CHARGE TO PEER REVIEWERS

Peer Review of:

ORD / OSW Integrated Research and Development Plan for
the Hazardous Waste Identification Rule

INTRODUCTION AND BACKGROUND:

The Hazardous Waste Identification Rule (HWIR) is being developed as an amenc to existing regulations governing the disposal of hazardous wastes under the Resour Conservation and Recovery Act (RCRA). Specifically, the HWIR 99 methodology is des to establish safe, constituent-specific exit levels for low risk hazardous wastes. assessed under HWIR are those designated as hazardous because they were listed, or mixed with, derived from, or contained listed wastes. One of the intended outcomes to reduce possible over-regulation arising from application of the "mixture" and "d rules that were promulgated as part of the first comprehensive regulatory program f management of hazardous wastes under RCRA in May of 1980. The mixture rule defined hazardous any solid waste that is mixed with one or more listed wastes, and the der rule labeled as hazardous any solid waste generated from the treatment, storage or listed hazardous waste. Both of these rules remain important in reducing risk to h and the environment associated with the management of hazardous wastes, but since t regardless of the concentrations or mobilities of hazardous constituents present in they also open the possibility of over-regulation. One of the primary purposes of provide a basis for identifying possible instances of over-regulation and to provid the safe relief from Subtitle C disposal regulations.

Some aspects of the HWIR methodology have been under development for a number years, and date back to the Toxicity Characteristic (TC) Rule promulgated in 1990. proposal focused on the groundwater / drinking-water exposure route to humans. In of 1995 the Agency proposed, for the first time, a comprehensive, multimedia analys included both human and ecological multi-pathway exposures and impacts. this metho came to be known as the HWIR 95 approach. It utilized the EPACMTP (EPA's Composite Model for Leachate Migration with Transformation Products) approach for the groundw pathway analysis and the revised Indirect Exposure Methodology (IEM) for the non-gr pathways. The revised IEM methodology came top be known as the Multiple Pathway Re Analysis (MPRA) approach. One of the characteristics of the HWIR 95 methodology wa each exposure pathway was analyzed independent of other pathways, with the full pol available to each. During an extensive series of reviews of the HWIR 95 proposal, Science Advisory Board (SAB) and others urged the Agency to consider using a simult mass-constrained analysis that would account for dispersal, and transport and trans contaminant mass through all media and exposure routes. This was perhaps the most and strongly expressed element in all of the review comments received. The followi summarizes this comment along with several of the other major ones. A brief accoun Agency's response to each is included.

Major Science Advisory Board (SAB) Comments

on the 1995 HWIR Model and EPA's Response

SAB Recommendation

"The Subcommittee recommends that the proposed method of calculating exit criteria abandoned in favor of true multipathway calculations in which a receptor concurren connecting the source and receptors concurrently, is exposed to those contaminants forth depending on the receptor) and the dose corresponding to each route is accou is acceptable."

"The Agency should conduct a systematic examination of parameters to ensure a cons Ilapproach to selecting highend or centraltendency values. Further, the full suite Ilall parameters in the equations) needs to be addressed for the final methodology."

"The Subcommittee recommends . . . that the Agency discard the proposed [ecologica Ilrisk] screening procedure for selecting the initial subset of chemicals for ecolog Ilanalysis and instead require that a minimum data set be satisfied before ecologica Ilbased exit criteria are calculated."

"The Subcommittee strongly recommends that OSW actively seek the substantive Ilparticipation, input and peer review of Agency scientists, and outside peer review Ilgroups as necessary, to evaluate the individual elements of the proposed methodology Ilmuch greater detail than the subcommittee is able to provide."

"The Agency should conduct substantial validation of the overall methodology and o Ilindividual elements, against actual data derived from laboratory or field experime: IJobservations, prior to implementation of the methodology."

The HWIR document should be reorganized and rewritten for both clarity and ease of

In addition to the issues above, many other comments were received from the environmental groups, industry, academia and the stakeholder community during the r process of HWIR 95. These involved a multitude of details. Some of these details rendered moot by changes made in the process of addressing the major issues above. are addressed in the new methodology to theJextent possible considering time, resou scientific constraints. Of particular interest in this Phase I peer review is an e well the research plan is addressing the major issues above, and if the Agency has identified the major issues from the long list of comments received.

MATERIALS OFFERED FOR REVIEW:

The HWIR 99 development effort is being implemented via eight cooperative rep teams addressing the various needed improvements in the methodology. Together, the have produced a comprehensive research plan that defines the path being taken to pr revised methodology. This plan, formally entitled, the "ORD / OSW Integrated Resea Development Plan for the Hazardous Waste Identification Rule (HWIR)" is the documen offered for review in this first stage of the overall HWIR 99 peer review process.

It should be noted that the "plan" is not intended to reflect the end product

development effort. This review is only Phase I of -a multi-phase review process. be implemented beginning later this year, and will involve detailed reviews of the modeling components by panels of reviewers with special technical expertise in each media / modeling component / issues to be reviewed. In implementing Phase II, we w to provide overlap between the Phase I and SAB HWIR 95 reviews so as to impart a st measure of continuity / consistency to the overall Phase I and II processes. Final completed HWIR 99 methodology will undergo a Phase III review at the time the compl methodology is proposed for public comment in the Federal Register. Phase III is p consultation with the SAB Environmental Models Subcommittee during the October, 199 frame. Details of the Phase III review are still uncertain pending concurrence by

CHARGE TO THE REVIEW PANEL:

The overall goal of this development effort is to develop a methodology suit determining constituent-specific waste stream concentrations that represent a thres which Subtitle C disposal will not be required, and thus the waste may "exit" the h waste management system. Since HWIR 99 is to be a risk-based rule, the intent is t levels such that no significant risk to human or ecological health shall occur as t implementing the new exit levels. In characterizing risks, HWIR 99 will employ mat models to simulate the multimedia release of contaminants from land-based waste man units, their multimedia transport, and the subsequent exposure and risk to human an receptors. This plan reflects the early strategy for developing such a methodology it is intended to address the major review comments obtained on the earlier proposa

The HWIR 99 methodology described herein embodies six general objectives: 1) developing a revised risk-based assessment strategy, 2) developing a site-based mul multi-pathway exposure .and risk model, 3) developing the required assessment databa developing a computer-based technology for implementing the strategy, 5) developing science foundation for the assessment, and 6) conducting the necessary peer reviews the technical requirements underlying these objectives is presented in Table 6.1 of plan. In addition, the methodology under development is framed by a number of assu that are elaborated in the plan. In brief, these are: 1) concentration limits to b chemical-specific, 2) receptors of concern are within a 2 km radius of the site, 3) ecological impacts of exposure are based on near-field, long term exposure, 4) the
given chemical in the waste management unit (WMU) is finite, 5) mass balance is con the source at all times, 6) calculation of measures of protection is performed at t aggregated over sites to estimate National statistics, 7) waste management units ar indicated in OSW's industrial Subtitle D database, 8) impacts on receptors are calc the beginning of the site operation and until a maximum time when all impacts are i 9) receptors will be subject to exposures from all pathways simultaneously.

The HWIR 99 technical approach is based on Agency's risk paradigm and is coma five basic elements as follows:

* Assessment Strategy
* Assessment Data
* Assessment Model
* Science Support
* Peer Review

These research plan provides and overview of how these elements are combined to pro technical basis for developing the exit levels described earlier.

Since HWIR 99 is a direct attempt to improve the hazardous waste management regulations by addressing important limitations identified in a previous peer revie (SAB and others of HWIR 95), the most important feedback needed is an indication of the present, integrated HWIR 99 research and development effort is addressing the m raised in that review. The review panelists should focus their efforts on providin answer to that question, with specific recommendations for improvements identified practical and implementable in the time frame involved, if at all possible. In so that each panelist address the following component aspects of this general question

1) Given your understanding of the regulatory context and application niche for the approach suitable for its intended purpose? If not, why not?

2) Does the modeling approach have balance? That is, does it incorporate the right pathways at the right levels of detail and scale for the intended purpose? Are the is over simplified or too complex? Does it treat all exposure pathways reasonably appropriately in light of available data, knowledge, and current capabilities?

3) Is the methodology being developed in such way that it will have an acceptable t basis? Process descriptors? Sources? Endpoints / effects measures?

4) Are the proposed data sources and parameter estimation procedures adequate for t purpose?

5) Are the assumptions that underlie the modeling approach reasonable? Appropriate

6) Does the proposed approach adequately address the issues of uncertainty and vari light of constraints due to data limitations, computational burden and implementati

7) Are the technical criteria underlying the modeling effort reasonable? Appropria

8) All things considered, is the approach generally responsive to the earlier revie (i.e. on HWIR 95) it is intended to address? If not, what specifically needs to be done within the available time frame?

9) How successful has the Agency been in applying the regional, site-based approach design, actual site and receptor data - rather than hypothetical site and receptor how useful is this approach in evaluating the protectiveness of national exit level

being regulated?

This charge is based on Section VI of the EPA 100-B-94-001, July 1994, "Guidz Conducting External Peer Review of Environmental Regulatory Models". However, it i intended to in any way limit the technical areas the reviewers choose to address. reviews are due in writing to the ERD Peer Review Officer, Dr. Robert Swank, within receipt of the peer review package.

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December 14, 1998

Dr. Robert R. Swank, Jr.
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Dear Robert:

I have reviewed the document "ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR)" along with the November 6, 1998 "Charge to Peer Reviewers" and the EPA response to the "Major SAB Comments". As per your request I am providing my review comments of the proposed HWIR approach. I have refrained from reviewing the details of the proposed modules and focused on a number of global modeling issues as described below.

1. The integrated approach is a welcome improvement to the process of establishing safe, constituent-specific exit levels for low risk hazardous wastes. The integrated multi pathway exposure/risk analysis is indeed the desired approach.

2. The proposed approach seems to be an attempt to integrate various existing single-medium models (with the exception of EXAMS which contains various aquatic compartments) to allow estimation of concentration levels in the various media of interest. The proposed approach relies on serial linking of various modules and thus is not a true multimedia based analysis. A true multimedia analysis would require that all media are linked simultaneously and solved as one integrated unit. Obviously, this is a difficult task-which may not be required for the "classification of hazardous waste". However, it is possible that errors may result in some situations. For example, Section 3.5.2 indicates that "re-emissions of fluxes from soil and water to the atmosphere" are not considered. There are other places in the proposed modules where mass problems may be encountered. Clearly, this potential problem is recognized in some of the proposed modules. The proposed HWIR tracking of mass lost and gained is useful but may be an incomplete solution. It would be useful to create an executive program which will use the

mass balance information to determine if (as a consequence of violation of mass balance) concentrations .in the various media are underestimated or overestimated and if such deviations are acceptable or unacceptable (given a specified tolerance). Accomplishment of the above task will undoubtedly require extensive model testing for a variety of possible conditions.

It appears that the use of true multimedia models to assess the importance of intermedia transport processes and thus the impact on the overall mass balance is proposed in HWIR (see section on Science Support Activities). This is certainly a valid approach and can be an integral part of the approach discussed above. However, it unclear as to how and if such models will be incorporated into HWIR.

3. The use of Monte Carlo simulations to arrive at distributions of exposure and risk will be useful when arriving at appropriate classification and safe-level decisions. However, there is a fundamental problem to utilizing Monte Carlo simulations in an integrated system. In addition to the need for distributions for various model parameters, it is crucial to . identify which scenarios (i.e., a set of model parameters are physically inappropriate) could not occur in nature in the combination that may arise out of the Monte Carlo process of-sampling parameter values from the various distributions. While the above problem can usually be handled easily for simple models (e.g., a single medium), tracking impermissible combination of selected parameter values may be especially needed in an integrated multimedia system. This could be done using a companion processor to the Monte Carlo processor. Without such a supervision over the Monte Carlo analysis, confidence in the resulting distribution will be uncertain.

4. The user-interface appears to have many useful features. However, it is difficult to judge from the supplied description of the system how user-friendly the system will be. I would suggest that the system be tested with "real users" and modified based on feedback from the users.

5. Another issue of concern is the neglect of so-called episodic events. In some situations the effect of intermittent processes (e.g. rain) could lead to accumulation of chemicals . (especially semi-volatiles and non-volatiles) in the aquatic and terrestrial environment. For example, it is questionable wether accumulation in the soil environment, due to rain scavenging, can be adequately described by an. "equivalent" average rain scavenging process. Likewise, the impact of intermittent wind-resuspension processes may be important in-some areas.

6. Finally, the importance of unsteady-state versus steady-state analysis should be carefully considered. Most of the modules consider steady-state analysis. However, the time scales for chemical intermedia transport and accumulation within the various. compartments can be very different. Therefore, an analysis based on steady-state can be misleading in certain circumstances. Here, the use of simpler temporal multimedia models (see item 3)

might be useful to assess the deviation from steady-state over the time period over which exposure and risk are to be determined. Such an approach should be feasible given the flexibility and sophistication level of the HWIR software system.

I hope that the above comments will be useful to you in assessing the design of the HWIR system. Based on my review of the HWIR documents, it is apparent that the HWIR system is an enormous undertaking. It is a major progress towards integrated analysis. EPA should be commended for the effort to integrate various models developed by EPA and others into the HWIR system. The modular approach should allow for future revisions as new knowledge is developed and experience is gained with the HWIR system.

Please do not hesitate to call me (310-825-8766) should require clarification regarding my comments or further assistance.

Regards,.
c
aoT-O~

Yoram Cohen Professor Chemical Engineering and, Director Center for Environmental Risk Reduction

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December 3, 1998

Dr. Robert Swank
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Athens, GA 30605-2700

Dear Dr.. Swank:

Enclosed is my review of the "ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR)." I tried to keep my comments at a pretty high level - I'm not sure whether this is what you wanted, but it is where I thought I could make the most useful contribution.

I honestly don't remember when or to whom I agreed to do this review (I must be involved with too many committees), but I'm sure I did. In any case, I'm glad to help in this effort and I hope that some of my suggestions will be useful.

Best regards,

Mitchell J. Small
Professor

Review of
"ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR)"
by
Mitchell J Small
_____signed__12/3/98_____
Carnegie Mellon University
Pittsburgh, .PA 15213
December 1998

Background and Overview

In response to comments provided by the EPA. Science Advisory Board and members of the public; the EPA Office of Research and Development (ORD) and Office of Solid Waste (OSW) have jointly undertaken efforts to design a new multimedia chemical fate, transport, exposure and risk model, to serve as the basis for identifying leachate test concentration criteria for listing or delisting wastes as hazardous under the Resource Conservation and Recovery Act (RCRA). This review provides an assessment of the draft plan for this model development, as presented in the draft report, "ORD/OSW Integrated. Research and: Development Plan for the Hazardous Waste Identification Rule (HWIR)," dated October, 1998. This review was specifically charged with identifying how responsive the proposed modeling plan is to the comments received by EPA on a previous (i.e.,1995) version of the HWIR model, and the overall suitability of the modeling approach.

The major recommendations made by the SAB following review of the 1995 model included:

1. The HWIR model-should involve an integrated multimedia fate, transport and exposure approach which conserves mass and considers all relevant pathways;

2. A full and systematic evaluation and incorporation of uncertainty should be undertaken;

3. Criteria for ecological risk require reconsideration in light of data availability and limitations;

4. More detailed peer reviews of the individual elements of the proposed modeling approach are needed;

5. Substantial validation against actual laboratofy and field data are needed; and

6. The documentation requires reorganization for clarity and ease of use.

This review focuses upon issues 1,2,5 and 6; with some discussion of item 4. ORD/OSW review of item 3 is intended for future peer reviews.

In general, the report is responsive to the recommendations outlined above. A scientifically credible method for multimedia fate, transport and exposure assessment, which conserves mass and. considers relevant exposure pathways, has been proposed. However, as outlined below, I am not sure that this is necessarily the best approach that could be taken, particularly when I consider other activities at the Agency and the likelihood of success of the proposed effort. Concerning recommendation 2, state-of-theart methods are outlined for a systematic evaluation of uncertainty, with proper attention to the need to separate variability and uncertainty. This represents a significant step forward, though I am not sure that this step will be easy to either validate or communicate within the proposed modeling framework. This brings us to recommendations 5 (validation) and 6 (clarity and ease- of use), where I believe some additional effort is needed. I .address each of the principal. recommendations. of interest in: detail in the following sections. Following this,. 1, provide a. suggestion concerning-. a--major-need for further scientific study for future development of a more representative: and: effective modeling framework, involving multiple chemicals. Finally, I provide a few more specific comments on the draft report.

HWIR Approach to Multimedia Modeling

The proposed HWIR modeling framework utilizes linked, individual media models along groundwater, surface water, air and biota/food-chain pathways, insuring mass balance by allowing for source reduction over time as mass is transported away from the site by each of the individual pathways. This approach is similar to that utilized in the Battelle PNNL MEPAS modeling framework, and is one approach to multimedia modeling. It is an approach which follows logically from previous versions of the HWIR model, involving EPACMTP, etc., where a single model was used to predict the distribution of groundwater impacts at downgradient well receptors. The approach allows the previous groundwater models to be retained, with the addition of new models for the air and surface-water pathways. Furthermore, the other modules chosen (e.g., the ISCST3 model for the air pathway, EXAMSII for surface water, the AqFW model for bioaccumulation, etc.) appear to be at a sirhfar (and appropriate) level of complexity and capability for their respective tasks.

As noted above, the proposed linking of multiple models is not the only approach which could be utilized to assess multimedia fate, transport and exposure. An alternative approach involves the development of. a single, multimedia partitioning model which, while generally constrained to simpler representations along any individual pathway, has the advantages of 1) inherently conserving mass; and 2) being much simpler to implement and track. This second approach, based on the fugacity models of Mackay and coworkers and recently implemented in extensive modeling frameworks (including exposure and risk) such as CalTox, has been adopted by the EPA Office of Air Quality Planning and Standards (OAQPS) for their-proposed Total Risk Integrated Methodology ('TRIM, and the TRIM.FaTE Module) to evaluate multimedia effects of hazardous air pollutant emissions. (I have been exposed to this work through my service-on the SAB Advisory Committee reviewing their proposal.) Aside from the higher-level issue of

whether a single approach to multimedia modeling should be used for regulatory assessment and development throughout the Agency, for consistency, efficiency and synergy of effort, etc., which I shall assume is beyond the scope of my review, I do feel in a position to comment on- the likely utility and probability of success of the two different modeling approaches being adopted by OAQPS and OSW. Frankly, I believe that both -have set themselves with very difficult, albeit important challenges in their proposed multimedia modeling frameworks. Of the two, however, I believe that the single-model approach of TRIM.FaTE is more likely to yield success in terms of software development, implementation of the system, and. ease of. conveying appropriate ways to use the program and interpret results for users of the system. The challenges involved with linking 6-10 individual modules, compared to a single model which inherently conserves mass, are simply that much greater. Furthermore, I believe that, given the overall uncertainty in chemical properties and environmental inputs and processes, the more-highly aggregated type of output that one obtains from the single model (e.g., the overall distribution and partitioning of the chemical to various environmental/exposure compartments, focusing more on order-of-magnitude results) is sufficient for the regulatory purpose of the HWIR - separating out the most potentially dangerous materials from those that are clearly benign. I am not saying that the proposed, multiple-model approach cannot work - only that it will be much more difficult to, pull off (and sell, once completed).[1]

Full and Systematic Evaluation and Incorporation of Uncertainty

The approach to variability and. uncertainty analysis described in the report is appropriate and state-of-the-art: The use of a 2-dimensional, matrix-sampling methodology to evaluate the uncertainty in the variation of exposure and risk across a target population is very innovative. As noted below, however, I believe it will still be very difficult for most users of the system to follow much of the explanation provided in the report. The single example referred to on page 43 is a good start, but more will be needed using actual input for a particular chemical being considered for a particular waste-management unit.

Validation

The issue of validation remains a thorny one in this application, since the principal predictions of the model will be hypothetical exposures and risks. The current report relies primarily. on code validation of the overall model against the individual module codes upon which it is based, and previous or ongoing validation of the individual module codes in their respective field or laboratory test applications. I think more should be done for the overall model.

[1] I do note that there are now workshops being given by PNNL on MEPAS, GENII and FRAMES, so perhaps the development of the linked, multi-model system for health risk assessment is further along than I have assumed (and is apparent from the draft report). If so, the report should give-specific examples of current analyses that can be done with FRAMES. However, even if this is the case, I still believe that in the long run, the type of uncertainty analyses. and general insights that are important for multimedia fate, transport and exposure are easier to obtain with a single, compartmental model of the type, being developed for TRIM-FaTE.

First, I think the model should be evaluated for how it partitions, chemicals into the target environmental media, including air, water, soil, and biota. Does the model get the order-of-magnitude distribution correct for different chemicals with varying vapor pressures, water solubility and octanol-water partition coefficients? This is the type of comparison (to observed data, for general distributions of chemicals in the environment) that is typically undertaken for the environmental compartmental models discussed above, and should be undertaken here as well.

Second, I think the model should focus more on intermediate outputs along the fate, transport. and exposure route. This might again allow for rough comparison to broadscale information on chemical occurrence in. different media. For example, are: there certain chemicals in certain types of waste which are predicted to result in frequent values of concentrations in .groundwater above, detection limit, or above drinking water standards? . .. . and are these same chemicals found more often in national or state databases? 1' believe that this might also help identify an output that will be of interest to regulators (and the regulated community). That is, if the model predicts negligible-risks; but at the same time predicts frequent concentrations above current detection limits or ambient standards, there may still be reason for concern (e.g., disposal of the waste may lead to a future need to clean up the site, even if negligible health risks are now predicted).

Finally, is there any way to conduct some type of post-audit on the performance of the previous HWIR modeling framework? Are there any wastes that were permitted under the previous rule that we now believe (e.g., due to occurrence in groundwater) should have been listed as hazardous and inappropriate for Subtitle D disposal? If so, which ones and why? There has been a significant amount of Subtitle D monitoring data collected since RCRA, was initiated. Has it ever been put together and analyzed in a coherent manner? Perhaps states keep records of chemical hits or violations? This is admittedly a big job, but one that should be undertaken for ultimate evaluation of the validity and safety of any nationwide modeling estimate.

Document Clarity and Ease of Use

The proposed modeling framework, and the way it will be used with Monte Carlo evaluation, is neither simple nor straightforward. I do not envy the task of trying to make it accessible to a general audience (or even a technically skilled audience). While a reasonable start has been made, the current document is still too difficult to navigate and follow, and further steps can be taken to simplify the presentation. First, break up Chapter 3 into a number of individual chapters. This will help compartmentalize the presentation more and allow the reader to better understand the big picture and how the individual components fit together. Second, move the figures and tables up into the text, rather than grouping them at the, back (perhaps this was only done in this case, because this is a draft). Finally, present the equations first using a simpler notation with fewer subscripts.2 Even if this is not as rigorous, -if the reader can't follow the big idea, they won't get the details. Perhaps you can present a more formal derivation in an appendix.

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[1] I must admit that Equation 5 and the sentence preceding Equation 5 on page 26 provide one of the most dubious examples of complex notation/explanation that Lhave ever seen. I did-think of a good way to

Future Work: Multiple Chemicals

With all the work that has now gone into making the HWIR framework multimedia and probabilistic, it seems that the next "frontier" demanding attention is the consideration of wastes which leach multiple chemicals. Just because each individual chemical is safe, does not mean that the overall risk is negligible. Even ignoring possible interactive effects among chemicals in the environment (e.g., cosolubilization), it seems that there should be at least the option of adding risks from multiple chemicals generated by a waste.

Specific Comments .

l. Bottom of page 31, top of page 32`. If "values other than unity" are assigned, to WR(fgh)"to reflect the relative importance of the- species", then the- user has introduced a.subjective, "values" element into the analysis,. whereas the rest of the model deals solely with "scientific" -quantities. I would be very careful with this, and perhaps remove this option from the model.

2. Item 1 on page 39: It seems to me that the "probability subsample of 200 WMU facilities" from the 1986 survey should be updated. A lot has happened since 1986.
Perhaps this would provide the opportunity to explore the availability of monitoring data for specific chemicals at sites that are surveyed in a new sample?

3. In Appendix A, some of the results for the normal model with normally distributed uncertainty in the mean can be derived analytically, without simulation. This would provide a further opportunity to validate (and illustrate) how the simulation method works. Also, be careful with Figures such as A.1 and A.2, where some of the plotted lines (apparently in light colors in the original) have disappeared in the xerox copies.

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remember it, however. PRwO;j,T stands for the pathway risk "before getting hljackl'". (The sentence beginning "More formally, let..." in the middle of page 31 gets second prize.)

Paul F.. Deisler, Jr., Ph.D.,
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Phone and FAX., (512) 480-9810

December 15, 1:998

Robert R. Swank, Ph:D., Director of Research,
United States Environmental Protection Agency,
National Exposure Research Laboratory,
960 College Station Road,.
Athens, GA 30605-2700

Dear Dr. Swank:

Here is my-review of the report, "ORD/OSW Integrated Research And Development Plan For The Hazardous Waste Identification Rule" (HWIR), dated October, 1998 which you requested. I am sending it by Express Mail rather than by FAX because I am enclosing a paper which may explain one of my remarks.

I hope this review is of assistance to you in completing the major task of finalizing the monumental HWIR99. I have, as you requested, reported only what I found to be the major items needing clarification or reworking. I have not searched, with a fine toothed comb, for small matters.

If-you have any questions of me, please let me know.. I will be gone on another long trip, completely out of pocket while traveling in the southern portions of South America, from about January 5 through February 7, 1999.

Sincerely,

Signed: Paul F. Deisler, Jr.

Received DEC 1 9 1998

Comments On "ORD/OBW IntegrstedResearch And Development Plan For
The Hazardous Waste Identification Rule (HWIR)",
Dated October. 1998

GENERAL COMMENTS..

The current report is incomparably better than the original HWIR95 report. It is apparent not only that the criticisms leveled at that earlier report have been carefully considered but that real, thoughtful, expert effort has gone into the preparation of the present report.

Some general and specific criticisms are brought forth in this review further on.. When these are carefully considered aid responded to in a final report .I believe a fine document will have been produced which-will provide the basis for going ahead to do the further research to test, develop and prove the HWIR methodology so as to ready it for use.

In the next section of this review comments on specific items are made. These mainly occur in the early parts of Section 3-0 and earlier where questions, some serious, are raised as to the validity of certain key equations, as to the clarity of definitions, and as to the clarity of methods for assessing the risks which are to be compared to target risks (and what these are). Subsections dealing with the modules and later material were clearly written, the equations appeared to be well derived and presented, the programs were clear and worthy of pursuit, and no obvious problems were found. Other reviewers with particular expertise may find problems in these sections but I did not.

In the descriptions of the modules in Section 3.0 I found the layout of the subsections for each module to be very helpful; particularly useful were the subsubsections setting forth the criticisms of HWIR95 pertinent to the module as a context for the rest of the subsection and the subsubsections on limitations.. These latter subsubsections not only provide necessary caveats but they also suggest areas for further research.

I was satisfied that every reasonable means is being used to validate that which can be validated with existing data as well as to validate portions of the model against more complete models (e.g., see page 113). I would encourage further work along these lines wherever it can be done.. Use'of the HWIR in specific cases, down time, will provide further opportunities for validation and correction (where necessary).

Finally there are two further general observations:

(1) The SAB's Integrated Risk Project report on Integrated Environmental Decision-Making (IED) is nearing completion. When

available, I would recommend examining it and the HWIR model to see where the two can come together. The HWIR does address the integration of risks in many respects but it does not address the full IED cycle of integration. I believe that addressing the full IED cycle will significantly improve the HWIR and that it is worth pursuing 'this- avenue.

(2) I do not know to what extent the HWIR will actually be used for delisting hazardous wastes. With the necessary conservatisms already built into the component parts of the model it is possible that exit values so stringent will emerge that few uses of this method will be found. - This is not a conclusion but merely a statement of my own concern, well in advance ,of seeing results of any calculations.. I hope I am wrong since the basic idea of having the HWIR is commendable-

However, even -if I am right I believe the effort being expended in. developing the HWIR is worthwhile: it stands as a major attempt to do in this field what is increasingly obviously needed elsewhere, namely, to address multiple risks to multiple receptors from multiple contaminants arriving at and being taken into those receptors via multiple, simultaneous. pathways and multiple routes. Whatever is found to work or not to work in this effort will have direct application to other complex situations. So, even if its total value were to be primarily as a means. of researching this type of problem, this effort will have great value.

Here are the specific comments referred to above.

SPECIFIC COMMENTS.

0 EXECUTIVE SUMMARY

o Page viii, 1st paragraph.

Although defined later, it might be well to define "exit levels" here where first used for the convenience of the reader..

0 Section 2.0.

o Page 19 , top of the page.

The sentence beginning "For ORD the long-term vision..." can be controversial. The thought appears to be included or inferred that human and ecological risks can somehow be "merged" and that the science and modeling assessments can be "merged". Is this sentence necessary? If it is, then it would be a good idea to expand on it to make clear what is intended. The sciences behind human health and ecological risk assessment now seem to be miles apart; what is meant by "merging" these risks? Indeed, human cancer risk assessment is the only one that is actually risk-based;

human non-cancer adverse effects risks are not actually assessed in defining RfDs; ecological risk assessment touches on risk only occasionally when it takes account of the likelihood of exposure -for the most part it is "consequence" assessment; and the "risk taker" is different for human health and ecological risks (humans and ecosystems (at some scale)) making the scientific merging of risks still more difficult. The "merging" of human health and ecological comparative or other types of risks are now generally understood to be not possible on the basis of science, alone (except in certain well-defined situations*), without including human values or preferences. I think this sentence may, as currently written, be misinterpreted in too many ways, diverting attention from your chief purpose.

0 Section 3.0.

o Page 22, 2nd key decision/ assumption from the top of the page.

Risks from individual chemicals are summed to yield aggregate risks (e.g.-, equation (8)). It would be worthwhile, here, to distinguish between aggregate risks and cumulative risks so the reader won't have to dig these definitions out for him- or herself ..

o Page 22, 7th key decision/ assumption from the top of the page.

If WMUs are confined within an area such that their 2 km limits overlap (or, to be more rigorous, even if they are more distantly spaced), why not consider all at the same time and not just one at a time? It would seem possible, using expressions of the form of equations (8) or (9), to make such aggregate calculations from the individual WMU calculations. The existence of nearby WMUs would seem relevant to the actual curtailment of risk to receptors in setting "site-specific" exit concentrations.. Perhaps I have misunderstood the statement; in which case, it needs to be clarified.

o Page 22, 8th key decision/ assumption from the top. of the -page.

See comments on the "7th decision/assumption...", above; they would seem to apply here, too.

o Page 2.3, 3rd key decision/ assumption from the top of the page.

What about the case in which dermal data are or become available? It would seem reasonable to include such information in the analysis, when it is available, unless it can be shown that dermal absorption plays little role in generating risk.

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* See enclosed paper.

o Page 23, 6th key decision/assumption from the top of the page; equation (1).

(a) The terms in all equations need to be given more complete definitions (see (b), below), and sometimes different ones. Also, the units for each term or variable should be given; this makes it possible to ensure consistency in the use of units throughout any calculation and, for that matter, for the reader or user to check all equations for dimensional consistency (any equation not dimensionally consistent has something wrong with it and should be checked).

(b) Equation (1), is correct as written with the units of Qm(t) being mass per unit time (m/t). The definition of Qm(t) for t < to life gives some difficulty, however. The equation is repeated here for convenience:

$$Qm(t) = d\,(C_W \varrho_{HW} V_{Win} - CwoutPWoutVWout) / dt \qquad (A)$$

VWin and VWout are defined on page 24 as waste volumes entering. (or removed from) the WMU t time t (emphasis added). As stated it appears that the finite volumes are added to or taken from the WMU in single lumps t time t.. If so, the indicated derivative is not continuous; the derivatives of VWin and Vwout can have only three values: 0, +w or -w. Physically, the equation as written is extremely restricted and will not apply to volumes added over a time increment et, intermittently, or continuously with t. Moreover, since the C-values and p-values corresponding to. VWin and VWQut may also be . functions of time, equation (A) is incorrect as written. This is best illustrated by deriving the correct relationship by starting from first principles, as follows.

Instead of the, V-values as defined on page 24, use increments of volumes of waste added or removed, ΔVWin and ΔVWout, in a time interval At which stretches between t.and t+et. Then instead of equation (A) one can write the material balance for contaminant in the waste, assuming that gross additions or removals of volumes of waste are the only mechanisms by which contaminant is added or subtracted from the WMU (see (c), below), as follows:

$$AM = {}_{CW}(t,t+\Delta t)p_{HW}(t,t+\Delta.t)\Delta V_{Win} -$$

$$- C_{Wout}(t,t+\Delta t)p_{Wout}(t,+\Delta t)\Delta V_{Wout} \qquad (B)$$

where ΔM is the incremental change in the mass of contaminant over time Δt and the terms (t,t+Δt) indicate that the C-values and p-values are for the incremental volumes of waste added or removed in the time interval et. Dividing both sides of equation (B) by at and taking the limits as et approaches 0 (or, as t+Δt approaches t), equation (B) becomes:

$$dM / dt = Qm(t) = C_W(t)\, p_{HW}(t)\, dV_{win}/dt - C_{Wout}(t)\, p_{Wout}(t)\, dV_{Wout}/dt \qquad (C)$$

which is very different both physically and mathematically from equation ' (A) ; . differentiation of equation (A) , for example, with time-dependent C- and p-values, gives six terms, four of which are physically meaningless for the material balance. -Also, most importantly, the physical meaning of the V-values is different between equations (A) and (C): in equation (A) they are finite volumes of waste added or removed instantaneously at time t; in equation (C),. they are the totals of the volumes added from time 0 to time t and their derivatives are the time-dependent rates of addition -or removal of waste volumes.- Equation (C) holds for additions or removals of waste volumes which are instantaneous, regularly incremental, irregularly incremental, or continuous (or combinations 'of these). Equation (C) is a general, correct equation under the assumptions. given and should therefore ,.replace equation (A).- ,

(c) Omitted from these derivations and those in the report are terms for the addition or removal of contaminant-by mechanisms other than gross additions or removals of volumes of waste to or from the WMU.. Three terms not included are: (1) additions via physical pathways (e.g., blown dust, cinders, etc ....) from other, nearby sources; (2) removals via the pathways via which contaminant leaves the WMU (volatilization, leaching, etc...) already defined for the linking of the WMU and the receptors (and the rest of the environment); and (3) via the conversion of contaminant within the WMU into other chemical forms (as is now assumed to occur in the environment in the model in the report). Terms (1) will in most cases be trivial but should be kept in mind so that they will not be forgotten in those cases where they might matter.. Terms (.2) may or may not be trivial: for a WMU which is a simple waste pile to which no new waste .is added or volumes subtracted, they may be the only term to appear in the contaminant material balance rate equation; they, too, should be checked for materiality by summing the rates of removal of contaminant via the pathways described in the report to see whether omitting them from the main calculation is reasonable or not. And terms (3) may prove to be important in any number of cases: WMUs are not necessarily inert facilities; reactions can proceed within them. This last item may require additional research to see how important these terms are or to learn how to detect whether losses of contaminant are occurring, in a specific instance, through chemical conversion.

The possible existence of these additional material rate terms should be acknowledged in the report and the need for establishing their triviality or materiality as well.

o Page 24, equation (4)..

The term on the left-hand side and the first and last terms on the. right-hand side of the equation are exactly correct (if the Rip-values are constant);. the term Qm(t), however, needs to be changed for, as it now stands, it is only approximately correct (and it becomes more incorrect as of increases). The value of Qm(t) that should be indicated here is the average value across the interval At which begins at time t. A possible way to indicate this is to substitute Qm,av(t,At) for Qm(t) which shows that the average of Qm(t) is a function of both t and At. These points need to 'be considered and clarified in the text -

0 Page . 24,, equation (:2) ..

The definition of Qn (t) in. terms of VWin and YwpuV suffers from the same definitional problems as did the definition. of Qm(t), above. A fuller description of the physical model empoyed might help here, too.

o Page 24., equation (4).

This equation is not exact as written. The term Qm(t) needs to be replaced by Qm , av (t, t+et) , the average of Qm (t) over the interval At to be exact. The larger At is in the equation as originally written, the more inexact it will be..

NOTE: The material balance and other equations presented in the rest of the report appear to be soundly conceived and derived..

o Page 25,. 2nd key decision/ assumption from the bottom of the page and,. also, Ohk on page 26.

Using 1/RfD as,a measure of risk needs to have some discussion especially since no effort is made to measure risk insetting RfDs (unlike cancer, where the extrapolations., however questionable, at least have the form of probability of adverse effect). Since RfDs are probably the only readily-accessible quantities now. available for setting safety limits for non-carcinogens, they are about all that can be used:. However, it should be noted that the fact that the RfD of one substance is greater than that of another does not necessarily mean that the risks at dose-levels above the RfD are less for the first substance; this depends on the slopes of the response curves for doses above the RfD. Moreover, at doses at or below the RfD the risks are supposed to be zero or, at least, "insignificant" for both substances. Thus, the RfDs do not measure risk.

If anything, the RfDs reflect, grossly, the differences in sensitivity (not risk) to different agents, a higher RfD indicating a lower sensitivity.. The acknowledgment of the true nature of the

RfD and that it is a very crude (but very useful) tool used only for lack of another, better one in regulation needs to be made explicit as does the idea that better tools are needed and should be used when available. The very real value of using RfDs for regulatory or risk management purposes might be mentioned.

The use of the unit risk for carcinogens and the reciprocal of the RfD for non-carcinogens does put the two measures into the same units of measurement; however, it should be pointed out that while one offers a sort of measure of risk the other offers a measure of sensitivity, not risk: they do not mean the same thing nor do they measure the same thing.. -

o Page. 26 t last line..

.How At differs from dfgh needs to be better explained for the reader or user-

0 Page 30,. Contact Medium Risk.

More discussion is needed on how the sums of risks are made... Are they for the-same contaminant for the same end-point, assuming. independence of action? This whole matter of summing and the
allied matter of aggregating risks needs better fleshing out.

o Page 3'1.

The definitions of the RINDS and their use is a good idea.

o Page 32.

The way target risks are set or defined needs more explanation to ensure clarity for readers and users.

o Page 35, paragraph below the one containing equation (24).

Is 10-6 a limiting risk for one carcinogen. arriving at the receptor via one pathway and route, or via all pathways and routes, or is it for the total risk caused by all carcinogens which arrive by all the different pathways and routes? The method of combination of effects via different routes (the same or all carcinogens) needs to be explained since they are not all equally effective in inducing adverse effects.

For non-carcinogens is it assumed that Hazard Index (HI) < 1 yields adequate protection? How is this HI arrived at, if this is what is done? How are different modes of action accounted for? What assumptions are made? How are non-carcinogenic and carcinogenic risks factored together to,produce human health risk? All of this needs to be clarified at some point in the report. It may be desirable to indicate research that needs to be done to achieve better ways of estimating the combined risks that receptors

may face from more than 'one contaminant arriving by several pathways and routes. (I am glad that the need to address human and ecological risks separately is acknowledged further down this page; and how they are treated from a regulatory standpoint; the method is reasonable good). But the combination of human risks of different kinds, etc .... as described above, is not clear.