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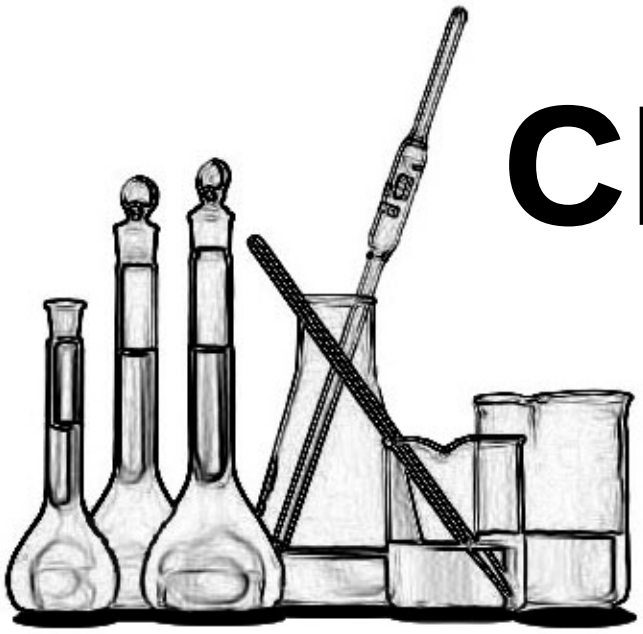
Chemicals in Our Community

News and Information



CHEMICAL TESTING

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What's New

Welcome to *Chemicals in Our Community*

Lynn R. Goldman, M.D.
Assistant Administrator for Pollution Prevention, Pesticides & Toxic Substances

At EPA we believe that giving people information on the chemicals to which they are exposed is the right thing to do and the smart way to reduce pollution. We know industrial facilities emit chemicals. But so does the local dry cleaner. And we are exposed to chemicals used in our schools, grocery stores — and homes. Chemicals are in thousands of consumer products we use every day, such as household cleaners — even children's toys. Every citizen has a right and need to know the chemicals that are transported, stored, released and used in their communities. Citizens now have some of that information, but they need more. Citizens need information on chemicals' toxicity and safe exposure levels, on how the chemicals act in the environment: Do they persist? Do they accumulate in our bodies? In other words, what are the risks?

Armed with this information, citizens could better decide for themselves which household products to buy, whether to allow their children to play in the school yard, or swim in a nearby lake or stream. They would be better able to persuade owners of a small local business or a giant multi-national corporation to switch to safer chemicals or reduce chemical use. Armed with good information on chemicals in their communities, citizens could simply better protect themselves and their children and create a safer world.

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Welcome to *Chemicals in Our Community*

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EPA is committed to taking direct actions to protect public health and the environment from industrial chemicals, as well as enabling citizens to better protect themselves from these potential threats.

The Toxics Release Inventory and other chemical right-to-know initiatives are making this vision a reality. Since TRI reporting began in 1988, industries required to report reduced their emissions by almost half, despite enormous growth in our economy. And we have seen an explosion in the public's demand for information on chemicals in their communities. Public access to existing web sites with right-to-know information now averages over a million "hits" or "visits" a day.

We are working hard to get all the information citizens need to make decisions to protect their health. This first issue of *Chemicals in Our Community* focuses on an important chemical right-to-know problem: a complete lack of publicly available basic toxicity data for 43 percent of the most widely produced industrial chemicals, and incomplete data for almost all the others. Not knowing if many of the thousands of chemicals to which we are exposed are toxic means that we cannot assess the health and environmental risks.

On the eve of Earth Day, Vice President Gore once again championed citizens right-to-know by announcing that EPA was challenging the chemical industry to provide health and ecological testing data for 3,000 of the most widely used chemicals in this country. EPA will issue a follow-up rule to require industry to fill in any gaps. And for the first time we will require TRI reporting about persistent chemicals that are toxic at very low levels and that build up in animal and human tissue and breast milk. We will direct special attention to those chemicals that children are most likely to encounter.

EPA is committed to taking direct actions to protect public health and the environment from industrial chemicals, as well as enabling citizens to better protect themselves from these potential threats. In the months and years ahead, we hope *Chemicals in Our Community* will help you to learn more about these efforts.

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Chemicals in Our Community is published by EPA's Office of Pollution Prevention & Toxics (OPPT) to increase public awareness of and access to news and information on toxic chemicals and pollution prevention available through OPPT. This resource is also available on the Internet at: **http://www.epa.gov/opptintr/opptpub.htm**.

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Chemical Right-to-Know

A New Era of Environmental Protection

William H. Sanders, III, Dr. P.H., P.E.
Director, Office of Pollution Prevention and Toxics

It's not often one gets the chance to hear the Vice President of the United States explain bioaccumulation to a group of fourth-graders. Not only did this unlikely event take place during Earth Week, but he did a terrific job. The kids were genuinely interested and went back to their classes with a lot to think over.

The occasion was the Vice President's announcement of the *Chemical Right-to-Know Initiative,* a major and important undertaking for OPPT that will greatly expand the information available on thousands of high-priority chemicals. ChemRTK arose from the realization that, even for the most common chemicals in commerce, there is very little data available on health and environmental effects. OPPT's "Chemical Hazard Data Availability Study" (see article on page 5) revealed that fewer than 7% of high-production volume (HPV) chemicals have a full set of baseline testing data publicly available, and almost half the chemicals have no data available whatsoever! The full study is available on OPPT's home page (www.epa.gov/opptintr/chemtest).

The *Chemical Right-to-Know Initiative* will fill in these gaps, and provide the basis for better and faster decisions on where chemicals present hazards to human health and the environment, and on steps to eliminate or manage these hazards. As such, ChemRTK is fast becoming one of the most visible and highest-priority efforts at OPPT. It focuses, at the outset, on the three specific actions identified by the Vice President:

Get baseline testing done on the 3,000 HPVs.

EPA will challenge industry to *voluntarily* undertake baseline testing on HPV chemicals on a very rapid schedule, using internationally-recognized testing protocols. Chemicals that are not covered by the voluntary challenge program will be subject to test rule requirements. We expect to publish a test rule proposal in early 1999.

Conduct extensive testing on chemicals to which children are disproportionately exposed.

Children can be especially sensitive to chemical exposures. OPPT will work with other offices, agencies and stakeholders to identify the chemicals in consumer products that lead to significant exposures in children, and will identify a battery of health tests needed to better screen the risks of these chemicals. Voluntary agreements, such as

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ChemRTK arose from the realization that, even for the most common chemicals in commerce, there is very little data available on health and environmental effects.

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enforceable consent agreements (ECAs), will be established with companies to test these chemicals. The chemicals not covered by such agreements will be included in a Children's Health Test Rule which EPA will propose by the end of 1998 and make final in 1999.

Collect TRI release information on high-priority PBT chemicals.

Persistent, bioaccumulative, toxic chemicals (PBTs) are of special concern due to their environmental persistence and tendency to concentrate in body tissues. Yet, many PBTs are not covered under the Toxics Release Inventory (TRI), the database which contains information about potentially hazardous chemicals and their use. We will propose a rule to lower the threshold for reporting of PBTs already on TRI, and to add other PBTs (also at the lower thresholds) to reporting requirements. EPA will propose the PBT Rule by the end of 1998 and make it final in 1999.

At the core of ChemRTK is EPA's commitment to making data available to the public in a form that is easy to access, use and understand. Virtually all of the information generated from this initiative will be made readily available through the Internet and in other forms, so that the public can access information about the chemicals in use in their homes, schools, workplaces and elsewhere.

