G R A D I E N T

TRENDS

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Environmental Data: Providing Context

While numerous publicly-available databases exist, few provide a meaningful risk context for their information.

Over the past 15 years or so, beginning with the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and subsequently fueled by the expansion of the Internet, there has been a virtual explosion in the environmental information readily available to the public. Data regarding hundreds of chemicals, measured at thousands of monitoring stations, and released from tens of thousands of facilities, are available. Even data regarding the same environmental medium, such as drinking water, can be found on different, non-overlapping databases. However, the individual databases are of different quality and have varying strengths and limitations. Moreover, the types of data provided (*e.g.*, pounds of emissions or number of enforcement actions) are typically presented without context, or sufficient information to draw conclusions regarding the potential health and environmental impacts of the chemicals or facilities under study. The following are some of the key databases for water, air, or specific facilities, an overview of their key features, and recommendations for interpreting this information. The table summarizes two of the EPA's integrated media databases and the individual databases they contain.

> *…the types of data provided… are typically presented without context, or sufficient information to draw conclusions regarding the potential health and environmental impacts…*

Water: STORET (STOrage and RETrieval) is the EPA's largest computerized environmental database. STORET is a general water quality database that contains information on biological, chemical, and physical data in surface water and ground-

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I N S I D E

Letter to our Readers

January 2003

Dear Colleague,

The "Information Age" may have started before the Internet, but the ability of the Internet to disseminate information, along with an increasing array of analytical chemistry tools, has provided us with an unprecedented amount of data on environmental chemicals. This issue of *Trends* explores the contents of environmental, biological exposure, and toxicity databases, and the information that is often lacking from each. Only by combining all of these pieces can the connection between the environment and health be understood.

Contributors to this issue include Dr. Barbara Beck, Gradient Principal and internationally recognized expert in toxicology, Dr. Teresa Bowers, Gradient Principal and specialist in exposure modeling, and Dr. Thomas Lewandowski, a senior toxicologist at Gradient. Joining them are Ms. Marsha Croninger and Mr. Chris Amantea, attorneys with the Los Angeles office of McDermott, Will & Emery, who have a fresh perspective on that state's Proposition 65; its successes and problems after 16 years.

We hope you enjoy this issue of *Trends*, and find food for thought the next time you "surf the Internet" in search of data.

Yours truly,

Neil Shifrin, Ph.D.
President

Trends is a free publication of Gradient Corporation, a national leader in risk assessment and negotiation of risk-based remediation. If you have a colleague who would benefit from this publication, please contact Bonnie M. Johnson at (617) 395-5000 or email us at *trends@gradientcorp.com.*

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Environmental Data: Providing Context

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water, as collected by the EPA, state agencies, tribes, and volunteer groups. Not all the information in STORET pertains to drinking water. Specific drinking water-related information is found in databases such as the SDWIS (Safe Drinking Water Information System), which reports compliance and enforcement information and in the NCOD (National Drinking Water Contaminant Occurrence Database), which contains information on regulated and unregulated contaminants obtained from public water systems, the U.S. Geological Survey, and other sources. The information in these databases can be used to evaluate trends in water quality over time, to help identify contaminants for possible future regulation, and to assess how well certain drinking water systems are complying with standards. However, none of the databases provide information on overall population risks from contaminants in drinking water because none are linked to actual population exposures involving patterns of tapwater use or contaminant concentration trends over time.

Air: As with water, environmental data regarding air can be found in several databases. For example, the AQS (Air Quality System) contains ambient air pollution data collected by the EPA, state, and local agencies. It focuses on the criteria pollutants, such as sulfur dioxide and ozone, and also contains meteorological information and descriptive information about each monitoring station. This information is used to assess air quality and make determinations regarding the attainment/nonattainment status of a particular region of the country. As with the drinking water data described above, the data do not directly provide risk information because the data are not directly linked to exposure. For example, monitoring stations are typically not at breathing height, and represent different population sizes and characteristics. In the case of ozone for example, understanding risk requires developing reasonable estimates of population exposure, and linking those estimates to behavioral patterns, including outdoor activity, in different sub-populations.

