May 22, 1996

EPA-SAB-EC-96-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Review of a Methodology for Establishing Human Health and Ecologically Based Exit Criteria for the Hazardous Waste Identification Rule (HWIR)

Dear Ms. Browner:

At the request of the Office of Solid Waste (OSW), the Executive Committee of the Science Advisory Board established an ad hoc Subcommittee to review the draft document, *Development of Human Health Based and Ecologically Based Exit Criteria for the Hazardous Waste Identification Protect* (dated March 3, 1995), prepared to support the Hazardous Waste Identification Rule (HWIR). The intent of HWIR is to establish human health-based or/and ecologically based concentrations (exit criteria) for constituents in wastes below which listed hazardous wastes would be reclassified and become delisted and nonhazardous wastes under the Resource Conservation and Recovery Act (RCRA). The draft HWIR document describes a proposed methodology for calculating exit concentrations of 192 chemicals for humans and approximately 50 chemicals for ecological receptors, based on a consideration of five types of waste management units (sources), numerous release, transport, and exposure pathways, and biological effects information.

The HWIR Subcommittee held two public meetings in Washington, D.C. (on April 26-27 and May 31-June 1, 1995) to hear presentations from the Agency, its contractors, and members of the public before drafting its recommendations on the proposed methodology. The Subcommittee made every effort to address the 17 specific questions in the Charge to the Subcommittee; these responses are summarized in Appendix A of the report. Our primary focus, however, was on the larger questions of the scientific defensibility of the overall approach taken for calculating exit criteria.

The proposed rule and the supporting risk analysis have received broad attention from many quarters, both because of the potential to improve the regulation of wastes on a risk basis

and because of the potential for groundbreaking use of true multi-pathway exposure analyses in assessing risk. The Subcommittee agrees that these are important scientific goals. While recognizing the considerable effort that has gone into developing the proposed methodology, however, the Subcommittee has concluded that the methodology at present lacks the scientific defensibility for its intended regulatory use. The Subcommittee believes, however, that an adequate scientific basis might be developed to support a national methodology either for deriving a single set of national-level exit criteria or for establishing several sets of sub-national criteria using parameterization based on more case-specific information. Which approach to use is a policy decision. We emphasize that the scientific bases for either approach, however, remain to be developed.

While our report contains a number of specific recommendations for revising and validating the proposed methodology, we would like to highlight the following general concerns:

1) **Multi-Pathway Risk Assessment**: The concept of assessing total, integrated exposure to a chemical by concurrently considering all relevant exposure pathways is a good one, and development of a methodology to do this would be a substantial constibution to the risk assessment field. However, despite the use of the term multi-pathway analyses in the HWIR document, the proposed method of calculating exit criteria is actually based on individually calculating each of many exposure pathways. This approach fails to maintain mass balance and may lead to significant, but unknown, errors in the exposure estimates. We recommend, therefore, that this approach be abandoned in favor of true multi-pathway calculations in which a receptor receives contaminants from a source via all pathways concurrently. Dr. Paul Deisler, a member of the Subcommittee, has prepared a paper (sent to the Agency under separate cover) suggesting a method for making true, simultaneous, multi-pathway calculations of exit values. Although the Subcommittee has not peer-reviewed the paper, the Agency may wish to contact Dr. Deisler directly for more information. In addition, the report mentions several available modeling packages that should be evaluated for this purpose.

2) **Validation and Peer Review**: The Subcommittee is seriously concerned about the level of scientific input and the degree of professional scientific judgment that have been incorporated into the methodology development. The Subcommittee strongly recommends that OSW actively seek the substantive participation, input, and peer review of Agency scientists, and outside peer review groups as necessary, to evaluate the specific elements (e.g., pathway equations) of the proposed methodology in much greater detail than the Subcommittee is able to provide. In addition, the total construct has not been validated against actual data derived from laboratory or field experiments or observations. Substantial validation of the overall methodology and its components is essential to developing any degree of confidence in the scientific defensibility of the resulting exit criteria.

3) **Ecologically Based Exit Criteria**: The Subcommittee applauds the Agency's effort

explicitly to calculate exit criteria based on ecological risk. The ecological analysis in the HWIR document is fundamentally flawed, however, because lack of data has been implicitly equated with lack of adverse ecological effect throughout the analysis. As a result, only a handful of well-studied chemicals have actually received a scientifically credible review. The Subcommittee recommends, therefore, that the Agency discard the proposed screening procedure for selecting the initial subset of chemicals for ecological analysis and instead require that a minimum dataset be satisfied before ecologically based exit criteria are calculated. For those chemicals for which the minimum dataset cannot be satisfied, the Agency should indicate clearly that the exit criteria are based solely on human health considerations. The exit criteria should be re-evaluated, however, when and if additional data on ecological effects become available.

4) **Supporting Documentation**: The HWIR document should be reorganized and rewritten for both clarity and ease of use. Despite careful study of the documentation provided by the Agency and extensive discussions with Agency staff and its contractors during four days of public meetings, the Subcommittee found the HWIR methodology for calculating exit criteria to be difficult to understand. Significantly improved clarity is required before scientific defensibility of the approach can be determined.

In summary, the Subcommittee finds that the proposed methodology has a number of critical flaws, but that a scientifically defensible national methodology could be developed for the HWIR. To do so, however, will require more than simply correcting deficiencies in the current proposal. Thus, the Subcommittee recommends that the next version of the methodology, which has been modified to correct the deficiencies noted by the Subcommittee, be subjected to thorough scientific review before exit criteria are implemented.

We estimate that a concerted effort to correct the major flaws in the methodology (including development of true multi-pathway calculations that account for mass balance, validation against actual data, systematic evaluation of parameters and uncertainties, calculation of ecologically based exit criteria for chemicals for which a minimum dataset is available, and rewriting the documentation for clarity and transparency) could be completed within a relatively short time period, perhaps one or two years, if a concerted effort is instituted with the appropriate scientific involvement. Such an effort has the potential to improve greatly not only the scientific defensibility of the HWIR, but other future multi-pathways analyses as well.

We hope these comments will be helpful to you as you make decisions about the nature and extent of the risk assessment that will support the Agency's proposed and final exit criteria under HWIR. We suggest also that a consultation with the Science Advisory Board during the conceptual phase of the project might have raised some of the issues noted in our report at a time when significant resources had not yet been invested in the risk analysis. In that spirit, we would

be willing to engage in a consultation with the Agency to discuss issues surrounding the development of a revised methodology, if you feel that would be helpful. We look forward to your response to the issues raised in the attached report.

Sincerely,

Genevieve M. Matanoski

Dr. Genevieve M. Matanoski, Chair
Executive Committee

Mark A. Harwell

Dr. Mark A. Harwell, Co-Chair
HWIR Subcommittee

Dr. Ishwar P. Murarka, Co-Chair
HWIR Subcommittee

U.S. Environmental Protection Agency

NOTICE

This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

ABSTRACT

At the request of the Office of Solid Waste (OSW), the Executive Committee of the Science Advisory Board established an ad hoc Subcommittee to review the draft document, *Development of Human Health Based and Ecologically Based Exit Criteria for the Hazardous Waste Identification Project* (dated March 3, 1995), prepared to support the Hazardous Waste Identification Rule (HWIR). The intent of HWIR is to establish human health-based and ecologically based waste constituent concentrations (exit criteria) for constituents in wastes below which listed hazardous wastes would be reclassified and become delisted and nonhazardous wastes under the Resource Conservation and Recovery Act (RCRA). The draft HWIR document describes a proposed methodology for calculating exit concentrations of 192 chemicals for humans and approximately 50 chemicals for ecological receptors, based on a consideration of five types of waste management units (sources), numerous release, transport and exposure pathways, and biological effects information.

The Subcommittee concluded that the proposed methodology has a number of critical flaws that must be corrected in order to develop scientifically defensible exit criteria. The Subcommittee recommended that the proposed method of calculating exit criteria, which considers each exposure pathway individually, be abandoned in favor of true multi-pathway calculations in which a receptor receives contaminants from a source via all pathways concurrently. In addition, the Subcommittee urged the Agency to: conduct substantial validation and peer review of the overall methodology; provide a systematic examination of parameters and uncertainties; calculate ecologically based exit criteria for those chemicals for which a minimum dataset is available; and rewrite the documentation for clarity and transparency. The Subcommittee estimated that a concerted effort to correct the major flaws in the methodology could be completed within a relatively short time, perhaps a year or two, if a concerted effort is instituted with the appropriate scientific involvement.

