

REVIEW OF THE -

**HUMAN HEALTH RISK ASSESSMENT OF THE
FREDERICK STREET AREA**

Final Report - January 28, 1999

for

The Sierra Club of Canada, Ottawa

by

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IMPORTANT NOTES

► Definition of Terms

HRA	- Human Health Risk Assessment of the Frederick Street Area carried out by CanTox, Inc..
Assessment	- Human Health Risk Assessment of the Frederick Street Area carried out by CanTox, Inc..
Report	- the report of the Human Health Risk Assessment of the Frederick Street Area carried out by CanTox, Inc..
Paragraph	- A numbered paragraph in CanTox's Health Risk Assessment document
Author(s)	- The author(s) of the CanTox Human Health Risk Assessment of the Frederick Street Area
We	- the International Institute of Concern for Public Health
Review	- This Review of the HRA by the IICPH
Section	- A numbered section of the IICPH Review
Neighbourhood	- Frederick Street and adjacent zones
CCME	- Canadian Council of Ministers of the Environment
SQG	- Soil Quality Guideline

- Format: All quotations from the CanTox HRA are *given in italics*.
Specific portions of the quotations are ***italics bolded***.
Reference to page numbers in the CanTox HRA are thus [p.1]

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1 INTRODUCTION

In writing this Review, we have attempted to use a style which will present the important issues in a manner understandable to persons with limited previous experience in dealing with the processes and conclusions of human health risk assessments. Consequently, where deemed useful at various stages in our documented, we have added a little extra explanatory material. Neither our review protocol nor our conclusions are affected by the use of this style.

1.1 SCOPE OF THIS REVIEW

This Review addresses only the information provided in the Human Health Risk Assessment of the Frederick Street Area, by CanTox Environmental, dated 11th. August 1998, augmented by a two-day visit to site on 2nd. and 3rd. December, 1998.

As is pointed out in CanTox's Health Risk Assessment Report, a voluminous amount of environmental monitoring data is available covering the general area of Muggah Creek, Whitney Pier, the Tar Ponds and adjacent residential zones such as Upper and Lower Frederick Street. The CanTox authors appropriately point out that the scope of their HRA did not allow for a thorough review of all available data, and that for the most part, they had to "take on trust" the validity of the data they were either given or chose to incorporate in their Study.

In a similar vein, we would point out that we have not undertaken any form of evaluation of the laboratory analytical methods used by the various organizations, since this would be a task of considerable proportions. Equally, we would have no immediate reason to question the field monitoring *technical procedures* used by these organizations. On the other hand, we have identified areas of concern regarding the "where, when and how many" aspects of some of the samplings and data-gathering exercises upon which this human health risk assessment relies.

We have not addressed the subject of cancer incidence in dogs. This is not because it is unimportant - domestic animals unfortunately serve as very important biomarkers of environmental abnormality - but more because we feel the issue, if it is to be addressed at all, requires substantially more time and attention than the Assessment has been allowed.

1.2 THE ENVIRONMENTAL HEALTH RISK ASSESSMENT PROCESS

It may be helpful to the public reader if we make brief reference to the stages in any HRA which are most likely to introduce uncertainty into the final health risk conclusions.

A human health risk assessment based on the presence of potentially hazardous chemicals in the environment is by its very nature, an exercise in probability. A number of algorithms are employed (computer "models") which attempt to predict events, and the outcome or quantitative nature of such

events. In general terms, the objective is to determine the highest exposures and greatest risks to which a population may be exposed. Despite its apparent complexity, all an environmental health risk assessment achieves in the end is a prediction of the likelihood over time of the following events happening:

- (a) Release of contaminants (hazardous agents) from the environment (e.g. from soil and water,)
- (b) Exposure. The likelihood of a person coming into contact with such hazardous agents, in the case of this current Assessment - short-term contact with toxic chemicals from the contaminated areas close to Frederick Street and,
- (c) Dosage. The quantity of such a chemical received and absorbed by persons who are exposed to it.
- (d) Health Effects. Here, the science of toxicology attempts to understand and describe⁽¹⁾ the health effects of the dose absorbed, so that an *assessment of health risk* can be made. Most of the scientific information available in this area is derived (extrapolated) from animal studies in the laboratory. Adjustments are made to animal dose-response findings in order to apply them to human beings.

[Figure 1 on page 5 of the HRA provides a simplified idea of the overall process.]

Clearly, there are many interim steps involved on the way from (a) to (d), and there is a need to input the most accurate information available during the various steps. Some of this input information is available in a reliable form, - however much of it is not. Therefore assumptions have to be made which can create uncertainty in:

- the computer model's prediction of exposure and dosage of the chemical received by the individual, and,
- the acute and chronic health effects which the absorbed dosage may produce.

A serious weakness in many health risk assessments is the lack of toxicological information on the effects of exposure to multiple chemicals (combined exposures.) For chemicals with certain similarities in molecular structure and demonstrating similar (pharmacokinetic) behaviour once inside the human body, it is not unreasonable to simply add the dosages from each, in order to obtain a total dosage. However, for dissimilar chemicals this additive process can be applied in only a very small number of cases.

Uncertainty itself can be analyzed statistically, though a short-cut is often followed by taking worst case scenarios (upper bound limits.) This is a reasonable step to take provided the worst case scenario has been reliably identified. For example in this HRA, the authors have fed into their computer model the highest concentrations found in soil samples. (HRA Table A-2 p.A-4 compares maximum backyard surface soil concentrations with various guidelines and remediation criteria.)

1

The Environmental Defense Fund has carried out a study of the lack of reliable toxicological information for industrial chemicals. See Appendix C on page 38 of this Review.

Obviously, if enough assumptions have to be made in a human health risk assessment, then the limiting boundaries for drawing health risk conclusions become relatively wider, making computer outputs subject to higher levels of uncertainty. The challenge to the investigator is to reduce uncertainty as much as possible based on the quantity and quality of the available input data.

2 COMPUTER MODELING

The authors confirm that:-

The methods used to conduct the human health risk assessment of the chemicals found in the Frederick Street area were based on human health risk assessment procedures used by regulatory agencies such as Health Canada and the United States Environmental Protection Agency (USEPA.). [p.5]

The Report provides few details regarding the computerized statistical processes used in this Study, but we assume that "Monte Carlo" type iterations and the creation of input parameter distributions are involved. In spite of the small number of air, soil and water samples available for the assessment, the stochastic model is presented as the ultimate solution to these deficiencies. This is to be expected, since such probabilistic approaches form the basis of most health risk assessments. However, we do not believe that the stochastic risk assessment model can adequately compensate for large gaps in the primary data, such as are evident here.

We draw attention to the high levels of uncertainty which can result from such inadequacies in the input data. The US EPA offers cautionary advice in this area. With regard to the application of the Monte Carlo procedure, we would note the following:-

From:-

Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part A, Interim final) - EPA/540/1-89/002, and, Guiding Principles for Monte Carlo Analysis, EPA/630/R-97/001, March 1997:-

Uncertainty analysis (Sec. 6.8, pp 6-50 of EPA/540)

First order uncertainty analysis & Monte Carlo analysis

".. These methods and their limitations..... Be used only after approval of the EPA Project Manager, and then only as a part of the uncertainty analysis, and not as a basis for the reasonable maximum exposure" (Further ref. Sec. 8.4, pp 8-17 of EPA/540).

The relevant phrase is underscored by us. Further discussion on risk assessment versus hazard assessment is found at Appendix A.

3 SITE CHARACTERIZATION AND SAMPLING DATA

We appreciate that this HRA is limited in its scope due to deficiencies in the primary data. However, CanTox's response to this problem reveals some inconsistency in that the authors throw different perspectives on the relevance of the data problem at various points in the Report.

3.1 DATA LIMITATIONS

The limitations in the raw data can be expected to create wide ranging uncertainties in the estimations of individual exposures, and this uncertainty problem is duly and responsibly noted by the authors:-

Every effort is made to ensure these assumptions and data adequately represent conditions at the site, however data are often limited, resulting in uncertainty in the assessment. [p.44]

Data and information constraints are addressed earlier in the Report by CanTox's disclaimer which states that.....

*Any information or facts provided by others, and referred to or utilized in the preparation of this Report, is **believed to be accurate without any independent verification or confirmation by CanTox Environmental, Inc.** This Report is based upon and **limited by circumstances and conditions** stated herein, and upon information available at the time of the preparation of the Report.*

However we find that the Assessment does in fact use and interpret information which is based on such *limited circumstances and conditions*. For example, unacceptable constraints may have been placed on the receptor characterization phase of the Study (see Section 7.2, p. 28) by ignoring the possible health consequences due to earlier exposures, viz:-

*With respect to the available data and reports, a vast number of studies have been conducted on the Tar Ponds and Coke Ovens. **These materials, for the most part, were not reviewed for this project**, since a review of this degree was far beyond the scope of this project. [p.7]*

With regard to the "larger" study commissioned by the IMT, we read that:-

....The purpose of this study was to determine:

- *The source and extent of contamination*
- ***To identify data*** which are required to establish resultant potential risks to the residents of Lower Frederick Street. [p.2]

The IMT investigators having identified such needed data, we would then expect to see a statement of rationale for the subsequent chosen sampling protocol - in terms of how such a protocol would satisfy the identified data need. We are informed only that “*This study involved sampling in a number of areas.....*” [p.2], with a truncated description of the areas where sampling was carried out.

Nevertheless, the authors again emphasize the data constraints:-

*A vast number of studies have been produced related to chemical characterization in the overall Sydney area. All of these reports could not be reviewed and incorporated into this document, since this study was undertaken in approximately 2.5 weeks, and a **detailed review of all associated documents was considered beyond the scope of this assessment.*** [p.45]

While we find the above to be a cogent statement, it unfortunately serves to confirm that there may be significant gaps in the available raw data. We also note with concern that:-

*The chemical characterization of the Frederick Street area **was limited.** There were **no surface soil samples taken** in the Upper Frederick Street area.* [p.45]

and,

*As in any risk assessment study, **the findings of the assessment are based on the available data from the specific study area** (such as soil concentrations, vegetable data, etc.) and the scientific literature in conjunction with a number of assumptions.* [p.44]

While this latter statement may be true in some cases, we would point out that many HRA's do not simply rely on “*available data*” as in the case of this study, but are carried out based on sampling measurements and monitoring protocols which are specifically designed to properly and fully assess the site in question.

With regard to the conservative approach claimed by the authors:-

*Where uncertainty exists, assumptions are made and data are selected so **as to err on the conservative side.** Limitations and sources of uncertainty associated with the assessment are highlighted below.* [p.44]

In the absence of a site-specific risk assessment approach to constructing acceptable soil and water criteria, it is difficult to establish a “conservative side” if the available data do not present a true picture of the extent of contamination. We believe that, due to the complex site characteristics of the Muggah Creek - Frederick Street zone (including the toxics release profile of the municipal landfill,) only the most intensive and thorough soil/water sampling programme can ensure that pockets of toxic chemicals do not remain undetected, and that all possible transportation pathways in such a frequently disturbed environment have been adequately identified.

3.2 CONTAMINANT SOURCES

The authors provide no deposition time-frame for what they refer to as “recent contamination.”

*The objective of this study was to evaluate **the recent contamination** found in the Frederick Street area, and as such, reports and information related to this area were considered. [p.7]*

Because of the history of smelting, coking, bulk materials storage, transportation, handling and support operations in this zone, samples would have to be taken very selectively in order to isolate *recent* contamination. Pending closer scrutiny of sampling and analytical techniques, the reports and information which the authors used would very likely have provided sampling results containing a mixture of recent and previously accumulated deposits. Therefore we suspect that *recent* contamination was probably not adequately segregated.

We believe that this constraint in sample interpretation should have been more clearly explained in the Assessment.