Of particular importance to me as the Director of OPPT is the development of a comprehensive Chemical Right-to-Know Strategy to put these activities into a larger context. Data alone can be a powerful agent for change, but OPPT clearly has a responsibility beyond simply providing new data. We must be prepared to *act* in a timely and decisive fashion when new information suggests heretofore unrecognized risks. The Chemical Right-to-Know Strategy will lay out the approaches OPPT will use to assess risks, establish priorities for testing and for risk reduction, and to take actions so that there are no industrial chemicals which pose "unreasonable risks."

This truly is the beginning of a new era in environmental protection. Stay tuned to this publication for more information.

For further information about EPA's Chemical Right-to-Know Testing Program, please contact:

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Chemical Hazard Data Availability Study

EPA's Chemical Hazard Data Availability Study finds major gaps in the basic information that is readily available to the public on high production volume chemicals.

Charles Auer, Director
Chemical Control Division

In an Earth Day 1998 announcement, Vice President Gore and Administrator Browner committed EPA to three initiatives aimed at strengthening the public's right and ability to know about the potential health and environmental risks from toxic substances. These initiatives build on OPPT's work in our Right-to-Know and TSCA programs. In the near future, OPPT will be asking chemical manufacturers to voluntarily increase critical testing for 3000 high production volume (HPV) chemicals, pursuing new rules to guarantee that the chemicals children are exposed to are fully tested for their health effects, and proposing new, lower reporting thresholds for the most persistent and bioaccumulative chemicals on EPA's Toxics Release Inventory (TRI).

The announcement on the testing of high production volume chemicals is a direct result of OPPT recent analysis of the public availability of basic testing and screening information on chemicals produced or imported at more than 1 million pounds per year (HPV chemicals). EPA/OPPT recently released its analysis on the availability of SIDS (Screening and Information Data Set) test data on US HPV chemicals (see article on page 7). SIDS is considered the minimum set of tests that can allow an informed screening-level evaluation of a chemical's hazards. A full text of the EPA report, entitled "Chemical Hazard Data Availability Study: What do we really know about the safety of high production volume chemicals?", is available on the Internet at www.epa.gov/opptintr/chemtest/hazchem.htm.

The study found that of the 3,000 U.S. HPV chemicals, a full set of SIDS testing was publicly available for only 7% of the chemicals and that no SIDS data were available for 43% of the chemicals. The report also considers specific subsets of chemicals including TRI-listed chemicals, those with occupational exposure standards, and those used in certain consumer products. In addition, the report discusses the costs of completing the tests needed to fill the data gaps on these chemicals and offers a preliminary look at how individual companies who produce HPV chemicals compare in terms of the data available on their products.

Here are some of the highlights we found when we analyzed the available data on these subsets of chemicals of special interest.

Office of Pollution Prevention & Toxics

CHEMICAL HAZARD DATA AVAILABILITY STUDY

What Do We Really Know About the Safety of High Production Volume Chemicals?

EPA'S 1998 Baseline of Hazard Information That Is Readily Available to the Public

(April 1998)

Chemicals reported under TRI — 203 HPV chemicals appear on the TRI list. One would expect TRI chemicals to be relatively well tested, and, in fact, over half of these high-volume TRI chemicals have all six of the basic screening tests, and all of the TRI HPV chemicals have at least some data available. Clearly, there are more test data available on the TRI chemicals than on the full set of all HPV chemicals, but there are still data gaps — about 20% of the HPV TRI chemicals were missing 2 or more of the basic SIDS tests. On the other hand, many of the HPV chemicals not listed on TRI lack the basic information needed to determine if they should be listed on TRI — nearly half of the non-TRI listed HPV chemicals have no data available and fewer than 4% have the full set of basic tests. (See Figure 1, next page.)

...the majority of the HPV chemicals not listed on TRI lack the basic information needed to determine if they should be listed on TRI.

Chemicals in the products we use — Chemicals contained in consumer products are of concern due to the likelihood of their exposure to children, as well as other

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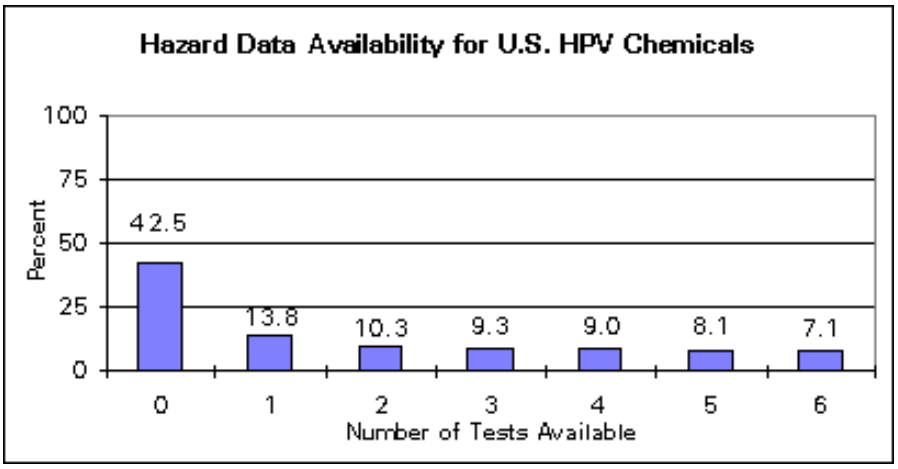

Figure 1

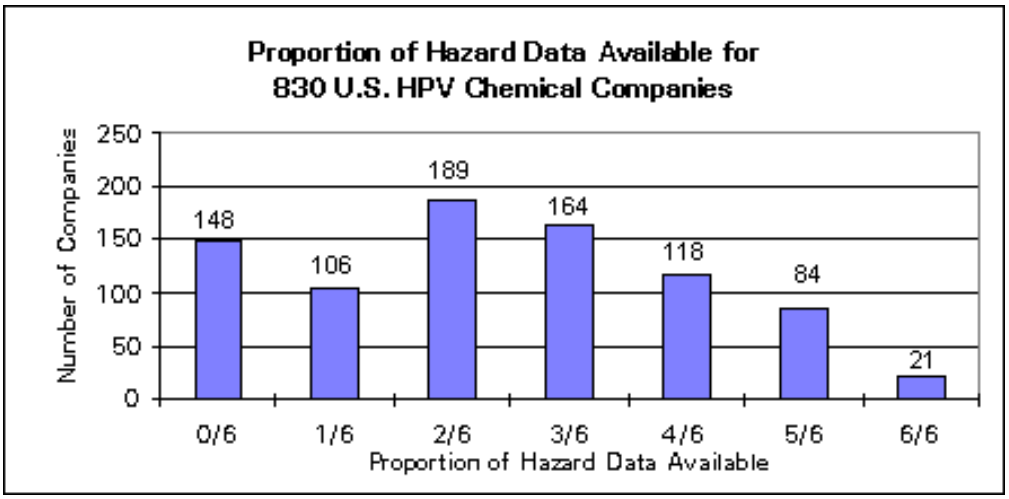

Figure 2

EPA is launching a Chemical Right-to-Know Initiative aimed at creating the information base that is needed to accurately assess the potential risks ...of chemicals in commercial use today.

sensitive populations. Fortunately, the industry has completed basic testing for more of these chemicals than is the case for other HPV chemicals — of the 491 HPV chemicals listed on EPA's Indoor Air Source Ranking Database, 25% have data publicly available for all six SIDS tests, while only 7% have no data available. Nonetheless, the great exposure potential of consumer products and the fact of children's exposure suggests the need for additional testing beyond the SIDS level so that we can adequately assess the risks of such chemicals.