KEY WORDS: multi-pathway risk assessment, RCRA, human health risk, ecological risk

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1. EXECUTIVE SUMMARY

At the request of the Office of Solid Waste (OSW), the Executive Committee of the Science Advisory Board established an ad hoc Subcommittee to review the draft document, *Development of Human Health Based and Ecologically Based Exit Criteria for the Hazardous Waste Identification Project* (dated March 3, 1995), prepared to support the Hazardous Waste Identification Rule (HWIR). The intent of HWIR is to establish human health-based and ecologically based waste constituent concentrations (exit criteria) for constituents in wastes below which listed hazardous wastes would be reclassified and become delisted and nonhazardous wastes under the Resource Conservation and Recovery Act (RCRA). The draft document (hereafter referred to as the HWIR document) describes a proposed methodology for calculating exit concentrations of 192 chemicals for humans and approximately 50 chemicals for ecological receptors, based on a consideration of five types of waste management units (sources), numerous release, transport and exposure pathways, and biological effects information.

The HWIR Subcommittee held public meetings in Washington, D.C. on April 26-27 and May 31-June 1, 1995 to hear presentations from the Agency, its contractors, and members of the public regarding the proposed methodology for calculating exit criteria. In addition to reviewing the proposed methodology, the Subcommittee requested and reviewed sample calculations for two compounds in order to evaluate the implementation of the total methodology. The Charge to the Subcommittee (Appendix A) contains 17 specific questions about the proposed methodology. The Subcommittee discussed the charge and agreed to focus primarily on the larger issues, in recognition that a detailed peer-review of each of the individual equations, parameters, or assumptions was beyond the resources available to the panel. However, summary responses to the charge questions are included in Appendix A, along with references to specific sections of this report.

While recognizing the considerable effort that has gone into developing the proposed methodology, the Subcommittee has concluded that the methodology at present lacks the scientific defensibility for its intended regulatory use. The Subcommittee believes, however, that an adequate scientific basis might be developed to support a national methodology either for deriving a single set of national-level exit criteria or for establishing several sets of sub-national criteria using parameterization based on more case-specific information. The selection of a national vs. sub-national approach, while having implications for the variability and applicability of the resulting exit values, is a policy decision for the Agency. Regardless of the spatial scale ultimately chosen by the Agency, the Subcommittee has the following specific recommendations for the development and validation of a national methodology.

a) The Subcommittee recommends that the proposed method of calculating exit criteria, which considers each exposure pathway individually, be abandoned in favor of true multi-pathway calculations in which a receptor receives contaminants from a source via all pathways connecting the source and receptor concurrently, is exposed to those contaminants via different routes (lung, gut, skin, leaf, root, and

so forth, depending on the receptor), and the dose corresponding to each route is accounted for in an integrated way so that the overall, total dose is acceptable. The proposed approach of individually calculating each of many exposure pathways fails to maintain mass balance and may lead to significant, but unknown, errors in the exposure estimates.

b) The Agency should conduct substantial validation of the overall methodology and of its individual elements, against actual data derived from laboratory or field experiments or observations, prior to implementation of the methodology; this has not been done and is essential to developing any degree of confidence in the methodology.

c) The Agency should conduct a systematic examination of parameters to ensure a consistent and uniform application of the proposed approach to selecting high-end or central-tendency values. Further, the full suite of uncertainties, e.g., the distribution of parameter values for all parameters in the equations, needs to be addressed for the final methodology.

d) The ecological analysis in the HWIR document is fundamentally flawed because lack of data has been implicitly equated with lack of adverse ecological effect throughout the analysis. As a result, only a handful of well-studied chemicals have actually received a scientifically credible review. The Subcommittee recommends, therefore, that the Agency discard the proposed screening procedure for selecting the initial subset of chemicals for ecological analysis and instead require that a minimum dataset be satisfied before ecologically based exit criteria are calculated. For those chemicals for which the minimum dataset cannot be satisfied, the Agency should clearly indicate that the exit criteria are based solely on human health considerations. The exit criteria should be re-evaluated, however, when and if additional data on ecological effects become available.

e) The Subcommittee strongly recommends that OSW actively seek the substantive participation, input, and peer review of Agency scientists, and outside peer review groups as necessary, to evaluate the individual elements of the proposed methodology in much greater detail than the Subcommittee is able to provide. The Subcommittee is seriously concerned about the level of scientific input and the degree of professional scientific judgment that have been incorporated into the methodology development. While it has been the goal of the Subcommittee to provide a peer review of the overall methodology and larger issues, the Subcommittee identified a number of important omissions and errors in the methodology.

f) The HWIR document should be reorganized and rewritten for both clarity and ease of use. Despite careful study of the documentation provided by the Agency and extensive discussions with Agency staff and its contractors during four days of public meetings, the Subcommittee found the HWIR methodology for calculating exit criteria to be difficult to understand. Significantly improved clarity is required before scientific defensibility of the approach can be determined.

In summary, the Subcommittee finds that the proposed methodology has a number of critical flaws, but that a scientifically defensible national methodology could be developed for the HWIR. To do so, however, will require more than simply "correcting" deficiencies in the current proposal. Thus, the Subcommittee recommends that thenext version of the methodology, that has been modified to correct the deficiencies noted by the Subcommittee, be subjected to thorough scientific review before exit criteria are implemented. We estimate that a concerted effort to correct the major flaws in the methodology could be completed within a relatively short time period, perhaps one or two years, if a concerted effort is instituted with the appropriate scientific involvement.

2. INTRODUCTION

At the request of the Office of Solid Waste (OSW), the Executive Committee of the Science Advisory Board established an ad hoc Subcommittee to review the draft document, *Development of Human Health Based and Ecologically Based Exit Criteria for the Hazardous Waste Identification Project* (dated March 3, 1995), prepared to support the Hazardous Waste Identification Rule (HWIR). The intent of HWIR is to establish human health-based and ecologically based waste constituent concentrations (exit criteria) for constituents in wastes below which listed hazardous wastes would be reclassified and become delisted and nonhazardous wastes under the Resource Conservation and Recovery Act (RCRA). The draft document (hereafter referred to as the HWIR document) describes a proposed methodology for calculating exit concentrations of 192 chemicals for humans and approximately 50 chemicals for ecological receptors, based on a consideration of five types of waste management units (sources), numerous release, transport and exposure pathways, and biological effects information.

The HWIR Subcommittee held two public meetings in Washington, D.C. to hear presentations from the Agency, its contractors, and members of the public regarding the proposed methodology for calculating exit criteria. The Charge to the Subcommittee (Appendix A) contains 17 specific questions about the proposed methodology. The Subcommittee discussed the charge and agreed to focus primarily on the larger issues, in recognition that a detailed peer-review of each of the individual equations, parameters, or assumptions was beyond the resources available to the panel. At the conclusion of the first meeting, held April 26-27, 1995, the Subcommittee requested that the Agency prepare sample calculations for hexachlorobenzene and cadmium to illustrate implementation of the total methodology. The Subcommittee discussed the sample calculations and additional methodological issues at a second meeting (held May 31-June 1, 1995).

Ideally, in order to establish the scientific credibility of the HWIR risk analysis, a number of questions should be evaluated:

a) Whether the individual equations representing each path-segment are as good as they can be and are used correctly, in context;

b) Whether these equations, linked together to form the different path algorithms, are applied consistently so as truly to take into account multiple pathways between source(s) and receptor(s) and mass balances;

c) Whether there is a clear, consistent, reproducible, and scientifically defensible method for deciding what the "central" and "high end" parameter values are; and

d) Whether the parameter values chosen ("central" or "high end") lead to a “reasonably conservative” and nationally applicable set of exit values.

While raising these issues, the Subcommittee has also suggested some possible approaches to improving the HWIR document.

