G R A D I E N T

TRENDS

Risk Science & Application

Fall 2004

Background Risks: An Overview

The simple concept of background risks can quickly become convoluted.

Just the term "background" evokes different images for different people: it's either the concentrations found in the natural pristine environment before it was touched by humans, or, on the other extreme, it's everything put there by anybody other than me. This use of multiple definitions is a source of confusion; let's clarify what we really mean by these different definitions of background.

> *…where does background stop and contamination begin?*

"Natural background" refers to pristine conditions prior to the effects of industrialization. Metals and other elements have a natural background concentration in soils, groundwater, surface waters, and even air. Some organic compounds such as polycyclic aromatic hydrocarbons also occur naturally. Natural background is variable, changing with soil type, parent rock material, water chemistry, and even climate. The most comprehensive survey of natural background conditions in U.S. soils currently available is based on sampling done by Shacklette and Boerngen in the late 1960s, who sought to sample soils in areas away from human influence (see related article for current plans to update that survey). The U.S. Geologic Survey also maintains databases for background groundwater conditions.

"Anthropogenic background" refers to the results of human redistribution of naturally occurring compounds, as well as to levels of man-made compounds not associated with pollution point sources. The latter includes various pesticides, PCBs, and dioxin compounds, among others, found in many locations in the environment.

But where does background stop and contamination begin? Anthropogenic background can include concentrations arising from non-point sources outside of

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I N S I D E

Letter to our Readers

September 2004

Dear Colleague,

Background levels of chemicals in our environment stem from naturally occurring sources, redistribution of natural deposits by human industry, and the introduction of man-made chemicals which now show up in areas widely scattered from their point of origin. Whether background chemicals are natural or man-made, they form a backdrop of risk, against which all site risks can be measured. This issue of *Trends* examines the nature of background and describes the different approaches taken by various regulatory agencies in dealing with risk associated with background.

Contributors to this issue include Drs. Teresa Bowers and Barbara Beck, Gradient Principals and risk assessors who deal with background risks in their work, as well as Rosemary Mattuck, an environmental scientist and exposure expert. Joining them as our guest authors are Drs. David Smith and Martin Goldhaber of the U.S. Geological Survey who describe their initial efforts to get a large, new soil background study of North America underway.

We hope this issue of *Trends* will provide you with new insights on the role of background levels of chemicals in risk assessment.

Yours truly,

Neil Shifrin, Ph.D.
President and Founder

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 Melissa Marieb at (617) 395-5000 or email us at *trends@gradientcorp.com*.

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Background Risks: An Overview

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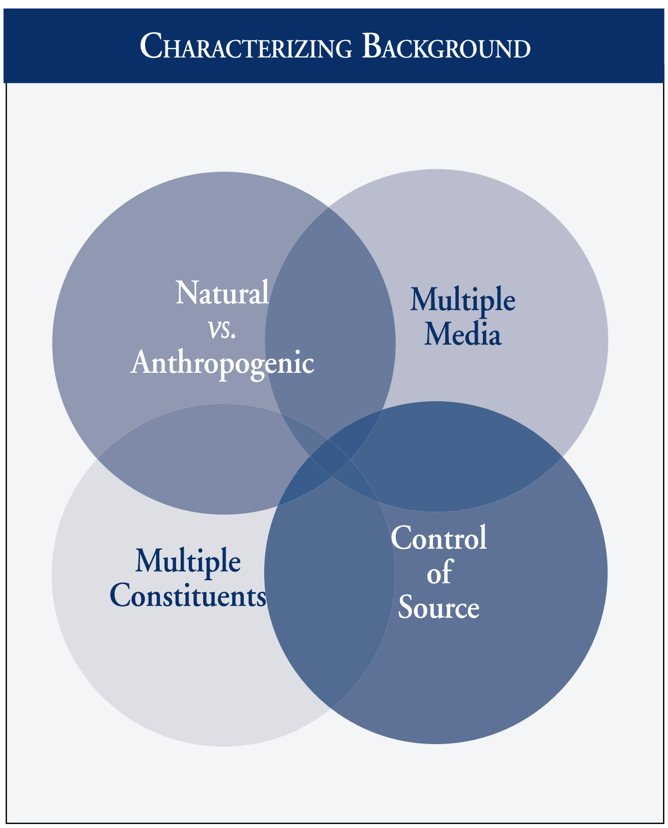
the site area under investigation, or concentrations from point sources at the site next door. Even contamination present as a result of an unrelated source at the same site can be considered anthropogenic background under some air regulatory programs (EPA, 1999). Perhaps the easiest way to think about anthropogenic background is that it includes everything not controlled under the current regulatory framework or by the regulated entity. This definition is unsatisfying to some (see related article), but brings to the forefront the issue of control. Industries are unable to affect contaminant levels outside of those that result from their own processes, and yet are sometimes required to remediate to a concentration threshold that falls within the range of anthropogenic, or even natural, background. In such instances, it is clearly important to separate site influences from background concentrations.

