Public Briefing on the

## Independent Expert Review Panel (IERP) for the Human Health Risk Assessment Sudbury Soils Study

September 19, 2006 7:30-8:30 PM Collège Boréal

# AGENDA

- Welcome and Introduction of Toxicology Excellence for Risk Assessment (*TERA*) – Sudbury Soils Study Technical Committee
- II. Overview of the Independent Expert Review Panel process Ms. Jacqueline Patterson, *TERA*
- III. Introduction of the IERP
- IV. Questions on the IERP process

After this session, members of the Technical Committee will be available to answer any additional questions on the Soils Study.

Toxicology Excellence for Risk Assessment (TERA) www.tera.org

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## The Independent Expert Review Panel (IERP) Process

This Independent Expert Review Panel (IERP) and meeting have been organized by Toxicology Excellence for Risk Assessment (*TERA*). *TERA* is an independent non-profit organization with a mission to protect public health through the best use of toxicity and exposure information in the development of human health risk assessments. *TERA* has organized and conducted peer review and consultation meetings for private and public parties since 1996 (see <u>http://www.tera.org/peer</u> for information about the program and reports from meetings).

*TERA* scientists are well-experienced in toxicology, risk assessment, and conducting peer reviews. *TERA* was selected by the Technical Committee to independently organize and conduct this expert panel review. *TERA* has experience in risk assessment and toxicity of metals and has performed this work for a variety of public and private clients. None of *TERA*'s previous work related to the Sudbury Soils Study, nor has *TERA* worked for Inco or Falconbridge.

*TERA* has conducted reviews and worked on projects involving some of the contaminants considered at the Sudbury site, including arsenic, nickel, copper, lead, cadmium, and selenium, for a variety of clients. These projects were supported by the U.S. EPA, Health Canada, the Metal Finishing Association of Southern California, the International Copper Association, the U.S. Bureau of Land Management, Elf AtoChem North America Inc., the U.S. National Institutes of Occupational Safety and Health, and a metal refiner in South Africa. For the Ontario MOE, Dr. Lynne Haber of *TERA* peer reviewed the Rodney Street risk assessment and has been asked by MOE to be a peer reviewer for a community risk assessment currently being prepared.

## **Independent Expert Review Panel**

Peer review is commonly used in the sciences to judge the scientific merit of a manuscript or document. The intent of a peer review is to have a group of external experts evaluate a document's conclusions and the scientific basis for those conclusions. The purpose of this peer review is to have a panel of experts carefully evaluate the science and conclusions of the human health risk assessment. The Sudbury Soils Study and human health and ecological risk assessments have been undertaken to determine if there are unacceptable human health or ecological risks associated with metal and arsenic levels present in the Sudbury area. Based on the available information for Sudbury, the study will provide a measure of the risk level from metals and arsenic in soils, and may determine site-specific soil guidelines for the Sudbury area.

*TERA* staff were solely responsible for the selection of the IERP. *TERA* followed the U.S. National Academy of Sciences (NAS) guidance on selection of panel members to create a panel with a broad and diverse range of knowledge, experience, and perspective, including diversity of scientific expertise and affiliation. *TERA* reviewed

dozens of scientist's credentials and selected these panel members for their extensive knowledge and experience in their fields. *TERA* believes this group of experts is well-equipped to conduct a thorough review of the materials and provide expert advice. The panel members serve as *individuals*, representing their own personal scientific opinions. They do not serve as representatives of their companies, agencies, funding organizations, or other entities with which they are associated. Their opinions should not be construed to represent the opinions of their employers or those with whom they are affiliated.

An essential part of panel selection is the identification and disclosure of conflicts of interest and biases. Prior to selecting the panelists, each candidate completed a questionnaire to identify activities, financial holdings, or affiliations that may pose a real or perceived conflict of interest or bias. The completed questionnaires were reviewed by *TERA* staff and discussed further with panel candidates as needed. (See <a href="http://www.tera.org/peer/COI.html">http://www.tera.org/peer/COI.html</a> for *TERA*'s conflict of interest and bias policy and procedures for panelist selection).