3.2.1 Coal removal activities

With regard to coal dust exposures:-

*There were **no specific data** on the dust levels occurring in the Frederick Street neighbourhood as a result of coal removal activities. [p.45]*

Thus an important issue which has been ignored is the possibility that coal dust from such a source, itself arising from a (previous) steel-making and coke oven environment, may include mineral compounds (e.g. silica,) and be carrying adsorbed polyaromatic hydrocarbons (PAHs.)

An attempt is made to rationalize this data deficiency by trivializing the health effects:-

*Since dust concentrations during the coal removal activities are not available, a quantitative assessment of potential risks could not be conducted. Qualitatively, the dust exposures would be short-term, and could result in a number of short term health effects if exposures were high enough. **These effects include coughing and throat irritation, sore eyes, etc.** Several of the residents of the Frederick Street area complained of these types of effects, which would suggest that concentrations were high enough to be having a **short-term irritation effect** on some of the residents. [p.49]*

These are medically insufficient explanations, leading the reader to believe that the only health effect presented by coal dust is “*short-term irritation.*” Since coal dust exposure can cause, among other things, pneumoconiosis leading to chronic pulmonary fibrosis, we would suggest a further assessment be carried out, designed to take a more detailed look at total (including coal)

dust exposures in this community⁽²⁾.

3.2.2 The Coal Ash Pile

Again, not well documented:-

*The coal ash pile located next to 36 Frederick Street has not been well characterized from a chemical concentration perspective, and the two samples taken **differed substantially** with respect to their arsenic concentrations (<2 mg/kg to 435 mg/kg.) [p.45]*

The widely differing sampled arsenic concentrations underscore the point that insufficient and therefore unrepresentative samples have been obtained in this and other areas (e.g. backyards.)

3.2.3 The CBDC railbed

*While conducting their investigation, CBDC **dug up the surface contamination** at the seep site, and covered the area with gravel or fill. This was done to remove the contamination, and therefore reduce the potential exposure of nearby residents to the chemicals present within the seep. [p.2]*

Digging up the surface contamination and covering up with gravel may temporarily suppress emissions, but it does not guarantee to remove the problem - it just hides it for a while. This procedure ignores the possibility of residual deeper contamination continuing its migration patterns to other areas. In fact one of the two stated objectives for investigating this seep was to determine "*Whether other areas, such as the soils in a number of resident's backyards may have been contaminated by this seep, flooding or other past activities.*" [p.1]

Therefore unless tests were carried out to verify that complete containment was achieved, the steps taken were of limited value. CanTox's addendum that these measures would "*therefore reduce the potential exposure of nearby residents,*" without further qualification is unsubstantiated.

This issue crops up again in Appendix A.1.1 viz:-

*It should be noted that the surficial contamination in the seep area was recently dug out and covered with fill; thus **the soil concentrations measured in the seep area samples are no longer present.** [p.A-2]*

2

The documented health impacts of dust exposures are largely the legacy of studies carried out in the industrial workplace, where, among other variables, the content of the dusts (particulates and adsorbed materials) can be relatively easily identified based on those materials known to be present in the workplace. In the public environment this information is not as readily available. Frederick Street is such an environment.

Again, if what the authors are concluding is that there is no further contamination to be found in the seep, then we would have to reject this conclusion pending further hydrogeological investigation and sampling.

3.2.4 Residential Soils in the Lower Frederick Street Area

The residential soils in the Lower Frederick Street area contained elevated concentrations of several heavy metals (lead, copper, molybdenum) and some PAHs (including naphthalene,) when compared to CCME residential/parkland guidelines. These soil samples were taken from the surface, as opposed to from deep test pits. [p.3]

Arsenic, which inexplicably is not mentioned here, was also found in high concentrations (51.91 mg/kg. compared with CCME-1997 12mg/kg.) Table A-2 [p.A-4] compares maximum backyard surface soil concentrations with various guidelines and remediation criteria.

In further reviewing the above statement, we find that the PAHs found at high levels do not just include naphthalene, but also the more hazardous benzo(a)pyrene, a proven carcinogen (2.06 mg/kg compared with CCME-1997 0.07 mg/kg.) Another carcinogen, dibenzo(a,h)anthracene is also found at 0.5 mg/kg, approaching the older "guideline" level of 1 mg/kg (CCME-1991). It should be noted that although the "guidelines" exist, because of latency periods associated with the development of cancer, there is no incontrovertible evidence to confirm that they adequately address the cancer risk.

The data for Table A-2 were extracted from Table B-2 [p.B-2]. What we find here is that ALL the (maximum) PAH levels were found in one sample, labeled SS-2, and as noted previously, PAH analysis was not carried out for the four samples taken at the premises of 36 and 44 Frederick Street. We are unable to identify where sample SS-2 was taken.

The fact that these fifteen PAH's have been identified in Frederick Street residential areas at these concentrations (sample SS-2, Table B-2) is cause for concern - regardless of what the prevailing "guideline" numbers are. Most if not all of these hydrocarbons will have found their way into the top-soil principally by adsorption to airborne particulate matter emanating from earlier coke oven operations and from by-product-containing deposits following shut-down. Since the area is characterized by these deposits, we would point out that there could be a cancer risk requiring further attention. A more detailed site-specific investigation is required here.

3.2.5 Seeps and Streams

It is not clear in the HRA whether the seep area on the Frederick Street Brook is linked in any way with the seep area under the CBDC railbed. We assume that for the purposes of the HRA, that it is not.

The seep area on Frederick Street Brook near Lower Frederick Street (consisting of the stream bed and a culvert filled around 1983) contained elevated concentrations of a

number of heavy metals (arsenic, antimony, molybdenum) and benzo(a)pyrene (a PAH) when compared to CCME commercial/industrial guidelines. [p.3]

These are toxic and carcinogenic materials. Table A-1 [p.A-3] "Comparison of Maximum Frederick Street Seep Soil Concentrations....." does not include antimony and the PAH's, thus making it difficult for the reader to follow the subsequent rationale for selecting (screening) chemicals for consideration in the HRA.

It must be clearly stated that these exceedances over guidelines occurred in deep "test pits", which were dug out on the coke ovens side of the tracks (next to the coke ovens fence). These "test pits" were between one to eight feet deep. For a resident to become exposed to this material, they would have to cross the brook, cross the rail tracks, and dig down into the soils. [p.3]

It should be equally clearly stated that the higher commercial/industrial guidelines are being applied here, not the residential guidelines; and that the statement ignores the possibility of further seepage and migration of contaminants. Until an accurate hydrogeological profile is developed, interpretations of sampling depth are of limited value.

Other PAHs detected within the infill material near the culvert were greater than residential/parkland guidelines. These samples were also taken from the deep "test pits". In addition, some chemicals detected within the groundwater of the test pits dug on the railbed side of the brook were present at concentrations greater than guidelines set for the protection of aquatic life (Health Canada. 1995). [p.3]

The very fact that "some chemicals" were detected in the groundwater of the test pits requires further investigation to ensure that these input parameters are included in the exposure model.

The soils within the infill area on Frederick Street contained concentrations of PAHs (benzo(a)pyrene, naphthalene and other PAHs) which were greater than CCME residential/parkland guidelines. [p.3]

We are unable to locate any further information in the Report regarding the details of these findings.

*It must be clearly stated that **this area contains no residential houses**, and is not actively used by the residents. Stream sediments in this area contained concentrations of arsenic, zinc and PAHs at concentrations which exceeded Environment Canada's interim sediment quality guidelines and CCME residential/parkland guidelines. There was a seep found in this area, coming from the CBDC railbed. [p.3]*

Even so, we point out that because there are no residences in this immediate area does not mean that there is no contact between humans and toxics. Because of the potential for migration and transportation, the toxics identified in stream sediment and the previous findings in

groundwater, call into question any statement or inference that there is no health risk based on such findings.

Under the above circumstances, and because of the highly site specific nature of this environment, comparisons to the generic numbers found in the various guideline documents (CCME, etc.) have limited interpretation. A more detailed site-specific assessment is required in order to establish meaningful values for permissible safe soil levels in this zone.

3.3 SAMPLING

3.3.1 Soil Sampling by CBEG and Environment Canada

It appears that only two samples were taken at 36 Frederick St., two at 44 Frederick St., and three more identified only as SS-2, SS-5 and SS-6 [Table B-2.] There is no information provided in Table B-2, or the pre-ambule paragraph B.1 as to where or when the three "SS" samples were taken. As noted earlier, non of the four backyard samples was analyzed for the 15 poly-aromatic hydrocarbons (PAHs) listed. This represents a significant gap in the continuity and credibility of the available data.

Even if PAHs had been elucidated, we question that soil sampling from four backyards in the Lower Frederick Street area is sufficient to make a true assessment of the contribution of soil contaminants to the overall toxic exposure problem. To estimate true chemical concentrations in soil with any degree of statistical confidence under these circumstances, the size of the (statistical) sample must recognize the size and spatial dispersion of the population of all values, i.e. the extent and coverage of suspected contamination. Otherwise the sampling is a hit-and-miss exercise.

Therefore the question to be answered is, - in taking samples from 4 backyards, non of them analyzed for PAHs, what overall area of possible neighborhood contamination was being accounted for in the sampling plan?

3.3.2 Blood and hair samples

Several residents indicated an interest in having blood and hair samples taken and analyzed for chemicals, to ensure that their exposures were not elevated. Dr. Scott oversaw the collection of blood and hair samples from numerous families living on Frederick Street, and these samples were sent to laboratories for lead and arsenic analysis, respectively. [p.3]

*The biological monitoring is a more definitive indicator of **potential** levels than the computer modelling effort. [p.36]*

Biological monitoring of this nature does not indicate "potential" levels of anything, environmental

or biological. It indicates residual body burden due to accumulated exposure to date.

For the reader to understand how the results of these analyses have been incorporated into this HRA, further information is needed. For example, lead and arsenic levels present in hair tissue are not just a result of "present day" environmental concentrations, but represent accumulation over time. Biological monitoring of this nature is usually carried out as part of a scheduled longer-term exposure monitoring procedure, with concentration levels being compared to "norms," in order to detect abnormal exposure situations. No details are given as to how these results from the numerous families have been applied to the HRA, or if any plans for removal from exposure have been set up in the event that these biological samples reach the action level for the control of exposure.

Accumulated toxics are rarely evenly distributed in hair tissue: also it is required that the effects of hair length, new growth/old growth, shampoo and permanent wave chemicals be considered in the analytical procedure. Thus, before the results of the hair sampling programme can be validated, further details are required regarding the field protocol, and the sensitivity and specificity of the laboratory procedures used.

3.3.3 Air monitoring

*This study which was conducted by Washburn & Gillis Associates Limited, was divided into two phases (one phase **to determine background air concentrations of particulate, polycyclic aromatic hydrocarbons, and metals, and a second phase to determine the concentrations of same chemicals during the coal removal work**). Only the first phase (background) has been completed at this time, and all measured concentrations were **below available air quality guidelines (Washburn & Gillis, 1998)**. The Nova Scotia Department of Transportation and Public Works have indicated that coal removal activities will not resume until the health risk assessment has been completed. [p.4]*

This is an exercise to assess the additional air quality impact of coal removal work, over and above a background which has already been shown to be significantly contaminated. We question the usefulness of such a stand-alone endeavour in a complex environment such as this, particularly with the limited data available to this assessment. Even so, we assume that the results will be evaluated set against the air quality guidelines referred to.

3.3.4 Vegetable data

*The vegetable data used in this risk assessment (from Washburn & Gillis Associates, 1998) were collected late in the season, and only included a small number of vegetables (mainly root vegetables, as opposed to root and leafy vegetables). While this could **influence risk estimates slightly**, leafy vegetables tend to be washed prior to consumption, which functions to remove most of the adhered soil dust (which tends to be the major source of contamination for this group of vegetables).*

Because of the data gaps, assumptions and uncertainty found elsewhere in this investigation, we question whether this particular net-pathway-input to the computer exposure model would be influenced by the variables which distinguish between root and leaf content; the issue may be something of a diversion. What is more to the point is that a proper and timely (season-wise) protocol be set up to make a realistic assessment of percutaneous and ingestion exposures arising from the handling and overall consumption of locally grown produce, root, leaf and fruit.