Management of risks in light of background levels of contaminants is another controversial topic (see related article for approaches selected by some agencies). Again there are two viewpoints: the "risk cup" approach where high background levels fill up most of the risk cup and therefore allow only for a low increment resulting from contamination; or, alternatively, situations where elevated background risks suggest there is little public health benefit associated with remediation of small additional sources. The public is, predictably, much more tolerant of risks associated with compounds that are naturally high (*e.g.*, natural levels of arsenic in some states' drinking water aquifers) than with the ubiquitous background levels of pesticides and other man-made chemicals in our environment. However, remediation of both can be equally difficult.



Describing background may involve one or more of these typologies.

...background levels are often poorly understood by all parties: the public, the regulators, and the regulated.

Beyond the difference in perception of naturally-occurring *vs.* man-made background levels is the fact that background levels are often poorly understood by all parties: the public, the regulators, and the regulated. Often background is described by a single value, which may or may not be further identified as an average or upper percentile. Such single values do not do justice to the range inherent in either natural or anthropogenic background. Large-scale studies, such as that soon to be undertaken by the U.S. Geologic Survey, should help to broaden everyone's awareness of background levels of metals and other contaminants in our environment.

Understanding the role and influence of background levels of contaminants at a site can involve several different typologies (see figure). Calculations of either total or incremental risks from background exposures require consideration of natural *vs.* anthropogenic background. It also can involve the contributions from multiple media (*e.g.*, background levels of arsenic may be high in soil, but at low concentrations in groundwater). Additionally, multiple constituents are present at varying background levels. Finally, there is the issue of control – that is, one regulated entity cannot control the environmental conditions resulting from other sources of contamination – sources that become the local background. To properly incorporate a consideration of background into environmental risk-based decision making, these multiple attributes of "background" must be examined both individually and collectively.

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References:

U.S. EPA. 1999. Residual Risk Report to Congress. Office of Air Quality Planning and Standards. Research Triangle Park, N.C. March. EPA/453/R-99/001.

Cultural Issues in Exposure Assessment

Certain culture-specific exposure assessments require unique approaches.

Risk assessors typically use any of a number of guidance documents and literature sources in evaluating exposures to populations that may reside near waste sites, live in areas of industrial activities, or consume potentially contaminated foodstuffs. Example source materials include the U.S. EPA Risk Assessment Guidance for Superfund, the EPA Exposure Factors Handbook, and any of a number of memoranda focused on specific exposure pathways. While risk assessors may differ regarding selection of specific intake assumptions in different scenarios, in general, these materials have served as useful resources in characterizing population exposures.

However, there are situations where such resources are not adequate to evaluate population exposures. Of particular interest are exposures to Native American populations, who, because of their unique cultural heritages, may experience exposures that may not be adequately characterized using the above source materials. In this article we explore the nature of such exposures, demonstrating the importance of obtaining relevant, site-specific information in order to conduct an adequate exposure assessment. We also note other sub-populations where unusual exposure conditions may exist.

Types of non-typical exposure scenarios include: contact with an unusual source material; non-standard contact with a particular exposure medium; greater than typically considered exposure intakes; and existence of high (non-site related) background exposures to a particular chemical. Examples of such scenarios follow:

> *…conducting a scientifically-supported exposure assessment for Native Americans or other sub-populations requires development of appropriate ethnographic information…*

Contact with an unusual (for standard risk assessments) source material: A number of exposure assessments of Native American populations in the western U.S. have noted that basket-weaving may be part of a traditional lifestyle. In certain situations, the raw plant materials used for basket weaving may contain herbicides applied to clear roadways; use of these materials in basket weaving may result in potential dermal and oral exposures. Populations may also consume certain foodstuffs, such as groundhogs or snapping turtles, that are not typically addressed in exposure assessments.