Facilities: Facility-specific data regarding compliance and enforcement information, chemical releases, and demographics of the surrounding population can be found in a number of databases. For example, the FRS (Facility Registry System) contains information on an individual facility as reported from 13 different systems, such as the SDWIS and the TRI (Toxics Release Inventory). The TRI is a database of annually reported releases of specific chemicals to air, water, and land from select industries. TRI data have been useful in tracking trends in total emissions over time and in understanding geographic differences in chemical releases. TRI emissions can appear quite large – *e.g.*, billions of pounds of reportable chemicals were released from manufacturing industries in 2000 – however, the relevant parameter is not how many pounds of chemicals are released, but the resulting long-term concentrations and toxicities of the materials to which populations are exposed. In the case of electric utilities, whose emissions totaled nearly 800 million pounds in 2000, actual risks associated with these emissions have been shown to be relatively modest and do not exceed typical regulatory limits (see *Trends*, Fall 2001).

The bottom line is that, without context, data do not inform and may only obscure. As the availability of data increases, one must not confuse information with knowledge. The information contained in most of the currently-available environmental databases is only meaningful when exposure data are viewed in the context of chemical hazard information, and *vice versa*.

Barbara D. Beck, Ph.D., DABT, FATS
Email: bbeck@gradientcorp.com

Two Key EPA Integrative Media Databases

Database Title	Internet Address	Description	Data Sources
Envirofacts Data Warehouse	www.epa.gov/enviro/index.html	Provides the user with information about environmental activities that may affect air, water, and land anywhere in the U.S.	Seven major EPA databases: waste, water, toxics, air, land, maps, and other.
Facility Registry System (FRS)	www.epa.gov/enviro/html/fii/index.html	Contains an integrated source of comprehensive environmental information (air, water, and waste) about facilities, sites, or places.	EPA's national program systems (*e.g.*, TRI and Risk Management Plans) and state master facility records.

The EPA is moving towards providing a more comprehensive presentation of data.

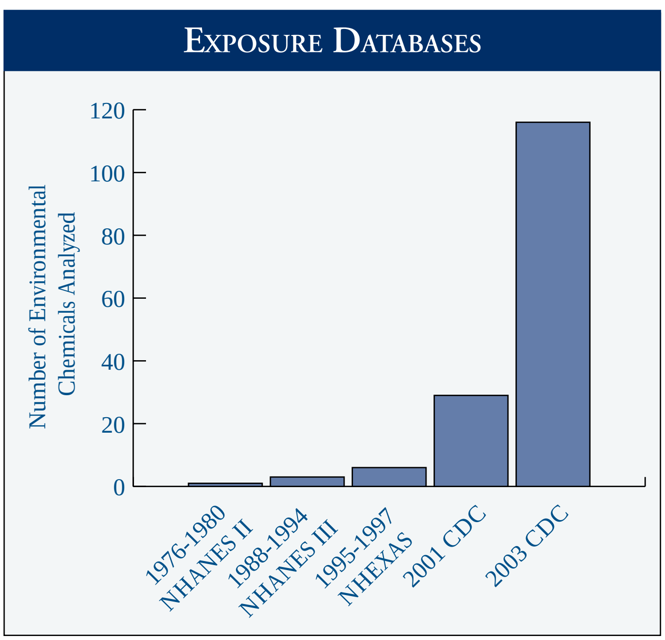
Understanding Exposure Databases

Biomonitoring databases are growing in sophistication in terms of the number of persons tested and the list of analytes.

The concept of biological exposure databases began as a reaction to the 1956 National Health Survey Act, which gave federal authorization to develop continuing surveys that would provide statistical data on measures of health and diet in the U.S. population. Since that time, biological exposure databases, which provide information concerning concentrations of chemicals in blood, urine, exhaled breath, and even hair, have grown both in terms of the number of people surveyed and the number of chemicals analyzed. The surveys provide information on general trends in the population, but generally do not provide any insights into the public health significance of these findings. This article summarizes some of the key exposure databases and provides comments regarding appropriate interpretation of these databases.

> *It must also be recognized that the mere presence of a chemical in the body… does not indicate elevated health risk.*

NHANES II and III (National Health and Nutrition Examination Survey): These surveys of approximately 10,000 (1976-1980) and 27,000 (1988-1994) individuals provide comprehensive information about lead in blood for both children and adults, and form the basis for our understanding of how lead exposure has changed over the last several decades in the U.S. On its web page, the Centers for Disease Control (CDC) credits the NHANES studies with providing the first evidence of elevated blood lead levels on a population basis that led to the phase-out of leaded gasoline.