The Subcommittee's examination of the two sample calculations was an attempt to "spot check" the equations, assumptions, and parameter values. However, the Subcommittee clearly was not able to evaluate all of the details of the proposed methodology. **Therefore, the Agency should not conclude that the Subcommittee has reached a peer review judgment on the scientific validity of any specific exit concentration that may be generated with the final methodology**. Rather, the Subcommittee efforts focused on the scientific merit of the overall approach.

3. GENERAL COMMENTS

The Subcommittee recognizes that considerable effort has gone into the development of the methodology as presented, and we appreciate the complexity of the tasks undertaken by OSW. We also recognize the regulatory, data, and resource constraints imposed on the development of the methodology, and we commend the OSW team for their energy and willingness to address such a complex activity. Nevertheless, the Subcommittee has concluded that the proposed methodology at present lacks the scientific defensibility for its intended regulatory use. In recognition of the court-ordered schedule for the Agency to develop a draft and final rule, the Subcommittee's recommendations focus on changes that should be addressed, in the near-term, prior to application of the methodology.

The Subcommittee has distilled the following issues (discussed more fully in subsequent sections of the report) for the Agency to resolve before the methodology can be deemed scientifically valid for use:

a) **Development of a true multi-pathway analytical approach**: The proposed approach of individually calculating each of many exposure pathways fails to maintain mass balance and may lead to significant, but unknown, errors in the exposure estimates. How far the results would diverge from those of a true multi-pathway approach cannot be determined without actually going through a representative number of multi-pathway calculations. However, a true multi-pathway analytical approach could be implemented using modified pathway equations from the HWIR document and a revised method of calculation designed to integrate exposures occurring via the various pathways, as discussed in this report. The scientific validity of the overall methodology would be significantly enhanced by the use of a true multi-pathway approach. Also, a true multi-pathway approach must take account of the several routes by which contaminants, when delivered to a receptor, are absorbed by the receptor, and the dose pertaining to each route must be taken into account in determining an acceptable total dose delivered to the receptor.

b) **Mass balance**: The proposed approach in the HWIR document violates a fundamental scientific principle, i.e., the conservation of mass. The Subcommittee concludes that the absence of a mass-balance approach in the proposed methodology engenders lack of confidence in results, no matter what they might be. An overall mass balance can be maintained, however, if a revised method of calculation is used that simultaneously considers all pathways.

c) **Validation**: The Subcommittee is very concerned that there has been little grounding in reality of the overall methodology and of its individual elements. The issue of validation, or testing of the model, its elements, and parameters against

actual data derived from laboratory or field experiments or observations, is essential to developing any degree of confidence in the methodology. This issue transcends all scales of the approach, from individual parameters (e.g., comparing measured soil-column volatility rates with volatility rates predicted by the model), to individual equations (e.g., confirming that an equation is a reasonable representation of the process being modeled), to the application of the overall model in real-world case studies to see if calculated numbers have any relationship to what would happen in the environment. At present, there is literally no way to evaluate the validity of the methodology or its components, and results well-removed from realistic conditions might result. In fact, the Subcommittee noted several instances where calculated values were simply not credible. The Subcommittee is not suggesting establishing an expensive or time-consuming research initiative before the methodology is applied; rather, we believe there are many opportunities to produce limited validation through existing databases. The Subcommittee recommends that the Agency focus this validation effort on a few key exposure pathways of concern, and on those parameters that have major impact to risks to human health and the environment. This can be done through a systematic sensitivity analysis of the aggregate model, as discussed in Section 10.

d) **Systematic evaluation of parameters and uncertainties**: The Subcommittee observes that there has not been a systematic examination of parameters to ensure a consistent and uniform application of the proposed approach to selecting high-end or central-tendency values. For example, the approach seems to have been inconsistently applied to human health and ecological effects calculations. Further, the full suite of uncertainties has not been scientifically or adequately addressed. For example, each individual equation includes many parameters, each with its own variance or imprecision. Some systematic approach, such as Monte Carlo simulations, is necessary to look at the distribution of parameter values for all parameters in the equation, not just for one or two parameters, and establish the imprecision of the result. This will complement the case study validation recommended by the Subcommittee and help to identify the model's ability to extrapolate from the case examples to other real world circumstances. Without these calculations, the degree of protectiveness defined by using the overall methodology can be at best described as probably greater than the 50th percentile. Since this is a major foundation of the applicability of the approach as a nation-wide standard, the Subcommittee concludes that this critical issue must be resolved before proceeding.

e) **Consideration of ecological effects**: The Subcommittee finds that the ecological analysis is fundamentally flawed because lack of data has been implicitly equated with lack of adverse ecological effect throughout the analysis. As a result, only a handful of well-studied chemicals have actually received a scientifically credible review. We recommend, therefore, that the Agency discard the screening

procedure described in the HWIR document, and instead require that a minimum dataset be satisfied before ecologically based exit criteria are calculated. For those chemicals for which the minimum dataset cannot be satisfied, the Agency should clearly indicate that the exit criteria are based solely on human health considerations. The exit criteria should be re-evaluated, however, when and if additional data on ecological effects become available.

f) **Use of the available science**: The Subcommittee concludes that OSW has not adequately drawn upon the best existing science, including the knowledge available from the Office of Research and Development and elsewhere in the Agency. This concern, in concert with the lack of outreach to external scientific expertise and peer review and a generally noted lack of sound professional scientific judgment in the development of the proposed methodology, leads the Subcommittee again to seriously question the validity of the exit criteria being defined by this methodology. We recommend, therefore, that OSW actively seek the substantive participation, input, and peer review of Agency scientists, and outside peer review groups as necessary, to evaluate the individual elements of the proposed methodology in much greater detail than the Subcommittee is able to provide.

The Subcommittee emphasizes that these issues are critical to the scientific defensibility of the HWIR methodology, but fortunately will not require a long-term investment of major resources for satisfactory resolution. The initial estimate by the Subcommittee is that a concerted program to correct these major flaws could be completed within a relatively short time period, perhaps one or two years, with the appropriate scientific involvement. The Subcommittee further recognizes that other, sometimes very important, research issues remain, many of which are detailed in this report; however, these research issues are of general importance to the Agency for building a sound science base for risk assessment and are not limited to the HWIR methodology. Consequently, the Subcommittee has concluded that the critical flaws in the proposed methodology are addressable in a reasonable time with reasonable resources and should result in establishing a scientifically defensible methodology for the HWIR.

4. SCALE AND AGGREGATION ISSUES: NATIONAL VS. SUB-NATIONAL VS. SITE-SPECIFIC EXIT VALUES

For a variety of reasons, summarized in the previous section, the Subcommittee concludes that the proposed methodology lacks an adequate scientific basis and thus cannot defensibly be applied to derive national exit criteria. There are at least two potential avenues the Agency could take to develop a defensible methodology: 1) the Agency could develop the scientific basis for establishing a single set of national-level exit criteria, if sufficient attention is placed on the deficiences in the proposed methodology, as discussed in this report. Significant advances would be required in the methodology, however, and the modified methodology for national-level criteria should be subjected to scientific review before national-scale numbers were implemented. It should be noted that it might prove to be impractical to develop such a methodology or that such a national-level set of criteria would be so overly protective at most sites as to be ineffective in addressing the original intent of the HWIR. Or 2) the Agency could develop a consistent methodology for establishing sub-national exit criteria; i.e., a systematic approach that, with appropriate parameterization based on more case-specific information, would yield site-specific exit criteria or exit criteria for groups of wastes or sites with similar characteristics. In essence, such an approach could supplement the current case-by-case delisting process, avoiding the diversity of analytical approaches and databases through the development of a single set of models and scenarios that are simply parameterized individually. This, of course, would not replace the current formal delisting process, so that route would remain an option for the situations where warranted.

In principle, the Subcommittee believes that an adequate scientific basis might be developed to support either approach, but only after appropriate methodology development had occurred and the scientific validity of the methodology had been demonstrated. Since data analyses do not yet clearly identify a superior approach, the Agency should retain the flexibility to select the most appropriate basis for establishing exit criteria (e.g., national, sub-national, or site-specific). Which approach is chosen is a policy decision for the Agency. At the present time, however, neither approach has been developed in a scientifically defensible way. Some of the issues that the Agency should consider in deciding which route to choose are discussed below.