Chemical companies need to do more to deal with this problem: Our preliminary analysis shows that, out of 830 companies making HPV chemicals in the US, 148 companies have no SIDS data available for any of their products. An additional 459 companies sell products for which, on average, half or fewer of the SIDS tests are available, while only 21 companies produce chemicals that are fully tested. (See Figure 2)

Much remains to be done — While these groups of chemicals are relatively more fully tested than the bulk of HPV chemicals, it is alarming that basic testing on human health hazards and ecotoxicity have been not completed on such large numbers of HPV chemicals. EPA is launching a Chemical Right-to-Know Initiative aimed at creating the information base that is needed to accurately assess the potential risks posed by the trillions of pounds of chemicals in commercial use today. A key element in this initiative is focused on engaging chemical manufacturers, interest groups, and other Federal agencies in the US, along with government and industry in other countries, in an enlarged effort to rapidly complete SIDS testing on all HPV chemicals.

OECD's Screening Information Data Set (SIDS)

Richard Hefter
Risk Assessment Division

Since the 1970's, member countries of the Organization for Economic Cooperation and Development (OECD) have been working together to address issues of chemical safety. The OECD includes the U.S., Mexico, Canada, European countries, Japan, Korea, and Australia. One of the major problems is that of evaluating the tens of thousands of chemicals already in commerce - "existing chemicals." OECD members decided to focus on the chemicals having the highest worldwide production (over 2 million pounds), and to collect for each one a standard minimum set of data. OECD would then use the data to screen these "high-production-volume" (HPV) chemicals for their potential risks to society. By 1990, the United States and the other OECD member countries were ready to start this voluntary international testing program.

The basic level of testing and other information gathered is called the Screening Information Data Set, or SIDS. The SIDS includes information on the identity of the chemical, its physical and chemical properties, uses, sources and extent of exposure. The testing required is designed to answer basic questions about the chemical. For instance, environmental fate testing can tell us whether the chemical degrades quickly in the environment and how it is distributed throughout the environment.

The toxicity testing is designed to measure how potent the chemical is from acute or one-time exposures such as from accidental ingestion or skin contact. Other tests measure the effects from longer exposures as might be encountered in the workplace or in communities near production facilities, such as mutagenicity tests which could indicate a potential to cause cancer.

Tests are also required that measure the chemical's ability to interfere with reproduction (fertility) and fetal development. Finally, a number of studies are required that indicate the potential for environmental effects such as to fish and aquatic plants should the chemical be released to water from production and wastewater treatment facilities. While all these tests do not fully measure a chemical's toxicity they do provide a minimum set of information that can be used to determine if additional testing is necessary.

Once sponsor countries and their industries have selected chemicals to work on, they collect data; prepare SIDS Dossiers (standardized summaries of the available information) and Testing Plans (for chemicals lacking some of the SIDS data); circulate SIDS Dossiers and Testing Plans to other countries for review and approval; review and comment on the documents prepared by other countries; carry out SIDS testing and add the new data to the Dossier; and prepare a SIDS Initial Assessment Report (SIAR). OECD review of SIARs (at SIDS Initial Assessment Meetings, or SIAMs) determines whether chemicals have a low priority for further work or whether further (Post-SIDS) testing or analysis of more detailed exposure information is needed.

The results of the SIDS program are available to all countries through the International Registry of Potentially Toxic Chemicals (IRPTC) and the International Program for Chemical Safety (IPCS). The program also cooperates with other international programs concerned with chemical safety, such as the World Health Organization.

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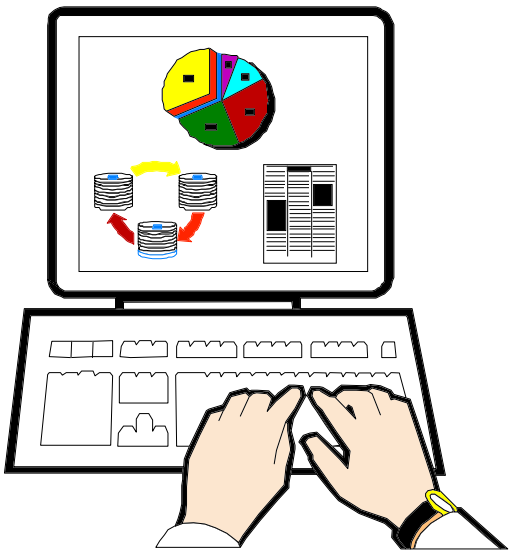


Considering the Costs of Testing

Lynne Blake-Hedges
Economics, Exposure and Technology Division

The results of EPA's analysis of the costs can be used to help shape the testing requirements put forth by EPA.

Chemical toxicity testing is often required by the EPA under Sections 4 and 5 of the Toxic Substances Control Act (TSCA). Manufacturers of the chemicals are generally responsible for paying the cost of testing. Costs of testing can vary significantly, and certain tests can be expensive. The Agency estimates that many tests can exceed $100,000 and some, such as cancer toxicity tests, can exceed $100,000. A Screening Information Data Set (SIDS), a typical battery of testing, generally ranges from $200,000 to $280,000. Recent Chemical Marketing Reporter (June 29, 1998) estimates for chemical industry value of shipments exceed $391 billion, some percentage of which is attributable to those chemicals with little toxicity information.

Therefore, to balance the need to gather information about chemical toxicity against the desire to minimize costly regulatory actions, the Agency considers testing costs in its decisions about chemical testing. This consideration of the costs of testing requirements is a relatively straightforward concept. Agency economists carefully anticipate which companies will be subject to the requirements of the rule. They assess the value of sales from a chemical, usually based upon the estimated volume produced and/or processed and the chemical sales price.

In cases where the chemical is new and not yet commercialized, price and production projections from the manufacturer are used. Judgments are then made about the affordability of the testing when multiple manufacturers produce a chemical, and they might share testing costs. The Office of Pollution Prevention & Toxics (OPPT) generally considers that test costs exceeding 1 percent of sales value suggest a possible adverse effect on the businesses involved. In this case, the Agency will more closely examine the testing requirements. Similarly, the Agency also evaluates the potential effects on small businesses of chemical testing.

For existing chemicals, the value of all sales is compared with the costs of the testing requirements to assess the industry's ability to afford the testing without adverse effects. With new chemicals, the Agency considers both the ability to afford testing and the time at which testing costs are recovered based upon projected production.

Estimates of the costs of testing include laboratory costs (equipment, supplies, etc.) and laboratory labor hours. Other costs considered include costs of soliciting laboratory bids, selection of laboratories, preparing test protocols, monitoring tests under progress, and preparing reports to EPA on the testing. The cost of testing requirements can extend beyond the actual test itself and include forming agreements with other manufacturers for cost-sharing and export notification. Further, if EPA requires chemical testing, that chemical is automatically covered by export notification requirements. That is, if the chemical is exported, the company must notify EPA, and EPA notifies the destination country that they are receiving this chemical.

The results of the EPA's analysis of the costs can be used to help shape the testing requirements put forth by EPA. Frequently, testing requirements may be tiered, such that more expensive or advanced testing may be required only if results of a screening test suggest a need for further testing. For new chemicals, the time at which test results are required is often related to the estimated time for those costs to be recovered through sales.