3.3.5 Drinking water

Drinking water data collected from the Frederick Street area were only submitted from nine homes.

What is more important than numbers of samples here is the source of the drinking water; samples from nine homes may be enough if they adequately describe the source and type of piping distribution.

4 IDENTIFICATION OF CHEMICALS TO BE ASSESSED

The authors state that:-

*To select chemicals to be evaluated in the risk assessment, **maximum chemical concentrations** identified in surface soil, seep and coal ash samples collected from the Frederick Street area were compared to soil quality guidelines. [p.16]*

From the little sampling data available, the investigators cannot be sure that the maximum concentration of chemical X from the sampling data is in fact the highest concentration of chemical X present in the contaminated zone. We feel that the data provided to CanTox by Environment Canada and the CBEG do not incorporate enough samples to provide sufficient confidence that maximum concentrations have been captured.

Furthermore, in justifying the inclusion of chemicals found in surface soil samples only, the authors add the following footnote:-

If there is no exposure to a chemical, regardless of how toxic it may be, there is no potential for the development of adverse health effects from that chemical. For this reason, surface soil, seep and coal ash samples (that is samples collected from approximately 0 cm to 6 cm below the surface) were compared to regulatory guidelines for soil. Samples collected from one to 10 feet below the surface were not used in the current assessment as there would be no potential exposure to the concentrations measured at these depths. [Footnote p.16]

We consider the second statement first. Here, the authors are in effect saying that only chemicals

found up to a depth of 6 cm are worth including in their HRA, adding that (inexplicably switching units of measure) samples collected from one to 10 feet below the surface were not used “...as there would be no potential exposure to the concentrations measured at these depths...” (It is unclear what consideration was given to the soil layer between 6 cm (2.4") to 12") By ignoring chemicals found at a depth greater than one foot, the authors have dismissed the (strong) possibility of sub-surface transportation of toxics via seepage and natural groundwater flow, and migration into household basements.

We are compelled to state that the lack of sufficient soil sample data (including the lack of PAH analyses in those samples which have been taken) and the discarding of available data from lower depths, can only contribute to the uncertainty in the stated conclusions of this HRA.

This equating of contaminant depth to potential human exposure is carried out in support of the earlier statement that “...If there is no exposure to a chemical, regardless of how toxic it may be, there is no potential for the development of adverse health effects from that chemical.” This assertion is of course the fundamental premise of all human health risk assessments. It is often thought of as a sweeping generalization, since it requires that there be considerable future stability in the environment in question. It may be true if, over time, the following conditions are met:-

- The chemical is truly contained for ever; nothing happens to cause the chemical to be displaced or put in motion by -
 - building projects
 - re-development projects
 - floods
 - subterranean disturbances
 - natural seepage
 - wind erosion
 - storms;
- Should there be a chemical-release episode, then no human being is present at the end of any exposure pathway, viz: respiratory, direct contact or food and water ingestion, during or at any time after the event, until such released toxic has safely dispersed.

In the real world of contaminated sites and chemical landfills the above requirements may be elusive at best. Further commentary on the ‘no exposure - no health risk’ hypothesis is provided at Appendix A.

4.1 CHEMICALS OF GREATEST CONCERN - TOXIC POTENCY

*It is common practice in human health risk assessments to **limit the number of chemicals evaluated to those chemicals which represent the greatest concern to people living in the area under consideration** (referred to as chemicals of potential concern.) This is done because **it is impractical in terms of time and cost to conduct a risk assessment for every chemical that has been found in the area.***

[p.15]

Taking the first point; “chemicals which represent the greatest concern to people living in the area.” Concern in the toxicological sense must invoke an evaluation of degree of exposure and toxic potency, - important concepts requiring specialized knowledge of contaminant dispersion pathways and toxicology. The statement suggests, perhaps inadvertently, that CanTox is leaving this decision in the hands of people who live in the area; suggesting that the whole exercise is substantially directed by the judgement of persons who cannot reasonably be expected to identify and rank chemicals based on toxic potency.

However:-

*To determine which of the chemicals identified in the Frederick Street area samples were present at elevated concentrations, **maximum chemical concentration** identified in the following areas were compared to Canadian regulatory soil quality guidelines:..... [p.16]*

The chemicals of “greatest concern to people living in the area” are therefore re-defined as those which, as a result of limited sampling, are found to have maximum values in excess of the available guidelines.

Again, with regard to maximum values, “How do we know that the maximum concentrations found in the few samples taken are, in fact, the true maximum values existing in the soils of the neighbourhood? What about the “samples” which were not taken?” This problem calls for further site characterization.

The authors note that it is *impractical* (presumably impracticable) to deal with every chemical for economic reasons - time and cost. Again this is a common constraint with most HRA's, but to the affected citizen it may appear to be saying that investigation and research into their environmental health threats are circumscribed not by the real dangers of chemical intoxication, but by the budget available for such investigation and research.

The discomfort here is increased by the statement that:-

*It is much better to comprehensively evaluate a smaller number of chemicals which represent the greatest concern to people living in the area under consideration, than to conduct a less detailed risk assessment on all chemicals. **If no unacceptable risk is predicted for the chemicals evaluated, then no unacceptable risk would be predicted for any of the chemicals which were not evaluated.** [p.15]*

This depends on which chemicals were not evaluated. It appears that these fall into two groups:

- Those that were identified but deemed to be toxicologically unimportant, and
- Those that may be present but unidentified due to inadequate site characterization prior to this Assessment being carried out.

In the first case we find that such an exclusion criterion is unacceptable without further explanation and documentation. Since the second grouping contains unidentified chemicals, there cannot be any exclusion criteria applied anyway.

We feel that the above rationale is an inappropriate selection process because of the complexity of the Muggah Creek - Frederick Street zone. It leaves the possibility that those chemicals left out when the "no predicted unacceptable risk" label is attached, may in fact possess significant toxic potency.

4.2 BACKGROUND

4.2.1 Background Risk Assessment

*There were little to no "background" site data available for some chemicals (such as background concentrations of polycyclic aromatic hydrocarbons and arsenic in local surface soils), for either the Sydney area or for Cape Breton in general. Due to this lack of data, a background risk assessment could not be conducted for other areas (not located near Frederick Street) to obtain a **perspective of risk estimates** in Sydney in general, or in Cape Breton. [p.44]*

The utility of a "background" risk assessment for the Frederick Street zone, because of its complex contaminant profile, is arguable. Simple observations of site conditions, known industrial activities (particularly coking) and linked chemicals-contamination of soil and water (the Tar Ponds for example,) the proximity of housing, the municipal dump, the obviously polluted waterways - all clearly attest to excess exposures to harmful chemicals.

We submit that the human health risk, by whatever means it may be eventually quantified, is undoubtedly present.

Likewise it becomes a humanitarian judgement call as to whether, at this point, there is any comparative benefit or public health rationale in pursuing the question of "chemicals found naturally in the area" viz:-

*..... In addition, the concentrations of many chemicals associated with a particular site **may be similar to chemical concentrations found naturally in the area and not as a result of industrial activities.** [p.15]*

Except for purposes of statistical analysis, the issue seems to fade into insignificance.

We therefore question the usefulness of trying to differentiate between chemicals found "naturally" and those resulting from industrial activities. It is safe to assume that much of the industrial activity over the last 75 years or so has not been documented, particularly the leaking and dumping of substantial quantities of toxic wastes. The distinction between natural and

anthropogenic contamination is probably totally obscured - and it becomes impossible to define a background scenario.

*Therefore, if the amount of a chemical measured within the Frederick Street area is equal to or less than the amount of that chemical typically present in similar areas which are not affected by industrial emissions (called background areas), **it is not necessary to evaluate the possible human health risks associated with that chemical, since humans will be exposed to that chemical concentration even if they did not live on Frederick Street.*** [Appendix A.1.2.1, p. A-9]

Since the authors have frequently noted the implications of the shortage of authentic environmental data for background areas, we find the above comment to be somewhat theoretical and of limited application to the assessment of health risk of persons living in the Frederick Street area.

*The soil concentrations identified in Frederick Street area soils, the coal ash pile and the surficial soil contamination in the seep soil samples were therefore **compared to soil background concentrations for Nova Scotia, where available, or to typical soil concentrations from the areas.** With the exception of sulfur, all of the chemicals without guidelines were present at concentrations less than **typical background values** and were excluded from further assessment.* [p.18]

(We assume that "from the areas" should read "from other areas.")

Since this comparison procedure was used to reject chemicals for further consideration in the HRA, it is extremely important to know the basis and authenticity of the "typical background values" used in the screening process. What types of environment does "typical soil concentrations" include in this context? Would these environments have been mainly rural, or mainly industrial? If they were previously contaminated by un-documented industrial waste disposal activities they do not serve as acceptable background reference points⁽³⁾.

Where Nova Scotia background levels were unavailable, "general background concentrations" were utilized:-

3

Taking the standard health risk assessor's approach to "background" contamination in air, water and soil can lead to a failure to recognize the insidiously incremental nature of advancing environmental deterioration. For example, as "background" concentrations keep growing larger, new pollution loadings will appear to be proportionately smaller and smaller.

There is a danger here of falling into the trap of *sequential sacrificing*, resulting from applying the pre-contamination characteristics of a zone under assessment, or equivalent from similar areas ("*Cape Breton in general*"), in order to diminish the relative contribution of the new contamination in the zone under study (Frederick Street.) If not recognized at the outset, this manoeuvre can turn into a cascade process: each additional contaminating source increasing the sum-total background contamination (the denominator in the equation), so that the *relative* impact of each new source (the numerator) registers relatively smaller and smaller.

*For chemicals without guidelines or Nova Scotia background soil data, the maximum soil concentrations of these chemicals identified in the Frederick Street area were compared to **general background concentrations (Bowen, 1966.)** [p. A-10]*

The fact that the background data is almost 35 years out of date is troublesome; also, the range of “typical background soil concentrations” as shown in Table A-5, p. A-10, is so wide as to be of very limited use for screening chemicals of concern in this HRA. Equally questionable is the current credibility of these background concentrations. As noted above, this requires information as to where and how they were obtained, and some knowledge of the specificity and sensitivity of the analytical methods used thirty two years ago.

Having applied the above vaguely defined criteria to screening chemicals for further consideration (carry-forward) in the HRA, the authors select only sulphur, while rejecting the following:-

Aluminum	Iron	Magnesium	Manganese
Calcium	Lithium	Potassium	Sodium
Strontium	Uranium.		

Since the Report provides few details regarding the chemical compounds involved (*speciation* or element oxidation states,) we recommend that further basic site characterization be carried out to determine the chemical speciation of the above substances, before they are finally rejected from health risk analysis.

4.3 POLY-NUCLEAR AROMATIC COMPOUNDS

With regard to the 15 PAHs carried forward, 8 of these carry the following note:-

*Chemical did not exceed guideline but was **conservatively** included in the assessment....*
[Footnote to Table 2, p.19]

We note that the inclusion of PAHs found “below the guidelines” is described by the authors as a conservative measure. The generic guidelines applied in this HRA are quite definitely not sufficiently well developed to be used as acceptance - rejection criteria for this family of known and suspected carcinogens. Inclusion of PAHs should not be a “gesture of conservatism,” but rather conformance with scientific due diligence.