*TERA* has determined that each panel member has no conflicts of interest and is able to objectively participate in this peer review. None of the panel members has a financial or other interest that would interfere with his or her abilities to carry out the duties in an objective fashion. None of the panel members works for Inco, Falconbridge, the other companies or agencies represented on the Sudbury Soils Study Technical Committee, or the companies comprising the SARA Group. Nor do the panel members have financial interests in the two mining companies. None of the panel members was involved in the preparation of the Sudbury human health or ecological risk assessments.

The independent peer review panel includes seven scientists who have expertise in the key disciplines and areas of concern. Each panelist is a well-respected scientist in his or her field. The panel members have expertise in multimedia risk assessment, toxicology of metals and arsenic, bioavailability, environmental geochemistry, metal(loid) speciation in soils and mine waste, mineralogical analysis, probabilistic risk assessment, sampling and analysis of metals in various media, evaluation of human health hazards from soils and dust, and the calculation of soil clean up goals.

## Sudbury Human Health Risk Assessment Expert Panel

Gary L. Diamond, Ph.D. Senior Scientist Syracuse Research Corporation Akron, New York, USA

### Michael L. Dourson, Ph.D., DABT

Director Toxicology Excellence for Risk Assessment (*TERA*) Cincinnati, Ohio, USA

Andrew P. Gilman, PhD Research Fellow, University of Ottawa, Population Health Institute and President, Sustainable Solutions International Ottawa, Ontario, Canada

> D. Susan Griffin, Ph.D., DABT Senior Toxicologist U.S. EPA - Region 8 Denver, Colorado, USA

Heather E. Jamieson, Ph.D. Associate Professor

Department of Geological Sciences and Geological Engineering Queen's University Kingston, Ontario, Canada

#### Rosalind A. Schoof, Ph.D., DABT

Principal Integral Consulting, Inc. Mercer Island, Washington, USA

#### Joyce S. Tsuji, PhD, DABT

Principal Exponent Bellevue, Washington, USA

### **Review Package and Charge to Peer Reviewers**

The panel received the review package approximately two months prior to the meeting to ensure adequate time to carefully review the documents and prepare for the meeting discussions. Materials sent included Volume I– Background, Study Organization and 2001 Soils Survey and Volume II – Human Health Risk Assessment (Parts A and B). Review materials also included compact discs, including data and reports from the soil surveys, and appendices with key data and information. *TERA* developed a "charge to peer reviewers" document that outlined the key questions and scientific issues that need to be discussed by the panel in order to evaluate the quality and completeness of the risk assessment. The charge covers a number of comprehensive questions about

quality and scientific defensibility listed below. In addition, there are several dozen more detailed questions that the panel will use to help guide their discussions and conclusions.

## Questions for the Sudbury Soils Study Human Health Risk Assessment Expert Panel

- Was the approach used for this community assessment consistent with commonly accepted methods and procedures by government agencies (such as Environment Canada, Health Canada, the Canadian Council of Ministers of the Environment, and the United States Environmental Protection Agency [U.S. EPA])?
- 2. Is the Human Health Risk Assessment presented clearly and completely?
- 3. Overall, are the input data and assumptions valid and appropriate for the Sudbury community?
- 4. Are the conclusions for each chemical of concern valid and defensible, and are they supported by the risk assessment? Are there additional points that should be made?
- 5. Have the important uncertainties been identified and their impact on the characterization of risk and overall conclusions been discussed?
- 6. Have the key objectives of the Sudbury Soils Study been addressed by this assessment?
- 7. Are there additional important issues that should have been addressed?

## **Meeting Procedures**

The meeting will be organized to make the best use of the time available to hear and discuss the opinions of the panelists regarding the charge questions and the human health risk assessment. The meeting will begin with brief panel introductions and a discussion of conflict of interest and bias issues. The discussion will then address the four broad areas of the assessment: data collection and site characterization, exposure assessment, hazard assessment, and risk characterization. Before each discussion section, the authors of the assessment document will make a short presentation. These presentations will highlight the salient points and focus on important issues. There will be a brief time for panel member clarifying questions and then the panel will discuss the relevant charge questions. The panel recommendations and conclusions will be included in the final meeting report.

## **Meeting Report**

*TERA* will draft a meeting report that briefly summarizes the panel's discussions and recommendations. The meeting report will serve as a record of the peer review and will assist the authors in making revisions to the assessment. The report will be reviewed by the panel members for accuracy before it is finalized.