Given the number of industrial chemicals available today that have little or no toxicity data, toxicity testing will clearly continue to be necessary. In meeting the challenge to ensure the availability of such information while minimizing the costs to the businesses that provide it, the EPA will continue to include costs as one of the considerations in developing testing requirements.

Electronic Health and Safety Studies

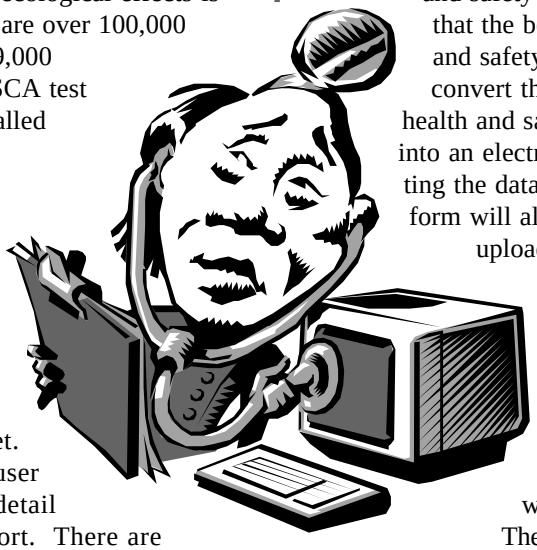
John Nowlin
Information Management Division

Chemical manufacturers have been submitting health and safety studies to the EPA since the inception of the Toxic Substances Control Act (TSCA) in 1976. These studies, submitted under Sections 4 and 8 of TSCA, include studies of chemicals or mixtures that may present an "unreasonable" (Section 4a) or a "substantial" (Section 8e) "risk of injury to health or the environment." EPA also asks for studies (Section 8d) on chemicals for which there are insufficient data. Most of these studies were submitted in response to chemical testing recommendations made by the TSCA Interagency Testing Committee (ITC). Every year the ITC reviews numerous Section 8(d) studies and decides whether testing for health effects, environmental fate, or ecological effects is needed. To date there are over 100,000 studies covering over 9,000 chemicals in EPA's TSCA test submission database called TSCATS.

Summary information from the TSCATS database can be accessed free of charge through the Right-to-Know Network (RTKNET) located at www.rtk.net. RTKNET allows the user to select the level of detail they want in their report. There are three levels of reports, the first of which allows the user to chose a report that will produce a description of each reference matching the search criteria. The second type of report provides the same information as well as a list of specific chemicals and studies. The third report provides all the information mentioned plus the full text of abstracts.

Although the health and safety studies themselves are not currently on-line, they are available from the EPA's Confidential Business Information Center (CBIC) located at 401 M Street SW, Room E-G099, Washington, DC 20460. A new EPA web site is being developed to allow industry submission of health and safety studies electronically. This effort, started over two years ago, is part of an Agency-wide initiative to improve electronic commerce throughout the EPA.

In July 1996, as part of the EPA's electronic commerce initiative, the EPA's Office of Pollution Prevention and Toxics (OPPT) invited industry, organizations, public interest groups, laboratories, the press, federal agencies and individuals to meet with the EPA in an open session to discuss ways to improve the timeliness, accessibility and quality of information reported under TSCA. The meeting generated tremendous energy, and resulted in a commitment to the electronic submittal and dissemination of health and safety data. The group agreed that the best way to collect health and safety data would be to convert the existing paper-based health and safety data (HaSD) form into an electronic means of submitting the data. This electronic HaSD form will allow for the direct uploading of health and safety summary data directly into TSCATS and to electronically attach the full study. Less than a year after the first meeting, the electronic HaSD form was put into use.



The electronic HaSD form is currently being used to collect health and safety data for the ITC. To date, the ITC has reviewed over 40,000 chemicals and will soon be using TSCATS to post information on these chemicals on their web site. To learn more about the ITC, visit www.epa.gov/opptintr/itc.

OPPT's new Chemical Right-to-Know (CRTK) program will also use the electronic HaSD form and TSCATS to post chemical information on EPA's web site. CRTK includes collecting studies on almost 3,000 high production volume chemicals - chemicals that are produced or imported in quantities greater than a million pounds a year.

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Every year the EPA reviews thousands of studies and makes a determination as to the use of the chemical in question.

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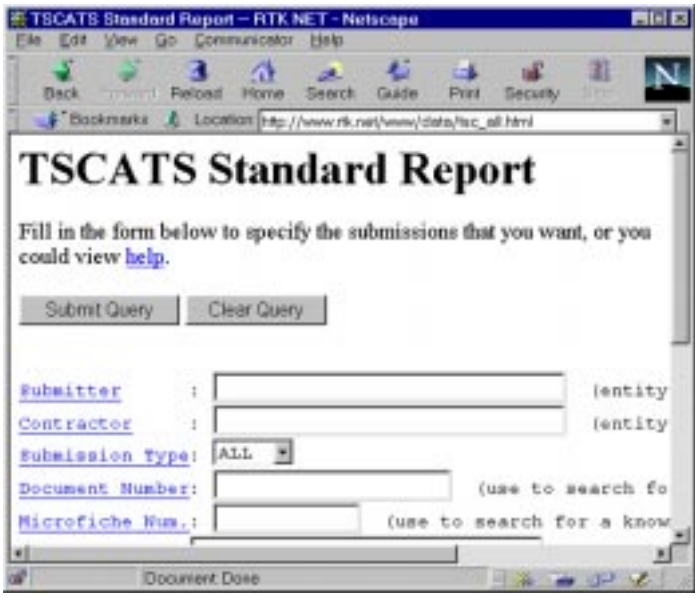


Figure 1

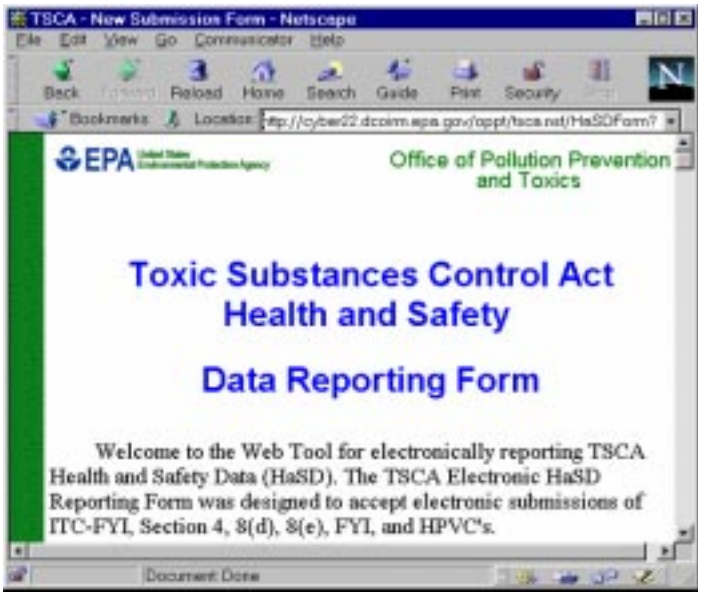


Figure 2

Data on these chemicals will be made available to the public under Vice President Gore's Chemical Right-to-Know initiative, an initiative to allow the public to easily access to information about chemicals in their community (see article on page 3).

OPPT plans to publish health and safety information on the EPA web site. The design of the web page includes a user-friendly interface that will allow the public easy access to information on chemicals of interest. The new web site will include the ability to access health and safety information at various levels of complexity (depending on the user's needs). OPPT will continue to improve its ability to collect and disseminate information to fulfill the communities' right to know about chemicals. As part of this commitment, OPPT holds regular open sessions on the electronic submission and dissemination of TSCA data.