The number of environmental chemicals monitored in blood and urine has been growing exponentially.

TEAM (Total Exposure Assessment Methodology) Study: This survey analyzed volatile organics in personal air, ambient air, exhaled breath, and drinking water in 600 people in four states. A major finding of the study was that indoor air at home and at work was more important than outdoor air as a route of exposure for the chemicals analyzed. The study pointed to building materials and consumer products as possible sources.

NHEXAS (National Human Exposure Assessment Survey): There were three NHEXAS surveys conducted in Baltimore, Arizona, and the EPA Region 5 states of Ohio, Indiana, Michigan, Illinois, Wisconsin, and Minnesota. The surveys focused on metals, pesticides, and volatile organics in blood, urine, food, drinking water, personal air, and indoor air, and collected extensive information about time and activity patterns that influenced human exposure. This database is distinguished from others by the tremendous amount and variety of participant-specific exposure information.

CDC National Report on Human Exposure to Environmental Chemicals: This report, released in 2001, measured concentrations of 27 environmental chemicals in blood or urine, including metals, pesticides, and phthalates. The report specifically noted that detection of a chemical in blood or urine did not mean that the chemical caused disease. Major findings of the report included reduced exposure to lead and environmental tobacco smoke over the last decade, and a basis for prioritization of phthalate research by identifying the phthalate metabolites found in highest concentrations.

The CDC is poised to release the second edition of the National Report in January 2003, and it will then be updated yearly. The second edition will contain information on an unprecedented 116 chemicals in blood and urine. Activists are concerned that the wrong chemicals are being measured, and critics fear that the results will herald increasingly strict regulatory policies without appropriate foundation. In this light, it is important to remember the types of information that exposure databases do not provide. While the databases can help illuminate trends in exposure over time and can help differentiate among exposures in different sub-populations, the databases do not generally provide information to differentiate among various exposure sources, including anthropogenic *vs.* natural sources, (although some surveys, such as the NHEXAS survey have simultaneously measured chemicals in various environmental media). It must also be recognized that the mere presence of a chemical in the body, as reflected in an exposure database, does not indicate elevated health risk. As with the environmen-

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Making Sense of Hazard Data

A number of recent chemical hazard testing initiatives are generating unprecedented amounts of toxicity data.

The U.S. EPA and the chemical industry have agreed to three new initiatives aimed at generating toxicity data for a substantial number of commercial chemicals. These initiatives address High Production Volume (HPV) chemicals, chemicals to which children have a high likelihood of exposure (the Voluntary Children's Chemical Evaluation Program, VCCEP), and chemicals that may affect the endocrine system (the Endocrine Disruptor Screening Program). Toxicity testing for each chemical will employ standard batteries of screening tests intended to rapidly fill data gaps in the existing toxicological literature for these chemicals.

In order for the data to have meaning, human exposures to these chemicals also will need to be evaluated.

While useful in their own right, the toxicity data will not be sufficient to accurately identify potential health risks. In order for the data to have meaning, human exposures to these chemicals also will need to be evaluated. Chemicals cannot pose a health risk if there is no route of exposure. Chemical-specific information will therefore have to be generated on potential uses, potentially exposed populations, additional sources of exposure, and methods of disposal. The EPA has acknowledged the utility of exposure information by permitting parties involved in the hazard testing initiatives to also supply exposure data for their products.

The exposure potential is just as important as the toxicity testing in determining whether a chemical presents a risk. Consider, for example, the chemical colcemide. Colcemide is highly toxic, being both mutagenic and a developmental toxicant. However, use of colcemide is largely limited to research institutions, where the chemical is used by trained professionals and the chemical is (hopefully) disposed of in an environmentally safe manner. Thus, even though the chemical is highly toxic, the tightly controlled use suggests a *de minimis* concern and a low priority for additional evaluation.

The U.S. EPA guidance indicates that hazard identification under these initiatives should be conducted in a phased or tiered approach. The evaluation starts with simple worst-case assessments using readily available data (*e.g.*, physical/chemical data, existing toxicity data, sales data). Progression to more extensive data collection and analyses is required only when the results of the first tier analysis indicate a potential public health concern. Each phase of the hazard identification should clearly state the outcome (*i.e.*, *de minimis* risk, additional testing required, or risk management needed) and should describe any data limitations. It is important to remember that hazard evaluation is intended to be a screening tool. Hazard identification is only the first step in the risk assessment process, as identified by the National Academy of Sciences. A positive result in a toxicity test does not necessarily mean that an actual risk exists. Such tests are designed to have a large number of false positives in order to be health protective. The most a positive result can tell us is that additional evaluation is required.