In the current proposal, the Agency has not yet demonstrated that the spatial-temporal scales implied by the risk equations are relevant to assessing waste constituents released from the sites under consideration. The model temporal scaling might not accurately provide protection for humans or other species that receive significant exposures in relation to events that occur on short time scales. For example, to the extent that critical exposures result from conditions not addressed by average daily values, such as seasonal or episodic exposures, the equations in the proposed methodology simply are not applicable. The Subcommittee is concerned by the inability of the proposed methodology to address transport associated with episodic events, such as intense rainfall or wind storms. It is often the case that most of the particulates transported by

a surface stream are moved following major rainfall events, just as severe flooding, hurricanes, and dust storms can result in large variations in exposure over time. The proposed methodology, by relying on average daily values, in effect averages over these events, thus excluding the driving forces that may dominate risk in real situations. The consequence of this missing element is the potential for significant underestimation of risks. While selection of an appropriate temporal scale remains an issue regardless of the Agency's final choice of spatial scale for the exit criteria, it is likely that the inclusion of transient transport in a national methodology would further increase the degree of conservatism of the resultant national exit concentrations.

The spatial scale (i.e., national level) underlying the proposed approach requires a series of worst-case assumptions for transport and exposure without accounting for differences among kinds of sites and wastes. As already noted, an alternate approach to a generic national criterion would be to develop models explicitly scaled for the kinds of sites and wastes of concern. Uncertainties could be propagated through these models to generate a probabilistic estimate of the effects of concern; i.e., risk. Models could be developed for each of the general kinds of sites under consideration and used to determine, from the bottom up, exit criteria developed from more site-specific approaches. However, while the site-specific approach is most desirable from a scientific perspective, because it is at that scale that the effects are realized, that approach might be inconsistent with the purpose of the regulatory action; i.e., having a national rule for exiting the listed hazardous waste system without having to petition for delisting on a case-by-case basis for each site and each waste. Additionally, a site-specific methodology would be severely limited by data availability. On the other hand, an intermediate-scale analysis that aggregates sites on the basis of similar characteristics would provide a greater degree of realism (e.g., more realistic values and combinations of values for variables such as source characteristics, soil properties, climatic conditions, and topography) without requiring very site-specific data.

Levels of variability and applicability also vary along this continuum of generality vs. specificity. For highly defined site-specific analyses, the applicability of the calculated criterion to that particular circumstance is heightened, but its applicability to another, different site may be very low, whereas the applicability of a national-level criterion may be low for any specific case, but overall high in terms of the policy-defined levels of protection. There is no simple or obvious point along the continuum to select for a national rule.

In order to develop a national exit criterion for each chemical of interest, the Agency must address the wide range of variability among not only the types of waste treatment units, but also among the local environmental conditions that govern the fate and transport of the chemicals and the types of receptors at risk. This variability does not imply that a national criterion is inherently "uncertain," however. Rather, the variability results in a broad distribution of accurate exit criteria, each corresponding to a different location. If the objective of developing a national exit criterion is to derive a number that will likely be adequately protective at the vast majority of sites, therefore, the exit criterion should reflect an accurate assessment of the waste concentration necessary to protect the site at or near the most sensitive end of the distribution.

In order to accomplish this objective, the Agency can legitimately develop a national methodology that is then used to develop a national exit criterion. However, because a national criterion would be designed to be protective at all (or nearly all) sites, it would, by definition, be overprotective at most sites. For example, the calculated exit concentration of a chemical chosen on the basis of a surface impoundment case inherently will be overprotective for the other four land disposal cases. It would be useful, therefore, for the Agency to develop a mechanism whereby the national methodology could be used to calculate less restrictive criteria for groups of sites that, by virtue of their environmental characteristics, fall at a different point on the distribution mentioned above. This objective could be accomplished by relatively straightforward adjustments in selected driving variables used in the analysis. Driving variables would include climatic characteristics, soil characteristics, and the nature of the recipient ecosystem, for example. The aggregation process should be driven by those important factors, in effect conducting a stratification of the national methodology. The definition of these driving variables and the appropriate ranges in assigned values, which has not been adequately done for the current methodology, would not only allow the development of finer-scale, aggregated criteria where desired, but would also improve the defensibility of a national-scale methodology. Further, the analysis would indicate whether the key parameters that will likely drive transport, exposure, and effects are included in the current set of equations for each source/chemical/pathway combination and whether the analytical framework is constructed so that the changes in these driving variables do result in appropriate changes in the exit criteria.

A list of the suite of driving variables and their acceptable ranges could be published by the Agency, along with the methodology for calculating exit criteria, perhaps in the form of an expert system, consisting of algorithms and computer programs that are selected based on the answers to a series of questions about a particular site (e.g., exposed populations, exposure pathways, the size and longevity of the waste facility, and site geology and geography).

A sequential approach to the assessment (i.e., screening using generalized equations, followed by classification of site conditions with the appropriate models, and, finally, use of site-specific information and appropriately scaled models) would be most effective in an adaptive approach to regulation. This approach, also referred to as an “iterative approach” to risk assessment, is also recommended by the National Research Council in their 1994 report on risk assessment, entitled *Science and Judgment in Risk Assessment*.

In summary, because of the flaws in the current methodology, the Subcommittee concludes that an adequate scientific basis for the methodology does not exist, and the methodology cannot defensibly be applied at present to derive national exit criteria. However, the Subcommittee agrees that, in principle, a defensible national methodology might be developed that would produce national or sub-national exit values. The following sections include recommendations for the development of such a methodology.

5. A TRUE MULTI-PATHWAY ANALYSIS

The Subcommittee identified substantive problems with several aspects of the conceptual framework presented in the HWIR draft document. In its simplest terms, the currently proposed approach is to identify source/chemical/pathway combinations, then run each pathway independently (and backwards) under conditions that would maximize exposure via that pathway. This approach will produce exit criteria that are more conservative (but to an unknown degree) for the selected pathway, but may be less conservative (but also to an unknown degree) than those that would result from a simultaneous consideration of exposures from all pathways.

In addition, since the calculations are not the result of internally consistent parameter values, mass balance is not achieved. Mass balance is fundamental to good science and needs to be fully considered for any given scenario in order to develop internally consistent calculations of release, transport, transformation, fate, and exposure. Since the current assessment calculates source concentrations for different pathways independently, overall mass balance across all relevant pathways is not being considered. However, an overall mass balance can be preserved if a revised method of calculation is employed to provide a simultaneous consideration of all pathways. The mass balance calculation should consider not only terms associated with transport, but those terms representing loss or elimination (biodegradation, sorption) as well. Careful attention to mass balance also will improve the clarity of the methodology; concentration numbers alone can be misleading to the public because of the inclusion of safety factors to account for the many uncertainties in toxicity and exposure assessments. Mass flow rate numbers calculated from a true mass balance calculation will help put the concentration numbers into better perspective and improve the ability of risk managers and the public to comprehend the relative significance of the calculated concentration numbers (exit criteria).

The Subcommittee recommends, therefore, that the present method, which is incorrect in principle and gives results of questionable value and credibility, be abandoned in favor of true multi-pathway calculations in which a receptor receives contaminants from a source via all pathways connecting the source and receptor concurrently, is exposed to those contaminants via different routes (lung, gut, skin, leaf, root, and so forth, depending on the receptor), and takes account of the dose corresponding to each route in an integrated way so that the overall, total dose is acceptable.

Combining all of the exposure pathways into a coherent framework would allow a set of internally consistent scenarios to be run for the entire framework in a forward direction. This exercise would accomplish several objectives, including: checking assumptions regarding the existence of a dominant pathway; allowing a mass-balance check on the overall system; and providing a common-sense check of the responsiveness of the framework to known driving variables.

The Agency may wish to evaluate available software packages for computing multi-pathways of exposure, including MULTIMED (U.S. Environmental Protection Agency, 1990), APIDSS (American Petroleum Institute, 1994), and SoilRisk (Labieniec et al., 1996), to determine their applicability to the HWIR.

6. VALIDATION OF THE METHODOLOGY

The Subcommittee is concerned that many models or equations used in the calculation were not validated and/or peer-reviewed. In addition, the total construct of models and equations represents a physically untested, unvalidated whole. For these and other reasons already given, some exit criteria so calculated may be overly conservative, whereas others may not be sufficiently conservative.