To request information on the next electronic open session meeting, write to: John Nowlin (7407), US EPA, 401 M Street, SW, Washington, DC 20460 or send an e-mail to nowlin.john@epa.gov.

Outside Experts Recommend Chemical Testing Process for Endocrine System Effects

Gary Timm
Chemical Control Division

In recent years, increasing scientific and public attention has been focused on the potential effects of synthetic chemicals on the hormone, or *endocrine*, systems of people and wildlife.

The endocrine system consists of the glands and the hormones they produce that help guide the development, growth, reproduction and behavior of animals including human beings. The glands of the endocrine system include the pituitary, thyroid, and adrenal, as well as the ovaries and testes. The hormones produced by these glands travel through the bloodstream and affect functions in other parts of the body. For example, adrenaline helps stimulate physical activity; estrogen affects the female reproductive system; and androgen affects the male reproductive system.

Chemicals that interfere with the normal function of these complex systems are known as "endocrine disruptors." For example, some chemicals may mimic a natural hormone, "fooling" the body into over responding to the hormone. Other chemicals may block the effects of a hormone in parts of the body normally sensitive to it.

In response to the increasing concerns about potential endocrine effects, Congress included provisions in the 1996 Food Quality Protection Act and amendments to the Safe Drinking Water Act that require EPA to develop by August 1998 a program for screening and testing chemicals for adverse effects to endocrine systems. To meet this ambitious Congressional deadline and to include the latest scientific thinking, EPA established the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) to provide advice and recommendations.

The EDSTAC met nine times between December 1996 and June 1998, and will submit its final recommendations by September. The committee focused on screening pesticides, contaminants, and commercial chemicals for estrogenic, androgenic, and thyroid hormone effects. With the universe of chemicals to be prioritized for endocrine screening and testing numbering more than 86,000, the committee has recommended a tiered process to detect endocrine disrupting chemicals and quantify their effects that includes initial sorting of chemicals, priority setting for chemicals to be tested, and a battery of eight *in vitro* and *in vivo* screening assays, and a battery of four multi-generation (rodent, fish, invertebrate) tests.

Updates on OPPT and EDSTAC activities can be found on the Internet at www.epa.gov/opptintro/opptendo.

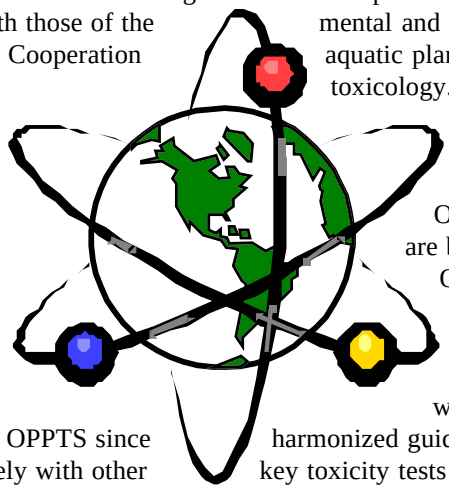
EPA established an advisory committee called the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) to provide advice and recommendations

OECD Test Guidelines in Health and Environmental Effects

Michael C. Cimino
Risk Assessment Division

Presently, 30 health effects guidelines and six ecotoxicity test guidelines have been harmonized between EPA/OPPT and OECD.

Differences in test guidelines between offices of the U.S. Environmental Protection Agency have the potential of leading to confusion and to unnecessary testing of chemicals. Similarly at the international level, differences in test guidelines between nations lead to unnecessary testing of chemicals in world commerce. To avoid duplication of testing, the Office of Pollution Prevention and Toxics (OPPT) and the Office of Pesticides Programs (OPP) have been in the process of harmonizing their guidelines for human health and ecotoxicity testing into a single set of guidelines for the Office of Prevention, Pesticides and Toxic Substances (OPPTS), and in the process are harmonizing these OPPTS guidelines with those of the Organization for Economic Cooperation and Development (OECD). The OPPT/OPP project was begun in 1990 and is nearing completion. The harmonization effort between OPPT with OECD had been ongoing since the mid 1980's.



International harmonization of test guidelines has been a high priority for Assistant Administrators of OPPTS since 1990. By cooperating closely with other Federal agencies, states, tribes, and non-governmental organizations, and with their counterparts in other countries, the EPA is reducing the burden to regulated industry, increasing efficiency in collecting test data and in assessing risk, avoiding duplication of effort, saving animal lives and expense, reducing non-tariff trade barriers and fostering the mutual acceptance of test data between the U.S. and other countries.

OPPT has published 118 guidelines not only in the areas of human health and ecotoxicity, but also in environmental fate and physical chemistry. OECD has published 55 guidelines in the same four areas. OPP has a total of 97 test guidelines in these areas, plus 129 additional guidelines for other specific requirements for OPP's evaluation of pesticides (e.g., product identity, performance, composition, application exposure).

Presently, 30 health effects guidelines and six ecotoxicity test guidelines have been harmonized between EPA/OPPT and OECD. Ten health effects guidelines and 13 ecotoxicity guidelines have been harmonized between OPPT and OPP to produce guidelines which are unique to OPPTS. Some of these OPPTS test guidelines incorporate recent and significant advances in the scientific knowledge and methodologies, particularly in the areas of neurotoxicity, developmental neurotoxicity, developmental and reproductive biology, aquatic plant toxicology and sediment toxicology. OPPT is currently leading many of the efforts to harmonize these improved guidelines with OECD. These guidelines are being revised in light of OPP Science Advisory Board (SAP) comments in May and October 1996.

In July 1998, EPA will publish 45 OPPT/OPP harmonized guidelines in health effects for key toxicity tests (acute toxicity, specific organ/tissue toxicity, subchronic toxicity, chronic toxicity, genetic toxicity, neurotoxicity, reproductive and developmental toxicity, immunotoxicity and metabolism and pharmokinetics) will be published in the Federal Register. They will also be available electronically in PDF (portable document format) on the EPA World Wide Web site at www.epa.gov/epahome/research/htm, or via the U.S. Government Printing Office (GPO) at ww.access.gpo.gov or in disk or paper form (call GPO at 202-512-0132).

It is expected that at least 10 guidelines in ecotoxicity (the 850 series) should be harmonized and finalized by the end of this year.

Hazardous Air Pollutant Test Rule

Richard Leukroth
Chemical Control Division

Since the Clean Air Act was amended in 1990, EPA's Office of Air and Radiation (OAR) has used a "technology-based" and performance-based approach to significantly reduce emissions of air toxics from major sources of air pollution. Under this approach, OAR develops standards for controlling the routine emissions of air toxics from each major type of facility within an industry group. These standards — know as "maximum achievable control technology" (MACT) standards — are based on emission levels that are already being achieved by the better-controlled and lower-emitting sources in an industry. To date, OAR's Office of Air Quality Planning and Standards has completed work on some 22 MACT standards. Eight years after a MACT standard is issued, OAR must assess the remaining health risk (also called residual risk) from that source category. If the residual risk assessment indicates a continued concern about potential health effects that may occur at MACT standard exposure levels, then OAR may implement additional standards that address any significant remaining risk.