In order to provide an exposure context for these hazard data, the Alliance for Chemical Awareness has developed a user-friendly framework to guide sponsors of chemical hazard testing programs in planning and conducting exposure assessments. Development of exposure information will greatly increase the value of these toxicity testing programs.

Thomas A. Lewandowski, Ph.D.
Email: tlewando@gradientcorp.com

For Additional Information:

Alliance for Chemical Awareness: http://www.chemicalawareness.org
Endocrine Disruptors: http://www.epa.gov/scipoly/oscpendo/
HPV Challenge Program: http://www.epa.gov/chemrtk/volchall.htm
VCCEP: http://www.epa.gov/chemrtk/childhlt.htm

By The Way...

Blood lead levels in the U.S. population as a whole declined from a geometric mean of 12.8 μg/dL in 1976-1980 to 1.5 μg/dL by 1999. Geometric mean blood lead levels in children under the age of six years declined from 15.0 to 2.0 μg/dL over this same time period.

Sources: Pirkle, *et al.* 1994. *JAMA* 272(4):284-291, and U.S. Public Health Service, Centers for Disease Control and Prevention. 2001. National report on human exposure to environmental chemicals. March.

What's New at Gradient

Upcoming Presentations

Salt Lake City, Utah. March 9-13, 2003. Society of Toxicology Annual Conference Poster presentations:

- **Leslie A. Beyer,** and **Barbara D. Beck.** "Derivation of Air Action Levels for Use in Monitoring During Site Remediation."
- **Sunessa Schettler, Mara R. Seeley,** and **Barbara D. Beck.** "Health Risks for Construction Workers in Industrial Redevelopment: A Major Risk Driver."
- **Mara R. Seeley, Thomas A. Lewandowski,** and **Barbara D. Beck.** "Evaluating Health Implications of Lubricating Oil on Orthopedic Medical Implant Devices."
- **Thomas A. Lewandowski, Mara R. Seeley,** and **Barbara D. Beck.** "Inter-Species Differences in Susceptibility to Perchlorate: A Critical Consideration for Human Health Risk Assessment."
- **Christopher S. Wells, Lorenz R. Rhomberg,** and **Thomas A. Lewandowski.** "Spontaneous Tumor Incidence in Humans and Rodents: Efforts to Reconcile the Observed Data with BBDR Model Predictions."

Pittsburgh, PA. March 31-April 4, 2003. 2003 American Association for Aerosol Research (AAAR) PM Meeting, Particulate Matter: Atmospheric Sciences, Exposure and the Fourth Colloquium on PM and Health.

- **Christopher M. Long** and J.A. Sarnat. "Infiltration Behavior of PM2.5 Chemical Components: Implications for PM Exposure Assessment and Epidemiological Associations."
- **Peter. A. Valberg** and **Christopher M. Long.** "Is PM More Toxic Than the Sum of Its Parts? Discordance Between 'Effect Functions' for PM Mass *vs*. Risk Assessment Toxicity Factors."

Kansas City, MO. April 7-9, 2003. Richard J. Blanchet. "Assessment of Deer Mice Populations and Chemical Tissue Residues at Two Military Installation Landfills." ASTM International Symposium – Landscape Ecology and Wildlife Habitat Evaluation.

Recent Articles

Botham, P.A., **A.W. Hayes**, and D. Moir. 2002. The International Symposium on Regulatory Testing & Animal Welfare: Recommendations on Best Scientific Practices for Acute Local Skin & Eye Toxicity Testing. *Institute for Laboratory Animal Research Journal* 43:S105-S107.

Bunn III, W.B., **P.A. Valberg**, T.J. Slavin, and C.A. Lapin. 2002. What is new in diesel. *Int. Arch. Occup. Environ. Health* 75(Supplement 1):122-132.

Faustman, E.M., R.A. Ponce, Y.C. Ou, M.A. Mendoza, **T.A. Lewandowski**, and T. Kavanagh. 2002. Investigations of methylmercury-induced alterations in neurogenesis. *Environ. Health Perspect.* 110(Supplement 5):859-64.