The Subcommittee believes that a substantial amount of model validation must be conducted prior to application of the methodology. Ideally, actual concentrations at sources and receptors should be compared with calculated values for a sufficiently large number of well-defined actual cases to determine whether there is any correlation between actual and calculated values and what overall degree of conservatism is built into the calculations. This validation approach, however, would be a very large and time-consuming project. An alternative approach in the short-term for assessing whether calculated concentrations are correlated with observed values in the field under similar conditions would be to consult readily accessible, published sources of data for cases that permit comparisons with calculations based on relevant, selected pathways or portions of pathways, or that permit expansion or validation of the information base on which the parameters ("central-tendency" and "high-end") are based. We believe there are many more existing databases that could be drawn upon than have been drawn on to date, including laboratory experiments on fate, transport, and effects processes, experimental manipulations or tests in microcosms and in the field, and landscape-level observational and monitoring databases from programs such as EPA's Midwest Agrichemical Surface/Subsurface Transport and Effects Research (MASTER) program. The DDT and dioxin data sets also might be useful for this purpose. These kinds of comparisons, fully reported, will help to reassure members of the regulated community and the public that the adopted calculation method is rooted in reality.

In addition, the Subcommittee suggests that calculations be done under a variety of scenarios to determine the degree to which changes in the fundamental conditions of calculation affect the outcome and whether such changes are reasonable as to direction and general magnitude. As noted previously, sensitivity calculations can be useful here, too.

For the longer-term, the Subcommittee urges the Agency to conduct complete comparisons in order to: a) determine whether the methods mirror reality and to what degree; b) determine whether the calculations are conservative, as desired, and to what overall degree; and c) determine what changes in the method or in the parameters might improve the correlation between calculated and actual values. The Subcommittee further suggests that the results from these comparisons are valuable in and of themselves since they will have use in other multi-pathway analyses.

7. IMPORTANT OMISSIONS OR ERRORS

The Subcommittee is seriously concerned about the level of scientific input and the degree of professional scientific judgment that, to date, have been incorporated into the methodology development. It was clear to the Subcommittee that there has been inadequate attention given to the state-of-the-science for human and ecological risk assessment that exists within EPA, let alone in the broader scientific community, in the development of the overall methodology, the identification of individual equations and associated parameters, the selection of models and their applicability, and the continual need for sound scientific judgment. The Subcommittee was unable to assess the pathways derived from groundwater transport in the context of the overall HWIR methodology as these are being developed separately and were not included in the materials provided to the Subcommittee. This is a concern since groundwater is clearly an important route for exposure of both humans and ecological receptors to chemicals. While it has been the goal of the Subcommittee to provide a peer review of the overall methodology and larger issues, the Subcommittee identified numerous instances, discussed below, where the approaches or equations used were flawed or poorly chosen from those available. There were many other cases where the sources of the parameters used were not clear or they were considered inappropriate, and there were questions about the actual values applied.

The Subcommittee strongly recommends, therefore, that OSW actively seek the substantive participation, input, and peer review of Agency scientists, and outside peer review groups as necessary, in order to ensure the scientific defensibility of the individual elements of the proposed methodology. That peer review is essential before the scientific basis of the methodology can be established.

Although it is well beyond the scope of this review to address each of the equations, their parameterization, and the selection of values, the Subcommittee has identified the following examples of implementation errors or analytical elements that are missing from the proposed methodology.

7.1 Biodegradation and Transformation

The present methodology does not incorporate biodegradation or physical/chemical degradation or transformation of the waste constituents. The issue of biodegradation in particular was identified as a major flaw in the current approach. In the Charge, the Agency acknowledged that the HWIR methodology does not account for biodegradation that occurs at waste management units, and the Subcommittee was specifically requested to provide advice on how to incorporate on-site degradation in the analysis. It is a well-demonstrated fact that organic constituents are adsorbed and degraded in land application units and that metals are sequestered via mechanisms such as ion exchange and/or precipitation.

Clearly, the reason for using land treatment of wastes and sludges, aerated tanks, and other related management practices is to take advantage of the biodegradative capability of microorganisms. By setting biodegradation rates to zero, there is no term to allow the pool of material to be removed or reduced over time in a land treatment unit. Thus, accumulation and eventual transport of contaminants from a site will be vastly overestimated. It is clear that biodegradation is one of the dominant processes controlling the fate of most organic compounds, even those slowly degraded, in most soil and sediment environments. There are adequate data on biodegradation rates for a number of the chemicals listed to generate generic loss terms. For example, the waste treatment literature contains a vast amount of data on rates of disappearance of land-applied material for many combinations of soil, climate, and an array of materials. Much of this is not chemical-specific but could be translated into rates. Also, the database assembled by Howard et al. (1987) could be used for this purpose. In this database, compounds are grouped into fairly broad biodegradation categories that could be equated to rate terms; e.g., slowly degraded being 1-5 percent annually, moderately degraded being 10-20 percent annually, and rapidly degraded being greater than 50 percent annually. The use of broad categories would yield conservative biodegradation rates that would appreciably change the calculated HWIR exit criteria.

On the other hand, neglecting physical/chemical transformations can cause the methodology to underestimate risk. For some inorganic chemicals (especially mercury and selenium), there is an adequate existing database to address transformations that significantly affect both the fate-and-transport and the effects assessments.

7.2 Application of the Jury Model

The Subcommittee's examination of sample pathway calculations for hexachlorobenzene (HCB) provided by the Agency revealed a significant problem inherent in the partitioning model. This problem, which is described below, relates to the application of Jury's volatilization model to releases from a land application unit (LAU). It illustrates how a peer-reviewed model, when inappropriately applied, can lead to physically unattainable results. To provide assurance that other similar errors are not present in the formulation or application of other submodels, a thorough review by qualified experts, within EPA's Office of Research and Development or elsewhere in the scientific community, is warranted.

Jury's volatilization model (equation 7-32) is based upon the assumption that the total waste concentration is uniform within a given depth of soil. In the HWIR documentation, this depth is assumed to be a constant (20 cm) for the LAU. Although the waste unit is assumed to be active over a 40-year period, the modeling approach appears implicitly to assume that the depth of contamination does not grow with continued waste application, and, furthermore, that the soil (waste) properties, including sludge/soil bulk density (BD), organic carbon content (f_{oc}), and moisture content (θ_w), do not change over time. As additional mass is applied, however, the total soil concentration (C_T) is modified through use of equations 7-29 and 7-30, implying that C_T grows linearly with the total mass. Similarly, mass volatilized also grows with total mass, since it

is directly proportional to C_t. The HWIR model fails to take into account that there is a maximum value for C_t based upon the assumption of equilibrium partitioning in a three-phase (soil, water, air) system:

$$C_T / _{max} = BD \bullet K_d \bullet C_e + \theta_w \bullet C_e + \theta_a \bullet H' \bullet C_e$$

where: C_e is the solubility of the contaminant in water.

If the total concentration exceeds the solubility limit for a contaminant, it implies that the contaminant exists as a free phase (organic liquid), thus violating the Jury model.

The model, as currently applied, does not have a total concentration limit, and thus, added mass will tend to increase the calculated volatilization mass, apparently without bound. This conclusion is supported by an examination of the spread-sheet calculations for HCB provided to the Subcommittee at the May 31-June 1 meeting. At t= 40 years, the predicted volatilized mass of HCB is almost half of the applied contaminant mass in that year. Such a level of volatilization is unreasonable for a compound with a K_{ow} on the order of 10^5 to 10^6.

In a real system, one would expect the contaminated soil depth to increase with application, eventually resulting in a uniform (small) volatilization rate based upon equation 7-32 with $d_s = \infty$ and $C_T = C_T / _{max}$. The error presented above would tend to overestimate the importance of the volatilization pathway and severely underestimate the persistence of the waste mass in the LAU. The situation is further complicated by the assumed absence of degradation, which, as noted in the previous section, would tend to lead to overestimates of the waste mass.