While OAR focuses efforts on developing MACT standards, they have asked EPA's Office of Research and Development to develop an approach to assess residual risk (see Residual Risk Report to Congress; 63 FR 19914; April 22, 1998) and to collaborate with EPA's Office of Pollution Prevention and Toxics (OPPT) to use TSCA section 4(a) as a means to obtain identified data needed for this future assessment. The data obtained through TSCA would be used to implement several provisions of section 112 of the Clean Air Act, including determination of residual risk, estimation of the risks associated with accidental releases of chemicals, and determinations regarding whether substances should be removed from the Clean Air Act Section 112(b)(1) list of hazardous air pollutants. In addition, the data will be important for EPA's Chemical Right-to-Know program as well as for other Federal agencies—the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission—for assessing chemical risks and taking appropriate actions within their programs.

As an initial effort to build this database, OPPT proposed the HAP Test Rule in June 1996. OPPT identified 21 High Production Volume chemicals from the List of Hazardous Air Pollutants that require additional data. The proposed rule would require that industry test these HAP chemicals for health effects from inhalation exposures using the eleven OPPTS harmonized test guidelines published in the Federal Register (FR6243820, April 15, 1998).

This is the first TSCA chemical test rule that gives industry the opportunity to submit alternative testing proposals which, if acceptable to EPA, would permit industry test sponsors to enter into Enforceable Consent Agreements (ECAs) with the Agency that would use state of the art methods to perform route-to-route extrapolations of health effects of chemicals from existing data where the route of exposure was not by inhalation. These methods — pharmacokinetics and mechanistic data—describe how the body absorbs, distributes, metabolizes, and excretes a chemical. OPPT has received alternative test proposals for almost half of the chemicals listed in the HAPs rulemaking.

On December 24, 1997, the proposed rule was amended to cross-reference the

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The proposed rule required that industry test HAP chemicals for health effects from inhalation exposures using the 11 OPPTS harmonized test guidelines...

Master Testing List (MTL)

Frank Kover
Chemical Control Division

EPA anticipates the size of the list to increase significantly with the addition of HPV chemicals and chemicals that may pose the greatest risks to children.

Since 1990, EPA's Office of Pollution Prevention and Toxics (OPPT) has used the Master Testing List (MTL) — a list of industrial chemicals that are considered to be the highest priority for its chemical testing program under the mandates of Sections 2 and 4 of TSCA. The MTL helps EPA program managers focus limited Agency resources on the highest priority chemical testing needs, publicize OPPT's industrial chemical testing priorities, obtain public input on program priorities, and encourage voluntary industry initiatives to conduct needed testing. OPPT adds individual chemicals and chemical categories to the MTL as a result of the TSCA Interagency Testing Committee activities and requests by other EPA program offices, other Federal agencies, as well as OPPT's Existing Chemicals Program.

The MTL currently lists over 600 chemicals and more than 15 chemical categories such as endocrine disruptors, oxygenated fuel additives, paint stripping products and chemicals, and hazardous air pollutants. All of the chemicals and categories on the list are "active" in ongoing testing programs, testing action development, or testing needs development.

With Vice President Gore's 1998 Earth Day announcement, EPA anticipates the size of the list to increase significantly with the addition of chemicals that may pose the greatest risks to children and the 3,000 chemicals, labeled High Production Volume (HPV) chemicals, that are produced or imported in amounts over one million pounds per year. EPA expects to issue the next version of the MTL sometime in 1999. Given the expanded scope from adding the HPV chemicals, it may be necessary to reformat the list.

The current (1998) version of the MTL is available in hard copy from OPPT's Public Docket and the TSCA Hotline, (202) 554-1404. The electronic version is on the Internet at www.epa.gov/opptintr/chemtest/index.htm.

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proposed testing requirements to the new eleven harmonized TSCA guidelines. In this amendment, the Agency removed certain testing requirements; revised the economic assessment; proposed criteria to help determine who is required to test a HAP chemical that is a byproduct or impurity; and described other changes and clarifications to the proposed test rule. To help meet requirements contained in the proposed amended rule, EPA also solicited ECA proposals on HAP chemicals for which proposals had not been received.

Once again, on April 21, 1998, the proposal was amended to modify the provisions for identifying persons who are required to test and to provide additional guidance in determining what their responsibilities would be under the rule.

With the close of the comment period, June 22, 1998, OPPT staff is working to complete the ECA negotiations and finalize the rule as soon as possible. Comments and support documents for the HAPs rulemaking can be found, on the Internet at www.epa.gov/fedrgstr/EPA-TOX/1997/December/Day-24/s-t33451.htm.

PMN (Premanufacture Notice) Chemical Testing Issues

David Schutz
Chemical Control Division

In implementing the Vice President's call to gather basic test data on the most widely used chemicals, EPA will have the ability to screen these chemicals for potential effects on human health and the environment. EPA's ability to perform toxicity screening has been substantially developed through its New Chemicals Program. Under this Program, the Agency routinely screens chemicals before they are manufactured for commercial use.

EPA's New Chemicals Program sets the pace for the chemical industry's testing of new chemicals for potential health risks. Section 5 of TSCA requires that anyone wanting to manufacture a "new" chemical, i.e., one that is not on EPA's list of chemicals in commerce known as the TSCA Inventory, must submit a Premanufacture Notice (PMN) for EPA approval. OPPT's New Chemicals Program then assesses the proposed chemical for its uses, benefits, and its potential to harm human health and the environment.

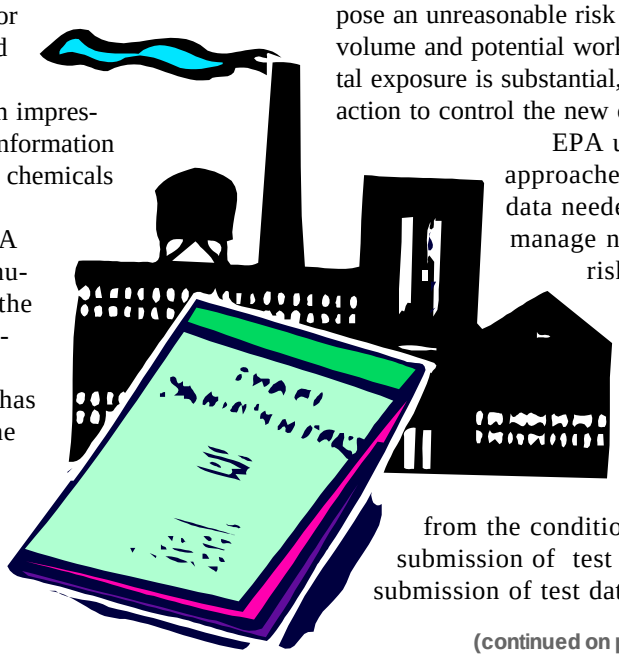
EPA's assessment of a chemical's potential risk is based partly on test results submitted its PMN and partly on existing information on similarly structured chemicals. EPA has been collecting and evaluating data on chemicals for almost 20 years, and as a result the program has built an impressive storehouse of information on the hazards such chemicals can pose.

Although TSCA requires that a manufacturer submit to the Agency any toxicological or environmental test data it has on a chemical at the time of its PMN application, there is no defined base data set of hazard information, and TSCA does not require prior testing of new chemicals. Less than half of the PMN applications include toxicological data. In evaluating PMNs for which no or little data is provided, EPA scientists predict toxicicity by assessing the chemical's structural similarity to chemicals for which toxicological data are available in a process called structure-activity relationship analysis (SAR).

The Agency's SAR knowledge base has largely been accumulated through the New Chemicals program and through testing submitted under sections 4 and 8 of TSCA. When data available to the New Chemicals Program is not adequate to assess the toxicity and risk of the new chemical, the Agency often requires that additional data be generated.

