3.uu0.00108 4010.0Bccy c

[58] National Oilseed Processors Association, Chemical Manufacturers Association, et al., v. EPA, 924 F. Supp. 1193 (D.D.C. 1996), appeal docketed . 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

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 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.

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 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 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.

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 e order to give

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

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.[61]

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

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.[62] 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.

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 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.

CHAPTER V NOTES

[59] 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.

[60] At first thought it might seem that TRI-listed chemicals must

Conclusion

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.[1] 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.[2] 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:[3]

underestimate of total environmental releases, because the requirements apply only to certain manufacturing facilities.[16] 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.[17]

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.

[11] 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

[12] 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/]. 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

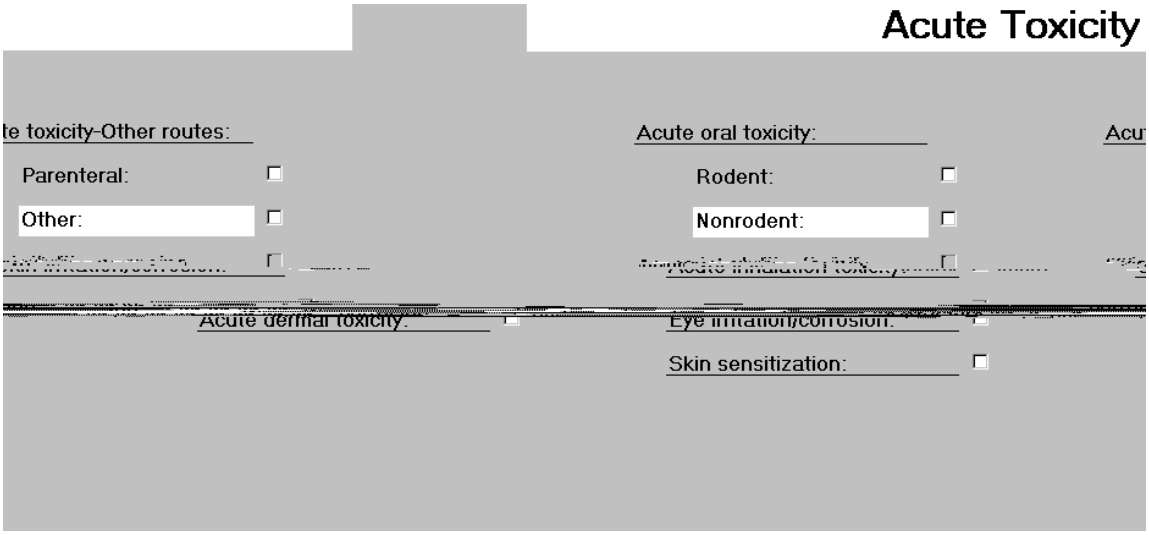
Appendix II. Toxicity Scoring Sheet

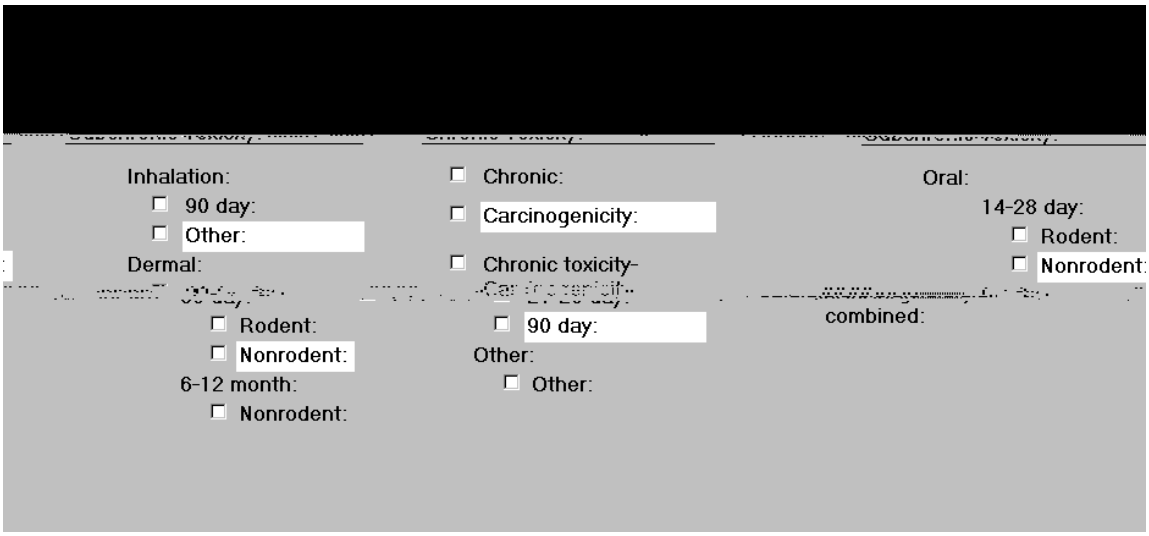
This appendix shows the scoring sheet used by EDF to record the availability or unavailability of toxicity test data for each chemical studied.