7.3 Partition Coefficients

The HWIR calculations/equations make extensive use of "partitioning coefficients" for estimating release, transport, and fate of all 200 chemicals being analyzed for the HWIR. The literature-reported values of partitioning coefficients such as K_d are quite variable and depend on a number of characteristics, including the chemical, the environmental medium, and the method of measurement. Moreover, the soil:water partition coefficients for organic constituents are controlled by the nature and amount of organic matter in soils, along with solution concentrations. However, soil:water coefficients for inorganic constituents are often dependent on the pH, redox conditions, and the type of clay particles in the soil (e.g., montmorilonite, vermiculite, or kaolinite). The inorganic and organic constituents are also constrained by their solubility limits such that partitioning coefficients may change as a function of the concentrations of the chemicals involved. These considerations should be incorporated in the HWIR equations to reflect the scientific knowledge on the release, transport, transformation, and fate of target constituents being evaluated.

The EPA Office of Water (OW) has addressed both organic and inorganic partitioning in the context of establishing sediment criteria under the Clean Water Act. The Subcommittee

notes, however, that previous SAB reviews of the equilibrium partitioning approach (EPA-SAB-EPEC-95-020; EPA-SAB-EPEC-93-002) concluded that the approach has been validated only for a limited class of compounds.

7.4 Missing Pathways

Although the Subcommittee did not systematically examine all pathways to identify missing ones, we note that two important pathways for exposure from surface impoundments have been omitted from the analysis and should be added prior to publication of the methodology. Significant bird use of surface impoundments (for habitat, feeding and reproductive activities) has been documented, particularly in the western United States (e.g., U.S. Fish and Wildlife Service, 1995). This use exposes birds to waterborne and, in many cases, food chain contamination. Direct bird use should therefore be added as a pathway. Similarly, discharges from surface impoundments have been excluded on the assumption that all discharges would be subject to NPDES permits. However, since surface impoundment discharge may be used for irri gation or groundwater recharge (activities that do not require an NPDES permit), this route of exposure should be included in the analysis.

In addition, the HWIR document does not include inhalation of volatiles while bathing. Although the document states that no appropriate chemical-specific algorithms could be found to address this pathway, we suggest that the Agency consult a study conducted by the Lawrence Livermore National Laboratory in the late 1980's (McKone, 1987).

7.5 Dermal Routes of Exposure

In the Charge, the Subcommittee was asked to comment on the use of oral toxicity data for the assessment of percutaneously absorbed substances in the absence of dermal toxicity data. In general, it is not scientifically defensible to use oral toxicity data in the absence of dermal toxicity data for dermal routes of exposure because of differences in absorption rate and metabolism for substances absorbed through oral vs. dermal routes. The ORD document *Dermal Exposure Assessment: Principles and Applications* (EPA/600/8-91/011B; January 1992) provides considerably more guidance on assessing dermal exposures than is implied in the HWIR documentation. There is a large body of information on dermal absorption of organic chemicals and the physical and physiological processes that govern absorption. Although there is a clear indirect relationship, based upon the dermal partition coefficient (K_p), between the absorption of organic chemicals by the oral and dermal routes, the relationship of potential effects (or risks) is less clear. Even if the absorption efficiencies via the dermal and oral routes are known, the rates of oral absorption tend to be much slower than the dermal rates of absorption, and this exerts major influences on the toxicokinetics of a substance. A percutaneously absorbed dose will travel with the venous circulation to the right side of the heart, from there through the lungs, and from there through the left side of the heart to the general arterial circulation. In contrast, an absorbed ingested dose will travel with the hepatic portal circulation through the liver, where considerable metabolic conversions and toxicologic interactions may occur. From there the substance and its

metabolites are transported through the right side of the heart to the lungs, and, by the same pathway as above, eventually to the general circulation.

In summary, while there are some relationships between risks from dermal and oral exposures, they cannot be addressed in the simplistic approaches suggested in the HWIR document. These issues have been addressed previously in *Risk Assessment for Multiple Chemical Exposures* (EPA-600/9-84-008) and in *Selected Approaches to Risk Assessment for Multiple Chemical Exposures*, J.F. Starra and L.S. Erdreich, editors (EPA-600/9-84-014a).

7.6 Unrealistic Management Scenarios

The HWIR document considers five types of waste management units as sources of hazardous waste constituents: ash monofill, land application unit, wastepile, quiescent surface impoundment, and aerated tank. In many respects, however, the waste management scenarios are poorly developed and do not incorporate established engineering design and operation practices. For example, the physical characteristics of each of the waste management units are determined by a statistical distribution of readily available data without consideration of appropriate design standards and meteorological and soil conditions; e.g., good design would preclude siting land application units in sand or clay soils, or in areas with short growing seasons. More realistic scenarios would be achieved if all units were sized and located in accordance with established engineering design practice. Further examples of standard operating practices that are not reflected in the management scenarios include the following:

a) The analysis assumes that daily cover is not applied to the ash monofill, although it is standard practice to do so;

b) Although food crops are commonly grown on some land application units, this possibility does not appeared to be addressed in the analysis;

c) The land application scenario states that water withdrawn from the river for residential use will be filtered prior to use; standard practice would also include chlorination of the water, which should oxidize any organic constituents remaining in the water and might also form some chlorinated hydrocarbons;

d) Sludge application rates to the land application unit should be consistent with current design practice, and the document should specify the method of application (e.g., sprayed, dumped, sub-surface injected, or flowed) since that may significantly impact the extent of off-site migration of waste constituents; and

e) The analysis states that the range of values calculated for surface impoundment depth are 1 to 150 feet; it is very difficult to believe that there is a surface impoundment with a 150-foot depth. In addition, the assumption that the surface impoundment is well mixed will greatly over-estimate the extent of volatilization;

surface impoundments, especially deeper ones, are known to exhibit extensive stratification.

In summary, the overall sense of the Subcommittee is that the waste management unit models have been developed without regard for established practices and are a combination of statistical correlations and quasi-mechanistic models used in ways never imagined by their developers. It is impossible, therefore, to assess whether or not the source characterizations are an accurate representation of reality.

8. SELECTION OF ENDPOINTS AND BENCHMARKS

The human health endpoints and benchmarks in the HWIR document focus on the 10^{-6} cancer risk and the hazard quotient of 1.0 for reasonably exposed individuals. These must be recognized as policy decisions, not necessarily justified by science. The reliance on HEAST and IRIS for cancer slope factors and reference dose values is standard practice, but the usual concerns and caveats apply: a) it remains difficult to assess the degree of conservatism introduced into the assessment using these factors; b) the selection of uncertainty factors appropriate for use in the HWIR methodology to assess hazardous waste releases needs additional consideration and justification; and c) endpoints other than cancer and those addressed by the "no observed adverse effects levels" (NOAELs) might be important in assessing the toxic effects of hazardous wastes on humans. The key point is to ensure that the updated values from these sources are routinely incorporated into any assessment.

The development of ecological benchmarks parallels the human health assessment. Toxicological benchmarks were developed for selected populations of plants, mammals, birds, fish, aquatic invertebrates, and soil invertebrates. Endpoints included effects on reproduction, growth, mortality, and survival. The Subcommittee noted several limitations of the ecological benchmarks in the HWIR document.

One, there appeared to be a comparative paucity of chemicals for which ecological toxicity data were developed. More thorough examination of the literature may well provide toxicity data for additional species (e.g., claims of the public commentors). For example, valid benchmarks are available for more chemicals in sediments that those listed. Even though the Agency has published sediment criteria only for a suite of nonionic organic compounds, a considerable literature exists that would support the development of benchmarks for other chemicals that could be used in this analysis. In its recent review of sediment criteria for metals, for example, the SAB noted that bulk chemical data can be used as an initial screen for some applications (EPA-SAB-EPEC-95-020). Further, acute (LD_{50}) and chronic "no observed effect concentration" (NOEC) data have been developed for many compounds to support regulatory compliance efforts under the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These data should be consulted and used for more realistic assessment of ecological risks and model validation for HWIR.

Two, the equations for ecological exposure omit consideration of significant factors such as behavior and life history characteristics and chemical transformations that take place in the environment. For example, chemicals such as selenium and mercury are transformed between the source and receptor into chemical forms that are far more damaging. In the case of selenium, food chain exposure then becomes the more damaging pathway for some receptors. These characteristics, where known, should be included in the exposure analysis and in the calculation of the benchmark dose. (It was unclear from the documentation whether or not the benchmark doses for selenium and mercury were based on the more toxic forms.)