The authors comment further:-

*Since **polycyclic aromatic hydrocarbons (PAHs) act on the body in similar fashions, all PAHs were evaluated in the assessment, even if they did not “screen on” in the screening process. This allows for an assessment of possible additive effects which can occur when exposure to numerous similarly-acting chemicals occurs simultaneously.** [p.19]*

Since the polyaromatic molecular structure is common to all PAHs, there is consequently a certain similarity in the pharmacokinetic behaviour of this family of compounds. However, since not all PAHs have demonstrated carcinogenic properties, the statement that “*polycyclic aromatic hydrocarbons (PAHs) act on the body in similar fashions,*” requires some modification. Most carcinogens and mutagens have no safe dose limits: sufficient research has not been carried out.

5 SOIL QUALITY: GUIDELINES, REGULATIONS AND CRITERIA - DISTINCTIONS AND DEFINITIONS

This HRA compares all analytical results with guidelines, criteria and recommendations from various sources, predominantly the CCME (Canadian Council of Ministers of the Environment.) Such generic guideline data have applicability under certain site assessment circumstances, for example in defining the relative seriousness of a contamination problem, or for prescribing site remediation criteria.

However, as discussed further below, such “guideline” soil contamination numbers can play only a limited role in defining health risk to human beings. They are of questionable use in this assessment because of the highly site-specific nature of the zone. For the Frederick Street area, the apparent extent of the deposition of toxics and the complexity of their hydrogeological environment, would severely proscribe the interpretation of any generic soil quality guidelines for purposes of evaluating human health impact.

The authors reveal some confusion with regard to “Regulations” versus “Guidelines,” referring frequently to “Regulatory Guidelines.” Perhaps we may clarify the point a little:-

In Canada, as in most western countries, Regulations are enforceable requirements set by legislative bodies, and as such are subject to lawful compliance. Guidelines on the other hand, are just that - they are recommended levels promulgated to guide and assist in the achievement of certain objectives; they are not subject to statutory compliance.

Soil quality guidelines (SQGs) such as those currently being developed by the CCME, are set with certain objectives in mind. These may be for the “best achievable clean-up” of a contaminated site, for comparisons versus natural background levels, or with other objective criteria in mind for the minimization of damage to surrounding soils, waters, plants and animals. SQGs for the maintenance of human health are offered, but are exceedingly difficult to justify because of the numerous and complex sources of variability and uncertainty inherent in contaminant release rates, exposure pathways, and in the definition of human receptors.

Legislating bodies frequently adopt guidelines, sometimes modified to address specific situations,

and use them as the basis for Regulations⁽⁴⁾.

5.1 INAPPROPRIATE INTERPRETATION OF SOIL QUALITY GUIDELINES & CRITERIA

In discussing soil quality guidelines the authors confirm that,

“..... the CCME (1997) states that the soil quality guidelines “are intended as general guidance only” and, when applying these values, site-specific conditions should be considered.” [p.17]

Having made this very important point, we note that they then over-interpret the link between generic soil quality guidelines and human health:-

*“The guidelines are developed to be conservative so that **if concentrations on a particular site are below the guidelines, then one can be confident that human and ecological health are protected.**” [p.17]*

Current soil quality guidelines promulgated by various authorities do not offer the guarantee that, *“..... one can be confident that human and ecological health are protected.”*

The gesture of confidence offered above is only palatable if it is based upon a site-specific assessment, where the investigator is confident that all relevant exposure pathways and human receptor characteristics have been properly incorporated into the risk assessment model. As a statement based on generic soil quality guidelines, it is invalid, and likely to cause a false sense of security among the affected population.

5.2 CCME - RECOMMENDED SOIL QUALITY GUIDELINES - 1997

As explained above, the generic soil quality guidelines (SQGs) set by the CCME -1997/98 (few though they are) and earlier “Criteria” (dated 1991) cannot, at this point, be regarded as *human health based* numbers. The CCME’s guidelines are still (1998) largely based on consensus numbers from 13 Canadian political jurisdictions each struggling to reach an accord, - have their roots partially in the federally aborted National Contamination Sites Remediation Programme, and are inevitably influenced by practical feasibility, non-human health objectives and historically achievable levels. The CCME is still working on its health-based soil quality guidelines, and is likely to be doing so for many years to come. See Appendix E for a further review of CCME soil and water quality guidelines.

Of the 22 substances covered, about 8 are lacking in health-based input. CanTox itself holds a contract with the CCME to provide health effects documentation for these substances, which will still need to be submitted to Health Canada for review.

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One ready example of this is the adoption by various authorities throughout the world of the Workplace Threshold Limit Exposure Values published by the American Conference of Governmental Industrial Hygienists

5.3 CCME- CANADA-WIDE STANDARDS - 1998

The SQG Task Group is working on only the following:

- Benzene
- Particulate matter and ozone (together)
- Petroleum hydrocarbons in soil
- Mercury in all media
- Dioxins and Furans

The salient point here is that scientifically supported epidemiological or direct human dose/response documentation linking soil concentrations of toxic chemicals directly to actual human receptor-specific health effects is sparse; sufficient research has not been carried out. The residents of Frederick Street and neighbourhood may care to take note of this whenever CCME Soil Quality Guidelines, or any other authority's guidelines, are applied to evaluate the toxic risk associated with contaminated soils.

In the meantime, we are reminded that - no knowledge does not mean safe.

6 EXPOSURE ASSESSMENT & EXPOSURE RATIOS

6.1 LONG-TERM EXPOSURE

No attention is given to contaminant source measurements and exposures other than those prevailing today (mid 1998.) Thus, the manner in which such earlier cumulative exposures may have modified or compromised the definition of today's human receptors, that is - the persons who continue to experience exposures in the neighbourhood as of today, has been effectively ignored.

6.2 MULTIPLE EXPOSURE

One of the most serious deficiencies in any environmental health risk assessment is the lack of toxicological information on the effects of exposure to multiple chemicals (combined exposures.) When the exposure is to a mixture of chemicals, there are added uncertainties related to synergistic or antagonistic interactions, involving the chemicals themselves and environmental factors, including the internal body environment.

Chemicals with certain similarities in molecular structure and demonstrating similar (pharmacokinetic) behaviour once inside the human body, may reasonably be considered as toxicologically equivalent (same toxic end-points,) and it is not unreasonable to simply add the dosages from each, in order to obtain a total dosage. However, we cannot find any discussion in the HRA on the important toxicological issue of non-additive health effects; i.e. synergism, antagonism and potentiation; other than a reference to groups of chemicals that "act on the body in a similar

fashion.”

Further discussion can be found at Appendix B on page 37.

6.3 ARSENIC EXPOSURE

*Exposures to arsenic suggest a **moderate theoretical increase** in risk, based on the computer modelling effort conducted (ER=18.3).....[p.36]*

An exposure ratio of 18.3 is hardly a “moderate theoretical increase.” It describes a significant over-exposure.

*Some of the surface soil concentrations within the backyards are below the CCME guidelines (3 out of 7 samples,) and those that exceed guidelines exhibited only **marginal exceedances** (0.8 times the guideline to 4.3 times the guideline.) [p.36]*

The public perception is that 4.3 times the guideline is not a “marginal exceedance,” but rather that it is 430% higher than the guideline.

7 HUMAN RECEPTORS, DOSE - RESPONSE AND RISK

7.1 MEDICAL - CLINICAL STATEMENTS

The authors present no corroborating data when attributing certain clinical conditions to causes other than exposure to toxic chemicals. We find these un-supported conclusions disturbing. Confirmation of such diagnoses and causal links requires the input of an experienced epidemiologist or environmental health physician. For example, on page (ii) of the Report’s summary paragraph, the following statements are made:-

***No measurable adverse health effects** in local residents are predicted to result from **long-term exposure** to chemicals in the Frederick Street neighbourhood. While several residents have reported a variety of health effects (such as ear infections, kidney infections, general malaise, etc.,) many of these effects are **infections which are bacterial or viral in nature, and are not likely to be associated with chemical exposures**. These ailments are reasonably common in the general population, and the reported incidence on these **may well be within the expected range for Sydney for this past winter**. [Report Summary p.(ii)]*

Taking the bolded portions in sequence:-

7.1.1 *“Measurable adverse health effects”*

The computerized roles of probability and prediction are pivotal in this Assessment. The model demands measurements for input, even though such measurements may be circumscribed by the uncertainties of “distributions” and “confidence limits.” Equally, the end result of exposure to environmental toxics has to be measurable, otherwise conclusions on health effects are unsupportable.

In order to measure, one has to have a “ruler,” or a measuring system by any other name. The expressions “*measurable long-term health effects*” and “*measurable adverse effects*” used in this HRA with regard to toxic impact on human beings, require some clarification on a number of counts; remembering that we are not just talking about computer print-outs, but more importantly the possible impact of toxic chemicals on people’s health and well-being, psychological as well as physiological.

What is “measurable?” As frequently employed adjectival phrases in this Report, what do “*measurable long-term health effects*” and “*measurable adverse effects*” mean in the contexts in which they are used? Referring to what measurable factor(s); measured by what particular criteria and using what scales of measure? Clinically diagnosable disease with acute or chronic ramifications? Signs of impairment? Symptoms of dysfunction? Death? Have physiological or psychological profiles or biomarkers⁽⁵⁾ been considered for matching with these statements? As one of many examples, a given *measurable* index of health impairment for an elderly male is not necessarily measurable for an early-teens female. Since the Report does not evaluate any actual measured health effect, adverse, acute, long-term or anything else, the use of the expression “measurable” is meaningless in terms of describing these effects.

7.1.2 *“Infections which are bacterial or viral in nature, and are not likely to be associated with chemical exposures”*

This statement is inadmissible in that it ignores the possibility of immuno-compromisation, chemical sensitization and the intensification of susceptibility resulting from acute or chronic exposure to certain chemicals.

7.1.3 *“May well be within the expected range for Sydney for this past winter”*

“May well be” is a speculative statement of no affirmative value to this assessment. Has the data been compared with that available from the MoH’s office; or perhaps from a consensus of general practitioner’s findings over this period? It would have been more appropriate to check the

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Note on biomarkers: For most chemicals in the environment, sensitive and specific human indicators of long-term exposure, are elusive. They are difficult to define by extrapolation from animal studies, due to (among other discrepant variables) - differences in normal “life spans” between animals and humans, and extended latency periods. A considerable amount of research is currently taking place to identify reliable and consistent human physiological biomarkers of exposure to toxics.

applicable medical registry of disabilities and diagnosable diseases, from which more definitive information on incidence and prevalence could have been extracted.

7.2 RECEPTOR CHARACTERIZATION

Human health risk assessments require that exposed human receptors of toxic chemicals be “defined” in terms of factors which would affect the dosage, metabolic response and health consequences of such exposures. Groupings of hypothetical people, called “composites,” are thus formulated, as described on pages 20/21 of the Report.

Standard procedures for health risk assessments include a number of questionable generalizations, e.g.:-

“.... since females are generally more sensitive to chemicals than males based on their lower body weight” [p.21]

Regardless of the exposure pathways, eating, working and playing routines accorded to these receptor groups, we should point out that setting exposure standards for women does not consist of merely adjusting the men's standard to the lung capacity and body weight of the woman. The interaction of a chemical with women's different internal hormonal environment is also important⁽⁶⁾.

The authors create confusion by using the word “sensitivity” in two different contexts. Firstly there is the biomedical sensitivity associated with the body’s response to toxic chemical absorption; then they introduce a computer-based “sensitivity” to describe relative dosages received based upon body weight⁽⁷⁾. It must be assumed that the latter definition is used in the following:-

*“...If no potential health risks are defined for the female composite, then it can be assumed that **the less sensitive male composite also would not be at risk**” [p.21]*

The above statement is contingent upon the hypothesis that the only relevant dose is derived from an estimated composite exposure in terms of mg/kg body weight. There are of course “small men” who fall outside the definition of the “composite male,” who would in reality, receive a larger dose than that predicted by the computer.