Lewandowski, T.A., C.H. Pierce, S.D. Pingree, S. Hong, and E.M. Faustman. 2002. Methylmercury distribution in the pregnant rat and embryo during early midbrain organogenesis. *Teratology* 66(5):235-241.

Understanding Exposure Databases

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tal databases (see related article), exposure databases are most informative when considered in the context of other information, including assessment of sources or linkage to levels associated with health effects.

Teresa S. Bowers, Ph.D.
Email: tbowers@gradientcorp.com

For Additional Information:

Pirkle, J.L., D.J. Brody, E.W. Gunter, R.A. Kramer, D.C. Paschal, K.M. Flegal, and T.D. Matte. 1994. The decline in blood lead levels in the United States: The National Health and Nutrition Examination Surveys (NHANES). *JAMA* 272(4):284-291.

Sexton, K., D.E. Kleffman, and M.A. Callahan. 1995. An Introduction to the National Human Exposure Assessment Survey (NHEXAS) and related Phase I field studies. *Journal Exposure Analysis and Environmental Epidemiology* 5(3):229-332.

U.S. Public Health Service, Centers for Disease Control and Prevention (Atlanta, GA). 2001. National report on human exposure to environmental chemicals. March.

Wallace, L. 1987. The Total Exposure Assessment Methodology (TEAM) Study; Summary and Analysis: Volume I. Prepared for the U.S. EPA, Office of Research and Development (Washington, D.C.) EPA-600/6-87-002a. 192p. June.

Guest Editorial: Looking Back on California's Proposition 65: Taking Science Out of Context

Proposition 65 warnings and lawsuits are numerous and widespread in California, but good science can be used to distinguish those that are important.

> *...Proposition 65 places important burdens on the business to, in effect, "prove compliance" rather than on the plaintiff to prove the violations alleged.*

Proposition 65 is a unique California law that requires that businesses give warnings to individuals before exposure to any one of hundreds of chemicals identified by the state as causing cancer or reproductive toxicity, (the "Proposition 65 List"). The law also prohibits the discharge of a Proposition 65 List chemical where it passes or probably will pass into any source of drinking water. Proposition 65 was enacted in 1986 by California voters through the state's ballot proposition process.

Noncompliance with Proposition 65 can result in significant penalties and in litigation that is costly for businesses from both public relations and financial perspectives. The vast majority of Proposition 65 enforcement actions have been brought by citizen groups, who receive a percentage of the civil penalties ultimately collected (the so called "bounty hunter" provision). This has spawned an industry of citizen enforcers. Most cases settle before trial because, unlike most laws, Proposition 65 places important burdens on the business to, in effect, "prove compliance" rather than on the plaintiff to prove the violations alleged. This burden can encourage the use of bad data or assumptions to allege a violation. Some courts have allowed plaintiffs to proceed even though they claim no specific data supporting the alleged violation.

As a result, in California, Proposition 65 warnings are everywhere – on product labels, on the entrances to buildings, at supermarkets, in virtually every retail store, in model homes, and in gasoline stations, to name a few. There are so many "warnings" that most consumers ignore them and the Attorney General's Office has threatened to take action to prevent "over warning." In one cartoon, a mugger was shown giving a Proposition 65 warning to his victim before threatening to shoot with lead bullets.

Ultimately distinguishing between good data with sound analysis and pseudo science can make a difference in a Proposition 65 case. For example, in a recent case it was claimed that brass keys were exposing people to lead in violation of Proposition 65. Careful analysis of the exposure data proffered by the plaintiffs showed that important assumptions and test methods were inaccurate and unverifiable and that they did not consider the type of exposure – dermal rather than ingestion.

In 2002, the state legislature amended Proposition 65 supposedly to make it more difficult for citizen groups to bring claims without a scientific basis. However, the amendments are not viewed by businesses as likely to be effective. Thus, Proposition 65 with all its scientific flaws and issues remains an industry of its own in California.

Marsha S. Croninger, Esq. & Chris M. Amantea, Esq.
McDermott, Will & Emery

In the next issue:

Scientific Evidence in the Courtroom

Strategies for Scientific Communication

Mediating Environmental Disputes

Guest Editorial: Pushing Tort Reform to the Forefront

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Gradient Corporation
238 Main Street
Cambridge, Massachusetts 02142
Phone: (617) 395-5000
Fax: (617) 395-5001
Internet: trends@gradientcorp.com

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