



TERA

**Toxicology Excellence
for Risk Assessment**

*a nonprofit corporation
dedicated to the best use
of toxicity data for risk values*

Toxicology Excellence for Risk Assessment (*TERA*)

Articles of Incorporation: Statement of Purpose & Mission

Toxicology Excellence for Risk Assessment (*TERA*) is a non-profit, 501(c)(3) corporation organized for scientific and educational purposes.

The mission of *TERA* is to protect public health by developing and communicating risk assessment values, to improve risk assessment methods through research, and to educate the public on risk assessment issues.

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TERA: Specific Activities

- Establishing high quality risk assessment values through the Verifiable Estimates for Risk Assessment (*VERA*) program;
- Compiling and distributing peer reviewed risk values through the International Toxicity Estimates for Risk (*ITER*) database;
- Sponsoring expert peer consultation and review of risk values;
- Improving the underlying methods for risk assessment through research and publication;
- Educating diverse groups through training courses, scientific support and the State Hazard Evaluation Lending Program (State HELP);
- Facilitating improved risk assessment and management decisions through informed and neutral guidance.

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Who Is *TERA*?

- *TERA* is home to 10 technical/scientific staff and 3 administrative staff.
- Our scientific staff, which includes 3 board certified toxicologists, has a combined experience of more than 125 years in the fields of risk assessment, environmental science, and regulatory toxicology
- *TERA* has its origins in EPA's risk assessment programs and continues to produce cutting edge risk assessments following EPA methods:

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- Michael L. Dourson is the founder and Director of *TERA*. With 15 years at EPA, he was instrumental in developing EPA's non-cancer risk assessment methodology and was Chair of the RfD/RfC Work Group.
- Jacqueline Patterson spent 10 years with EPA and was the key person responsible for the development and management of the IRIS database.
- Joan Strawson (formerly Dollarhide) spent 5 years with EPA as the Director of the Superfund Health Risk Technical Support Center, developing provisional risk values for site assessments.
- Lynne Haber spent 6 years with an EPA contractor, developing assessment documents for review by the RfD/RfC Work Group and documenting the Work Group process.

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What is *ITER*?

International Toxicity Estimates for Risk (*ITER*) is a free Internet database of human health risk values from organizations around the world for 620+ chemicals. (<http://www.tera.org/iter>)

ITER presents key risk data from multiple organizations in a side-by-side table format along with a synopsis that explains differences in risk values derived by different organizations.

ITER includes links to each organization's website for more detailed information.

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Why Did *TERA* Create *ITER*?

To provide risk assessors and managers easy access to current international risk information

- Each agency that develops risk values publishes its own work in printed documents and/or on its own website; therefore, risk assessors and managers need to search several websites, databases, and documents to find data
- Organizations may have different chemical priority lists so derive values for different chemicals

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To help risk assessors and managers understand differences in risk values derived by different organizations

- Risk values are derived by a variety of organizations and may differ due to scientific judgments, methods, and/or availability of new data

To provide a forum through which independent parties can share their risk values.

- Non-governmental entities also derive values for chemicals, but do not typically have an avenue to make them publicly available.



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***ITER* Contains Data From:**

- Agency for Toxic Substances & Disease Registry (ATSDR) – Toxicological Profiles
- Health Canada – Priority Substances Assessment Reports
- National Institute of Public Health & the Environment (RIVM), The Netherlands – Maximum Permissible Risk Level Reports (in progress)
- U.S. Environmental Protection Agency (U.S. EPA) – IRIS
- Independent parties whose risk values have undergone independent peer review (see www.tera.org/peer)

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How is an Independent Value Added to *ITER*?

- The value must have undergone an independent peer review, for which both the process and results were clearly documented.
- At that review, potential and real conflicts of interest (COI) of the panel should have been identified; no one with a real COI served on the panel. The process for managing COI at the meeting was clearly described.
- The value has been derived following an identified, commonly used methodology.
- All significant recommendations of the review panel have been followed in developing the final value.
- All meeting and assessment documents are made available to anyone on request.

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TERA's Peer Review Process

- TERA's peer review is the primary review mechanism for *ITER* values.
- *TERA* reviews the Sponsor package to identify key scientific issues for panel selection and charge development.
- Panel must have all required scientific expertise as well as have a balance of affiliations in order to be credible.
- *TERA* forms panels drawing primarily from the pool of reviewers pre-approved by the *TERA* Board of Trustees. Additional, *ad hoc* reviewers may be recruited to provided needed expertise. Sponsors and stakeholders may suggest panel members, but *TERA* makes all final decisions on panel members.

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- *TERA's* COI policy defines issues of COI and bias. Prior to each meeting, *TERA* determines what is a COI for that chemical and sponsor and develops a COI questionnaire in order to identify COI issues for potential panel members. No one with an actual conflict is selected to participate. COI management is discussed at the start of each meeting.
- Open and transparent process – all review materials available to the public on *TERA's* website, public announcement of reviews, meetings open to the public and observers permitted to make comments; final meeting reports made available to public.

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How do Regulatory Agencies use *ITER*?

- Health Canada is the agency that develops risk values for Priority Substances under the Canadian Environmental Protection Act (CEPA). Health Canada uses *TERA*'s peer review program to review its values and *ITER* to communicate its values to the public.
- The State of California used *ITER*'s independent value for coal tar shampoos to resolve issues under Proposition 65 regulations.



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- U.S. EPA Region 6 used ITER's site-specific RfD to determine site clean-up levels based on ingestion of mercury-containing fish.
- U.S. EPA Office of Water is using ITER's independent values for soluble nickel compounds to develop a new MCL for soluble nickel.

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Anecdotal Evidence

- *TERA* currently has a review of a pesticide in progress. U.S. EPA's Office of Pesticide Programs has indicated that, once the assessment is on *ITER*, it will forward the entire documentation to its Science Advisory Panel for consideration in re-registration decisions for the pesticide.
- Several State risk assessors (CA, GA, OH, NJ) have indicated that *ITER* is a source they consider as they develop risk assessments for deriving standards and guidelines.



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- One State risk assessor has indicated (to both *TERA* and potentially responsible parties) that he would accept independently derived *ITER* values for setting site clean-up levels, if the PRPs would sponsor and conduct the work needed to get values onto *ITER*.
- Federal and state risk assessors regularly participate as members of *TERA* peer review panels

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Other *ITER* Information=

- The National Library of Medicine has decided to add *ITER* to the TOXNET collection of databases – look for *ITER* on TOXNET by the end of December 2003.
- *TERA* is currently in the process of adding IARC assessments to *ITER*.
- *TERA* has just established a partnership with another organization to add its values to *ITER*.

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