Also, children have significant physiological differences compared with adults. Scaling of safe exposures is not merely dependent on body size and lung capacity, as this HRA assumes. For example, when a child ingests lead, proportionally more would be incorporated into bone (because of their rapid bone growth) than would occur for an adult ingesting a comparable dose. Children,

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For example, when men and women are exposed to the same dose of radioactive iodine based on body weight, women would be expected to develop three times as many thyroid nodules and cancers as men.

7

Except perhaps for very specific clinical profiles, there is not necessarily a connection between biomedical sensitivity and body weight.

because of their long life expectancy have the probability of developing cancers with long latency periods. Adults often die before these rare cancers can develop, making their statistical risk appear to be less. The relative risks for cancer in the thirties age group are often related to exposures in early infancy, and can be thirty times greater than comparable exposures later in life.

*If no potential for adverse effects are identified for the most exposed and **most sensitive** receptors, then no adverse effects would be expected for less exposed, less sensitive receptors [p.20]*

This reflects another of the sweeping assumptions attached to the health risk assessment process. The “most sensitive receptor” hypothesis is acceptable only insofar as the most sensitive receptors have been properly identified; the decision process usually reflecting the developmental biology of the various life-stages (e.g. neonates, expectant mothers, the elderly,) and persons with specific diagnosable diseases such as asthma. Rarely if ever are “sensitive” receptors in a given community defined on the basis of chemical sensitization, chemical allergy or multiple chemical sensitivity acquired due to prior cumulative exposure to the toxics being considered in the current health risk assessment. Therefore, conventional receptor compartmentalization breaks down and the assessment of risk becomes flawed.

For the above and similar reasons, we must question the criteria used in defining receptor groups - as to their adequacy for handling individual susceptibilities acquired from previous cumulative or sporadic site-specific toxic exposures.

7.3 ACCEPTABLE RISK

Despite some excursions into the community-interview arena, the conclusions of this HRA are ultimately based on computer-generated numbers. As such the Assessment resorts, in the end, to purely quantitative methods based on the theory that stochastic methodologies can predict human impairment and sickness to a level of confidence which *should be acceptable* to the individual (in modeling terms,... the human receptor).

For Frederick Street, it is self-evident that this expectation of acceptability has not been fulfilled. It may be helpful here to refer to the Ontario Environment Network handbook⁽⁸⁾ on public consultation which states (from the point of view of the Community member), “..... we don’t want to be told, as we often are, that the risk to us and our families from some hazard is ‘acceptable’. Experts have no business telling us what is acceptable. This is a judgement we must make for ourselves.”

8

Quoted from:- *Overcoming NIMBY in Municipal Waste Management Planning*; Kelly D. McGee, Regional Municipality of Ottawa-Carleton, in *Municipal Solid Waste Management - Making Decisions in the Face of Uncertainty*, Ed:- Murray E. Haight, Institute for Risk Research, University of Waterloo.

7.4 DERIVATION OF DOSE-RESPONSE INFORMATION

*In the toxicity assessment, information relating to the dose-response relationships of each chemical is evaluated (**usually from laboratory animal studies and studies of human exposure in the workplace**) in order to determine the maximum dose of chemicals to which humans can be exposed that would be associated with a very low probability of experiencing adverse health effects. [p.28]*

This paragraph conveys the idea that safe levels of human exposure to environmental chemicals are well established, tried and tested. This of course is very far from the case. The most contentious point here arises from the remark contained in brackets. Safe exposure levels are most difficult to define by extrapolation from animal studies, due to (among many discrepant physiological variables,) differences in normal "life spans" between animals and humans, and, for studies of chronic effects, the extended latency periods required to allow for the proper study of outcomes. Numbers have been derived from animal studies, but there is no evidence that such numbers, even attenuated by a factor of 100, are implicitly safe; again because of the time-spans required to investigate chronic effects. This extrapolation protocol also ignores the effects of simultaneous exposure to other toxic chemicals; thus the impact of the synergistic mechanism is excluded.

Human toxicological data is often a "best estimate" based only upon that data which IS currently available (often extrapolated.) The scarcity of appropriate human dose-response data on which to base the final conclusions is a significant source of uncertainty in this HRA. Further discussion is found at Appendix C.

7.5 DANGERS OF EXTRAPOLATING FROM PERMISSIBLE WORKPLACE EXPOSURES

For a number of reasons, the practice of extrapolating community exposures from established workplace exposures brings its own set of errors.

ACGIH TLVs for respiratory exposure are time-weighted-average personal breathing zone values; i.e. they are directly linked to dosage through integration of the *time-concentration* curve. The 8-hour time-weighted average threshold limit values published by the ACGIH are not to be used to extrapolate permissible Community exposures. Further discussion is found at Appendix D.

7.6 CANTOX-DERIVED EXPOSURE LIMITS

*In the event that a **regulatory exposure limit was not available** for a chemical of potential concern, an exposure limit was derived by CANTOX using procedures similar to those recommended by regulatory agencies. Exposure limits are designed to be protective of all members of a population including sensitive life stages (such as the elderly, pregnant women) and individuals of compromised health (such as asthmatics). [p.31]*

Very few, if any regulatory exposures have been ultimately proven to protect asthmatics and persons with multiple chemical sensitivity (MCS.) The lack of a published regulatory exposure may simply

indicate a lack of appropriate research and clinical experience.

We would question the premise behind the statement that “*an exposure limit was derived by CanTox using procedures similar to those recommended by regulatory agencies,*” simply because the methodologies practiced, and end-point medical criteria adopted by regulatory bodies can vary significantly, depending upon the type of environment which they are attempting to regulate, and the class of person they are attempting to protect. The fact is that on an international basis, *recommended* maximum exposures for the community very often do not find their way into any form of regulatory framework. Those that do are often adjusted to meet imperatives other than the protection of human health.

Also, such a procedure is perceived by the public as the unilateral appointment of a private sector commercial organization to the status of sole arbiter of what is a “safe” community exposure limit; while at the same time clearly contradicting CanTox’s own earlier assurance that -

The acceptable level of risk is set by regulatory agencies, as opposed to risk assessors, [p.29.]

8 CONCLUSIONS

This HRA is an attempt to cross-sectionally analyze a historic and ongoing problem, using whatever existing environmental sampling data happened to be available from various official sources. As the authors make clear, no attention is given to source measurements and exposures other than those taken recently (1998.)

8.1 FAILURE TO DETERMINE HUMAN-RECEPTOR PROFILES:

Due to lack of time and shortage of information, this Assessment has not been able to adjust its conclusions to allow for the manner in which earlier cumulative exposures may have modified or compromised the definition of today’s human receptors. Inevitably this exclusion weakens the risk characterization step [HRA Paragraph 6] by causing a failure to consider possible cases of, for example, immuno-compromisation or aggravated susceptibility to environmental toxics (chemical sensitization or multiple chemical sensitivity,) resulting from cumulative exposures.

8.2 INADEQUATE SITE CHARACTERIZATION:

We have concerns regarding the adequacy of the primary data supplied to the computer model for evaluating human exposures. We find that the sampling protocols are unlikely to provide an adequate picture of the chemical nature and extent of the contamination in the Muggah Creek - Frederick Street area. The authors take care to point out such limitations at appropriate stages in the Report, but unfortunately this does not resolve the problem. In site-specific terms, we believe that the soil and water distribution of contaminants, their concentrations and their transportation pathways, have not been adequately appraised.

As becomes increasingly apparent in the Report, the problem with this type of sampling scenario is that it can spawn too many assumptions with regard to the relevance of the available monitoring and analytical information. Contamination in the Muggah Creek - Frederick Street zone is substantial and complex. Even after applying conservative or "worst case" modifiers, the gaps in site-specific contamination data place a significant amount of uncertainty right at the front end of the Assessment's computer model. Since uncertainty tends to be amplified as data is processed through the risk assessment algorithm, we find it most unlikely that meaningful exposure and dose predictions have been established.

8.3 CONJECTURE AND DESCRIPTIVE INFORMATION:

We have sometimes found it difficult to separate the descriptive socio-medical commentary from considerations based on the quantitative data fed into the computer - which data only are relevant in support of the ultimate human health risk conclusions.

We recognize that it is often difficult when carrying out health risk assessments, to decide what is, and what is not, a valid assumption. This is often a judgement call, leaning heavily upon the investigator's previous experience in the specific area of concern. For example:-

*Since the main issues of the concern were related to the seep, the coal dusting activities, and proximity to the coke ovens site (all of which are more prevalent in the Lower Frederick Street area), **it is anticipated that** soil concentrations in the Upper Frederick Street area would be similar to, or less than those from Lower Frederick Street. [p.45]*

We submit that "anticipation" of soil concentrations is not an acceptable characterization step for a site such as this one, where there is evidence of undetermined sub-surface contaminant movement throughout the zone. Also, Upper Frederick Street is closer to the municipal landfill which, being a poorly contained dump, will very likely make its own contribution to the overall toxics loading.

With regard to pre-emptive statements, the following conclusion is placed at the beginning of the Report:-

*As indicated previously, the Medical Officer of Health had stated on several occasions that he felt that the contamination (related to the dust, soils, seep and infill areas) found in the Lower Frederick Street area **did not pose an immediate threat to health** [p.4]*

We find this an unusual statement to place in the opening pages of an "independent" human health risk assessment report. It effectively challenges the true objectivity of the HRA by inferring that the outcome of the assessment is a foregone conclusion, - that is, there is no immediate health risk. Such pre-emptive conclusions can create a very poor public perception of the whole HRA process, and make it more difficult for the investigators to carry out their work.

Certainly the MoH's comment calls into question the next statement, which declares that -

The Nova Scotia Department of Health and Health Canada contracted CanTox Environmental to provide the following:

- *An **independent**, scientifically-based opinion..... [p.4]*

This Assessment in fact overwhelmingly dependent upon un-confirmed third party sampling data.

8.4 REJECTION OF THE CANTOX HRA CONCLUSIONS

The outcome of the CanTox HRA is a community health risk conclusion which we are unable to support based on the meager sampling data and the uncertainties contained in the methodologies employed. With regard to assumptions applied in the derivation of human-receptor profiles, and limitations in the primary environmental data, we feel that the authors should have clearly pointed out the significant uncertainty created by these assumptions - at the same point in the Report where they offer their conclusion that:-

"No measurable adverse health effects in local residents are predicted to result from long-term exposure to chemicals in the Frederick Street neighbourhood"
[p. ii]

8.5 RECOMMENDATIONS

A more deterministic approach from the epidemiological perspective (rather than the conventional health risk assessment perspective) seems to be called for. The resolution to this situation would require the acquisition and analysis of a considerable amount of retrospective epidemiological data. The case-control implications of such a study in this particular population would be challenging but not insurmountable. Also, it is known that some investigative work has been carried out in the past by various authorities, addressing the health status and health risk of persons employed by SYSCO, or living near its various industrial operations at Sydney. We suggest that an attempt be made to look at the feasibility of consolidating what is already known in terms of cause-effect and attributable risk.

Appendices

APPENDIX A RISK ASSESSMENT VERSUS HAZARD ASSESSMENT

THE ALTERNATIVE CONSIDERATIONS

(I) If there is no exposure to a chemical.....

“If there is no exposure to a chemical, regardless of how toxic it may be, there is no potential for the development of adverse health effects from that chemical.”

This is true if the chemical is truly contained for ever and a day, i.e:

- Nothing ever happens to cause the chemical to be displaced or put in motion by:
 - building projects
 - re-development projects
 - floods
 - subterranean disturbances
 - natural seepage
 - wind erosion
 - storms;
- Should there be a chemical-release episode, then no human being is present at the end of any exposure pathway, viz: respiratory, direct contact or food and water ingestion, during or at any time after the event until such released toxic has safely dispersed.

Provided that the aforementioned conditions can be assured, then the “no exposure - no health problem” axiom is entirely valid. However, in the real world this type of “risk” based approach is equivalent to evaluating the toxicity of a substances in terms of a direct dependency on the continuing status quo of many social, industrial, commercial and environmental variables, not the least requirement being climatic and geological stability.