Non-standard contact with a particular exposure medium: Exposure assessments for groundwater typically consider

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Representative Federal and State Sites Involving Native Americans

Site	Tribe	Location
Celtor Chemical	Hoopa Valley	Humboldt, California
Commencement Bay, Near Shore/ Tide Flats	Puyallup	Tacoma, Washington
Tar Creek	Cherokee	Ottawa County, Oklahoma
Tucson Airport	San Xavier Tohono O'Odham	Tucson, Arizona
UNC Church Rock	Navajo	McKinley County, New Mexico
General Motors, Central Foundry	St. Regis Mohawk	Massena, New York
Prewitt Abandoned Refinery	Navajo	McKinley County, New Mexico
East Michaud Flats	Fort Hall Shoshone-Bannock	Pocatello, Bannock, and Power Counties, Idaho
Bunker Hill Smelter	Coeur d'Alene	Shoshone County, Idaho, and Spokane, Washington
Tulalip Landfill	Tulalip Tribe	Marysville, Washington
Champion International/Cass Lake	Leech Lake Chippewa	Cass Lake, Minnesota
Potlatch Landfill	Fond du Lac Chippewa	Cloquet, Minnesota
Rio Tinto Mine Site	Shoshone-Paiute	Mountain City, Nevada

Considering Background in Risk Assessment

Although the regulatory approaches to background may differ, certain statistical tenets must remain constant.

"Background" refers to naturally occurring or anthropogenic levels of constituents in the environment that would exist even in the absence of the site under consideration. Examples include naturally occurring levels of arsenic in soil, and pesticides present in soil as a result of area-wide agricultural pesticide application. A baseline risk assessment is generally conducted to characterize the potential threat to human health that may be posed by contaminants at a site (EPA, 2002a). Federal and state agencies have differing requirements for consideration of background in risk assessment.

Federal and state agencies have differing requirements for consideration of background in risk assessment.

Recent EPA guidance recommends that even if compounds of potential concern (COPCs) are present at background levels, they should be retained in the baseline risk assessment if they exceed risk-based screening levels, such as the Region 9 Preliminary Remediation Goals (PRGs) (EPA, 2002a). Thus COPCs above screening levels must be retained in the risk assessment even if they are not related to releases from the site. The contribution to site risks from COPCs present at background concentrations should then be discussed in the risk characterization (EPA, 2002a). This approach is designed to present a more thorough characterization of site risks for risk managers and the public, and prevent the inadvertent omission of potentially release-related contaminants from the risk assessment (EPA, 2002a).

In contrast, the Massachusetts Department of Environmental Protection (MADEP) focuses assessment and remediation resources on contamination that is directly attributable to a release, and has the potential to pose a significant risk to public health. Therefore, chemicals which are present at levels consistent with background are eliminated from the risk characterization process, and are considered by definition to be at a level of "no significant risk" (MADEP, 1995). The approach used by the California Department of Toxic Substances Control (DTSC) falls somewhere in between the EPA and the MADEP; it allows metals that are present at naturally-occurring background levels to be eliminated from quantitative risk assessments, but notes that evaluating background risks may provide important information to risk managers as well as the affected public (DTSC, 1992).

Irrespective of how a particular agency chooses to incorporate background data, it is important to recognize that both site and background data are represented by data distributions, rather than point estimates. Thus, in comparing site data to background levels, the same distribution parameter (*e.g.*, the mean) should be used as the comparison statistic for both sets of data. The EPA recommends using a statistical test, such as a t-test, to determine whether the site mean is greater than the background mean at a certain level of statistical significance (EPA, 2002b). The appropriate statistical test depends on the distribution of the underlying data (EPA, 2002b). In addition, in some situations, individual site data points may be compared to an upper percentile of the distribution of background data. In either case, it is important to ensure that the appropriate descriptors of site and background risk are being compared (*i.e.*, means to means or individual data to upper percentile values). To do otherwise would diminish the utility of considering background in the first place.