Three, several of the wildlife benchmarks were developed using allometric scaling techniques, the extrapolation of toxicity data across different species. While this method omits consideration of several important variables that cause different species to exhibit different sensitivities, it is probably a reasonable approach for this analysis.

Four, although the document describes potential risks posed by hazardous wastes to populations, communities, and ecosystems, the primary approach focuses on population-level impacts assessed through the use of toxic benchmarks ("no effects levels") in a simple quotient calculation. The toxicity data represent a collection of species-level benchmarks that are used to define a value that protects some fraction (e.g., 95 percent) of the species. The "communities" are simply generic assemblages of terrestrial and aquatic populations. The emphasis on species interactions that serve as the foundation for community ecology are not addressed in the current assessment. While the development of the toxicity benchmarks for the aquatic, sediment, and soil communities seems justified in the context of current practices, the document should not label population-level or species-level assessments as "community-level" assessments.

In addition, the sections on generic ecosystems are clearly a case of mislabeling. The ecosystem descriptions really refer to bioconcentration, bioaccumulation, dietary preferences, and trophic transfers for generalized terrestrial and aquatic food chains. The physical, chemical, biological, and ecological constraints and feedbacks between biotic and abiotic system components are certainly absent from this "ecosystem" description. Further, the use of two generic ecosystems is not a conservative approach because it does not define the most at-risk of the wide range of ecosystems. In other words, the generic systems do not bound the extremes in variability of actual systems (such as a peat bog or southwestern desert, which will be at risk from different types of source/chemical combinations), nor are they consistent with the methodology employed elsewhere in the HWIR analysis of selecting environmental conditions that maximize exposure along any given pathway. Nonetheless, use of the generic systems is probably acceptable for an initial iteration of the methodology.

Finally, not including microorganisms in the soil effects category neglects over 80% of the soil biomass. While there are few data available on pollutant impacts on soil communities, there is sufficient information to include this important group in the impacted community (e.g., see Sikkeman et al., 1995). This is especially important given that this community is critical in catalyzing the biogeochemical transformations that drive the rest of the biology.

9. ECOLOGICALLY BASED EXIT CRITERIA

It is not scientifically defensible to assume that an exit criterion derived to protect human health will be equally protective of ecological resources. The Subcommittee, therefore, applauds the Agency's effort explicitly to calculate exit criteria based on ecological risk. The conceptual framework of the analysis, however, is flawed in two fundamental respects.

First, the analysis develops exit criteria for 192 chemicals, but only evaluates a subset of 51 chemicals for ecological risk. To derive this subset or "priority list of constituents" (Appendix B of the HWIR document), the Agency used a screening procedure based on 5 stressor characteristics that, although not independent of each other, were considered to be indicators of chemicals most likely to represent ecological risk at levels derived from human health-based exit criteria calculations. The subset of chemicals selected represented those that were flagged under 2 or more stressor characteristics. The approximately 23 chemicals that were flagged under only a single stressor characteristic, however, were not included in the subset because of Agency resource and time constraints (see Appendix B of the HWIR document). According to Agency staff, the 141 chemicals not contained within the subset will be assigned human health-based exit criteria. The implicit conclusion of this approach is that unless a chemical is flagged by the screen, human health-based criteria will adequately protect ecological resources. This conclusion is not defensible scientifically, because 1) the screening procedure was inadequate to identify all of the chemicals of ecological concern, and 2) all screening procedures are inherently data-driven and data are often lacking for the ecological evaluations. Furthermore, in the HWIR document, lack of data is implicitly equated with lack of adverse ecological and human health effect.

Second, few of the chemicals that were flagged by the screening procedure received an adequate risk assessment because of the paucity of available data. Tables 4-4 and 4-5 in the HWIR document show that data for mammalian, avian, and at least one other receptor were available for only a handful of the 51 chemicals. For the remainder, ecologically based exit criteria were derived from only one or two receptor classes. For the vast majority of these chemicals, it is not scientifically defensible to claim that an adequate ecological assessment was performed.

In summary, the HWIR document currently does not fulfill the Agency's stated goal to "identify constituent levels in waste that do not present a threat to human health *or the environment* when managed as nonhazardous waste" (emphasis added). While broadly claiming to provide "health-based and ecologically based" exit criteria, the document actually provides a credible ecological analysis of very few chemicals, and incorrectly implies that the rest have been analyzed or screened for significant ecological effects.

To address this problem, the Subcommittee recommends that the Agency discard the current screening procedure and instead define a minimum benchmark dataset for each of its two "generic ecosystems." A minimum dataset might, for example, require that

benchmark values be available for mammals, birds, and terrestrial plants or aquatic organisms across a range of exposure routes. The addition of reptiles and/or amphibians should also be considered, since they may be highly exposed. For those chemicals for which the minimum dataset cannot be satisfied, the Agency should clearly indicate that the exit criteria are based solely on human health considerations. The exit criteria should be re-evaluated, however, when and if additional data on ecological effects become available. We encourage the Agency to develop additional ecological benchmarks; this will be valuable not only in the HWIR proceeding, but also in a broad array of other risk assessments.

10. UNCERTAINTY AND SENSITIVITY ANALYSES

EPA's presentation of the sensitivity analyses left the Subcommittee with questions about what sensitivity analyses were carried out and whether or not the correct sensitivity directions were generated in such calculations. The Subcommittee found that the Agency's effort to date lacks a systematic approach for evaluating all variables/parameters and how they impact the calculations. The approach for assigning high-end or central-tendency values to model parameters seemed to be inconsistently applied for human health and ecologically based criteria calculations. For example, the ecological effects calculations apparently do not have any high levels assigned, whereas the Subcommittee noted that, for example, the use of a range of values for BCF factors would be most appropriate and necessary to examine a potentially important or sensitive parameter. Similarly, some of the parameters stated to be central tendency were in fact merely levels of accepted usage, which might not be central at all, and other parameters characterized as high levels were in fact not bounding.

The Subcommittee discussed the use of deterministic, stochastic, and other potential approaches for doing the calculations to obtain HWIR exit values. The Subcommittee concludes that there is clearly a need for use of an iterative, converging, and complete evaluation to check the consistency and to establish the degree of confidence and uncertainty in the results. Multiple sites with all of the physical, meteorological, and other process parameters should be used to generate such results for establishing at least a qualitative or semi-quantitative level of confidence. Systematic sensitivity analysis will complement the case study validation recommended by the Subcommittee and help to identify the model’s ability to extrapolate from the case examples to other real world circumstances.

The approach for estimating high-end exit criteria is based on a sensitivity analysis in which a few input parameters were assigned conservative values while the remaining parameters were assigned central-tendency values. Since the HWIR document does not provide the sensitivity analysis performed for this task, it is difficult to evaluate whether the approach taken was comprehensive and/or aggregated the appropriate co-varied parameters correctly. A more rigorous probablistic approach, which will estimate the uncertainty in the exit criteria given the uncertainty in input parameters, is warranted for this analysis. (Note that when the probability distribution is not available for input parameters, a uniform distribution with a low and high end may be employed.) This type of analysis will yield the location of the exit criteria on the distribution of possible criteria levels. The Multimedia Exposure Assessment Model (MULTIMED) for evaluating the Land Disposal for Wastes (U.S. EPA, 1990), for example, uses the Monte Carlo analysis technique to allow a quantitative estimate of the uncertainty in the concentration at a receptor point associated with uncertainty in chemical-specific, media-specific, and receptor location-specific parameters.

Although it is important that some quantitative determination of the conservatism in the overall approach be made, it should be noted that this statement need not be in terms of a

percentile value derived from a probability distribution. Thus, while Monte Carlo or other methods may prove useful for evaluating different components of the overall procedure, there need not be an automatic reliance on these methods for evaluating the overall conservatism of the methodology.