EPA toxicologists, chemists, biochemists, engineers, and experts in other disciplines work together to predict the potential risks to human health or the environment from each new substance. Most of the new chemicals submitted to the program complete the review process without being restricted or regulated in any way. However, if the Agency determines that a new chemical substance may pose an unreasonable risk or that production volume and potential worker or environmental exposure is substantial, EPA can take action to control the new chemical.

EPA uses a variety of approaches in obtaining test data needed to assess or manage new chemicals risks: (1) permit the PMN submitter to manufacture or import the new substance under specified conditions, where deviation from the conditions would require submission of test data; (2) require submission of test data before a speci-



... anyone wanting to manufacture a "new" chemical must submit a premanufacture notice (PMN) for Agency approval.

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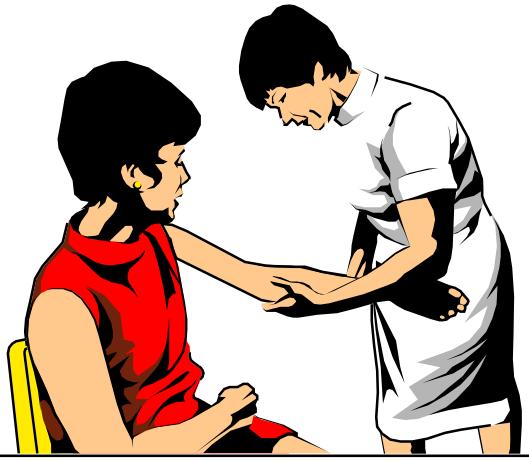
Dermal Absorption Rate Testing for OSHA

Keith Cronin
Chemical Control Division

EPA is developing a proposed Test Rule under Section 4(a) of the Toxic Substances Control Act (TSCA) that could require manufacturers (including importers) and processors of 47 chemical substances of interest to the Occupational Safety and Health Administration (OSHA) of the Department of Labor to conduct dermal absorption rate testing.

EPA was asked by the TSCA Interagency Testing Committee (ITC) to require the chemical industry to test about 80 chemicals for dermal absorption rates. The request came from OSHA, which needs absorption rate data to determine whether workers need to wear protective equipment when handling certain chemicals. In anticipation of this request, the Office of Pollution Prevention and Toxics (OPPT) and ITC developed a method for *in vitro*-dermal absorption rate tests for screening workplace chemicals. On the basis of the test method, EPA solicited Enforceable Consent Agreement (ECA) testing proposals from industry. Through an ECA, industry agrees with EPA to conduct specific tests on a specified schedule. The ECA is a more flexible tool for all parties than rulemaking. EPA received one offer from industry to test one chemical via an ECA. OPPT is currently preparing a proposed TSCA Section 4 Test Rule for 47 chemicals with the highest production volume and highest number of workers exposed for which no adequate data have been reviewed. At a later date, EPA will propose testing for the remaining chemical substances of interest to OSHA.

OPPT and ITC developed a method for *in vitro*-dermal absorption rate tests for screening workplace chemicals.



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fied production volume or date is reached (known as "triggered" testing); or (3) permit the PMN submitter to suspend the review period while developing additional test data (this approach works best where the needed testing can be completed relatively quickly). EPA takes action to control new chemicals for about 10% of the cases.

When the Agency specifies (using a consent order under Section 5) conditions under which it will permit manufacture or import of a new substance pending development of test data, manufacture of the new substance can take place under precautions for workers or environmental safeguards (e.g., protective equipment, use restrictions, methods of waste disposal) which the Agency believes provide a remedy for the possible risks. In cases where the Agency determines that a new substance will present an unreasonable risk, EPA can prohibit the manufacture, processing, or distribution in commerce of the substance.

For more information on this program visit the New Chemicals Program website at www.epa.gov/opptintr/newchms.

ChemAlliance

Compliance Assistance Center Coming Soon!

David Piantanida
Environmental Assistance Division

Who is ChemAlliance?

ChemAlliance is a compliance assistance center designed for the chemical industry. It was established in the fall of 1997 under a cooperative agreement funded by EPA's Office of Enforcement and Compliance Assurance (OECA). EPA has partnered with the National Center for Clean Industrial and Treatment Technologies (CennCITT), Pacific Northwest National Laboratory (PNNL), and the University of Wisconsin - Solid and Hazardous Waste Education Center (SHWEC) in this effort.

What is ChemAlliance?

ChemAlliance is designed to assist the chemical industry to more efficiently achieve and maintain compliance with environmental regulations with an emphasis on pollution prevention. Specifically, ChemAlliance will:

- Provide information that addresses the environmental compliance needs of the chemical industry.
- Improve information transfer between individual companies and EPA, and among assistance providers.
- Provide practical information on how chemical manufacturers can improve compliance while reducing costs and improving quality.
- Help chemical manufacturers decrease the costs and increase the effectiveness of compliance.

Information will soon be provided via a World Wide Web site and will contain an "expert help desk" function that will enable users to locate important information quickly. The ChemAlliance web site and toll-free hotline will be launched in September 1998.

Who are Expected to be the Primary Users of this Center?

- Individual company representatives charged with compliance at one or several facilities
- Individuals or organizations that provide assistance to industry

The Center's objectives in serving each of these markets are to assist the company level individual in understanding and maintaining compliance and to enhance the capabilities of industry by providing useful and accurate information.

Why ChemAlliance?

ChemAlliance will help users to sort through existing information and direct them immediately to the best solution.

ChemAlliance is designed to assist the chemical industry to more efficiently achieve and maintain compliance with environmental regulations with an emphasis on pollution prevention.

What's New

1996 TRI Data Release Announced

Through its Toxics Release Inventory (TRI), the U.S. EPA recently reported industrial releases of toxic chemicals in U.S. communities decreased from 2.5 billion pounds in 1995 to 2.4 billion pounds during 1996, a decline of 4 percent or 100 million pounds. Since industry first began reporting releases in 1988, releases have decreased by almost 46 percent.

The 1996 TRI report also includes industry-specific analyses of five major industry sectors that are required to report their toxic chemical releases. Over the past 10 years, all of these industries have reduced the amount of toxic pollution they report to EPA. Of these five industry sectors, declines in TRI chemical releases were led by chemical manufacturing, followed by primary metals, electrical equipment, pulp and paper, and petroleum refining. EPA will complete a report later this summer containing analyses of the additional 15 industries that report to the TRI.

Information on TRI is available in public libraries, or on-line at www.epa. gov/opptintr/tri, or by calling the TRI User Support at (202) 260-l53l.

New Standards and Information Program Help Protect Families and Children from Lead Paint Hazards

EPA has proposed new standards and is issuing a final rule, effective June 1999, that addresses health hazards from lead-based paint. The proposed standards identify levels of lead and provide consumers with information about lead-based paint hazards of renovating or remodeling their homes. The new rule will require renovators, who are working for compensation, to give homeowners and tenants information on how to protect themselves from lead hazards before renovation begins.