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References:

U.S. EPA. 2002a. Role of Background in the CERCLA Cleanup Program. Office of Solid Waste and Emergency Response. Office of Emergency and Remedial Response. April 26. OSWER 9285.6-07P.

U.S. EPA. 2002b. Guidance for comparing background and chemical concentrations in soil for CERCLA sites. Office of Emergency and Remedial Response. September 2002. EPA/540/R-01/003; OSWER Publication 9285.7-41. http://www.epa.gov/superfund/programs/risk/background.pdf.

MADEP. 1995. Guidance for disposal site risk characterization – in support of the Massachusetts Contingency Plan (Interim final policy). Massachusetts, Dept. of Environmental Protection, Bureau of Waste Site Cleanup and Office of Research and Standards (Boston, MA). July 1995. BWSC/ORS-95-141.

DTSC (California). 1992. Office of the Science Advisor. Guidance. Chapter 5. Selection, Use and Limitations of Indicator Chemicals for Evaluation of Exposure to Complex Waste Mixtures. Interim Final. July 1992.

Two recent studies (one in the United States and one in Argentina) on arsenic in drinking water and bladder cancer did not find elevated incidence of the cancer. These studies provide additional evidence that cancer risks estimated from Taiwan populations may overestimate risks for U.S. populations.

Sources: Steinmaus, C., Y. Yuan, M.N. Bates, and A.H. Smith. 2003. Case-control study of bladder cancer and drinking water arsenic in the western United States. *Am. J. Epidemiol.* 158:1193-2001.

Bates, M.N., O.A. Rey, M.L. Biggs, C. Hopenhayn, L.E. Moore, D. Kalman, C. Steinmaus, and A.H. Smith. 2004. Case-control study of bladder cancer and exposure to arsenic in Argentina. *Am. J. Epidemiol.* 159(4):381-389.

What's New at Gradient

Gradient Appointments

Dr. Barbara D. Beck has recently been appointed to the scientific advisory panel for the Manganese Health Research Program.

Upcoming Presentations

Boston, MA. September 21-24, 2004. Lorenz R. Rhomberg. "Cancer Dose Response and the New EPA Guidelines," lecture for the Harvard School of Public Health continuing professional education course, Analyzing Risk: Science, Assessment, and Management.

Philadelphia, PA. October 26-27, 2004. Lorenz R. Rhomberg. "Introduction and Concepts: Fundamentals in Applying Toxicology to Risk Assessment," lecture in the American Chemical Society Short-Course: Toxicology – Principles and Applications.

Portland, OR. November 14-18, 2004. Fourth SETAC World Congress posters and sessions:

- **Richard J. Blanchet**, **Shijin Ren**, and **Jennifer Garber.** "Development of ECORASS or Ecological Risk Assessment Software Computer Model," poster presentation.
- **Shijin Ren.** "Toxicity of Complex Mixtures," session chair.

Palm Springs, CA. December 7-10, 2004. Thomas A. Lewandowski and **Lorenz R. Rhomberg.** "Choosing a Single Value for the Inhalation Unit Risk for Trichloroethylene (TCE) from the Range in the 2001 Draft U.S. EPA Reassessment Document," paper at the 2004 Society for Risk Analysis annual meeting.

Recent Articles

Schoen, A., **B.D. Beck**, R. Sharma, and **E. Dubé**. 2003. Arsenic toxicity at low doses: Epidemiological and mode of action considerations. *Toxicol. Appl. Pharm.* 198(3):253-267.

Lewandowski, T.A., **M.R. Seeley**, and **B.D. Beck.** 2004. Interspecies differences in susceptibility to perturbation of thyroid homeostasis: A case study with perchlorate. *Regul. Toxicol. and Pharm.* 39(3):348-362.

Ren, S. 2004. Assessing wastewater toxicity to activated sludge: recent research and developments. *Environment International.* 30(8):1151-1164.

Ren, S. and P.D. Frymier. 2004. Reducing bioassay variability by identifying sources of variation and controlling key parameters in assay protocol. *Chemosphere.* 57(2):81-90.

Valberg, P.A. 2004. Is PM more toxic than the sum of its parts? Risk-assessment toxicity factors versus PM-mortality "effect functions." *Inhalation Toxicology* 16(1):19-29.