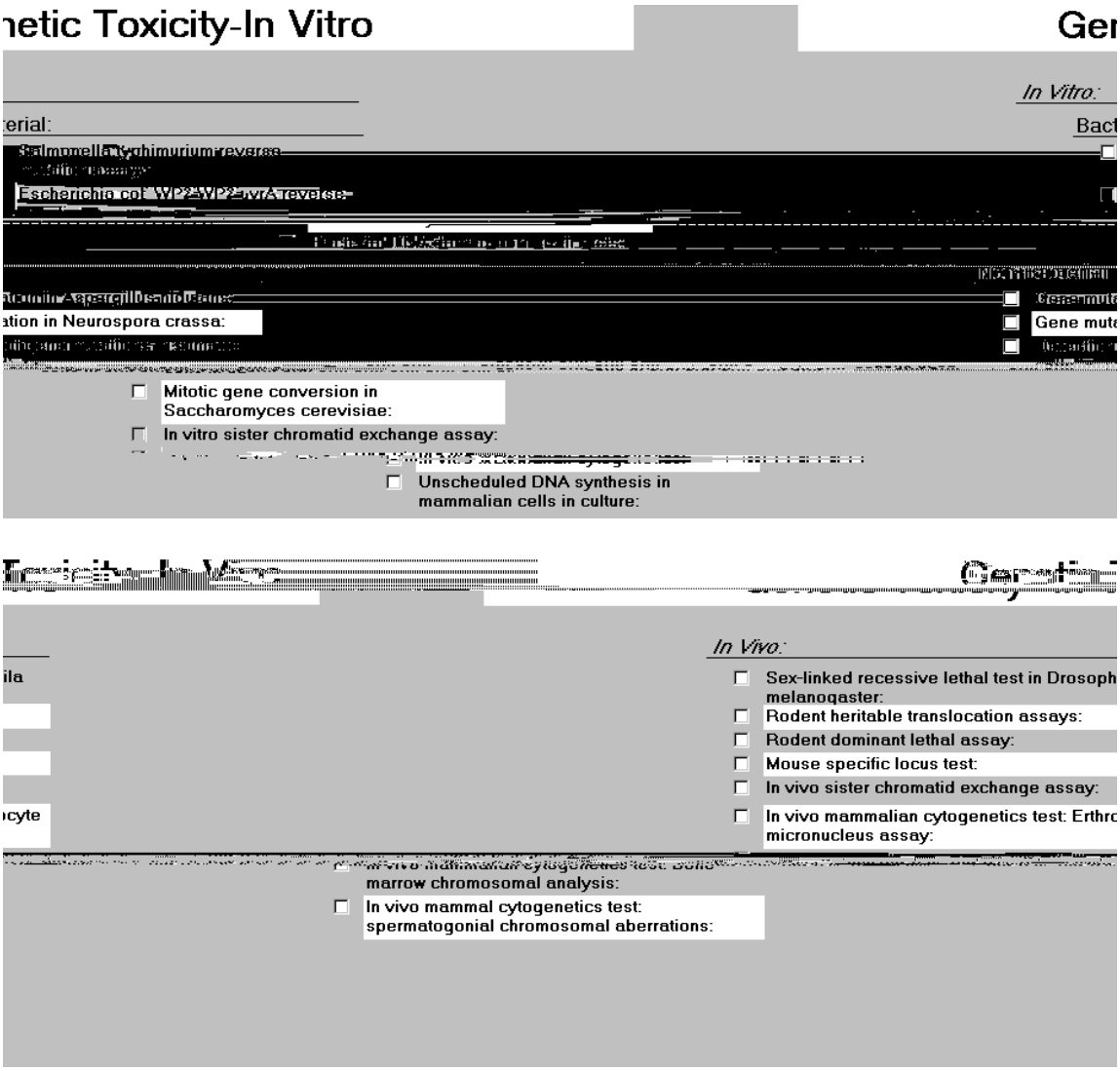
SIDS Checklist

CAS Number:

Chemical Name:






netic Toxicity-In Vitro
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Gene mute
Mitotic gene conversion in Saccharomyces cerevisiae:
In vitro sister chromatid exchange assay:
Unscheduled DNA synthesis in mammalian cells in culture:
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Sex-linked recessive lethal test in Drosoph melanogaster:
Rodent heritable translocation assays:
Rodent dominant lethal assay:
Mouse specific locus test:
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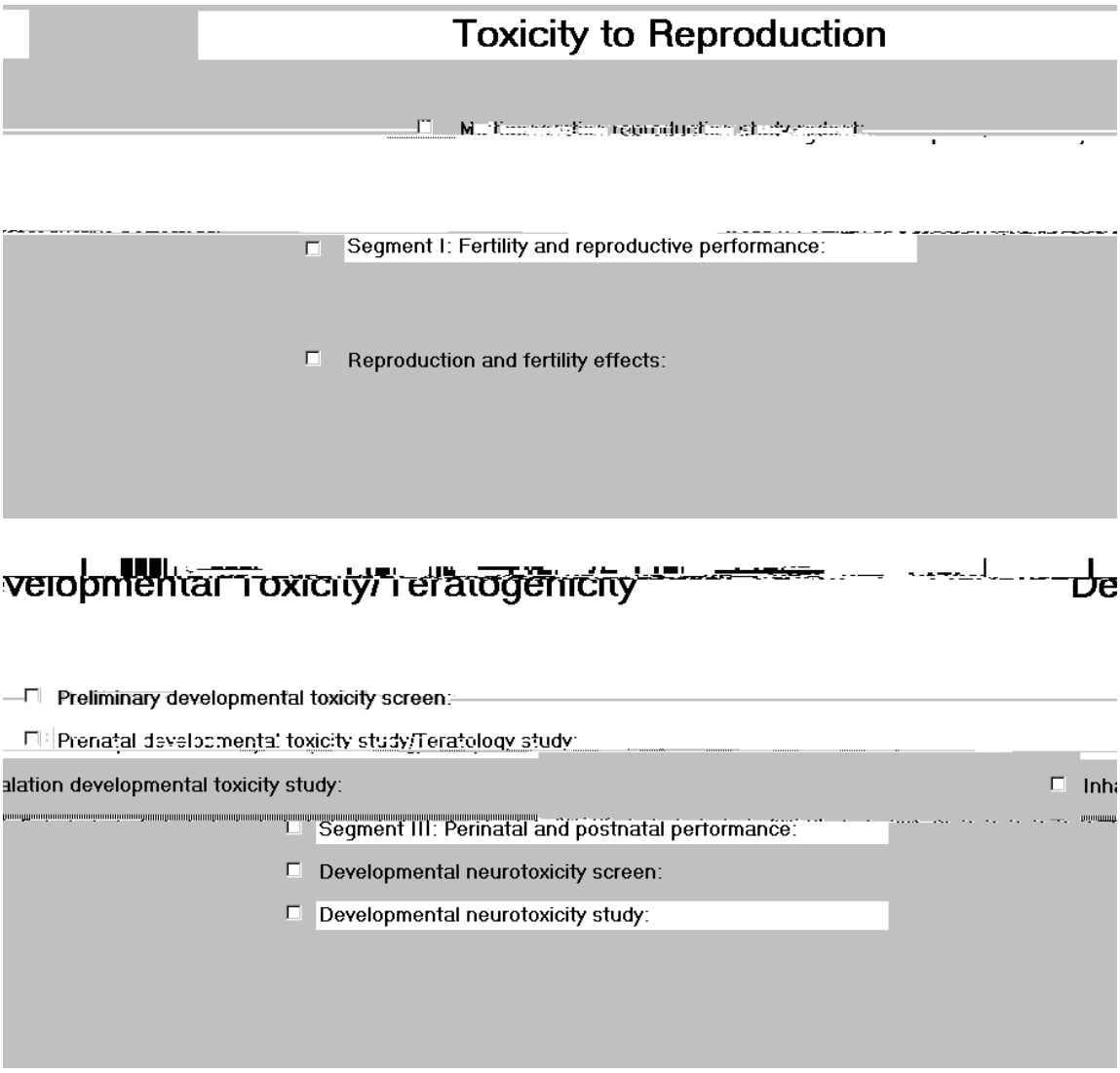
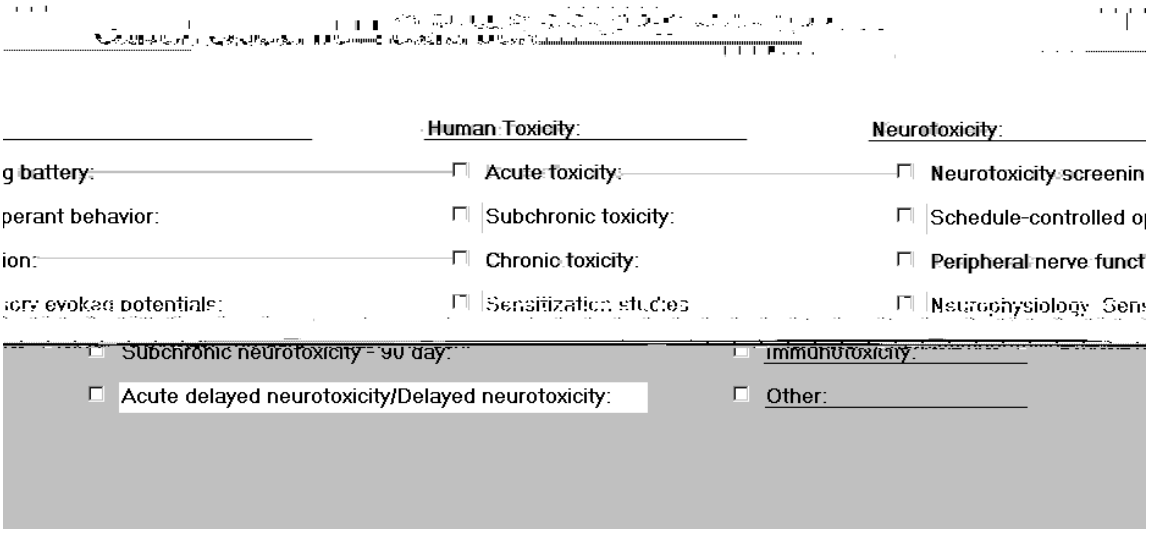
In vivo mammalian cytogenetics test: Erthro micronucleus assay:
marrow chromosomal analysis:
In vivo mammal cytogenetics test: spermatogonial chromosomal aberrations:


