

Terms defined in the A & C Interpretation Agreement which appear in this Appendix without definition shall have the meanings ascribed to them in the A & C Interpretation Agreement.

Scope of Work

The scope of work covers a review of the two reports from the CHAP A and C studies along with external reviews associated with these documents and a determination of whether further case-control studies should be carried out using the guidelines set out in the Protocol B Decision document. While there will be some deviation from the specifications in the decision document, these are mainly a result of the A and C studies having been reported somewhat differently from what was anticipated. These deviations, and the reasons for them, will be identified in the course of this work.

Task 1. Review CHAP A and CHAP C reports and identify those health conditions with an effect size large enough to be declared statistically significant using the conventional 2-tail p value of 0.05. Highlight areas of uncertainty, and resolve discrepancies in the results obtained using different statistical methods. Identify comparisons which may be appropriate. Conduct additional analyses of the data, as necessary.

Task 2. For those statistically significant conditions calculate the minimum sample size that would be necessary in a case-control study to provide 80% power to detect an effect of the same size as reported in either the A or C reports. Estimate for each of these conditions, using the criteria set down in the Decision Document, whether the number of available cases would be large enough for a case-control study in light of the minimum number estimated in the sample size calculation.

Task 3. Conduct literature reviews, focusing on biological, toxicological, and epidemiological evidence of effects of the four chemicals of concern, and on the methodological limitations of the studies done to date.

Task 4. Formulate recommendations for future studies, as necessary, including methodological studies of measurement and analytic studies of risk.

Process Steps and Deliverables

1. The University shall submit an initial draft of the A&C Interpretation Report (“Draft #1”) that is clearly marked “Draft - For discussion purposes only - Subject to further revision”, to the chair of the Technical Subcommittee (the “TSC”) of the Public Liaison Committee (the “PLC”), Rob Watters (the “Chair”).
2. The Chair will distribute Draft #1 to the technical representatives of the TSC (being the members of the TSC appointed by the Company, the Niagara Region Health Department, the Ontario Ministry of the Environment and Watters Environmental Group) for review and comment.

3. At least two of the Principal Investigators will meet once with the technical representatives of the TSC to discuss Draft #1.
4. Upon receipt of the comments of the technical representatives of the TSC on Draft #1, the University shall revise Draft #1 to reflect or respond to such comments ("Draft #2") and shall clearly mark it "Draft #2 - For discussion purposes only - Subject to further revision".
5. The University will provide a copy of Draft #2 to the Chair for distribution to all of the members of the TSC for review and comment. For greater certainty, once Draft #2 has been distributed to all of the members of the TSC, it will be a public document and will be available to any interested party, including the PLC and members of the general public.
6. At least two of the Principal Investigators will meet with the TSC, the PLC and with members of the general public at an open house to discuss Draft #2.
7. If the TSC, the PLC or members of the general public have any comments on Draft #2, the University shall revise Draft #2 to reflect or respond to such comments (the "Final Report") and shall clearly mark it as "Final Report".
9. The University shall provide a copy of the Final Report to the Chair for general distribution for review and comment.
10. At least two of the Principal Investigators will meet once again with the TSC, the PLC and with members of the general public at another open house to discuss the Final Report.
11. If the TSC, the PLC or members of the general public have any comments on the Final Report, the University shall reflect any new comments in an addendum to the Final Report and will provide such addendum to the Chair for general distribution.