Cultural Issues in Exposure Assessment

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ingestion and dermal contact with drinking water, and inhalation of volatiles released from water during showering. However, water poured over heated rocks to create steam in a sweat lodge may result in elevated inhalation exposures to volatile chemicals. Another scenario involving non-standard contact with a particular exposure medium involves riding dirt bikes over contaminated tailing piles at former mining sites, resulting primarily in potential inhalation and dermal contact exposures.

Greater than typically considered exposure intakes: Subsistence consumers of fish and game may have intakes of certain foods much greater than those of the typical U.S. resident. While data are available for subsistence populations, intake rates for fish, as an example, can vary significantly even among such populations. Thus extrapolation from one population to the population of interest may be associated with much uncertainty, especially in the absence of information on the comparability of the two populations.

Existence of high (non-site related) background exposures to a particular chemical: Non-site related exposures to metals in particular may be another important consideration. For example, use of lead in eye cosmetics among some middle-eastern populations, or mercury in folk remedies among some Mexican Americans, can result in a exposure to these metals greater than the typical U.S. estimates. Adequately characterizing such exposures can be important in understanding total exposure to a metal (the relevant parameter for risk assessment), interpreting biomonitoring data, and developing appropriate risk management strategies.

It is clear from the above examples that conducting a scientifically-supported exposure assessment for Native Americans or other sub-populations requires development of appropriate ethnographic information through both literature sources and well-designed interviews with knowledgeable individuals. Information related to both site and non-site exposures of specific chemicals must be part of the data development process.

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For Additional Information:

Harper, B.L. *et al.* 2002. Example risk assessment considering Native American exposures. *Risk Analysis* 22:513-525.

Guest Editorial: Updating the Soil Background Database

Proposed soil geochemical survey of North America enters pilot phase.

The U.S. Geological Survey, in collaboration with partners in Canada and Mexico, has initiated a project called Geochemical Landscapes that has as its long-term goal a soil geochemical survey of North America. Our understanding of the variability in chemical composition of the soils on the North American continent is very limited. Neither Canada nor Mexico has a national-scale soil geochemical database, and the most-often-quoted data set for soils of the conterminous United States (Shacklette and Boerngen, 1984) contains only 1,323 samples (one sample per 2,300 square miles). As a result, our ability to recognize and quantify changes to soil composition caused by urbanization, industrialization, agriculture, mining, waste disposal, and other human activities is severely impaired.

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The proposed sample design for the survey consists of a uniform grid of 10,000 sites across the continent. At each site, up to five samples will be collected: 1) the upper five cm; 2) O-horizon (if present); 3) a composite of the uppermost mineral soil horizon; 4) the most representative B-horizon; and 5) C-horizon. The analytical protocol includes an extensive array of major and trace elements using ICP-AES and ICP-MS following a four-acid extraction to determine total elemental content of the samples. This is being supplemented by single-element determinations (Hg, Se) as well as total carbon, carbonate carbon, and total sulfur. An estimate of bioaccessibility will be made by a distilled-deionized water extraction and a simulated human gastric fluid extraction followed by ICP-MS. A limited number of organic compounds will be analyzed to study long-range transport of organic pollutants and the distribution of pesticides, PAHs, and their breakdown products. The A-horizon samples will undergo microbiological characterization by a combination of phospholipid fatty acid analysis, BIOLOG analysis, and enzyme assays.

The project has just entered a pilot phase to test and refine these protocols. Sampling is currently being conducted along two transects across the continent. One transect extends from northern Manitoba into central-southern Mexico. The other extends from just north of San Francisco to the Maryland shore. The goal of these transects is to determine continental-scale variation in the soil geochemistry and microbiology. Sampling will be completed during 2005. A more detailed regional-scale pilot study is underway in an area of approximately 12,000 square miles just north of the San Francisco Bay area and extending from the Pacific Ocean to the California-Nevada border. This pilot study will address 1) the impact of sample design on resultant geochemical maps and 2) the variation of soil geochemistry and microbiology with land use, geology, and soil type. This regional-scale pilot study should be completed by the end of 2006.

We welcome comments and suggestions regarding this effort.

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U.S. Geological Survey

In the next issue:

Nanotechnology: An Overview

Hazards of Nanoparticles

Exposures to Nanoparticles

Guest Editorial: Regulatory Challenges

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