In the opinion of many citizens, health scientists and environmental engineers, risk analysis is an excuse not to address the real problem, which is the inherently hazardous nature of certain chemicals. “Risk” assessments (as opposed to hazard assessments) have an interesting spawning ground in the government/corporate world. It is often convenient for those who profit from the production, distribution, use and disposal of toxic chemicals, to support a long, complex, and tedious process of “risk” analysis, instead of dealing up front with the chemical’s inherent *hazard* characteristics. Such an “up-front” approach would however, call for earlier intervention in the “life cycle” of the hazardous material - such as restricting or eliminating its production and usage. The European Union is currently considering the pros and cons of the “hazard” based approach to environmental health assessments, rather than the “risk” based approach.

(II) The Canadian Institute for Environmental Law and Policy

..... has the following to say on the issue of "risk" versus "hazard" based approaches to the assessment of toxicity :-

The Canadian Chemical Producers Association holds that only a full risk assessment based approach to the evaluation of the toxicity of substances can be considered "good" science. This is not a valid statement. Both risk and hazard assessment approaches to the assessment of substances constitute "good" science if they are carried out in a competent and honest manner.

A hazard based approach, such as that proposed by the Standing Committee on Environment and Sustainable Development reflects the traditional scientific definition of toxicity "based on the intrinsic potential of a substance to damage organisms."

(III) Ontario Ministry of Environment

A hazard assessment approach was employed by the Ontario Ministry of Environment in the Development of its April 1992 Candidate Substances List for Bans or Phase-Outs. In addition, a hazard-based criteria approach to the assessment of the toxicity of substances was agreed to by all stakeholders, including industry, in the Accelerated Reduction/Elimination of Toxics (ARETS) process. In both programs, systems were developed for prioritizing action on substances on the basis of such intrinsic characteristics as bioaccumulative potential, persistence and toxicity, including acute toxicity, chronic/sub-chronic toxicity, carcinogenicity, teratogenicity, genotoxicity and mutagenicity.

The choice between risk and hazard based approaches is fundamentally one of policy, not one of "good" or "bad" science.

A hazard based approach is essentially precautionary in nature, and provides the basis for taking preventative measures with respect to substances due to their potential to cause harm to the environment or human health. Risk-based approaches, on the other hand, are fundamentally reactive in nature, and essentially wait for absolute proof of actual harm to the environment or human health before action can be taken.

In this context, it is hardly surprising that economic interests that produce, use, or dispose of potentially toxic substances prefer the more conservative risk-based approach, to the precautionary hazard-based model.

APPENDIX B INTERACTION OF CHEMICALS IN BIOLOGICAL SYSTEMS

In assessing the spectrum of responses, the accessibility of large numbers of toxicants creates an increasing necessity for consideration of interacting effects of toxicants. Interactions can occur in a variety of ways. The substances can interact with each other chemically, which usually results in a decreased response, produces altered rates of absorption, changes degrees of protein binding, and alters the rates of metabolism or excretion of one or both of the interacting toxicants. In addition to these known modes of interaction, the response of the organism to combinations of toxicants may be increased or decreased because of the toxicologic responses at the receptor sites. A number of terms have been used to describe pharmacologic and toxicologic interactions.

An additive effect is the situation in which the combined effect of two chemicals is equal to the sum of the effect of each agent given alone (example: $2 + 3 = 5$). The effect most commonly observed when two chemicals are given together is an additive effect. For example, when two organic phosphate insecticides are given together, the cholinesterase inhibition is usually additive.

A synergistic effect is the situation in which the combined effect of two chemicals is much greater than the sum of the effect of each agent given alone (example $2 + 3 = 20$). For example, both carbon tetrachloride and ethanol are hepatotoxic agents, but together they produce much more liver injury than the mathematical sum of their individual effects on the liver would suggest.

Potentiation is the situation when one substance does

not have a toxic effect on a certain organ or system, but when added to another chemical it makes the latter much more toxic (example: $0 + 2 = 10$). Isopropanol, for example, is not hepatotoxic, but when isopropanol is added to carbon tetrachloride, the hepatotoxicity of carbon tetrachloride is much greater than when it is not given with isopropanol.

Antagonism is the situation in which two chemicals, when given together, interfere with each other's actions or one interferes with the action of the other chemical (example: $4 + 6 = 8$, $4 + (-4) = 0$, $4 + 0 = 1$). Antagonistic effects of chemicals are often very desirable effects in toxicology and are the basis of many antidotes.

Courtesy: Casarett and Doull's - *Toxicology: The Basic Science of Poisons*: 2nd. Ed., 1980; Macmillan Publishing Co., New York.

APPENDIX C TOXIC IGNORANCE (REPORT BY THE ENVIRONMENTAL DEFENSE FUND - 1997)

The full report (with excellent references) is available from:

Environmental Defense Fund (www.edf.org),
257 Park Avenue South
New York, NY 10010, USA

In the early 1980s, the National Academy of Sciences' National Research Council completed a four-year study and found that 78% of the chemicals in highest-volume commercial use had not had even "minimal" toxicity testing. Thirteen years later, there has been no significant improvement.

Chemical safety can't be based on faith. It requires facts. Government policy and government regulation have been so ineffective in making progress against the chemical ignorance problem, for so long, that the chemical manufacturing industry itself must now take direct responsibility for solving it. It is high time for the facts to be delivered. Step one toward a solution lies in simple screening tests, which manufacturers of chemicals can easily do. All chemicals in high-volume use in the United States and Canada should long since have been subjected to at least preliminary health-effects screening, with the results publicly available for verification. There is already international consensus on just what needs to be done as a first step. A model definition of what should be included in preliminary screening tests for high-volume chemicals was developed and agreed on in 1990 by the U.S., Canada and the other member nations of the Organization for Economic Cooperation and Development, with extensive participation from the U.S. chemical manufacturing industry.

This report documents that, today, even the most basic toxicity testing results cannot be found in the public record for nearly 75% of the top-volume chemicals in commercial use.

In other words, the public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not much less how serious the risks might be, or whether those chemicals are actually under control. These include chemicals that we are likely to breathe or drink, that build up in our bodies, that are in consumer products, and that are being released from industrial facilities into our backyards and streets and forests and streams.

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Analysis of the extent of health-hazard information on chemicals is rare. In 1980, the National Academy of Sciences' National Research Council began an extensive study to determine what need there was for additional toxicity testing. It concluded in 1984 that 78% of the chemicals in U.S. commerce with production volume of greater than one million pounds per year lacked even "minimal toxicity information." This report is the first public attempt to update the 1984 findings on the extent of toxicity testing for chemicals in U.S. commerce.

The chemicals addressed in this report do not include all, or even most, of the approximately 75,000 chemicals that the U.S. Environmental Protection Agency lists as being made in the U.S. in 1996. This report covers only those chemicals that are produced in or imported into the U.S. in amounts greater than 1 million pounds per year (high-production-volume chemicals), as documented by the U.S. Environmental Protection Agency. Because EPA's list does not include certain categories of chemicals, such as food additives, drugs, and pesticides, this study excludes those materials.

This report uses the same approach as the 1984 National Research Council report, analyzing the availability of hazard identification data (i.e., toxicity testing results) by examining chemicals in a randomly selected representative sample and then extrapolating the sample results to all high-production-volume chemicals.

As in the 1984 report, the results from the sample are extrapolated to all 3,000 high-production-volume chemicals. This approach almost certainly overstates the degree of knowledge about hazard information for this larger group of chemicals, as explained above, and thus understates the actual degree of ignorance.

In measuring whether a chemical qualifies as having hazard identification data available, this report takes the internationally accepted definition of a minimum screening information data set that was created by the Organization for Economic Cooperation and Development (OECD) Chemicals Program in 1990. It focuses only on the portion of the definition that covers screening for human health effects ("Toxicological Data"). If enough data to meet this portion of the OECD minimum screening requirements were found to be available for a particular chemical, it was assumed that an informed preliminary judgment about that chemical's potential human health hazards could be made.

There is international consensus that this data set represents the minimum amount of data required for a preliminary assessment of human health hazard of a chemical. However, it is important to note that the minimum screening information data set generally does not include enough data to conduct a comprehensive health risk assessment. It is only a starting point, and it is no substitute for the risk assessment that is called for under most major toxic chemical control laws.

The analysis in this report uses only information from publicly available sources. For some chemicals there is undoubtedly private information as well: for example, tests on specific chemicals that major manufacturers have performed, or paid for, which to date have not been made available to the public. A specific example is discussed below at the end of this chapter. However, a report like this has no way to evaluate private data. More importantly, for purposes of assuring the public about the safety of specific chemicals, non-public data are of no real value. To rely on them is to ask the public to take chemical safety on faith the exact opposite of the intent of modern toxic chemical control laws passed by Congress since 1970.

The actual facts are particularly hard to establish for chemicals with no hazard identification data because, almost inevitably, such chemicals are not tracked or monitored. Proving whether people are being exposed to such chemicals or not is therefore extremely difficult. **Nearly three quarters (71%) of the sampled high-priority chemicals do not meet the minimum data requirements for health hazard screening** set by the Organization for Economic Cooperation and Development Chemicals Program.

Thus, for the group of chemicals with the highest volume use in the United States, there is no basis for assurance that their use does not pose health risks to the American people, whether that assurance is offered by industry or by government.

Lack of meaningful assurance is not the same as proof of harm, of course. It is only proof of ignorance. But ignorance means that any conclusion about safety is unfounded. A system that relies on ignorance has no basis for inviting public confidence that chemical risks are under control even from the chemicals being sold and used in the largest amounts. For approximately 75% of those chemicals, minimum critical information is lacking. **Of the potential health effects ("endpoints") that would be covered by minimum screening tests, a majority of chemicals in the high-priority sample have been tested for only two: genetic toxicity (i.e., ability to cause mutations) and developmental toxicity (e.g., ability to cause birth defects).**

Reproductive toxicity tests have not been conducted on 53% of high-priority chemicals. Carcinogenicity tests have not been conducted on 63% of high-priority chemicals. Neurotoxicity tests have not been conducted on 67%. Immunotoxicity tests have not been conducted on 86%. **Endpoints of particular concern for evaluating impacts on children (such as postnatal performance and developmental neurotoxicity) have not been assessed for more than 90% of high-priority chemicals.**

Exposure to these high-priority chemicals can occur from various sources, including from use of consumer products, from indoor or outdoor air, and in the workplace. In the workplace, use of chemicals can result in regular occupational exposures to production workers. Workplace use may also lead to ongoing exposures to the general public if these chemicals are released to the environment or are included in consumer products. To assess the safety of chemical use in such contexts, it is important to have data from chronic toxicity tests; i.e., tests investigating the effect of exposure to the chemical over substantial periods of time. More than half of the sampled high-priority chemicals have not been tested for any form of chronic toxicity. For acute toxicity, by contrast, testing is much more likely to have occurred: over 90% of the sampled chemicals have been tested for some form of acute toxicity (usually death).

Most toxicity testing has not focused on the route of exposure that is most relevant for assessing human health risks. Both for the general public and for workers, the predominant route of exposure to many compounds is likely to involve breathing contaminated air (inhalation exposure). Yet more than two-thirds of high-priority chemicals have not been subjected to chronic inhalation tests that evaluate long-term air exposures to a toxicant.

These results, for high-priority chemicals as a whole, are dismayingly meager. But an observer might raise the possibility that, despite their priority for regulators and their high volume of commercial use, the chemicals under study might not be representative of those actually out in the environment. Perhaps, for example, chemicals we are most likely to be exposed to outdoors have been tested, even if other high-volume chemicals have not. To test this possibility, EDF looked only at the chemicals in its sample that are reported on the national Toxics Release Inventory as being released by industry into the environment, a total of 47 chemicals.

Even of the sampled chemicals that are known to be released into the environment, 51% do not meet minimum screening requirements for health hazard identification. This result is particularly striking, since to be included on the Toxics Release Inventory a chemical must already have been found to be "toxic" on the basis of some evidence of harm. This finding illustrates an important point: that even with chemicals for which one health hazard may have been found, we are likely not to have even a preliminary idea whether other health hazards are also presented.

For the portion of the sampled chemicals for which we have especially strong reasons to anticipate human exposure, the results are similar. The U.S. EPA has established criteria for assessing the exposure potential of chemicals based on bioaccumulation and persistence; i.e., whether they are likely to build up in our bodies, and whether they are likely to last for a long time in the environment. Looking only at sampled chemicals with "high" and "medium" exposure potential, a total of 42 chemicals, 57% do not meet minimum screening requirements for health hazard identification. This finding means that chemicals with special likelihood of exposure have not been tested to any significantly greater degree than other chemicals. Just because regulators can identify chemicals with special likelihood of exposure does not mean that better testing for their potential health effects has yet occurred, or that the results of any such testing are publicly obtainable.

APPENDIX D ACGIH WORKPLACE EXPOSURE LIMITS

AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS

INTRODUCTION TO THE CHEMICAL SUBSTANCES

[TAKEN DIRECTLY FROM THE 1994-1995 EDITION OF "THRESHOLD LIMIT VALUES FOR CHEMICAL SUBSTANCES AND PHYSICAL AGENTS AND BIOLOGICAL EXPOSURE INDICES"]

Threshold Limit Values (TLVs) refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be affected more seriously by aggravation of a pre-existing condition or by development of an occupational illness. Smoking of tobacco is harmful for several reasons. Smoking may act to enhance the biological effects of chemicals encountered in the workplace and may reduce the body's defense mechanisms against toxic substances.

Individuals may also be hypersusceptible or otherwise unusually responsive to some industrial chemicals because of genetic factors, age, personal habits (smoking, alcohol, or other drugs), medication, or previous exposures. Such workers may not be adequately protected from adverse health effects from certain chemicals at concentrations at or below the threshold limits. An occupational physician should evaluate the extent to which such workers require additional protection.

TLVs are based on available information from industrial experience; from experimental human and animal studies; and, when possible, from a combination of the three. The basis on which the values are established may differ from substance to substance; protection against impairment of health may be a guiding factor for some, whereas reasonable freedom from irritation, narcosis, nuisance, or other forms of stress may form the basis for others. Health impairments considered include those that shorten life expectancy, compromise physiological function, impair the capability for resisting other toxic substances or disease processes, or adversely affect reproductive function or developmental processes.

The amount and nature of the information available for establishing a TLV varies from substance to substance;

consequently, the precision of the estimated TLV is also subject to variation and the latest TLV *Documentation* should be consulted in order to assess the extent of the data available for a given substance.

These limits are intended for use in the practice of industrial hygiene as guidelines or recommendations in the control of potential health hazards and **for no other use, e.g., in the evaluation or control of community air pollution nuisances; in estimating the toxic potential of continuous, uninterrupted exposures or other extended work periods; as proof or disproof of an existing disease or physical condition;** or adoption or use by countries whose working conditions or cultures differ from those in the United States of America and where substances and processes differ. These limits *are not* fine lines between safe and dangerous concentration **nor are they a relative index of toxicity.** They *should not* be used by anyone untrained in the discipline of industrial hygiene.

The TLVs, as issued by the American Conference of Governmental Industrial Hygienists are recommendations and should be used as guidelines for good practices. In spite of the fact that serious injury is not believed likely as a result of exposure to the threshold limit concentrations, the best practice is to maintain concentrations of all atmospheric contaminants as low as is practical.

The American Conference of Governmental Industrial Hygienists disclaims liability with respect to the use of TLVs.

APPENDIX E

CCME: CANADIAN SOIL QUALITY GUIDELINES - CONTAMINATED SITES ASSESSMENT AND REMEDIATION (February 9, 1998)

Health Risk Assessments carried out in Canada lean heavily upon soil and water quality guidelines and regulations, published by various jurisdictions, predominantly the Canadian Council of Ministers of the Environment (CCME.)

Ultimately however, it is the individual person whose life and health may be affected by the manner in which these risk-based evaluation and management tools are used to predict human exposures and dosages during the health risk assessment process. Accordingly we have provided below some background on the reasons, rationale and limitations attached to the setting of permissible (maximum) soil and water concentrations, specifically the soil quality guidelines (SQG.)

ACKNOWLEDGEMENT: THE FOLLOWING IS EXTRACTED FROM THE CCME'S OWN BULLETIN EXPLAINING THE CURRENT STATUS OF SOIL QUALITY GUIDELINE DEVELOPMENT IN CANADA - 1998.

In late 1989, CCME identified contaminated sites management as a national priority and launched the *National Contaminated Sites Remediation Program (NCSRP)* with the intent to:

- encourage development of "polluter pays" legislation;
- provide a fund for remediation of high priority orphan contaminated sites;
- stimulate development and demonstration of new remedial technologies;
- ensure a consistent and effective approach to the identification, assessment and remediation of contaminated sites.

However, nationally coordinated activities under the first three goals were wound down at the formal termination of the NCSRP in 1996.

For the fourth goal, foundational work during the NCSRP has guided further work on risk-based evaluation and management tools including soil quality guidelines. Two multistakeholder consultation workshops were held in 1990 to establish principles for the NCSRP and provide early technical guidance that would allow remedial work to proceed on orphan sites. A framework was needed that allowed classification and prioritization of contaminated sites, and which provided both generic and site-specific assessment and remediation tools, placing equal emphasis on human health and environment.

Assessment begins with an evaluation of site, receptor and contamination characteristics so as to allow classification; this would normally proceed to sampling and chemical analysis for known or suspected contaminants. Data obtained would then be compared to generic assessment guidelines to determine

whether concentrations exceed the expected background. Where concentrations exceed background these would be further compared to generic remediation guidelines based on land use. Exceedances here could be addressed through remediation of the affected media or, alternatively, further evaluation and management using site-specific risk assessment. Whether the assessment and remediation is carried out on a generic basis or through site-specific risk assessment, a site-specific objective is developed.

The approaches differ, however, in the amount of information required to manage risks. An important feature of the generic or guideline-based approach in the CCME framework (Methods 1 and 2) is the ability to adapt guidelines to respond to certain types of site-specific information. At the time the framework was developed this feature was of limited value because the scientific basis for the guidelines of the day -- including assumptions about receptors and exposure -- was not transparently documented. **There was a need for transparent, scientifically defensible generic guidelines;** as well as guidance on their appropriate application – including the circumstances under which they should be set aside in favour of site-specific risk assessment.

These needs have been addressed through development of a science-based protocol for guideline development (CCME 1996a) and a guidance manual on development of site-specific objectives (CCME 1996b).

(I) Interim Canadian Environmental Quality Criteria

In September 1991, the CCME released the *Interim Canadian Environmental Quality Criteria for Contaminated Sites (CCME 1991)*. Those criteria were established for defined land uses by adopting existing criteria for soil and water used by various jurisdictions in Canada. **However, many of the interim criteria for soil are not scientifically defensible and are now being updated based on current scientific information.**

A new set of Canadian soil quality guidelines (as they are now referred to, instead of criteria) has been developed specifically for protection of the ecological receptors in the environment or for the protection of human health associated with the identified land uses. These guidelines were derived using the procedures described in the *Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME 1996a)* which will be referred to as the Soil Protocol .

The use and interpretation of the terms guidelines, objectives, and standards vary among different agencies and countries. Previous CCME publications about the National Contaminated Sites Remediation Program used the term “soil criteria”; however, the term “criteria” will now be replaced by “guidelines” for consistency with other environmental media (water, sediments, etc.). For the purpose of this document, these terms are defined as follows:

<u>Guidelines</u>	-	Numerical limits or narrative statements recommended to support and maintain designated uses of the soil environment.
<u>Objective</u>	-	Numerical limits or narrative statements that have been established to protect and maintain designated uses of the soil environment at a particular site.

Standards - Guidelines or objectives that are recognized in enforceable environmental control laws.

(II) What is the Soil Protocol and How is it Used?

The Soil Protocol was developed by the Subcommittee on Environmental Quality Guidelines for Contaminated Sites (SEQGCS) to provide a method for replacing the Interim Remediation Criteria for soil with scientifically-defensible generic guidelines accounting for both scientific and management considerations. The Soil Protocol provides the public, industry, and regulatory agencies with the basic concepts and methods employed in generic guideline development (CCME 1996a.)

The 1991 Interim Remediation Criteria for soil are revised on a substance-by-substance basis after a comprehensive review of the physical/chemical characteristics, background levels in Canadian soils, toxicity and environmental fate and behaviour of each substance. This information is used in a structured exposure analysis to develop soil quality guidelines for each of four land uses as specified in the Soil Protocol. Details of guideline derivation are presented in a technical series of guideline supporting documents available from Environment Canada for the environmental guidelines and from Health Canada for the human health component of the guidelines.

Once guidelines have been drafted and received scientific peer and agency review they are released as *“Recommended Soil Quality Guidelines”*. A one-year public comment period follows this release. Public input is then used to finalize guidelines. **It is recognized that contaminants are likely to occur in mixtures. However, there is insufficient understanding of the behaviour and toxicology of contaminant mixtures at this time to allow a general treatment within the guideline derivation process.**

Petroleum hydrocarbons represent a special case where recent intensive research has provided an opportunity to extend the principles and procedures of the Soil Protocol to a mixture.

(III) Guiding Principles for Soil Protocol

Soil is a complex heterogeneous medium consisting of variable amounts of minerals, organic matter, water and air, which is capable of supporting organisms such as plants, bacteria, fungi, protozoans, invertebrates and other animal life. It is an open, dynamic component of the terrestrial ecosystem that is crucial to life. An essential principle is that soil, at the guideline levels, will provide a healthy functioning ecosystem capable of sustaining the current and likely future uses of the site by humans and ecological receptors.

Protecting the Environment

To protect the terrestrial ecosystem, the derivation process outlined in the Soil Protocol considers the adverse effects resulting from direct contact exposure to soil-based contaminants as well as those resulting from ingestion of contaminated soil and food. Potential exposure pathways, receptor arrays, and exposure scenarios are assumed for major land uses. Based on these exposure scenarios, ecological receptors that sustain the primary activities for each land-use

category are identified.

A literature review is conducted to determine the environmental fate and behaviour of the contaminant as well as its toxicity in soil. A standard procedure is used to derive an effects-based soil quality guideline for soil-dependent organisms (i.e., invertebrates, plants and microbes) from acceptable toxicity data. For higher trophic level consumers (i.e., livestock and terrestrial wildlife), pathways have been identified to derive environmental quality guidelines that consider the ingestion of contaminated soil and food.

Protecting Human Health

Human health soil quality guidelines provide concentrations of contaminants in soil, at or below which no appreciable human health risk is expected. To protect human health, derivation processes for threshold and non-threshold toxicants are differentiated, taking into account background daily exposure from air, water, soil, food, and consumer products.

Indirect exposure routes resulting from contaminated soils, such as contaminated groundwater; contaminated meat, milk, and produce; contaminated produce from private gardens; infiltration into indoor air; and wind erosion resulting in deposition on neighbouring property are also considered during derivation of human health guidelines. These indirect exposure routes are evaluated conservatively by applying simplified transport and redistribution models using generic site characteristics in a variety of site conditions. Key components of the risk-based generic human health guidelines include an assessment of multimedia background exposure unrelated to contaminated sites and a generic human exposure scenario relevant to each land use.

In the multimedia exposure assessment, total background exposure by all sources (i.e., air, water, food, soil, and consumer products when appropriate) and all pathways (i.e., inhalation, ingestion, and skin absorption) are estimated. The soil quality guidelines are established after accounting for this background exposure to ensure that the total tolerable contaminant intake is not exceeded.