Toxicity to Reproduction
Segment I: Fertility and reproductive performance:
Reproduction and fertility effects:
Developmental Toxicity/Teratogenicity
Preliminary developmental toxicity screen:
Prenatal developmental toxicity study/Teratology study:
Segment III: Perinatal and postnatal performance:
Developmental neurotoxicity screen:
Developmental neurotoxicity study:


Human Toxicity:
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Acute toxicity:
Neurotoxicity screenin
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Subchronic toxicity:
Schedule-controlled o
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Chronic toxicity:
Peripheral nerve funct
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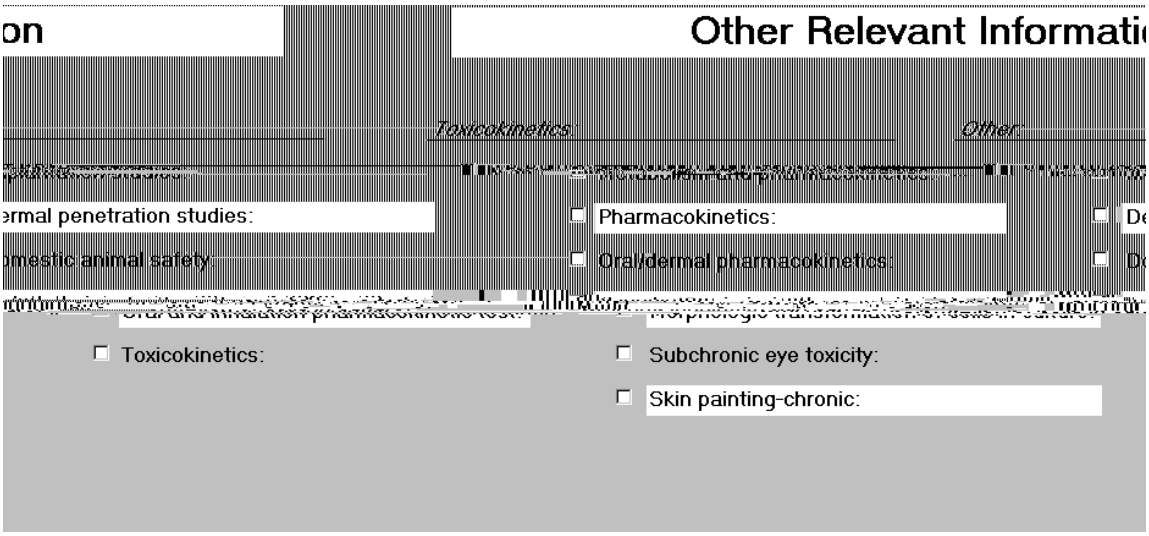
Sensitization studies
Neurophysiology Sens
Subchronic neurotoxicity - 90 day:
Immunotoxicity:
Acute delayed neurotoxicity/Delayed neurotoxicity:
Other: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Other Relevant Informati
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Oral/dermal pharmacokinetics:
Toxicokinetics:
Subchronic eye toxicity:
Skin painting-chronic: