PEER REVIEW OF EPA S HAZARDOUS WASTE IDENTIFICATION RULE RISK ASSESSMENT MODEL

Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model

Prepared for:
David Bartenfelder
Office of Solid Waste
U.S. Environmental Protection Agency
2800 Crystal Drive
Arlington, VA 22202

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Prepared by:
Eastern Research Group, Inc.
2200 Wilson Boulevard, Suite 400
Arlington, VA 22201-3324

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NOTE

This report was prepared by Eastern Research Group, Inc. (ERG), an EPA contractor, under Contract Number 68-W-99-001. The report presents comments provided by peer reviewers on the *Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model* document that is part of EPA's Hazardous Waste Identification Rule risk assessments.

The comments presented in this report have been compiled by topic and by individual peer reviewer. As EPA requested, this report provides the peer review comments exactly as they were submitted to ERG. Also attached are the original comments submitted by each individual reviewer.

Peer Review Charge for the HWIR Human Exposure and Human Risk Modules

Background

The Hazardous Waste Identification Rule (HWIR) is being developed as an amendment to existing regulations governing the disposal of hazardous wastes under the Resource Conservation and Recovery Act (RCRA). Specifically, the multi-media, multiple pathway and multiple receptor risk assessment (3MRA) methodology for HWIR is designed to establish safe, constituent-specific exemption levels for low risk hazardous wastes. Wastes to be assessed under HWIR are those currently designated as hazardous because they were listed, or had been mixed with, derived from, or contained listed wastes. One of the intended outcomes of HWIR is to reduce possible over-regulation arising from application of the "mixture" and "derived-from" rules that were promulgated as part of the first comprehensive regulatory program for the management of hazardous wastes under RCRA in May of 1980. The mixture rule defined as hazardous any solid waste that is mixed with one or more listed wastes, and the derived-from rule labeled as hazardous any solid waste generated from the treatment, storage or disposal of a listed hazardous waste. Both of these rules remain important in reducing risk to human health and the environment associated with the management of hazardous wastes, but since they apply regardless of the concentrations or mobilities of hazardous constituents present in the wastes, they also open the possibility of over-regulation. One of the primary purposes of the 3MRA is to provide a basis for identifying possible instances of over-regulation and to provide an avenue for the safe relief from Subtitle C disposal regulations.

In December 1995, the Agency proposed a comprehensive, multimedia analysis that included both human and ecological multiple pathway exposures and impacts. It utilized the revised EPACMTP modeling approach for the groundwater pathway analysis and non-groundwater pathways. One of the limitations the methodology was that each exposure pathway was analyzed independent of other pathways, with the full pollutant mass available to each. During an extensive series of reviews of the HWIR95 proposal, the EPA Science Advisory Board (SAB) and others urged the Agency to consider using a simultaneous, mass-constrained analysis that would account for dispersal, and transport and transformation of contaminant mass through all media and exposure routes. This was perhaps the most important and strongly expressed element in all of the review comments received.

The goal of the integrated 3MRA is to identify wastes currently listed as hazardous that could be eligible for exemption from hazardous waste management requirements. The 3MRA risk assessment estimates chemical-specific potential risks to human and ecological receptors living within a radius of 2 kilometers of industrial nonhazardous waste sites that could manage HWIR-exempted waste. These risk estimates, along with other information, may be used to identify the chemical-specific concentrations for exempted waste that would be protective of human health and the environment using different types of protection criteria.

The 3MRA assessment strategy provides a methodology to evaluate multiple exposure pathway risks to human and ecological receptors at a statistically representative sample of waste management units (WMUs) and associated environmental settings to estimate the distribution of risk nationally. It is a forward-calculating approach that begins with selected concentration range for a chemical in waste and estimates the associated hazards and risks to human and ecological receptors.

The risk assessment is designed to produce chemical-specific distributions of cancer risks or hazards to humans and ecological receptors living in the vicinity of industrial waste sites that could

manage HWIR-exempted wastes throughout their operating life. Using a range of chemical waste concentrations, for each site the model estimates risks for each receptor location and then sums the number of receptors that fall within a specified risk or hazard range (bin) to describe the distribution of risks for the population at each site. We can use the resulting distribution for a WMU/setting to determine whether the WMU/setting is protective based on the percentage of the population protected, for a specified cancer risk or hazard level, and the initial concentration in waste. The model then uses these data to generate a percentile distribution based on the number of WMU/settings protected at a specified risk level for each waste concentration to generate the national distribution.

The 3MRA Model consists of 17 media-specific pollutant fate, transport, exposure, and risk modules; 6 data processors to manage the information transfer within the system; and 3 databases that contain the data required for the model.

As shown in Figure 1, the 3MRA Model incorporates the following interacting modules:

- Source modules, which estimate the simultaneous chemical mass losses to the different media and maintain chemical mass balance of the releases from the waste management unit into the environment

- Fate/transport modules, which receive calculated releases from waste management units and distribute the mass through each of the media to determine the chemical concentrations in air, groundwater, soil, and surface water across space and time

- Food chain modules, which receive the outputs from the fate and transport modules and estimate the uptake of chemicals in various plants and animals

- Exposure modules, which use the media concentrations from the fate and transport modules to determine exposure to human and ecological receptors from inhalation (for humans only), direct contact (for ecological receptors only), and ingestion (for both receptor types)

- Risk modules, which predict the risk/hazard quotient for human and ecological receptors.

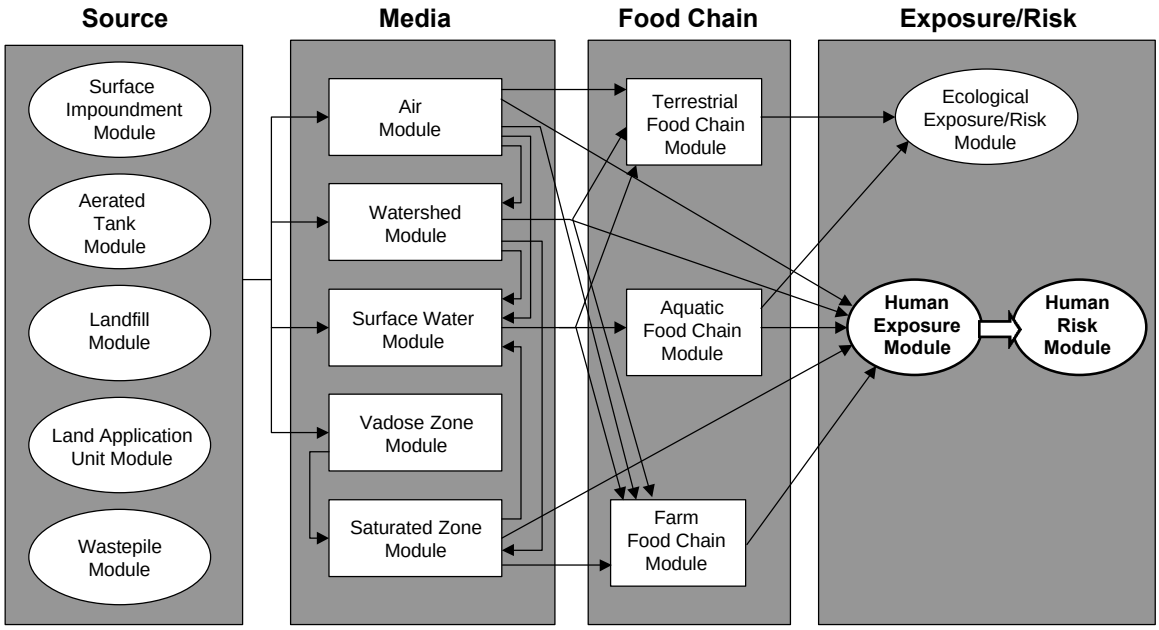

Figure 1. Source, fate, transport, exposure and risk modules of the 3MRA Model.

Human Exposure and Risk Modules

The Human Exposure (HE) Module receives annual average time series inputs of environmental media concentrations from the Air, Watershed, Surface Water, and Saturated Zone Modules; and food item concentrations from the Aquatic Food Chain and Farm Food Chain Modules. These concentrations are then converted into receptor doses in the Human Exposure Module for use as inputs to the Human Risk (HR) Module. Human Risk Module outputs are site-based cancer risk or non-cancer hazard statistics and are provided to the 3MRA Exit Level Processors (ELPs) I and II for national aggregation across sites. A detailed description of the HE and HR Modules is provided in *Background Document for the Human Exposure and Human Risk Modules for HWIR99 Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Model*, (EPA, 2000). A summary of the key functionality provided by these two modules follows below:

1. *The HE Module calculates applied dose (mg of chemical per kg of body weight) to human receptors from media and food concentrations.* These doses are determined for each receptor, cohort, exposure pathway, exposure area, and year.

2. *The HR Module calculates cancer risk and/or non-cancer hazard quotient (HQ) for each receptor, cohort, exposure pathway, exposure area, and year.* Whether risk, HQ, or both are calculated is determined as a function of the chemical under consideration. For carcinogenic chemicals, risks are calculated as average risks over a 9-year exposure duration. For noncarcinogens, HQs are calculated as a 1-year average.

3. *The HR Module then constructs cumulative frequency histograms for the distributions of receptor/cohort-specific populations among different levels of risk and/or HQ for each*

*exposure pathway and aggregation of pathways, where appropriate, and year***.** The populations consist of individual receptor/cohorts residing at the various exposure areas within certain radial distances from the waste management unit (WMU).

4. *The HR Module then determines and outputs cumulative risk and/or HQ distributions during that critical year for which the maximum cumulative risk and/or HQ occurs across the population***.** These critical year outputs are also specified for each receptor/cohort combination, exposure pathway and pathway aggregation, and radial distance.

Peer Review Charges

While reviewing the document, please address the following general issues:

1. Comment on the organization of the exposure and risk document. Does the document present the information in a clear, concise, and easy to follow format? If not, please provide suggestions to improve the presentation.

2. Do Sections 1 and 2 provide an adequate description of the purpose and context of the exposure and risk modules? If not, please explain.

3. As with any risk assessment, there are always additional data and method development efforts that could be undertaken to reduce the level of uncertainty. Are you aware of any major methodological or data gaps in the exposure and risk modules that have not been identified? If so, how should they be addressed?

In addition, the following specific issues should be addressed.

1. The set of receptors/pathways used for the 3MRA analysis is described in Section 1.3 of the Technical Background Document (TBD). For various reasons, such as the lack of adequate scientifically based methods, not all pathways are included, (e.g.,dermal exposure [inadequate toxicity benchmark data], subsurface vapors entering a residence [complexity of modeling horizontal gas migration in the subsurface]). Do you think that the pathways currently modeled include those exposures that place humans at the most risk from the various sources being modeled? If not, please provide your justification or references to help us evaluate additional exposures.

2. The behaviors that define exposures are independent for each receptor and across receptors. For example, it is assumed that there is no correlation between the amount of beef and vegetables that the farmer eats, because there were insufficient data to develop such correlations. Similarly, a fisher at the high end of the distribution for fish intake may also be at the high end for beef intake. Do you think that ignoring such correlations significantly compromises the analysis? If yes, could you identify appropriate data sources that could be used to fully develop the set of correlations that would be needed for the analysis.

3. The 1990 Census data were used to identify numbers of human receptors and their distributions within the study area (AOI) for each site. Exposure and risk calculations using this fixed population base were then generated for the entire simulation period,

which could be hundreds and, in some cases, thousands of years. The assessment does not account for future population increases and/or spatial redistributions (through land use changes, for example). However, because risk results are presented as population percentiles, not absolute numbers, the results will only be biased to the extent that differential population changes or changes in spatial distributions will occur among the 201 sites. Although it would be difficult, as well as highly uncertain, to attempt to introduce time-variability in populations used, do you see this as a significant limitation? If so, how would you propose to address it?

4. The exposure duration for carcinogens is fixed in the analysis at the peak exposure over 9 years and the exposure duration for noncarcinogens is fixed at the 1 year peak exposure. The 9 year exposure duration used for carcinogens is based on an average residence time, which was viewed as appropriate for this population based analysis. Data show that the range for this could be less than one year to greater than 40 years. The one year for noncarcinogens was selected to ensure that a peak from a temporal perspective was used in the evaluation of threshold effects. To the extent that actual exposure durations in some instances on either side of these values could disproportionately affect risk/HQ, the resulting outputs reflect uncertainty. For example, a site surrounded by predominately rural residents may entail much longer residence times than 9 years. For fixed constants, do you think the 9- and 1-year assumptions are appropriate for this population based analysis? If not, do you think that stochastically varying the 9 year exposure for carcinogens would result in significant changes/improvements in the analysis? Do you think that stochastically varying the one year exposure for noncarcinogens could result in changes in the analysis that lower the exposure due to temporal averaging, thus underestimating exceedences of the health benchmarks?

5. It is suggested in the literature that individuals exposed to some carcinogens in the first few years of life may be at an increased risk of developing cancer relative to exposure as adults. However, most animal studies from which many cancer potency factors are calculated include exposures at very early ages analogous to infancy and childhood. Thus, it has also been suggested that potency factors derived from these types of data account for early childhood exposure scenarios. We did modify the exposure factors for children to account for differences between adult and child receptors (e.g., intake rates, body weight). We did not adjust the cancer slope factors. Do you see this as a significant uncertainty or shortcoming? If so, can you suggest a methodology for such an adjustment?

6. As described in Sections 1.4, 5.4, and 5.5 of the TBD, a time series of population histograms is analyzed to determine that year out of the entire time series that represents the “critical” risk year (for a given receptor/cohort/pathway/distance ring). The criterion is used to compute the total risk across all individuals in the histogram for each year, and select the year that maximizes this total risk. This criterion is concerned only with the total risk in the histogram, not how those risks are distributed. For example, 1500 people incur a common, but low, individual risk of 10^{-6} would be selected as critical over a distribution with 10 of those people having a significantly higher risk (i.e. 10^{-4}) while the remaining population at that site had zero risk. (This particular example could occur if the pathway resulting in the 10^{-6} risk were due to inhalation at one point in time and the pathway driving the 10^{-4} in contaminated drinking water at a different point in time). Do

you consider this an appropriate method for selecting the critical years to include in the analysis? If not, could you suggest another method?

7. The fraction of the population that is served by drinking water wells is known only at the census block group level (census blocks comprise block groups) — often a relatively large proportion of the overall modeled area for any given site. Furthermore, where those residents are located who are on wells is unknown. Lacking readily available information on the spatial distribution of wells, it was assumed that, if any residents within a block group are on wells, then all residents within that block group (and all blocks within the group) are on wells and ingest groundwater. Of course, this assumption does not mean that all residents are ingesting contaminated groundwater — most wells could lie outside the plume of contamination. We have considered means of mitigating this assumption, such as using land use criteria for locating wells (e.g., residents inside a municipal boundary are unlikely to be on wells), but have not implemented any such measures. We invite comments on both the likely consequences of this assumption on the risk analysis as well as any suggestions (data or algorithmic) for mitigating such impacts.

8. Similar to the previous question, we have located receptors in two ways. For residents and home gardeners, the point of analysis is the centroid of the census block or, if the census block straddles one or more distance rings, the centroid of the polygon formed by the census block and distance ring. Since census blocks have a rather large variability in size based on how densely populated an area is, locating all receptors at the centroid of a census block adds uncertainty to the analysis. In locating farms we have used a random method of putting a representative farm in the agricultural land use for each block group having farms. Since farms could be distributed across fairly large land areas this approach also adds uncertainty to the analysis. Do you think the approaches used for locating human receptors adequately captures the potential variability in exposure across each site for use in a national assessment?

9. The Exposure Factors Handbook (EFH) (EPA, 1997) was the primary source for most of the exposure factors data used in HWIR. National distributions by age cohorts were developed for all exposure factors with sufficient data. A statistical approach was used to fit distributions to the percentile data, to determine the goodness of fit , and to develop the statistics needed to describe the distributions used in the 3MRA model. This approach was used instead of assuming a lognormal distribution when adequate EFH data are available to support maximum likelihood estimation. However, in a few cases (soil ingestion, breast milk consumption, and inhalation rate), data are not adequate to fit a distribution, and the lognormal model was assumed as the default. A few parameters were fixed based on central tendency values from the best available source, either because limited variability was expected or because available data were not adequate to generate national distributions. We invite comments on the appropriateness of this approach as well as any sources of recent data that are not included in the TBD.

References

U.S. EPA (Environmental Protection Agency). 2000. *Background Document for the Human Exposure and Human Risk Modules for HWIR99 Multimedia, Multipathway, and Multireceptor (3MRA) Risk Assessment Model*. Office of Solid Waste, Washington, DC.

Reviewer Comments Summary Report for the Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model

GENERAL ISSUES

1. *Comment on the organization of the exposure and risk document. Does the document present the information in a clear, concise, and easy to follow format? If not, please provide suggestions to improve the presentation.*

Dr. Butler: The authors have done a good job describing the Human Exposure (HE) and Human Risk (HR) modules of the 3MRA software system. Considering the technical complexity of this reference document, the material is presented in a clear and concise manner. The organization of the report follows a logical, relatively easy-to-follow format. The report appears to have been carefully written and edited, with considerable attention to detail. The authors have also identified a number of model limitations, data uncertainties and scenario assumptions, both throughout the document and in a separate section.

Nevertheless, I can offer two (related) recommendations for improving the presentation and assisting the reader in understanding the methodologies. The document reads more like a detailed technical appendix; indeed it is referred to as a "stand-alone reference." Having separate reference documents or a series of technical appendices is appropriate (probably necessary) for this type of comprehensive software system. However, it was not possible to review the document without first learning more about the overall modeling approach and relevant components of other modules. Therefore, I'd recommend adding a detailed section to the background document that integrates key elements of the other modules, discusses how the various "pieces" fit together, and evaluates the implications that assumptions in one module have on others. Along the same lines, there is a need for an overarching report that pulls all the information together, referencing the background documents as needed. This may already be planned, but the lack of this type of comprehensive document for providing context was a hindrance in reviewing the HE/HR modules document.

Dr. Kastenberg: The exposure and risk document appears to be well organized. I believe the long tables are placed correctly in the text, rather than at the end of the chapters or the end of the report. This provides better continuity for the reader. I am assuming that the readers of the document are well versed in risk assessment.

Dr. Washburn: The text relies too heavily on jargon, and the technical approach is sometimes difficult to follow, particularly in portions of Section 2.0 (e.g., Subsection 2.3) and 6.0. These portions of the text seem to focus more on explaining how data are processed by the computer program, than on the rationale for the technical approach. At a minimum, I would suggest that a glossary be included, providing a single resource for defining such terms as “block group coverages”, “clip census coverages” and “conditional frequency histograms”.

A number of inconsistencies and typographical errors still exist in the text. For example:

- The HQ ranges in the table on p. 5-8 do not agree with the bin ranges on p. 5-7, and have gaps (e.g., from HQ=1 to HQ=5). (It is also unclear why the bin ranges specified on p. 5-7 were selected for the HWIR Risk Assessment Module).

- The caption for Figure 6.2 appears to be incorrect, and at a minimum is confusing given

the very similar caption for Figure 6.3.

- Equations 5.2 and 5.3 appear to be inconsistent, and are confusing. For example, I believe that “Dose” in Equation 5.2 is called “ADD” in Equation 5.3 (another “dose” term is introduced in Equation 5.3). Furthermore, based on Equation 5.3, ADD is not the “average daily dose”, but rather the cumulative dose over the exposure period. ADD should not be the sum of the doses for each year within the exposure period (as implied by Equation 5.3), but rather the sum divided by the number of years in the exposure period.

Additional inconsistencies and typographical errors are indicated in the attached mark-ups of individual pages from the draft document. However, I did not attempt to identify all such inconsistencies and errors, and the document should be carefully checked by a technical editor.

2. *Do Sections 1 and 2 provide an adequate description of the purpose and context of the exposure and risk modules? If not, please explain.*

Dr. Butler: The stated purpose of the document is that it "...is intended as a stand-alone reference that describes the Human Exposure (HE) and Human Risk (HR) modules of the multimedia, multiple exposure pathway, and multiple receptor risk assessment (3MRA) software system." It is also intended to include overview information on the 3MRA model, as well as assumptions, limitations, methodologies, and input/outputs of the HE and HR modules. While the overview information presented is limited, the detailed description of the relevant human health and risk aspects of the model clearly conveys the purpose of these modules.

On the other hand, the context of the HE and HR modules is not as clear. As mentioned above in General Issues #1, the focus of this document is almost entirely on these modules, and what is lacking is either an additional section and/or a stand-alone document that integrates the various components of the 3MRA model and provides the context for how the individual modules fit into the overall framework for developing exemption criteria.

Dr. Kastenberg: Sections 1 and 2 provide an adequate description of the purpose and context of the exposure and risk models, providing the document is intended for knowledgeable readers and not the layperson.

Dr. Washburn: While Section 1.0 generally provides a good overview, the most succinct description of the objective of the HWIR analysis does not appear until Section 6.0:

> “The objective of the HWIR analysis is to determine the chemical concentration, for each chemical of interest and WMU type … that will result in an acceptable risk or HQ to a specified percentage of human receptors at a specified percentage of hazardous waste management sites at a specified confidence limit”. (p. 6-1)

This objective should appear at the outset, in Section 1.0, since it helps to understand the rationale behind the development of the technical approach in Sections 2.0 through 5.0.

I found Section 2.0 to be longer than necessary, because it includes technical detail regarding database operations that are not critical for understanding the conceptual approach for the risk assessment. (Such details may be of interest to database professionals; if so, I would suggest they go into a technical

appendix). For example, I do not see a compelling reason to include any of the information in Tables 2-3 through 2-6 in the main text.

3. *As with any risk assessment, there are always additional data and method development efforts that could be undertaken to reduce the level of uncertainty. Are you aware of any major methodological or data gaps in the exposure and risk modules that have not been identified? If so, how should they be addressed?*

Dr. Butler: A number of the major methodological and data gaps have been identified in the document, e.g., the HE and HR modules do not include background exposures and chemical mixture interactions. However, several limitations still need to be clearly identified and discussed in the document.

One major methodological gap that should be mentioned is that acute exposures or physical hazards from accidental releases at a waste management unit (WMU) are not evaluated. Another methodological issue is the uncertainty inherent in the use of toxicity data for the human health benchmarks. A related methodological problem has to do with the numerous chemicals for which human health benchmark values are missing. A number of HWIR constituents will need alternative benchmarks developed or adapted from other sources (e.g., NCEA's provisional values, ATSDR, and/or state regulatory agencies). Finally, while it was stated that the methodology is limited in not adjusting cancer slope factors to account for childhood exposures, the analogous methodological gap for noncarcinogens was not identified. As with cancer slope factors, reference doses and reference concentrations are usually based on adult toxicity data. This approach may not be appropriate for estimating noncancer effects in children, given their potentially increased susceptibility to chemical exposures.

While these types of gaps add significantly to the uncertainty of the analysis, they are difficult technical issues to resolve for inclusion in the model.

Dr. Kastenberg: I believe there are two areas worth looking into. The first involves the correct interpretation of individual dose versus population dose. These are clearly defined for radiation where individual dose is given in rads and population dose is given by person-rem. The former is based on delivered dose and the latter is an integrated value based on exposure and population density. This should be done in the chemical arena as well. As it stands now, the “population” exposures and hence risk, are numbers of people exposed at given individual risk levels. This is different than a population integrated exposure. I am aware that Dr. Debbie Hall Bennett of the Lawrence Berkeley National Laboratory considered ways of formulating population dose for persistent organic pollutants (POPS) in her Ph.D. Dissertation, and a manuscript that is being reviewed for publication in the Journal of Risk Analysis. She can be contacted at: DBHall@lbl.gov. The second area involves uncertainty and variability of both the Cancer Slope Factors and the Reference Doses. As stated in Section 5, only the EPA point values for the CSFs and RfDs are used in the Risk or HQ calculations. Moreover, they are given as one significant figure (in most cases) like 0.005 or 0.05, which tells me they are “educated guesses.”Given the sophistication of the exposure calculations, it would appear that some improvements in the CSF/RfD domain are in order so that the degree of uncertainty is not so disproportionate. In reality, the document provides for a methodology that estimates exposure, modified by a constant (and a not very accurate one at that), which is called risk.

Dr. Washburn: According to p. 1-4, the HWIR exposure and risk modeling simulations “can range from a few hundred years for chemicals that move quickly in the environment, are not persistent, and do not bioaccumulate to 10,000 years for the most persistent and least mobile chemicals such as some metals”.

Clearly, one of the greatest uncertainties in the HWIR modeling is in attempting to characterize risks and exposures so far into the future. (Imagine how different behavior patterns, land use, and other exposure factors were in 8,000 B.C., or even 1800 A.D., compared to today). These uncertainties dwarf virtually all other data gaps associated with the exposure and human risk modules, with the possible exception of incomplete toxicity data. The considerable uncertainties in attempting to estimate risks so far into the future make efforts to reduce uncertainties in other parts of the exposure and risk analysis a waste of resources, unless the modeling indicates that "critical risk" years usually occur within the first 20 or 30 years. Instead of addressing gaps in the human exposure and risk module, I would recommend focusing on the methodological and data gaps in the fate/transport and food chain models.

If the "critical risk" years typically occur within the next 20 or 30 years at most sites, then it may make sense to collect additional data to refine the exposure and risk module. In general, conservative assumptions are usually made by EPA to offset uncertainties and data gaps. Which data gaps are the most important to address should be identified through an analysis of the modeling results. Specifically, the pathways that most frequently drive the risk assessment should be evaluated to determine if key assumptions could potentially be refined through the collection of additional data.

At this point, it appears that major decisions must still be made in the area of risk management. For example, referring back to the objective of the HWIR modeling in Section 6.0, key risk management decisions include:

- What represents an unacceptable cancer risk and non-cancer hazard, both from an individual and population risk perspective?
- What is an acceptable "specified percentage" of receptors and waste management sites above the cancer risk and non-cancer hazard levels?
- What is an acceptable "specified confidence limit"?

Each of these decisions by itself could affect chemical-specific concentrations for exempted waste by an order of magnitude or more; together, these decisions could affect exemption levels by several orders of magnitude. It is unlikely that further refinement of the exposure and risk calculations (especially given the difficulties in predicting risks far into the future) could have anywhere near as much impact.

SPECIFIC ISSUES

1. *The set of receptors/pathways used for the 3MRA analysis is described in Section 1.3 of the Technical Background Document (TBD). For various reasons, such as the lack of adequate scientifically based methods, not all pathways are included, (e.g.,dermal exposure [inadequate toxicity benchmark data], subsurface vapors entering a residence [complexity of modeling horizontal gas migration in the subsurface]). Do you think that the pathways currently modeled include those exposures that place humans at the most risk from the various sources being modeled? If not, please provide your justification or references to help us evaluate additional exposures.*

Dr. Butler: It appears that the most significant exposure pathways are addressed in the 3MRA model. While it would be more comprehensive to address additional exposure pathways (e.g., dermal exposure and indoor infiltration), the drawbacks outweigh the advantages. Although it could be an important

pathway under certain conditions, the general lack of dermal toxicity data would preclude the accurate assessment of the dermal route of exposure for most chemicals. Similarly, the migration of subsurface vapor-phase contaminants into residences could be an important exposure pathway under certain site-specific conditions; however, it may be too difficult to accurately model this transport mechanism to represent a national distribution of indoor exposures near waste management units. Given the complexity of the 3MRA model and pathways already included, it is reasonable to focus on the most significant potential exposures and make conservative adjustments in assumptions to account for these omissions, as needed. However, I recommend adding a discussion in the Assumptions and Limitations section on the rationale for not including these exposure pathways in the model.

Dr. Kastenberg: *Inclusion of all pathways*. I believe all plausible exposure pathways should be included regardless of whether or not there is sufficient data. This is where the true data uncertainties enter and can be assessed. There is no way to tell whether or not the risk significant pathways are included if some pathways are left out. Dermal exposure may be dominant for some scenarios, particularly where there is water in which kids can swim (e.g. ponds, backyard pools, etc) or contaminated soil where kids can play. If the CSFs and or RfDs were formulated as distributions, then the effect of inadequate toxicity data can be accounted for and determinations can be made as to their relative risk significance. Similarly, subsurface vapors entering a residence have been considered in the work of Dave Rice and Dave Layton at the Lawrence Livermore National Laboratory regarding the Leaking Underground Storage Tank (LUST) issue, and the indoor air program at the Lawrence Berkeley National Laboratory has also considered similar issues. Even though modeling horizontal gas migration is complex, it can be taken into account with the proper analysis. This issue of modeling uncertainty has been dealt with for nuclear power plant risk analysis beginning with NUREG-1150, and more recently by Professor Theofanous at UCSB in a series of papers appearing in the Journal of System Safety edited by Apostolakis at MIT.

Dr. Washburn: In general, I agree that the pathways and routes currently modeled include exposures that place humans at the greatest risk from the sources modeled. Regarding other pathways that are not included in the module, I have the following comments:

- Dermal exposure. The charge statement indicates that dermal exposures were not included because there are "inadequate toxicity benchmark data". Not being a toxicologist, I will not comment on whether existing toxicity benchmarks are adequate or inadequate for evaluating dermal exposures. However, USEPA guidance does not seem especially clear on this issue. In some contexts (and some EPA Regions) evaluating the risks posed by dermal exposures is required, for example, by using USEPA's Risk Assessment Guidance for Superfund (RAGS).

- Vapor Migration into Building. The charge statement indicates that migration of subsurface vapors into residences is not evaluated because of the "complexity of modeling horizontal vapor migration". In terms of the Exposure and Risk Module, vapor migration from subsurface soil and/or groundwater into buildings could be readily evaluated. Thus, it is assumed that this pathway is not included because of complexities in the Fate/Transport Module. The Johnson and Ettinger (1991) model is capable of estimating indoor air concentrations resulting from vertical vapor transport from groundwater, assuming that horizontal transport of contamination in groundwater is first estimated using a different model. However, the model is highly sensitive to site-specific soil and hydrogeological conditions and thus there may be difficulties in applying the model on a regional or census-block scale, as in 3MRA.

- Surface Water. It appears that contamination of surface water is evaluated only in terms of consumption of fish (i.e., does not include swimming, drinking water, or other pathways). Since I have not been requested to review the Fate/Transport module, I do not know what pathways of surface water contamination have been addressed (e.g., direct deposition of contaminants from air, runoff from contaminated soil, groundwater discharge, etc.). From my experience, I would agree that fishing is likely to be significantly more important than swimming or other possible recreational exposures. However, was use of surface water as a drinking water resource (e.g., from reservoirs) considered?

The document should provide more complete justification for the exposure pathways and routes included (and excluded) from 3MRA.

2. *The behaviors that define exposures are independent for each receptor and across receptors. For example, it is assumed that there is no correlation between the amount of beef and vegetables that the farmer eats, because there were insufficient data to develop such correlations. Similarly, a fisher at the high end of the distribution for fish intake may also be at the high end for beef intake. Do you think that ignoring such correlations significantly compromises the analysis? If yes, could you identify appropriate data sources that could be used to fully develop the set of correlations that would be needed for the analysis.*

Dr. Butler: Treating certain exposure-related behaviors as independent for each receptor and across receptors would have an effect on the results of the analysis, although it's not clear to what extent. The examples in the charge statement are probably the behaviors of most concern (i.e., overlap between the high-end fisher and farmer receptors). Unfortunately, I am not aware of any data on the correlations between these exposures. However, this issue should at least be discussed in the Assumptions and Limitations section of the document.

On a related point, the omission of subsistence behavior in the fisher and farmer scenarios is perhaps a more serious limitation that should be addressed. Estimates of fish consumption rates are based on data from recreational fishers and adjusted for the fraction of fish intake from recreational fishing activities. Similarly, estimates of home-produced beef consumption intakes are based on data from households who farm and adjusted for farm households that raise beef cattle. The high-end values of the distributions of both fish and beef consumption rates do not account for subsistence behavior. It should be possible, however, to develop representative or generic subsistence fisher and farmer scenarios for inclusion in the model, or at least for providing an upper bound on the distributions. For example, consumption data are available on populations that include subsistence fishers and others who regularly eat large amounts of non-commercial fish; these populations often obtain fish from contaminated waters, providing further justification for evaluating these scenarios.

Dr. Kastenberg: I am not sure about this question. People eat a finite amount of food per day, which should be relatively easy to estimate. Also, it should be possible to correlate these if the variability distributions for intake of two different foods were considered, using a Monte Carlo sampling approach, to see if the result was even significant.

Dr. Washburn: Given other uncertainties in the Exposure and Risk Module (as well as the Fate/Transport, Food Chain, and Source Modules), I do not believe that ignoring correlations between exposure inputs significantly affects the analysis. It is recommended, however, that USEPA consider whether different soil ingestion rates are appropriate for resident adults and farmer adults. Intuitively, it

seems that the soil ingestion rate for an adult resident might be lower than for an adult farmer.

3. *The 1990 Census data were used to identify numbers of human receptors and their distributions within the study area (AOI) for each site. Exposure and risk calculations using this fixed population base were then generated for the entire simulation period, which could be hundreds and, in some cases, thousands of years. The assessment does not account for future population increases and/or spatial redistributions (through land use changes, for example). However, because risk results are presented as population percentiles, not absolute numbers, the results will only be biased to the extent that differential population changes or changes in spatial distributions will occur among the 201 sites. Although it would be difficult, as well as highly uncertain, to attempt to introduce time-variability in populations used, do you see this as a significant limitation? If so, how would you propose to address it?*

Dr. Butler: To attempt to incorporate time variability in the populations used would probably introduce as much uncertainty as it would remove. Presenting risk results as population percentiles, as opposed to absolute numbers, also reduces the need to attempt to predict population increases and mobility. The potential bias from differential population changes and/or spatial redistributions should, however, be explained in the limitations section of the background document.

Dr. Kastenberg: This is a difficult question to answer. Pelmulder, et al considered population growth in a paper published in Water Resources Research around 1995/1996. As noted above, Bennett integrated population exposure, to arrive at a population average dose. The latter is the more important issue, but the former can be handled by examining population statistics over time. Institutional controls may dictate future land use within the 2 km sector and may also contribute to uncertainty.

Dr. Washburn: As discussed in my comments above, attempting to predict exposures hundreds and even thousands of years into the future involves considerable uncertainty, to say the least. However, introducing time variability into the population estimates would not significantly reduce this uncertainty, and would make what is already a highly complex analysis even more complicated.

4. *The exposure duration for carcinogens is fixed in the analysis at the peak exposure over 9 years and the exposure duration for noncarcinogens is fixed at the 1 year peak exposure. The 9 year exposure duration used for carcinogens is based on an average residence time, which was viewed as appropriate for this population based analysis. Data show that the range for this could be less than one year to greater than 40 years. The one year for noncarcinogens was selected to ensure that a peak from a temporal perspective was used in the evaluation of threshold effects. To the extent that actual exposure durations in some instances on either side of these values could disproportionately affect risk/HQ, the resulting outputs reflect uncertainty. For example, a site surrounded by predominately rural residents may entail much longer residence times than 9 years. For fixed constants, do you think the 9- and 1-year assumptions are appropriate for this population based analysis? If not, do you think that stochastically varying the 9 year exposure for carcinogens would result in significant changes/improvements in the analysis? Do you think that stochastically varying the one year exposure for noncarcinogens could result in changes in the analysis that lower the exposure due to temporal averaging, thus underestimating exceedences of the health benchmarks?*

Dr. Butler: The one-year exposure duration assumption for noncarcinogens is a reasonable approach

because it avoids underestimating health effects that could occur by averaging out the peaks over a number of years. This is an appropriately conservative approach given the hazard quotient method of calculating noncarcinogenic effects. The nine-year exposure duration assumption based on the national average residence time is a reasonable point estimate for carcinogens. In addition, because this model is used for a national assessment and not to represent site-specific conditions, it may be sufficient to just use the average residence time. However, it would be more accurate to reduce the uncertainty introduced by much longer residence times in rural areas by stochastically varying the exposure duration for carcinogens. If the fixed nine-year exposure duration is still used, the potential for introducing a low bias in the final risk distributions should be discussed in the limitations section of the document.

Dr. Kastenberg: I believe that the question itself deserves an answer with an analysis using uncertainty/variability distributions. This should be carried out on a site-specific basis, however. Again, the question regards a level of detail for the exposure/dose calculation not afforded to the CSF/RfD calculation. It doesn't matter how sophisticated the exposure/dose calculation is if the CSF/RfD has large uncertainty.

Dr. Washburn: Exposures to carcinogens. It is not clear why the exposure duration for carcinogens has been assigned a fixed value of 9 years, when most of the other exposure inputs have been represented stochastically, by distributions. This should be explained. While I do not know if representing exposure durations to carcinogens stochastically would significantly change the results of the analysis, the text does not provide sufficient justification for relying on a fixed value for this parameter.

Exposures to non-carcinogens. It could be argued that a 7-year exposure duration would be more consistent with the definition of chronic exposure in USEPA's Risk Assessment Guidance for Superfund (RAGS). However, I understand that exposures of approximately 1 year could be considered chronic for a number of chemicals with respect to at least some types of health effects. (This should be confirmed with toxicologists within USEPA and the 3MRA review panel). Given that 1 year may represent a chronic exposure period for some chemicals and some health effects, I agree with the default of a 1 year assumed duration (and corresponding 1 year averaging period) for evaluating exposures to non-carcinogens. However, there may be some chemicals for which a longer exposure duration and averaging period is appropriate.

5. *It is suggested in the literature that individuals exposed to some carcinogens in the first few years of life may be at an increased risk of developing cancer relative to exposure as adults. However, most animal studies from which many cancer potency factors are calculated include exposures at very early ages analogous to infancy and childhood. Thus, it has also been suggested that potency factors derived from these types of data account for early childhood exposure scenarios. We did modify the exposure factors for children to account for differences between adult and child receptors (e.g., intake rates, body weight). We did not adjust the cancer slope factors. Do you see this as a significant uncertainty or shortcoming? If so, can you suggest a methodology for such an adjustment?*

Dr. Butler: It is possible that the use of cancer slope factors derived from lifetime animal bioassay data accounts for the carcinogenic risks from exposures during infancy and childhood. This is one of the fundamental assumptions that form the basis of a typical risk assessment (akin to the high-to-low dose and animal-to-human data extrapolations). So, from a risk assessment methodological standpoint, it is a reasonable assumption to include in the 3MRA model. That said, it should be emphasized that I still think it is a significant shortcoming in any risk assessment methodology because it is very likely that this basic

assumption still misses many of the unique childhood vulnerabilities during this critical developmental stage. There are experimental data that suggest that early exposures may increase human susceptibility to cancers. Therefore, it is very possible that the animal cancer bioassay data do not reflect any or all of the increased or unique vulnerabilities of children to certain chemical exposures received at a particular stage of development.

Although the use of child-specific exposure factors in the model is a reasonable first step, considerable uncertainty remains. Additional research is needed to develop biologically-based models of carcinogenesis to represent the complex exposure and dose-response relationships for early chemical exposures at vulnerable ages. Until these findings are available, adjusting cancer slope factors in the 3MRA model would be too simplistic to accurately reflect all of the age-related differences in exposure and toxicity that may lead to an increased risk of developing cancer from early childhood exposures.

Dr. Kastenberg: This is a shortcoming in all risk assessments. It is easy to differentiate age and gender exposure data. As noted, the CSFs do not take this into account because a single number represents them. Hence they would underestimate risk for children and overestimate risk for adults. The place to improve the exposure analysis is in gender difference. Men may weigh more than women, women may have more body fat, men may breathe more air, eat more meat, etc. Men may farm and fish more than women, and women may spend more time in gardens. Given the difficulty in refining the toxicity data as a function of age and gender, this may be an alternative improvement.

Dr. Washburn: Given other uncertainties in the Exposure/Risk, Fate/Transport, Food Chain, and Source Modules, as well as the approaches used by USEPA to develop cancer slope factors, I do not believe that an adjustment of slope factors is generally warranted when evaluating childhood exposures. However, such an adjustment may be appropriate for specific chemicals, based on a careful review of the basis for the USEPA slope factor and the mechanism of carcinogenicity for the chemicals in question.

6. *As described in Sections 1.4, 5.4, and 5.5 of the TBD, a time series of population histograms is analyzed to determine that year out of the entire time series that represents the critical risk year (for a given receptor/cohort/pathway/distance ring). The criterion is used to compute the total risk across all individuals in the histogram for each year, and select the year that maximizes this total risk. This criterion is concerned only with the total risk in the histogram, not how those risks are distributed. For example, 1500 people incur a common, but low, individual risk of 10^{-6} would be selected as critical over a distribution with 10 of those people having a significantly higher risk (i.e. 10^{-4}) while the remaining population at that site had zero risk. (This particular example could occur if the pathway resulting in the 10^{-6} risk were due to inhalation at one point in time and the pathway driving the 10^{-4} in contaminated drinking water at a different point in time). Do you consider this an appropriate method for selecting the critical years to include in the analysis? If not, could you suggest another method?*

Dr. Butler: The low risk/large population versus high risk/small population issue is always a problem when interpreting the results of a population risk analysis. Although total risk is calculated across all individuals in a histogram for a given year, the use of a set of risk ranges may still generally approximate the distribution of risks at a site. Therefore, the use of time series of frequency histograms is probably the most appropriate technique for selecting the critical years.

Dr. Kastenberg: Again, this depends on how you define population risk. This is a similar problem encountered by the risk assessors considering the Yucca Mountain site for high-level radioactive waste. In

this case the maximum individual and population dose occurs 100's of thousands of years into the future. It might be worthwhile to look at their approach. One approach might be to consider each pathway individually, rather than an aggregate. It gives more information to the decision makers.

Dr. Washburn: Based on my review, it appears that the HWIR methodology does not classify any individual risks as being de minimis. In other words, an individual risk level (no matter how low) is multiplied by the population at that risk level, in determining the population risk. I would suggest that USEPA consider assigning any individual risks less than one-in-one million ($1x10^{-6}$) a score of zero, and not included in determining the "critical year". Conversely, it may be appropriate to give additional weight to individual risks exceeding one-in-one thousand ($1x10^{-3}$), or some other risk level that is considered clearly elevated, and unacceptable on an individual level.

7. *The fraction of the population that is served by drinking water wells is known only at the census block group level (census blocks comprise block groups) often a relatively large proportion of the overall modeled area for any given site. Furthermore, where those residents are located who are on wells is unknown. Lacking readily available information on the spatial distribution of wells, it was assumed that, if any residents within a block group are on wells, then all residents within that block group (and all blocks within the group) are on wells and ingest groundwater. Of course, this assumption does not mean that all residents are ingesting contaminated groundwater most wells could lie outside the plume of contamination. We have considered means of mitigating this assumption, such as using land use criteria for locating wells (e.g., residents inside a municipal boundary are unlikely to be on wells), but have not implemented any such measures. We invite comments on both the likely consequences of this assumption on the risk analysis as well as any suggestions (data or algorithmic) for mitigating such impacts.*

Dr. Butler: It is assumed in the model that if any residents in a census block group are served by drinking water wells, then all the households within that census block group are on wells. The extent to which this conservative assumption overestimates groundwater ingestion by all the human receptors could be substantial, depending on the population and number of wells impacted by the groundwater plume. To get finer geographic resolution on distribution of wells (i.e., by block rather than block group), it should be possible to request a special analysis by the Census Bureau.

Dr. Kastenberg: Brendan Dooher, at the Lawrence Livermore National Laboratory considered such an issue in his assessment of Leaking Underground Fuel Tanks. He used a GIS system and a simulation package to determine individual exposures to contaminated well water in the NAPA Valley in Northern California. However, the level of detail here may be disproportionate to the validity of the CSF/RfD values.

Dr. Washburn: In 3MRA, it is assumed that if any resident within a block group is on a groundwater well, then all residents within that block group are on wells, all ingest groundwater, and all of the water that the residents ingest is groundwater. This assumption is conservative for at least three reasons:

- Only a fraction of the residents within a block group may be on groundwater wells.
- Only a fraction of the residents who are on groundwater wells may use the groundwater for drinking water.
- There may be additional sources of drinking water for those residents who ingest

groundwater (i.e., the fraction contaminated value for drinking water may be less than 1.0)

For these reasons, the groundwater pathway may be given too much weight in the 3MRA methodology, particularly for residents within a municipal boundary who would likely have a municipal water supply.

Ideally, information should be compiled on the fraction of residents within a block group who use groundwater for drinking water. However, this type of information is apparently not available and presumably would be resource-intensive to collect. Furthermore, the fraction may change significantly over time, especially the hundreds to thousands of years apparently modeled by 3MRA. Thus, I would recommend that, as a default, 10% of the residents within a municipal boundary, (within a block group that has at least one resident on a well), be assumed to use groundwater for drinking water. I believe that this assumption would still be conservative at the majority of sites, given the other assumptions made in evaluating the groundwater ingestion pathway. Outside municipal boundaries, I would recommend retaining the assumption that, if any resident within a block group is on a groundwater well, then all residents within that block group are on wells and ingest groundwater.

8. *Similar to the previous question, we have located receptors in two ways. For residents and home gardeners, the point of analysis is the centroid of the census block or, if the census block straddles one or more distance rings, the centroid of the polygon formed by the census block and distance ring. Since census blocks have a rather large variability in size based on how densely populated an area is, locating all receptors at the centroid of a census block adds uncertainty to the analysis. In locating farms we have used a random method of putting a representative farm in the agricultural land use for each block group having farms. Since farms could be distributed across fairly large land areas this approach also adds uncertainty to the analysis. Do you think the approaches used for locating human receptors adequately captures the potential variability in exposure across each site for use in a national assessment?*

Dr. Butler: The location of residents and home gardeners is at the centroid of the census block or at the centroid of the polygon formed by the census block and distance ring. This method of locating residents is likely to create a systematic bias in less densely populated areas. Areas of concentrated populations tend to be located proximate to bodies of water. A possible correction is to place residents at the mid-point between the centroid and the largest river or shore of the largest lake that intersects the polygon. An alternative method would be to place the population at the point on the river or lakeshore closest to the centroid

Dr. Kastenberg: Yes, see Question 7 above.

Dr. Washburn: It is not clear to me how much this assumption affects the analysis, without more detail on the size range for census blocks, particularly those near the facility, and how the fate/transport analyses are performed. For example, if the census block immediately adjacent to the facility is relatively large, and groundwater flow direction is taken into account, then the residential or farm receptor may be inappropriately placed outside the plume at one site (where homes are actually present within the plume), and within a plume at another (where homes would not actually be impacted by the plume).

9. *The Exposure Factors Handbook (EFH) (EPA, 1997) was the primary source for most of the exposure factors data used in HWIR. National distributions by age cohorts were developed for all*

exposure factors with sufficient data. A statistical approach was used to fit distributions to the percentile data, to determine the goodness of fit , and to develop the statistics needed to describe the distributions used in the 3MRA model. This approach was used instead of assuming a lognormal distribution when adequate EFH data are available to support maximum likelihood estimation. However, in a few cases (soil ingestion, breast milk consumption, and inhalation rate), data are not adequate to fit a distribution, and the lognormal model was assumed as the default. A few parameters were fixed based on central tendency values from the best available source, either because limited variability was expected or because available data were not adequate to generate national distributions. We invite comments on the appropriateness of this approach as well as any sources of recent data that are not included in the TBD.

Dr. Butler: In general, it seems reasonable to use a statistical approach for distributions of exposure parameters with sufficient data, combined with lognormal distributions and central tendency values when the data are lacking. However, I recommend having this approach reviewed by a statistician, which I am not.

Dr. Kastenberg: This seems appropriate, given the validity of the CSF/RfD data.

Dr. Washburn: Overall, the statistical approaches used to develop distributions appear to be appropriate. However, as indicated in my comments above, it is not clear why a fixed value was selected for exposure duration in evaluating exposures to carcinogens. According to the text, it also appears that certain parameters (e.g., fraction of contaminated soil ingested; fraction of contaminated water ingested) were selected as fixed values because of “EPA policy”. It is suggested that a technical basis be provided for all methodologies, inputs, and assumptions.

OTHER COMMENTS

Dr. Butler:
Cumulative Risks

It is stated in the limitations section of the document that only incremental exposure is modeled, but that "No provision is made for considering background exposures for the purpose of generating cumulative risk or HQ." However, elsewhere in the document (p. 5-1), it is stated that "The HR module then determines and outputs *cumulative risk* and/or HQ distributions during that critical year for which the maximum *cumulative risk* and/or HQ occurs across the population" (emphasis added). Clearly, these two statements are in conflict. To me, the implication of the first sentence is that the determination of cumulative risk is not possible without the inclusion of background exposures (which I personally agree with, in the truest sense of the word "cumulative"). However, it is possible that the first statement simply is poorly worded, and the intent was to point out that cumulative risks or HQs generated by the model do not include background exposures. In either case, this discrepancy in wording needs to be clarified.

More important, however, is how cumulative risk is defined and treated in the model, as well as the implications for future use of the model. Because the model is used to estimate only incremental exposures, without consideration of background exposures, cumulative risk should not be presented as an output of the model – unless it is clearly explained that "cumulative" is used in a statistical sense or that it is cumulative only for a single source. Otherwise, it will be very misleading. In addition, it is necessary to go into more depth in the limitations section of the document explaining the implications of analyzing for

incremental risks versus cumulative risks. For example, not considering interactive effects among multiple chemicals could lead to an underestimate or overestimate of risk. However, not considering background exposures will certainly lead to an underestimation of total or cumulative risks.

Clearly, a model that evaluates multiple media, pathways, and receptors can be considered one type of cumulative risk tool. In fact, it is likely to be adapted for use by others interested in evaluating cumulative risks in other populations and communities. Anticipating this, it would be a good idea to include some guidance and caveats on using this model for broader applications. While it is tempting to say that the model should just be used as intended in the waste program, the rapidly growing interest in cumulative and integrated risk issues makes this warning unlikely to be heeded. It is somewhat analogous to basing most of the 3MRA exposure module on the equations in EPA's *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions*, even though combustion is not one of the WMU types included in the model.

The most logical extension of the model at a particular WMU site would be to also run it for neighboring facilities in the study area. One could first establish a baseline of key contaminants from multiple sources in a study area, to which the incremental risks from a particular facility could then be added. While all background exposures would still not be accounted for (e.g., personal and workplace exposures), the evaluation of multiple sources (in conjunction with multiple media, pathways, and receptors in the model) would come much closer to estimating cumulative risk than is currently done with the single source, incremental risk approach typically used by EPA for evaluating chemical emissions from a single facility.

Model Validation

Confidence in the output of any model, but particularly one as comprehensive at the 3MRA model, depends on its validation. While comparing the modeled media concentrations and estimated exposures to actual site data would be ideal, the time and cost of such an effort would be prohibitive. However, some sort of reality check is needed to determine if the risk-based HWIR exemption criteria can be considered credible. It may be necessary to verify that selected modules (e.g., those with the greatest sensitivities and/or uncertainties) are, indeed, reasonably predictive. In addition, a validation exercise of this scope would inevitably require additional research to fill key data gaps.

Assumptions and Limitations

The discussion of assumptions and limitations in Section 7 is not nearly comprehensive enough. As noted in a number of my comments, there are significant areas of uncertainty that are not even addressed in the report. The issues that were included in Section 7 are also important, but the discussion was often lacking. Specifically, the implications of the assumptions were usually not explained. Although in some cases this involves professional judgment, it is still very important for those most knowledgeable about the model's strengths and limitations to attempt to interpret the implications of key assumptions for various parts of the methodology. It is apparent that some of the methodological weaknesses and areas of uncertainty will not be able to corrected because of a lack of alternative approaches, resource constraints, etc. Therefore, identifying all of the key assumptions and limitations and analyzing their implications is critical for understanding and applying the final risk results.

Dr. Kastenberg:
Overall Approach

The basic starting point is that risk is a function of two factors, the dose (exposure) and the chemical

specific cancer slope factor as given by Equation 5.1.The product of these two factors, which are expressed as the point values ADD and CSF respectively, then approximates risk. The point value of ADD is based on a number of very sophisticated time-series analyses concerning multi-media exposure, population behavioral patterns, individual age, etc. The point values of CSF are based on EPA derived data and are given in Table D-1.The CSF values are highly uncertain, given to one significant figure and are good to one order of magnitude at best. At worst, they are "guesstimates" obtained from limited extrapolations of animal data and their uncertainty may span many orders of magnitude. Hence the risk is the product of two factors, one of which (the ADD) is supported by sophisticated analyses, presumably with a narrow band of uncertainty, and one of which (the CSF) has a very large uncertainty band and is supported by no analysis.

I believe the two factors are not commensurate with one another. Nor do they satisfy the intent of a screening analysis, which this is supposed to be. That is, the exposure assessment has a level of detail (or uncertainty) that is not commensurate with the level of detail (or uncertainty) of the slope factors. Especially McKone at Lawrence Berkeley Laboratory has written much about screening assessments. Given the lack of robustness of the CSF data, other approaches could be undertaken:

1. The screening could be based solely on the calculated exposures, and not on risk.
2. The assessments could consider the uncertainty and variability in the CSF's, by using age and gender data, as well as 5th and 95th percent confidence limits.
3. Utilize another risk model such as that developed by McKone (CALTOX) for such screening assessments.

Assumptions

Contaminated surface and or groundwater should be considered outside the 2km boundary for those sites where it is appropriate.

Dr. Washburn:
Off-Site worker exposures

It appears that, in developing population risk estimates, only residents and farmers were considered. I would imagine that, at some locations, there may be a significant number of people working at industrial or commercial facilities within a 2-kilometer radius of a waste site, but who do not live within the area. Were exposures of off-site workers considered?

Farm products exported from the area of concern

For waste sites in highly agricultural areas, there may be few residents within 2-kilometers, but significant export of crops, meat, or other farm products outside the area. Thus, the true population risk would be driven not by exposures within the 2-kilometer radius, but by people consuming farm products outside the area. It is anticipated that the individual risks outside the area would generally be quite small because their food would be expected to come from many different sources; therefore, if any individual risks below $1x10^{-6}$ are considered de minimis and not included in the population risk evaluation, then this issue is not likely to be critical.

Population size in the national aggregation across sites

Based on my review of Section 6.0, it does not appear that population size is used to weight the results

from different sites, when aggregating across sites nationwide. This seems inappropriate. For example, consider the simple situation where we are aggregating across 3 sites, 2 with populations of 10,000 within 2-kilometers, and the third with a population of only 10 within 2-kilometer. Assume that one-in-one hundred thousand ($1x10^{-5}$) is selected as the "acceptable" risk level, and that this risk level is to be achieved for at least 95% of the population at greater than 90% of the waste sites. In Case #1, assume that a concentration of 100 ppm of Chemical A results in the following:

- At Site 1 (population 10,000), the risk is less than $1x10^{-5}$ for 98% of the population
- At Site 2 (population 10,000), the risk is less than $1x10^{-5}$ for 100% of the population
- At Site 3 (population 10), the risk is less than $1x10^{-5}$ for 80% of the population

In Case #1, would it be determined that 100 ppm of Chemical A is not suitably protective, because only 66.7% of the sites meet the acceptable criteria of having at least 95% of the population below $1x10^{-5}$? Note that in this case, about 99% of the total population would be protected to a risk level of at least $1x10^{-5}$. Compare this to Case #2:

- At Site 1 (population 10,000), the risk is less than $1x10^{-5}$ for 96% of the population
- At Site 2 (population 10,000), the risk is less than $1x10^{-5}$ for 96% of the population
- At Site 3 (population 10), the risk is less than $1x10^{-5}$ for 100% of the population

In Case #2, I assume that 100 ppm of Chemical A would be considered protective, because 100% of the sites meet the acceptable criteria of having at least 95% of the population below $1x10^{-5}$. However, note that in this case, only about 96% of the total population would be protected a risk level of at least $1x10^{-5}$, compared to Case #1, where 99% of the total population would be protected at that level.

ATTACHMENT A

Comments on Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model

James P. Butler, Ph.D.
Argonne National Laboratory

COMMENTS ON THE
BACKGROUND DOCUMENT FOR THE HUMAN EXPOSURE AND HUMAN RISK MODULES FOR THE MULTIMEDIA, MULTIPATHWAY, AND MULTIPLE RECEPTOR RISK ASSESSMENT (3MRA) MODEL

by

James P. Butler, Ph.D.
Argonne National Laboratory

October 2000

The following comments are based on my review of the *Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model* (August 2000). The first set of comments addresses issues raised in the Peer Review Charge for the HWIR Human Exposure and Human Risk Modules, followed by additional comments and recommendations that were not considered in the charge.

GENERAL ISSUES

1. Organization of the Document

The authors have done a good job describing the Human Exposure (HE) and Human Risk (HR) modules of the 3MRA software system. Considering the technical complexity of this reference document, the material is presented in a clear and concise manner. The organization of the report follows a logical, relatively easy-to-follow format. The report appears to have been carefully written and edited, with considerable attention to detail. The authors have also identified a number of model limitations, data uncertainties and scenario assumptions, both throughout the document and in a separate section.

Nevertheless, I can offer two (related) recommendations for improving the presentation and assisting the reader in understanding the methodologies. The document reads more like a detailed technical appendix; indeed it is referred to as a "stand-alone reference." Having separate reference documents or a series of technical appendices is appropriate (probably necessary) for this type of comprehensive software system. However, it was not possible to review the document without first learning more about the overall modeling approach and relevant components of other modules. Therefore, I'd recommend adding a detailed section to the background document that integrates key elements of the other modules, discusses how the various "pieces" fit together, and evaluates the implications that assumptions in one module have on others. Along the same lines, there is a need for an overarching report that pulls all the information together, referencing the background documents as needed. This may already be planned, but the lack of this type of comprehensive document for providing context was a hindrance in reviewing the HE/HR modules document.

2. Purpose and Context of Modules Adequately Described?

The stated purpose of the document is that it "...is intended as a stand-alone reference that describes the Human Exposure (HE) and Human Risk (HR) modules of the multimedia, multiple exposure pathway, and multiple receptor risk assessment (3MRA) software system." It is also intended to include overview information on the 3MRA model, as well as assumptions, limitations, methodologies, and input/outputs of the HE and HR modules. While the overview information presented is limited, the detailed description of the

relevant human health and risk aspects of the model clearly conveys the purpose of these modules.

On the other hand, the context of the HE and HR modules is not as clear. As mentioned above in General Issues #1, the focus of this document is almost entirely on these modules, and what is lacking is either an additional section and/or a stand-alone document that integrates the various components of the 3MRA model and provides the context for how the individual modules fit into the overall framework for developing exemption criteria.

3. Major Methodological and Data Gaps

A number of the major methodological and data gaps have been identified in the document, e.g., the HE and HR modules do not include background exposures and chemical mixture interactions. However, several limitations still need to be clearly identified and discussed in the document.

One major methodological gap that should be mentioned is that acute exposures or physical hazards from accidental releases at a waste management unit (WMU) are not evaluated. Another methodological issue is the uncertainty inherent in the use of toxicity data for the human health benchmarks. A related methodological problem has to do with the numerous chemicals for which human health benchmark values are missing. A number of HWIR constituents will need alternative benchmarks developed or adapted from other sources (e.g., NCEA's provisional values, ATSDR, and/or state regulatory agencies). Finally, while it was stated that the methodology is limited in not adjusting cancer slope factors to account for childhood exposures, the analogous methodological gap for noncarcinogens was not identified. As with cancer slope factors, reference doses and reference concentrations are usually based on adult toxicity data. This approach may not be appropriate for estimating noncancer effects in children, given their potentially increased susceptibility to chemical exposures.

While these types of gaps add significantly to the uncertainty of the analysis, they are difficult technical issues to resolve for inclusion in the model.

SPECIFIC ISSUES

1. Modeling Significant Exposure Pathways

It appears that the most significant exposure pathways are addressed in the 3MRA model. While it would be more comprehensive to address additional exposure pathways (e.g., dermal exposure and indoor infiltration), the drawbacks outweigh the advantages. Although it could be an important pathway under certain conditions, the general lack of dermal toxicity data would preclude the accurate assessment of the dermal route of exposure for most chemicals. Similarly, the migration of subsurface vapor-phase contaminants into residences could be an important exposure pathway under certain site-specific conditions; however, it may be too difficult to accurately model this transport mechanism to represent a national distribution of indoor exposures near waste management units. Given the complexity of the 3MRA model and pathways already included, it is reasonable to focus on the most significant potential exposures and make conservative adjustments in assumptions to account for these omissions, as needed. However, I recommend adding a discussion in the Assumptions and Limitations section on the rationale for not including these exposure pathways in the model.

2. Correlation Between Exposure Behaviors

Treating certain exposure-related behaviors as independent for each receptor and across receptors would have an effect on the results of the analysis, although it's not clear to what extent. The examples in the charge

statement are probably the behaviors of most concern (i.e., overlap between the high-end fisher and farmer receptors). Unfortunately, I am not aware of any data on the correlations between these exposures. However, this issue should at least be discussed in the Assumptions and Limitations section of the document.

On a related point, the omission of subsistence behavior in the fisher and farmer scenarios is perhaps a more serious limitation that should be addressed. Estimates of fish consumption rates are based on data from recreational fishers and adjusted for the fraction of fish intake from recreational fishing activities. Similarly, estimates of home-produced beef consumption intakes are based on data from households who farm and adjusted for farm households that raise beef cattle. The high-end values of the distributions of both fish and beef consumption rates do not account for subsistence behavior. It should be possible, however, to develop representative or generic subsistence fisher and farmer scenarios for inclusion in the model, or at least for providing an upper bound on the distributions. For example, consumption data are available on populations that include subsistence fishers and others who regularly eat large amounts of non-commercial fish; these populations often obtain fish from contaminated waters, providing further justification for evaluating these scenarios.

3. Lack of Time Variability in Populations Used

To attempt to incorporate time variability in the populations used would probably introduce as much uncertainty as it would remove. Presenting risk results as population percentiles, as opposed to absolute numbers, also reduces the need to attempt to predict population increases and mobility. The potential bias from differential population changes and/or spatial redistributions should, however, be explained in the limitations section of the background document.

4. Exposure Duration Assumptions

The one-year exposure duration assumption for noncarcinogens is a reasonable approach because it avoids underestimating health effects that could occur by averaging out the peaks over a number of years. This is an appropriately conservative approach given the hazard quotient method of calculating noncarcinogenic effects. The nine-year exposure duration assumption based on the national average residence time is a reasonable point estimate for carcinogens. In addition, because this model is used for a national assessment and not to represent site-specific conditions, it may be sufficient to just use the average residence time. However, it would be more accurate to reduce the uncertainty introduced by much longer residence times in rural areas by stochastically varying the exposure duration for carcinogens. If the fixed nine-year exposure duration is still used, the potential for introducing a low bias in the final risk distributions should be discussed in the limitations section of the document.

5. Adjusting Cancer Slope Factors for Early Childhood Exposures

It is possible that the use of cancer slope factors derived from lifetime animal bioassay data accounts for the carcinogenic risks from exposures during infancy and childhood. This is one of the fundamental assumptions that form the basis of a typical risk assessment (akin to the high-to-low dose and animal-to-human data extrapolations). So, from a risk assessment methodological standpoint, it is a reasonable assumption to include in the 3MRA model. That said, it should be emphasized that I still think it is a significant shortcoming in any risk assessment methodology because it is very likely that this basic assumption still misses many of the unique childhood vulnerabilities during this critical developmental stage. There are experimental data that suggest that early exposures may increase human susceptibility to cancers. Therefore, it is very possible that the animal cancer bioassay data do not reflect any or all of the increased or unique vulnerabilities of children to certain chemical exposures received at a particular stage of development.

Although the use of child-specific exposure factors in the model is a reasonable first step, considerable uncertainty remains. Additional research is needed to develop biologically-based models of carcinogenesis to represent the complex exposure and dose-response relationships for early chemical exposures at vulnerable ages. Until these findings are available, adjusting cancer slope factors in the 3MRA model would be too simplistic to accurately reflect all of the age-related differences in exposure and toxicity that may lead to an increased risk of developing cancer from early childhood exposures.

6. Selection of Critical Risk Years

The low risk/large population versus high risk/small population issue is always a problem when interpreting the results of a population risk analysis. Although total risk is calculated across all individuals in a histogram for a given year, the use of a set of risk ranges may still generally approximate the distribution of risks at a site. Therefore, the use of time series of frequency histograms is probably the most appropriate technique for selecting the critical years.

7. Locations of Drinking Water Wells

It is assumed in the model that if any residents in a census block group are served by drinking water wells, then all the households within that census block group are on wells. The extent to which this conservative assumption overestimates groundwater ingestion by all the human receptors could be substantial, depending on the population and number of wells impacted by the groundwater plume. To get finer geographic resolution on distribution of wells (i.e., by block rather than block group), it should be possible to request a special analysis by the Census Bureau.

8. Approaches for Locating Human Receptors

The location of residents and home gardeners is at the centroid of the census block or at the centroid of the polygon formed by the census block and distance ring. This method of locating residents is likely to create a systematic bias in less densely populated areas. Areas of concentrated populations tend to be located proximate to bodies of water. A possible correction is to place residents at the mid-point between the centroid and the largest river or shore of the largest lake that intersects the polygon. An alternative method would be to place the population at the point on the river or lakeshore closest to the centroid.

9. Statistical Approach for Developing Distributions

In general, it seems reasonable to use a statistical approach for distributions of exposure parameters with sufficient data, combined with lognormal distributions and central tendency values when the data are lacking. However, I recommend having this approach reviewed by a statistician, which I am not.

ADDITIONAL COMMENTS

Cumulative Risks

It is stated in the limitations section of the document that only incremental exposure is modeled, but that "No provision is made for considering background exposures for the purpose of generating cumulative risk or HQ." However, elsewhere in the document (p. 5-1), it is stated that "The HR module then determines and outputs *cumulative risk* and/or HQ distributions during that critical year for which the maximum *cumulative risk* and/or HQ occurs across the population" (emphasis added). Clearly, these two statements are in conflict. To me, the implication of the first sentence is that the determination of cumulative risk is not possible without

the inclusion of background exposures (which I personally agree with, in the truest sense of the word "cumulative"). However, it is possible that the first statement simply is poorly worded, and the intent was to point out that cumulative risks or HQs generated by the model do not include background exposures. In either case, this discrepancy in wording needs to be clarified.

More important, however, is how cumulative risk is defined and treated in the model, as well as the implications for future use of the model. Because the model is used to estimate only incremental exposures, without consideration of background exposures, cumulative risk should not be presented as an output of the model – unless it is clearly explained that "cumulative" is used in a statistical sense or that it is cumulative only for a single source. Otherwise, it will be very misleading. In addition, it is necessary to go into more depth in the limitations section of the document explaining the implications of analyzing for incremental risks versus cumulative risks. For example, not considering interactive effects among multiple chemicals could lead to an underestimate or overestimate of risk. However, not considering background exposures will certainly lead to an underestimation of total or cumulative risks.

Clearly, a model that evaluates multiple media, pathways, and receptors can be considered one type of cumulative risk tool. In fact, it is likely to be adapted for use by others interested in evaluating cumulative risks in other populations and communities. Anticipating this, it would be a good idea to include some guidance and caveats on using this model for broader applications. While it is tempting to say that the model should just be used as intended in the waste program, the rapidly growing interest in cumulative and integrated risk issues makes this warning unlikely to be heeded. It is somewhat analogous to basing most of the 3MRA exposure module on the equations in EPA's *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions*, even though combustion is not one of the WMU types included in the model.

The most logical extension of the model at a particular WMU site would be to also run it for neighboring facilities in the study area. One could first establish a baseline of key contaminants from multiple sources in a study area, to which the incremental risks from a particular facility could then be added. While all background exposures would still not be accounted for (e.g., personal and workplace exposures), the evaluation of multiple sources (in conjunction with multiple media, pathways, and receptors in the model) would come much closer to estimating cumulative risk than is currently done with the single source, incremental risk approach typically used by EPA for evaluating chemical emissions from a single facility.

Model Validation

Confidence in the output of any model, but particularly one as comprehensive at the 3MRA model, depends on its validation. While comparing the modeled media concentrations and estimated exposures to actual site data would be ideal, the time and cost of such an effort would be prohibitive. However, some sort of reality check is needed to determine if the risk-based HWIR exemption criteria can be considered credible. It may be necessary to verify that selected modules (e.g., those with the greatest sensitivities and/or uncertainties) are, indeed, reasonably predictive. In addition, a validation exercise of this scope would inevitably require additional research to fill key data gaps.

Assumptions and Limitations

The discussion of assumptions and limitations in Section 7 is not nearly comprehensive enough. As noted in a number of my comments, there are significant areas of uncertainty that are not even addressed in the report. The issues that were included in Section 7 are also important, but the discussion was often lacking. Specifically, the implications of the assumptions were usually not explained. Although in some cases this

involves professional judgment, it is still very important for those most knowledgeable about the model's strengths and limitations to attempt to interpret the implications of key assumptions for various parts of the methodology. It is apparent that some of the methodological weaknesses and areas of uncertainty will not be able to corrected because of a lack of alternative approaches, resource constraints, etc. Therefore, identifying all of the key assumptions and limitations and analyzing their implications is critical for understanding and applying the final risk results.

ATTACHMENT B

Comments on Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model

William E. Kastenberg, Ph.D.
University of California - Berkeley

Review of the: Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model

W.E. Kastenberg

General comments

The basic starting point is that risk is a function of two factors, the dose (exposure) and the chemical specific cancer slope factor as given by Equation 5.1.The product of these two factors, which are expressed as the point values ADD and CSF respectively, then approximates risk. The point value of ADD is based on a number of very sophisticated time-series analyses concerning multi-media exposure, population behavioral patterns, individual age, etc. The point values of CSF are based on EPA derived data and are given in Table D-1.The CSF values are highly uncertain, given to one significant figure and are good to one order of magnitude at best. At worst, they are "guesstimates" obtained from limited extrapolations of animal data and their uncertainty may span many orders of magnitude. Hence the risk is the product of two factors, one of which (the ADD) is supported by sophisticated analyses, presumably with a narrow band of uncertainty, and one of which (the CSF) has a very large uncertainty band and is supported by no analysis.

I believe the two factors are not commensurate with one another. Nor do they satisfy the intent of a screening analysis, which this is supposed to be. That is, the exposure assessment has a level of detail (or uncertainty) that is not commensurate with the level of detail (or uncertainty) of the slope factors. Especially McKone at Lawrence Berkeley Laboratory has written much about screening assessments. Given the lack of robustness of the CSF data, other approaches could be undertaken:

1. The screening could be based solely on the calculated exposures, and not on risk.
2. The assessments could consider the uncertainty and variability in the CSF's, by using age and gender data, as well as 5th and 95th percent confidence limits.
3. Utilize another risk model such as that developed by McKone (CALTOX) for such screening assessments.

General Issues

1. The exposure and risk document appears to be well organized. I believe the long tables are placed correctly in the text, rather than at the end of the chapters or the end of the report. This provides better continuity for the reader. I am assuming that the readers of the document are well versed in risk assessment.

2. Sections 1 and 2 provide an adequate description of the purpose and context of the exposure and risk models, providing the document is intended for knowledgeable readers and not the layperson.

3. I believe there are two areas worth looking into. The first involves the correct interpretation of individual dose versus population dose. These are clearly defined for radiation where individual dose is given in rads and population dose is given by person-rem. The former is based on delivered dose and the latter is an integrated value based on exposure and population density. This should be done in the chemical arena as well. As it stands now, the "population" exposures and hence risk, are numbers of people exposed at given individual risk levels. This is different than a population integrated exposure. I am aware that Dr. Debbie Hall Bennett of the Lawrence Berkeley National Laboratory considered ways

of formulating population dose for persistent organic pollutants (POPS) in her Ph.D. Dissertation, and a manuscript that is being reviewed for publication in the Journal of Risk Analysis. She can be contacted at: DBHall@lbl.gov. The second area involves uncertainty and variability of both the Cancer Slope Factors and the Reference Doses. As stated in Section 5, only the EPA point values for the CSFs and RfDs are used in the Risk or HQ calculations. Moreover, they are given as one significant figure (in most cases) like 0.005 or 0.05, which tells me they are "educated guesses."Given the sophistication of the exposure calculations, it would appear that some improvements in the CSF/RfD domain are in order so that the degree of uncertainty is not so disproportionate. In reality, the document provides for a methodology that estimates exposure, modified by a constant (and a not very accurate one at that), which is called risk.

Specific Issues

1. *Inclusion of all pathways*. I believe all plausible exposure pathways should be included regardless of whether or not there is sufficient data. This is where the true data uncertainties enter and can be assessed. There is no way to tell whether or not the risk significant pathways are included if some pathways are left out. Dermal exposure may be dominant for some scenarios, particularly where there is water in which kids can swim (e.g. ponds, backyard pools, etc) or contaminated soil where kids can play. If the CSFs and or RfDs were formulated as distributions, then the effect of inadequate toxicity data can be accounted for and determinations can be made as to their relative risk significance. Similarly, subsurface vapors entering a residence have been considered in the work of Dave Rice and Dave Layton at the Lawrence Livermore National Laboratory regarding the Leaking Underground Storage Tank (LUST) issue, and the indoor air program at the Lawrence Berkeley National Laboratory has also considered similar issues. Even though modeling horizontal gas migration is complex, it can be taken into account with the proper analysis. This issue of modeling uncertainty has been dealt with for nuclear power plant risk analysis beginning with NUREG-1150, and more recently by Professor Theofanous at UCSB in a series of papers appearing in the Journal of System Safety edited by Apostolakis at MIT.

2. I am not sure about this question. People eat a finite amount of food per day, which should be relatively easy to estimate. Also, it should be possible to correlate these if the variability distributions for intake of two different foods were considered, using a Monte Carlo sampling approach, to see if the result was even significant.

3. This is a difficult question to answer. Pelmulder, et al considered population growth in a paper published in Water Resources Research around 1995/1996. As noted above, Bennett integrated population exposure, to arrive at a population average dose. The latter is the more important issue, but the former can be handled by examining population statistics over time. Institutional controls may dictate future land use within the 2 km sector and may also contribute to uncertainty.

4. I believe that the question itself deserves an answer with an analysis using uncertainty/variability distributions. This should be carried out on a site-specific basis, however. Again, the question regards a level of detail for the exposure/dose calculation not afforded to the CSF/RfD calculation. It doesn't matter how sophisticated the exposure/dose calculation is if the CSF/RfD has large uncertainty.

5. This is a shortcoming in all risk assessments. It is easy to differentiate age and gender exposure data. As noted, the CSFs do not take this into account because a single number represents them. Hence they would underestimate risk for children and overestimate risk for adults. The place to improve the exposure analysis is in gender difference. Men may weigh more than women, women may have more body fat, men may breathe more air, eat more meat, etc. Men may farm and fish more than women, and women may spend more time in gardens. Given the difficulty in refining the toxicity data as a function of

age and gender, this may be an alternative improvement.

6. Again, this depends on how you define population risk. This is a similar problem encountered by the risk assessors considering the Yucca Mountain site for high-level radioactive waste. In this case the maximum individual and population dose occurs 100's of thousands of years into the future. It might be worthwhile to look at their approach. One approach might be to consider each pathway individually, rather than an aggregate. It gives more information to the decision makers.

7. Brendan Dooher, at the Lawrence Livermore National Laboratory considered such an issue in his assessment of Leaking Underground Fuel Tanks. He used a GIS system and a simulation package to determine individual exposures to contaminated well water in the NAPA Valley in Northern California. However, the level of detail here may be disproportionate to the validity of the CSF/RfD values.

8. Yes, see Question 7 above.

9. This seems appropriate, given the validity of the CSF/RfD data.

Assumptions

Contaminated surface and or groundwater should be considered outside the 2km boundary for those sites where it is appropriate.

ATTACHMENT C

Comments on Background Document for the Human Exposure and Human Risk Modules for the Multimedia, Multipathway, and Multiple Receptor Risk Assessment (3MRA) Model

Stephen T. Washburn
Environ Corporation

COMMENTS ON THE HWIR HUMAN EXPOSURE AND HUMAN RISK MODULES

Prepared for
Eastern Research Group, Inc.

Prepared by

Stephen T. Washburn
ENVIRON International Corporation

October 2000

COMMENTS ON THE
HWIR HUMAN EXPOSURE AND HUMAN RISK MODULES

General Issues Identified in the Charge to Reviewers

1. Organization and clarity of the exposure and risk document

The text relies too heavily on jargon, and the technical approach is sometimes difficult to follow, particularly in portions of Section 2.0 (e.g., Subsection 2.3) and 6.0. These portions of the text seem to focus more on explaining how data are processed by the computer program, than on the rationale for the technical approach. At a minimum, I would suggest that a glossary be included, providing a single resource for defining such terms as "block group coverages", "clip census coverages" and "conditional frequency histograms".

A number of inconsistencies and typographical errors still exist in the text. For example:

- The HQ ranges in the table on p. 5-8 do not agree with the bin ranges on p. 5-7, and have gaps (e.g., from HQ=1 to HQ=5). (It is also unclear why the bin ranges specified on p. 5-7 were selected for the HWIR Risk Assessment Module).

- The caption for Figure 6.2 appears to be incorrect, and at a minimum is confusing given the very similar caption for Figure 6.3.

- Equations 5.2 and 5.3 appear to be inconsistent, and are confusing. For example, I believe that "Dose" in Equation 5.2 is called "ADD" in Equation 5.3 (another "dose" term is introduced in Equation 5.3). Furthermore, based on Equation 5.3, ADD is not the "average daily dose", but rather the cumulative dose over the exposure period. ADD should not be the sum of the doses for each year within the exposure period (as implied by Equation 5.3), but rather the sum divided by the number of years in the exposure period.

Additional inconsistencies and typographical errors are indicated in the attached mark-ups of individual pages from the draft document. However, I did not attempt to identify all such inconsistencies and errors, and the document should be carefully checked by a technical editor.

2. Description of the purpose and context of the exposure and risk modules (Sections 1and 2)

While Section 1.0 generally provides a good overview, the most succinct description of the objective of the HWIR analysis does not appear until Section 6.0:

> "The objective of the HWIR analysis is to determine the chemical concentration, for each chemical of interest and WMU type … that will result in an acceptable risk or HQ to a specified percentage of human receptors at a specified percentage of hazardous waste management sites at a specified confidence limit". (p. 6-1)

This objective should appear at the outset, in Section 1.0, since it helps to understand the rationale behind the development of the technical approach in Sections 2.0 through 5.0.

I found Section 2.0 to be longer than necessary, because it includes technical detail regarding database operations that are not critical for understanding the conceptual approach for the risk assessment. (Such details may be of interest to database professionals; if so, I would suggest they go into a technical appendix). For example, I do not see a compelling reason to include any of the information in Tables 2-3 through 2-6 in the main text.

3. Major methodological or data gaps

According to p. 1-4, the HWIR exposure and risk modeling simulations "can range from a few hundred years for chemicals that move quickly in the environment, are not persistent, and do not bioaccumulate to 10,000 years for the most persistent and least mobile chemicals such as some metals". Clearly, one of the greatest uncertainties in the HWIR modeling is in attempting to characterize risks and exposures so far into the future. (Imagine how different behavior patterns, land use, and other exposure factors were in 8,000 B.C., or even 1800 A.D., compared to today). These uncertainties dwarf virtually all other data gaps associated with the exposure and human risk modules, with the possible exception of incomplete toxicity data. The considerable uncertainties in attempting to estimate risks so far into the future make efforts to reduce uncertainties in other parts of the exposure and risk analysis a waste of resources, unless the modeling indicates that "critical risk" years usually occur within the first 20 or 30 years. Instead of addressing gaps in the human exposure and risk module, I would recommend focusing on the methodological and data gaps in the fate/transport and food chain models.

If the "critical risk" years typically occur within the next 20 or 30 years at most sites, then it may make sense to collect additional data to refine the exposure and risk module. In general, conservative assumptions are usually made by EPA to offset uncertainties and data gaps. Which data gaps are the most important to address should be identified through an analysis of the modeling results. Specifically, the pathways that most frequently drive the risk assessment should be evaluated to determine if key assumptions could potentially be refined through the collection of additional data.

At this point, it appears that major decisions must still be made in the area of risk management. For example, referring back to the objective of the HWIR modeling in Section 6.0, key risk management decisions include:

- What represents an unacceptable cancer risk and non-cancer hazard, both from an individual and population risk perspective?
- What is an acceptable "specified percentage" of receptors and waste management sites above the cancer risk and non-cancer hazard levels?
- What is an acceptable "specified confidence limit"?

Each of these decisions by itself could affect chemical-specific concentrations for exempted waste by an order of magnitude or more; together, these decisions could affect exemption levels by several orders of magnitude. It is unlikely that further refinement of the exposure and risk calculations (especially given the difficulties in predicting risks far into the future) could have anywhere near as much impact.

Specific Issues Identified in the Charge to Reviewers

1. Pathways addressed

In general, I agree that the pathways and routes currently modeled include exposures that place humans at the greatest risk from the sources modeled. Regarding other pathways that are not included in the module, I have the following comments:

- Dermal exposure. The charge statement indicates that dermal exposures were not included because there are "inadequate toxicity benchmark data". Not being a toxicologist, I will not comment on whether existing toxicity benchmarks are adequate or inadequate for evaluating dermal exposures. However, USEPA guidance does not seem especially clear on this issue. In some contexts (and some EPA Regions) evaluating the risks posed by dermal exposures is required, for example, by using USEPA's Risk Assessment Guidance for Superfund (RAGS).

- Vapor Migration into Building. The charge statement indicates that migration of subsurface vapors into residences is not evaluated because of the "complexity of modeling horizontal vapor migration". In terms of the Exposure and Risk Module, vapor migration from subsurface soil and/or groundwater into buildings could be readily evaluated. Thus, it is assumed that this pathway is not included because of complexities in the Fate/Transport Module. The Johnson and Ettinger (1991) model is capable of estimating indoor air concentrations resulting from vertical vapor transport from groundwater, assuming that horizontal transport of contamination in groundwater is first estimated using a different model. However, the model is highly sensitive to site-specific soil and hydrogeological conditions and thus there may be difficulties in applying the model on a regional or census-block scale, as in 3MRA.

- Surface Water. It appears that contamination of surface water is evaluated only in terms of consumption of fish (i.e., does not include swimming, drinking water, or other pathways). Since I have not been requested to review the Fate/Transport module, I do not know what pathways of surface water contamination have been addressed (e.g., direct deposition of contaminants from air, runoff from contaminated soil, groundwater discharge, etc.). From my experience, I would agree that fishing is likely to be significantly more important than swimming or other possible recreational exposures. However, was use of surface water as a drinking water resource (e.g., from reservoirs) considered?

The document should provide more complete justification for the exposure pathways and routes included (and excluded) from 3MRA.

2. Correlations between exposure parameters

Given other uncertainties in the Exposure and Risk Module (as well as the Fate/Transport, Food Chain, and Source Modules), I do not believe that ignoring correlations between exposure inputs significantly affects the analysis. It is recommended, however, that USEPA consider whether different soil ingestion rates are appropriate for resident adults and farmer adults. Intuitively, it seems that the soil ingestion rate for an adult resident might be lower than for an adult farmer.

3. Time-variability in populations

As discussed in my comments above, attempting to predict exposures hundreds and even thousands of years into the future involves considerable uncertainty, to say the least. However, introducing time variability into the population estimates would not significantly reduce this uncertainty, and would make what is already a highly complex analysis even more complicated.

4. Exposure durations for cancer and non-cancer evaluations

Exposures to carcinogens. It is not clear why the exposure duration for carcinogens has been assigned a fixed value of 9 years, when most of the other exposure inputs have been represented stochastically, by distributions. This should be explained. While I do not know if representing exposure durations to carcinogens stochastically would significantly change the results of the analysis, the text does not provide sufficient justification for relying on a fixed value for this parameter.

Exposures to non-carcinogens. It could be argued that a 7-year exposure duration would be more consistent with the definition of chronic exposure in USEPA's Risk Assessment Guidance for Superfund (RAGS). However, I understand that exposures of approximately 1 year could be considered chronic for a number of chemicals with respect to at least some types of health effects. (This should be confirmed with toxicologists within USEPA and the 3MRA review panel). Given that 1 year may represent a chronic exposure period for some chemicals and some health effects, I agree with the default of a 1 year assumed duration (and corresponding 1 year averaging period) for evaluating exposures to non-carcinogens. However, there may be some chemicals for which a longer exposure duration and averaging period is appropriate.

5. Use of cancer slope factors for evaluating childhood exposures

Given other uncertainties in the Exposure/Risk, Fate/Transport, Food Chain, and Source Modules, as well as the approaches used by USEPA to develop cancer slope factors, I do not believe that an adjustment of slope factors is generally warranted when evaluating childhood exposures. However, such an adjustment may be appropriate for specific chemicals, based on a careful review of the basis for the USEPA slope factor and the mechanism of carcinogenicity for the chemicals in question.

6. Selection of critical risk years

Based on my review, it appears that the HWIR methodology does not classify any individual risks as being de minimis. In other words, an individual risk level (no matter how low) is multiplied by the population at that risk level, in determining the population risk. I would suggest that USEPA consider assigning any individual risks less than one-in-one million ($1x10^{-6}$) a score of zero, and not included in determining the "critical year". Conversely, it may be appropriate to give additional weight to individual risks exceeding one-in-one thousand ($1x10^{-3}$), or some other risk level that is considered clearly elevated, and unacceptable on an individual level.

7. Assumption of groundwater use

In 3MRA, it is assumed that if any resident within a block group is on a groundwater well, then all residents within that block group are on wells, all ingest groundwater, and all of the water that

the residents ingest is groundwater. This assumption is conservative for at least three reasons:

- Only a fraction of the residents within a block group may be on groundwater wells.
- Only a fraction of the residents who are on groundwater wells may use the groundwater for drinking water.
- There may be additional sources of drinking water for those residents who ingest groundwater (i.e., the fraction contaminated value for drinking water may be less than 1.0)

For these reasons, the groundwater pathway may be given too much weight in the 3MRA methodology, particularly for residents within a municipal boundary who would likely have a municipal water supply.

Ideally, information should be compiled on the fraction of residents within a block group who use groundwater for drinking water. However, this type of information is apparently not available and presumably would be resource-intensive to collect. Furthermore, the fraction may change significantly over time, especially the hundreds to thousands of years apparently modeled by 3MRA. Thus, I would recommend that, as a default, 10% of the residents within a municipal boundary, (within a block group that has at least one resident on a well), be assumed to use groundwater for drinking water. I believe that this assumption would still be conservative at the majority of sites, given the other assumptions made in evaluating the groundwater ingestion pathway. Outside municipal boundaries, I would recommend retaining the assumption that, if any resident within a block group is on a groundwater well, then all residents within that block group are on wells and ingest groundwater.

8. Locating receptors within a census block

It is not clear to me how much this assumption affects the analysis, without more detail on the size range for census blocks, particularly those near the facility, and how the fate/transport analyses are performed. For example, if the census block immediately adjacent to the facility is relatively large, and groundwater flow direction is taken into account, then the residential or farm receptor may be inappropriately placed outside the plume at one site (where homes are actually present within the plume), and within a plume at another (where homes would not actually be impacted by the plume).

9. Development of exposure factor distributions

Overall, the statistical approaches used to develop distributions appear to be appropriate. However, as indicated in my comments above, it is not clear why a fixed value was selected for exposure duration in evaluating exposures to carcinogens. According to the text, it also appears that certain parameters (e.g., fraction of contaminated soil ingested; fraction of contaminated water ingested) were selected as fixed values because of “EPA policy”. It is suggested that a technical basis be provided for all methodologies, inputs, and assumptions.

Other Issues

1. Off-Site worker exposures

It appears that, in developing population risk estimates, only residents and farmers were considered. I would imagine that, at some locations, there may be a significant number of people working at industrial or commercial facilities within a 2-kilometer radius of a waste site, but who do not live within the area. Were exposures of off-site workers considered?

2. Farm products exported from the area of concern

For waste sites in highly agricultural areas, there may be few residents within 2-kilometers, but significant export of crops, meat, or other farm products outside the area. Thus, the true population risk would be driven not by exposures within the 2-kilometer radius, but by people consuming farm products outside the area. It is anticipated that the individual risks outside the area would generally be quite small because their food would be expected to come from many different sources; therefore, if any individual risks below $1x10^{-6}$ are considered de minimis and not included in the population risk evaluation, then this issue is not likely to be critical.

3. Population size in the national aggregation across sites

Based on my review of Section 6.0, it does not appear that population size is used to weight the results from different sites, when aggregating across sites nationwide. This seems inappropriate. For example, consider the simple situation where we are aggregating across 3 sites, 2 with populations of 10,000 within 2-kilometers, and the third with a population of only 10 within 2-kilometer. Assume that one-in-one hundred thousand ($1x10^{-5}$) is selected as the "acceptable" risk level, and that this risk level is to be achieved for at least 95% of the population at greater than 90% of the waste sites. In Case #1, assume that a concentration of 100 ppm of Chemical A results in the following:

- At Site 1 (population 10,000), the risk is less than $1x10^{-5}$ for 98% of the population
- At Site 2 (population 10,000), the risk is less than $1x10^{-5}$ for 100% of the population
- At Site 3 (population 10), the risk is less than $1x10^{-5}$ for 80% of the population

In Case #1, would it be determined that 100 ppm of Chemical A is not suitably protective, because only 66.7% of the sites meet the acceptable criteria of having at least 95% of the population below $1x10^{-5}$? Note that in this case, about 99% of the total population would be protected to a risk level of at least $1x10^{-5}$. Compare this to Case #2:

- At Site 1 (population 10,000), the risk is less than $1x10^{-5}$ for 96% of the population
- At Site 2 (population 10,000), the risk is less than $1x10^{-5}$ for 96% of the population
- At Site 3 (population 10), the risk is less than $1x10^{-5}$ for 100% of the population

In Case #2, I assume that 100 ppm of Chemical A would be considered protective, because 100% of the sites meet the acceptable criteria of having at least 95% of the population below $1x10^{-5}$. However, note that in this case, only about 96% of the total population would be protected a risk level of at least $1x10^{-5}$, compared to Case #1, where 99% of the total population would be

protected at that level.