(IV) Land Use

Generic guidelines are derived to protect human and key ecological receptors that sustain normal activities on four land use categories: agricultural, residential/parkland, commercial, and industrial. Generic land use scenarios are envisioned for each category based on how the land is used and on how sensitive and dependent the activity is on the land.

Sensitivity to contamination increases among ecological or human health components most dependent on land use activities (i.e., agricultural and residential/parkland). The definition of each land use accommodates generic conditions and puts boundaries on the receptors and exposure pathways considered in guidelines derivation for that land use. The four defined land uses are:

Agricultural

The primary activity is growing crops or tending livestock and includes agricultural lands providing

habitat for resident and transitory wildlife as well as native flora.

Residential/Parkland

The primary activity is residential or recreational activity. Parkland is defined as a buffer zone between areas of residency and campground areas and excludes wild lands such as national or provincial parks.

Commercial

The primary activity is commercial (e.g., shopping mall), not residential or manufacturing and does not include zone where food is grown.

Industrial

The primary activity involves the production, manufacture, or construction of goods.

Key biological receptors and exposure pathways were identified for each land use to protect soil quality and maintain activities performed on these lands. Recognizing differences in analyzing human health and ecological issues, soil quality guidelines for each chemical are developed for both ecological and human receptors.

For each of the four land uses, to protect both human health and the environment, the most protective guideline is chosen as the recommended CCME soil quality guideline.

(V) Environment

The guidelines derivation process focuses on the effects of chemical stressors on the biotic component of a terrestrial ecosystem. Specifically, it evaluates the potential for adverse effects to occur from exposures to soil-based contaminants at point-of-contact or by indirect means (i.e., food chain transfer). Adverse effects data may come in a variety of forms, ranging from data collected in the field (e.g., mesocosm studies) to single species tests performed in the laboratory (i.e., using bioassays). Specific land uses are studied and guidelines based on the availability of terrestrial toxicity information are developed.

(VI) Level of Ecological Protection and Relevant Endpoints

The level of protection provided by the guidelines depends on the protection goals sought for individual land use categories. Therefore, for agricultural and residential/parkland land uses, it is necessary to achieve a level of ecological functioning that sustains the primary activities associated with these land uses. On commercial and industrial lands, the primary land use activities are not directly dependent on the need to sustain a high level of ecological processes.

The same key ecological receptors and endpoints examined for agricultural and residential/parkland land uses are also examined for commercial and industrial land use. However, the level of protection for commercial and industrial land use is reduced to correspond with the lower protection levels required by these land use categories. Despite the different levels

of protection, an important common principle exists for all land use categories. The level of ecological protection provided by the soil quality guidelines ensures that the remediated land has the potential to support most activities likely to be associated with each land use.

In developing Canadian environmental soil quality guidelines, only the endpoints related to the "direct effects" of chemical stressors to receptors are examined, and these do not account for the "indirect effects" (e.g., avoidance of polluted food items) that may occur from sublethal exposures. In terrestrial toxicity testing, most studies have focused on mortality (LC50) as a short-term endpoint and on reproduction, growth, development, behaviour, activity, lesions, physiological changes, respiration, nutrient cycling, contribution to decomposition, genetical adaptation, and physiological acclimatization as long-term, sublethal endpoints (EC50 , NOEC, LOEC;) (SECOFASE 1993).

Environmental soil quality guidelines rely on sensitive measurement endpoints for key receptors that act as "predictive sentinel species". Extrapolation to assessment endpoints is therefore restricted to the population level since single species measurements of endpoint data are used in guideline derivations. Information from laboratory studies must involve endpoints critical to the maintenance of a species, such as mortality, reproduction, and growth, which are required to complete a normal life cycle, and to produce viable offspring.

(VII) Finalizing the Environmental Soil Quality Guideline

Procedures used to unite the direct soil contact, soil and food ingestion and nutrient/energy cycling data to derive a final environmental soil quality guideline (SQG E) vary by land use. Some chemicals (e.g., copper and zinc) considered hazardous at high levels also provide minimum nutritional requirements for the maintenance of plant growth at lower levels. The candidate SQG E determined for these chemicals may fall below the nutritional requirements. For agricultural and residential/parkland land uses maintenance of nutritional requirements is critical to sustaining the primary activity on these lands (i.e., growing crops, grass, trees).

Accordingly, the candidate SQG E for these land use categories is compared to minimum plant nutritional requirements. If the candidate SQG E is below acceptable minimum plant nutritional requirement levels, the derivation is re-checked and, if no serious data deficiencies or errors are found, an adjustment is made to the candidate SQG E to bring it in line with plant nutritional requirements.

(VIII) Human Health

Guiding Principles for Human Health Soil Quality Guidelines

The following guiding principles are retained for the derivation of generic SQG HH protective of human health in Canada.

- Soil should pose no appreciable risk to humans for all activities associated with the

intended land use. Furthermore, there should be no restrictions as to the extent or nature of the interaction with the site for each specified land use.

- Guidelines are based on defined specific scenarios within which the exposure likely to arise on the site can be predicted with some degree of certainty.
- Guidelines are derived by considering exposure through all relevant pathways (soil, air, water, and food).
- A critical human receptor is identified for each land use and the defined exposure scenarios are usually based on the most sensitive receptor to the chemical, and the most critical health effect.
 - Guidelines are developed by applying scientifically derived information, backed by professional judgement where data gaps occur.

(IX) Outline of Human Health Soil Quality Guideline Derivation

The steps employed to derive Canadian soil quality guidelines based on human health are similar to those used for site-specific risk assessment and require that several basic assumptions be made in lieu of site-specific information. For a specified land use, a generic exposure scenario was defined which details a sensitive receptor (child or adult), the reference characteristics of that receptor (weight, amount of soil and water ingested daily, exposure duration, etc.) and specific pathways of exposure.

Few distinctions have been made for differing soil type, differing soil chemical, or physical composition, all of which might be incorporated at a site-specific objective level. Development of human health soil quality guidelines (SQG_{HH}) is done in two steps. The first step involves derivation of a preliminary soil quality guideline using direct soil exposure pathways (soil ingestion, soil dermal contact, and inhalation of soil particulate). The input values for exposure variables depend on the assumptions for each land use scenario, and include the choice of sensitive human receptor, exposure duration, frequency, and intensity.

The second step involves check mechanisms that attempt to quantify and respond to cross-media transfer of soil contaminants. These checks ensure that preliminary generic soil quality guidelines do not lead to unacceptable exposures from other media. Assumptions have been made about certain generic site conditions and simplified models have been deliberately chosen to describe the involved mechanisms in order to limit the need for additional assumed values.

(X) Role of Secondary Exposure Pathways by Land Use Category

Agricultural Land Use

First, the preliminary human health soil quality guideline (PSQG_{HH}) is calculated. For agricultural land use, the check mechanisms for indirect exposure to soil contaminants via ingestion of groundwater, infiltration of volatile compounds into indoor air, and ingestion of produce, meat, and milk produced on-site are all calculated. If these calculations indicate an

unacceptable exposure, the final SQG_{HH} is set at the lowest value generated by the check procedures. This ensures that the final SQG_{HH} is protective against all these potential contaminant media transfer pathways. If the check mechanisms indicate acceptable exposures, then the final SQG_{HH} is set at the level of PSQG_{HH}.

Residential/parkland Land Use

First, the preliminary human health soil quality guideline (PSQG_{HH}) is calculated. For residential land use, check mechanisms for indirect exposure to soil contaminants via ingestion of groundwater, and infiltration of volatile contaminants into indoor air are calculated. If these calculations indicate an unacceptable exposure for the PSQG_{HH}, then the final SQG_{HH} is set at the lower of the values generated by these checks. If the check mechanisms indicate acceptable exposures, then the final SQG_{HH} is set at the level of the PSQG_{HH}. For residential properties with backyard gardens, the check mechanisms for contamination of produce grown on-site is calculated and presented in the supporting document for possible use as a site-specific objective.

Commercial Land Use

First, the preliminary human health soil quality guideline (PSQG_{HH}) is calculated. For commercial land use, check mechanisms for indirect exposure to soil contaminants via ingestion of groundwater, and infiltration of volatile contaminants into indoor air are calculated. If these modeling procedures indicate an unacceptable exposure for the PSQG_{HH}, then the final SQG_{HH} is set at the lower of the values generated by these two models. If the check mechanisms indicate acceptable exposures, then the final SQG_{HH} is set at the level of the PSQG_{HH}.

Industrial Land Use

The preliminary human health soil quality guideline (PSQG_{HH}) is calculated. As with commercial land use, the check mechanisms for indirect exposure via ingestion of groundwater and infiltration of volatile contaminants into indoor air are applied to the industrial PSQG_{HH}. Where unacceptable exposures are found using these modeling procedures, the industrial PSQG_{HH} is set at the lower of the values generated by these check mechanisms. Where acceptable exposures are found, the original PSQG_{HH} is used. The procedure for checking off-site migration via wind and water erosion from an industrial site to adjacent more sensitive land use is then applied as a management adjustment factor to determine the final SQG_{HH}.

(XI) Finalizing the Human Health Soil Quality Guideline

The preliminary human health soil quality guideline, which has been modified to ensure protection of human health with respect to the check mechanisms, becomes the recommended human health soil quality guideline (SQG_{HH}).

Derivation of the Final Soil Quality Guideline

After secondary exposure pathways have been considered and any necessary adjustments made

to the preliminary environmental and human health values, the lower of the two resulting values is chosen to advance. Before release as a recommended soil quality guideline (e.g., CCME 1997), however, it must be confirmed that the value is reasonable, workable and usable. To this end, two final "reality checks" are performed.

First, the guideline must be easily and reproducibly measured -- so it is compared to the routine analytical detection limit. Where the candidate SQG F is below the analytical detection limit, the SQG F shall be set at the detection limit. Second, if the guideline is for a naturally occurring substance the candidate value is checked against available information on ambient concentrations in Canadian soils. For inorganic substances the upper limit of the normal geochemical range is consulted.

Because soil background concentration is incorporated in several ways in primary exposure pathway calculations, few conflicts are expected. Where conflict does occur, it is essential to establish the basis. Normally, the soil quality guideline would be adjusted to the geochemical background, however, there may be instances where the upper limit of the geochemical range might pose a risk for certain land applications. In such cases the guideline would be established at a safe level and any naturally occurring exceedances managed on a site-specific basis.

Once the final checks described above have been completed the SQG F is presented in a draft supporting technical document and passed through scientific peer and agency (regulatory) review. Final adjustments are made and the guideline is released as a recommended CCME soil quality guideline. This commences the one-year public review period. Public input is used to finalize the guideline.

(XII) Use of Canadian Soil Quality Guidelines

Canadian soil quality guidelines derived using the Soil Protocol replace the Interim Environmental Quality Criteria for Contaminated Sites (CCME 1991). This new set of guidelines represent "clean down to levels" at contaminated sites and not "pollute up to levels" for less contaminated sites. Like the Interim Criteria, these effects-based guidelines are for contaminated sites assessment and remediation and should not be used to manage pristine sites.

The new generic guidelines are intended to provide a high level of protection for designated land uses and are considered broadly applicable to Canadian soils (CCME 1996a). The general context for application of Canadian soil quality guidelines is provided by the framework for assessment and remediation. Three methods or tiers are supplied. The first tier consists in the direct adoption of Canadian soil quality guidelines.

However, the fact that some sites will present conditions that differ from those assumed in the exposure scenario used in the development of the guidelines (high natural background concentrations, different use or no use of groundwater, **complex mixtures of contaminants**, unusual exposure scenarios, etc.) must also be considered. For these sites, the second tier allows limited modification of Canadian soil quality guidelines by setting site-specific objectives (CCME 1996b). Finally, the third tier relies on the use of risk assessment procedures to establish remediation objectives at contaminated sites on a site-specific basis (CCME 1996c).

END