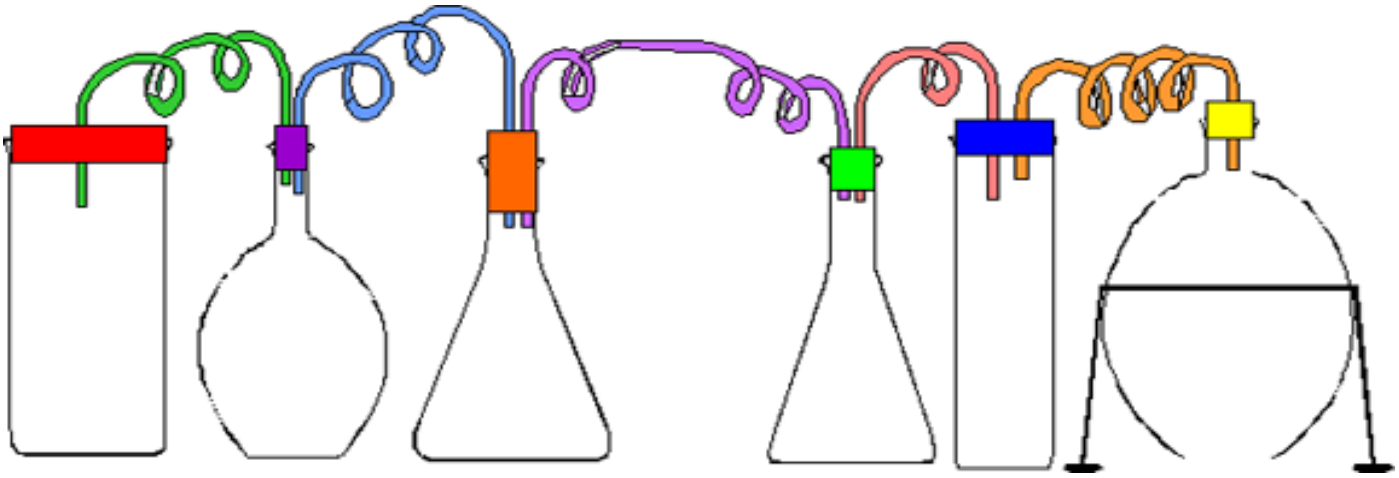
The new rule and proposed standards cover homes built before 1978. There is an estimated 80 percent of all residences built before 1978 which contain some lead-based paint. Although it can usually be safely managed, when lead-based paint is disturbed during renovation it can contaminate dust and soil and pose a significant hazard, especially to young children. Almost one million children under the age of six have unsafe levels of lead in their bodies, making lead poisoning the number one environmental health hazard for young children.

Copies of both the proposed and final rules as well as a pamphlet on lead hazards in the home for renovators to use are available on EPA's web site at www.epa.gov/lead or by calling the hotline at (800) 424-LEAD.

Final Report on Endocrine Disruptors Screening Due in July

At a final meeting of EPA's Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), committee members provided final comments on the draft report. This report recommends a strategy for screening and testing chemicals to determine whether they have potential to affect endocrine function in humans, fish, and wildlife.

The EDSTAC was established to implement a provision of the Food Quality Protection Act and Safe Drinking Water Act amendments that require screening and testing protocols for chemicals suspected of endocrine disrupting effects. More information on EDSTAC can be found on the web at www.epa.gov/opptintr/opptendo/index.htm or by calling the Keystone Center at (970) 468-5822.



What's New

EPA Publishes Final Guidelines for Ecological and Neurotoxicity Risk Assessment

EPA completed guidelines for doing ecological and neurotoxicity risk assessments. Both guidelines were developed to foster consistency across the Agency for planning and conducting risk assessments. The guidelines for ecological risk assessment describe three phases of the process, general principles, and examples of how the principles can be applied to situations such as hazardous waste clean-up, new pesticide registration, or watershed management. The neurotoxicity risk assessment guidelines are intended to guide the Agency's evaluation of chemicals suspected of causing adverse neurological effects, with a focus on the vulnerability of infants' and children's nervous systems. The guidelines are available on EPA's web site at www.epa.gov/ncea.

New Software Identifies Building Products for Environmental Performance

As part of its Environmentally Preferable Purchasing (EPP) Program, EPA has contributed to the development of a software program that helps to identify products that will reduce energy use, improve air quality and other conditions that can improve the environmental performance of buildings. The software program, Building for Economic and Environmental Sustainability (BEES), was developed under an Interagency Agreement by the National Institute of Standards and Technology with funding from EPA. The program will help federal facility managers make decisions about how to purchase building products based on cost and environmental considerations. For more information see the web site at www.usgbc.org.

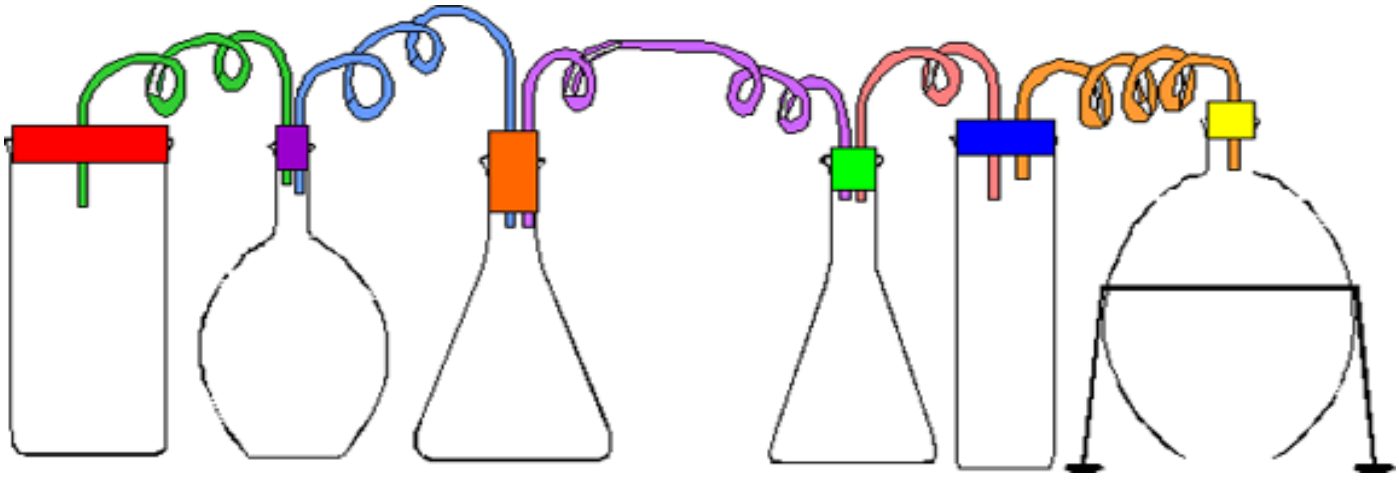
OPPTS Assembles Community-Based "Tool" Box

OPPTS has published an online version of *Act Locally*, a compilation of OPPTS databases, programs, funding opportunities, hotlines, training opportunities, and other pesticide/toxics related activities that can be used by communities to gather more information for improving their local environments. The listings will be updated periodically and nominations for new items are welcome.

Pollution Prevention Centers Across US Network for Better Service

EPA has established a new network for pollution prevention information and technical assistance through a grant program that is funding nine regional pollution prevention centers. In February 1998, representatives from each of the centers met to develop a decision making process, standardize bibliographies, establish quality assurance protocols, and discuss evaluation and measurement issues.

In addition to the grant program, OPPT allocated an additional one million dollars to fund activities in each of these centers that improve state cooperation. Without the states' investment of staff time and resources, regional centers cannot survive. The network, called the Pollution Prevention Resource Exchange (P2Rx) provides information that is readily accessible and updates technical information. The network is easy to search, collect, synthesize, and identify experts and other sources of information. More information about the network can be found on EPA's web site at www.epa.gov/p2.



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