Independent Process Observer



Quarterly Report

REPORT #19

Spring 2007 (January – March)

By Franco Mariotti

Five years and three months ago, I assumed my role as the Independent Process Observer for the Sudbury Soils Study.

In my last report, I stated that the Human Health Risk Assessment report would be released to the public sometime in March; however, in retrospect I recognize that I was being overly optimistic. Because of past announcements declaring impending releases that were not realized, for very legitimate reasons I might add, and to avoid yet another missed release date I will not forecast a specific date for the public release of the final report for the Human Health Risk Assessment, except to say that it is imminent.

In early March the Independent Expert Review Panel conducted two days of questions directed at the science behind the Ecological Risk Assessment, which was the exact same process as was done for the Human Health Risk Assessment in September of 2006. This was primarily a new panel of scientists (with the exception of one who served last fall) whose task it was to assess the validity of the scientific methods used by the SARA Group that carried out the Ecological Risk Assessment of the Sudbury Soils Study.

Process Observer reports are divided into two sections. The first section, *Past Issues and Recommendations*, is intended to be an update on matters discussed in my previous report (#18). The second section, *Current Issues and Recommendations*, deals with any new issues that have arisen since my last report.

PAST ISSUES and RECOMMENDATIONS

1. ISSUE: Post the backgrounds of members of the Independent Expert Review Panel for the Human Health Risk Assessment on the Sudbury Soils Study Website.

The process observer for the Sudbury Soils Study is independent of any organization or group involved in the study. He is impartial and his role is to advise on matters related to the study's Human Health Risk Assessment and Ecological Risk Assessment processes, both of which are managed by the study's Technical Committee with input from the Public Advisory Committee. As the observer, Franco Mariotti is required to report to the public on the study process four times each year.

RECOMMENDATION: Place the resumes of the Independent Expert Review Panel scientists on the Sudbury Soils Study website so that the public will know who they are and their area of expertise.

RESULT: This has not been done.

COMMENT: I urge the Technical Committee to post the backgrounds of the Independent Expert Review Panel scientists on the Sudbury Soils Study website. This action would further inform the public about who they are, and would enhance the transparency of the study.

2. ISSUE: Where is the Sudbury Soils Study data going to be housed? (Note, this issue is restated from my last report.)

COMMENT: Early in the Sudbury Soils Study, a commitment was made by Technical Committee members that all of the data from the Sudbury Soils Study would belong to members of the public and be accessible to them. This issue has been raised in the past but as yet has not been resolved.

RECOMMENDATION: It would be advantageous to the public and to future scientific researchers that an announcement identifying the location of the Sudbury Soils Study data be made at the public open houses being held for the Human Health Risk Assessment and Ecological Risk Assessment results.

CURRENT ISSUES and RECOMMENDATIONS

1. ISSUE: The two day scientific review of the Ecological Risk Assessment by the Independent Expert Review Panel.

BACKGROUND: Another significant milestone in the Sudbury Soils Study was attained when the Independent Expert Review Panel came to Sudbury for two full days of questions for the SARA Group scientists. The Independent Expert Review Panel is an international team of scientists, experts in their fields of environmental toxicology, which is independently reviewing the science behind the Ecological Risk Assessment. The TERA Group of Cincinnati, Ohio was chosen by the Technical Committee to act as the broker. They chose the scientists for the Independent Expert Review Panel who would assess the scientific process and methods used by the SARA Group to carry out the Human Health Risk Assessment.

On the evening of March 5, 2007, the Independent Expert Review Panel held a two hour briefing at College Boreal; members of the public were invited to attend. Although attendance was high, about 70 people, most people in the audience were associated with members of the Technical Committee and the Public Advisory Committee. In my estimation there were no more than 10 members of the public in attendance.

Jacqueline Patterson, a member of the Independent Expert Review Panel, hosted the evening. In her own words she defined the panel in this way, "The role of the expert panel is to conduct an in-depth evaluation and interpretation of the science, to ensure that the study follows acceptable principles and that the study is scientifically defensible." She went on to introduce the panel members and provided an outline of the agenda for the next two days.

For two full days, March 6 and 7, the Expert Review Panel questioned and assessed the science used by the SARA Group that carried out the Ecological Risk Assessment. These two days were closed to the public. The questions asked by the Independent Expert Review Panel covered every aspect of the Ecological Risk Assessment. Conclusions were not discussed nor questioned since the purpose was to explore the scientific methodologies used to carry out the studies. Essentially the panel wanted to ensure that the science used was both current and sound. Furthermore the panel's role was to make suggestions for any improvements and/or clarifications in the scientific methods used.

The two days were broken up into sessions that reflected the various aspects of the Ecological Risk Assessment draft report. The proceedings were chaired by Dr. Charles Pittinger, a member of the Independent Expert Review Panel, who was in total control of the proceedings. All the Independent Expert Review Panel members are scientific experts in their toxicological field. Each session was introduced by a Sara Group team member who provided a short synopsis on an aspect of the study. This was followed by questions and comments from Independent Expert Review Panel members on very technical elements of the report. Questions asked of the SARA Group covered diverse aspects of the Ecological Risk Assessment. Examples of questions asked include: Why were certain numbers used over others as part of a particular analysis? Why were certain procedures carried out, or not? How were they analyzed? How did they determine a certain conclusion and on what basis? The entire process was well organized and well controlled by the chair.

Individuals directly connected to the Sudbury Soils Study were allowed to observe during the two days; however, members of the public were not. These observers were not allowed to ask questions or speak directly to the panel except in cases where clarification of an issue was requested, or after a session between the Independent Expert Review Panel and the SARA Group was completed. They were, however, allowed to submit written questions, which were passed to an administrative assistant who then passed them on to the chair.

This approach mimicked the Human Health Risk Assessment session held in September of 2006 and was very effective as it allowed for external input and at the same time kept the procedure civil and moving forward.

The Independent Expert Review Panel has not released its detailed findings publicly as yet. Their report and the final Ecological Risk Assessment report are scheduled to be released to the public in the summer of 2007.

As in last fall's sessions of the Human Health Risk Assessment and the Independent Expert Review Panel review, there is justification for not releasing specific details. First, it will take time for the Independent Expert Review Panel scientists to write their detailed report and to reach consensus. Secondly, members of the SARA Group scientists have the right to receive the Independent Expert Review Panel comments first and need time to digest and consider these recommendations in order to respond appropriately.

In a press release dated March 9, 2007, the Independent Expert Review Panel members did agree on some general findings of their review:

- The panel concluded that the Ecological Risk Assessment represents the current state of science in ecological risk assessments and it has achieved its two major goals: to characterize the current and future risks of metals to terrestrial ecosystem components and to provide information to support activities related to the recovery of regionally representative, self-sustaining ecosystems in areas affected by the metals.
- The Ecological Risk Assessment approaches were consistent with commonly accepted methods and sound scientific procedures.
- The assumptions, methods, results and conclusions described in the assessment are generally clear and transparent.
- The panel recognized that the data from this terrestrial risk assessment will
 provide a valuable baseline from which to evaluate the effectiveness of risk
 management as it proceeds in the future.

2. ISSUE: Should the Independent Expert Review Panel's two day session on the Ecological Risk Assessment draft report have been open to the public?

COMMENT: My feeling on this issue has not changed since dealing with the identical issue of the Human Health Risk Assessment session of last September. I, therefore, provide again the complete response from my Independent Process Observer Report #17:

"I will state immediately that I am of mixed feelings on this. I will try to articulate the reasons for and against the public attendance as best as possible.

Reasons why the public should not have been there:

 Much of the conversation was very technical in nature. Non-specialists could have misconstrued the meaning or intent of the dialogue. Thus someone could have walked away from such a session with a different perspective than that which was intended.

- The Human Health Risk Assessment Report was a draft report. An audience observer could have walked away with a premature finding that may be different from the final report due to further scientific analysis as recommended by the Independent Expert Review Panel.
- Having a large number of people in the audience, including the media, may have intimidated or stifled open dialogue.

Reasons why the public should have been there:

- The public presence would have reinforced the claim that the Sudbury Soils Study is an open, fair and transparent process.
- Although the conversations between the Independent Expert Review Panel scientists and the SARA Group were very technical, the public would have seen for themselves that members of the Independent Expert Review Panel were not swayed or unduly influenced by any Technical Committee member."

My conclusion is that the Independent Expert Review Panel realistically reflected an honest, scientifically independent peer review process of the Ecological Risk Assessment of the Sudbury Soils Study. The Independent Expert Review Panel scientists acted professionally with the SARA Group scientists, and members of the Technical Committee did not influence its outcome.

3. ISSUE: Members of the Public Advisory Committee requested clarification from Health Canada regarding their role in the Sudbury Soils Study.

COMMENT: This is an ongoing issue that has never been properly clarified and remains unsolved. The Public Advisory Committee requested a letter from the supervisor of the Federal Native and Inuit Health Branch (FNIHB) representative who sits on the Technical Committee. That letter was to have been read at the March 27th Public Advisory Committee meeting; however, no response was presented. In the past, the FNIHB representative has assured everyone that reports, draft or otherwise, arising from the Sudbury Soils Study are being passed on to the appropriate officials. No response or comments have ever been made to any of these reports by officials of FNIHB.

Minutes of the Public Advisory Committee meeting on March 27, 2007 state:

"Role and Policies of FNIHB in Relation to the Sudbury Soils Study

To date there has been no response to the request from the Public Advisory Committee for FNIHB to describe its roles and responsibilities with respect to the Sudbury Soils Study. The Public Advisory Committee will continue to follow up on this request. There was a suggestion that if there continues to be no response from FNIHB, then this lack of response should be noted in the final copy of the report.

The Working Group (WG) mentioned that the Ministry of the Environment invited the FNIHB to participate in the study. The WG has asked FNIHB to clarify their role but has received no response. As well, FNIHB has received all documentation to date but no comments have been received.

There was some discussion regarding the fear that FNIHB might reject the study. It was noted that the Independent Expert Review Panel members have commended the Sudbury Soils Study stakeholders for the thoroughness, Sudbury-specific data and scientific integrity of both the Human Health Risk Assessment and Ecological Risk Assessment. Therefore, if the FNIHB chooses to reject the findings of the risk assessment at this late stage, then the onus will be on them to explain how their opinion differs from that of independent experts and why they have not responded earlier."

Members of the Public Advisory Committee have justifiably expressed concern that FNIHB should be responding in some manner, whether in agreement or not, with any findings to date. Personally I find this issue perplexing and do not understand why FNIHB has remained quiet after receiving so many requests from the Technical Committee and the Public Advisory Committee to clarify their position. This behaviour by a member of the Technical Committee is clearly a weak link and is responsible for a shortcoming in the Sudbury Soils Study process.

ISSUE: The FNIHB should clarify once and for all, through an official letter, exactly what their stance is on the draft Human Health Risk Assessment and the draft Ecological Risk Assessment reports to date.

Next Meetings: Please refer to the Sudbury Soils Study website (www.sudburysoilsstudy.com) or your local newspaper as to when the next TC and/or PAC meetings are to occur.

If you have any questions regarding the Sudbury Soils Study please contact our toll free number – 1 (866) 315-0228 or e-mail: questions@sudburysoilsstudy.com