One approach for examining the implications of uncertainty or variability in calculating exit criteria would be the use of Monte Carlo methods to assess the overall sensitivity of the submodels (i.e., fate and transport models) used in the assessment methodology. However, other methods (e.g., first order error analysis, fuzzy arithmetic, moment matching, or interval analysis) might prove useful as well and should not be discouraged. **In any case, care should be taken in developing input parameter distributions in the absence of data**. Distributions developed on the basis of expert opinion or professional judgment should be clearly noted. If these parameters turn out to be the more sensitive inputs, additional resources will be required to obtain valid estimates of these parameters. Additionally, the resulting output distributions will have to be interpreted with caution, particularly in assessing the degree of conservatism in the overall methodology for any particular application. In other words, "lack of data" or "absence of knowledge about probability distribution functions (pdf)" can neither be substituted by elegant mathematical analysis nor be replaced by assumed distributions for a Monte Carlo analysis without appropriate caveats. The Subcommittee also recognized that the input data for several calculations may not, as yet, be available, indicating that research should be done to generate such data for future adaptive use.

11. TRANSPARENCY AND CLARITY

The recent policy memorandum from Administrator Browner, "Policy for Risk Characterization at the U. S. Environmental Protection Agency" (March 1995), includes the statement that "risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgements, and the use of assumptions in the risk assessment are clearly articulated." The HWIR document currently fails to meet this standard of clarity.

Despite extensive discussions with the Agency staff and contractors during four days of public meetings, the Subcommittee found the implementation of the HWIR methodology for calculating exit criteria was very hard to understand and difficult to follow. It was unclear that the different equations were consistent in their assumptions and use. While each equation is generally a linear representation, inputs and cross-references to other derivations of the equations were not clearly or completely defined. In addition, the terminology used was often non-conventional and therefore confusing. For example, the use of the term "scenario" in the HWIR document to refer to specific source/pathway/receptor combinations is confusing and inconsistent with the standard definition of a scenario as being a set of internally consistent conditions which allow consequence analysis. Also, terms and units were not consistently used throughout the equations and the calculations.

The document needs a thorough review and rewrite for both clarity and ease of use. The introductory materials present the concepts used, but they are difficult to read, poorly illustrated, and do not clearly portray how the equations were selected, modified, and applied for the HWIR analysis. The highly fragmented nature of the presentation, with text sections separated by 20 or more pages of tabular material, does not add to the clarity of the document. The Subcommittee recommends that the Agency develop schematic presentations of the problem definition and a true multi-pathway solution, depicting the complete analysis for the waste management unit along with the release, transport, transformation, and fate routes, which then are linked to the effects/consequence analysis set of equations. The Subcommittee re-emphasizes its earlier recommendation that a complete, systematic, iteratively converging analysis be carried out by the Agency to generate the scientifically defensible documentation for the HWIR.

Although the Subcommittee finds that this lack of transparency results in part from formatting and presentation style, part of the problem arises from inconsistencies in the analytical approach. For example, the HWIR analysis mixes meteorological data from different locations in the country to carry out "single" pathway calculations. It is not clear that such use is consistent or even meets the desired/stated level of confidence/conservatism in the calculated exit numbers. Similarly, during discussions with Agency staff, the Subcommittee learned that several single pathway analyses were conducted in a mixed manner (that is partly backward and partly forward); this process is not transparent to readers and reviewers of the HWIR document. Further, the HWIR document should be revised to distinguish clearly between scientific judgment and policy

decisions; currently these are intermingled in the HWIR risk assessment. For example, in some cases, values were referred to as "central-tendency" when in fact they were values chosen as a result of a policy decision (e.g., cancer risk of 10^{-6}) and "high end" values did not always represent the high end of the range of applicable values. Also, the screening procedure employed for the ecological analysis was arbitrarily constrained due to resource limitations, but presented as a scientific test of potentially significant adverse effects.

12. QUALITY ASSURANCE

The issue of quality assurance (QA) was also of concern to the Subcommittee. The purpose of QA in this context is to ensure that the calculations represent what the developer thinks they represent. This is not a trivial question for any model development, but is especially difficult when spreadsheet software is used, as in this case, rather than a programming language because of the difficulties in identifying errors in individual cells in the spreadsheet or their connectivity to other cells. To date, QA has apparently been a matter of having three individuals go through the extensive number of cells in the various formula and data spreadsheets. We agree that this is an important and necessary component of QA. The Subcommittee believes, however, that there are additional QA issues that need to be addressed carefully, including: a) the quality assurance of the data that go into the spreadsheets (e.g., verification of numbers from published sources); b) the assurance that the developed methodology, which in its spreadsheet form is quite easily changed and therefore extremely subject to inadvertent or unnoted changes, is in fact the desired and approved methodology; c) the assurance that approved changes are made in all appropriate cells when improved data or models become available; d) the spreadsheet is adequately documented, in order to provide understanding of model parameters, assumptions, and so forth, in a reproducible way; and e) the assurance that output from exercise of the methodology in fact represents what the developers think it represents.

The set of example calculations prepared for the Subcommittee did not enhance our confidence that QA issues have had adequate attention to this point. In fact, that exercise illustrated a continual changing of values, both input parameters and resulting calculated outputs, that were reported to the Subcommittee. In addition, several additional errors were noted by the Subcommittee as it looked in more depth into individual pathways, and spot checking of equations by the Subcommittee showed examples of errors in the units (i.e., the units did not match on each side of the equation), further reducing confidence in the calculations. There is a sense that the calculations are presumed to converge as spreadsheet errors are corrected over time, yet there is no clear way to reach confidence that the latest set of numbers are in fact the correct ones. The Subcommittee recommends that a thorough examination of all aspects of QA be conducted prior to the publication of any exit criteria.

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APPENDIX A: CHARGE TO THE SUBCOMMITTEE AND SUMMARY OF RESPONSES

OSW has developed a new methodology for establishing the conditions under which wastes listed as hazardous may be delisted and therefore not subject to further regulation as hazardous wastes. This analytical methodology is a substantial modification from previous approaches for assessing risks from hazardous wastes. In particular, two major changes have been made: a) expanding the methodology to the full range of routes of exposure to humans (i.e., not focused solely on groundwater pathways); and b) expanding the methodology to include assessments of some ecological exposures and ecological effects. Consequently, OSW requests the US EPA Science Advisory Board (SAB) review the draft technical support document and comment on the scientific bases of the new methodology.

The new methodology addresses a large variety of issues relating to risks to humans and the environment from hazardous wastes. Because the draft technical support document is quite extensive, OSW recognizes that all details cannot be addressed by the SAB review. OSW requests, therefore, that the SAB comment on the overall scientific validity of the proposed methodology and that the SAB focus its review on key issues critical to scientific validity.

Specific areas requested for focus in the SAB review are the following:

<u>General Issue</u>

(1) While recognizing that there is often limited information on probability distributions for different parameters, OSW attempted to derive a methodology that seeks some consistency in conservatism across all pathways examined. In essence, a few parameters were assigned conservative values while the remaining parameters were assigned more central-tendency values. Is the approach taken for determining "high-end" or conservative estimates of risk producing moderately comparable levels of conservatism across the different pathways and receptors?

SUBCOMMITTEE RESPONSE: The Subcommittee finds that the method of calculation used is flawed and that more correct methods are available. Specifically, the current method should be abandoned in favor of a true, multi-pathway approach in which a receptor receives contaminants from a source via all pathways connecting the source and receptor, concurrently, and the receptor absorbs the delivered doses of contaminants by all relevant routes. Even if one were to continue to use the current method of calculation, the Agency's approach to assigning high-end or central-tendency values to model parameters does not appear to be systematic or consistently applied. As a result, the degree of protectiveness defined from using the overall methodology can at best be described as probably greater than the 50th percentile, even if the methodology were correct. See Sections 5 and 10.

Human Exposure and Effects Issues

2) Is the OSW approach for multiple pathway exposure to humans technically reasonable?

SUBCOMMITTEE RESPONSE: No. The OSW approach for multiple pathway exposure to humans - or other receptors - is not a full, consistent, multiple pathway approach and, as proposed in the draft HWIR document, it yields source (exit) concentrations that are non-conservative by unknown margins for cases where receptors receive pollutants from more than one path from a source, concurrently, and absorb them by different routes, simultaneously (e.g., via the skin, lung, gut, leaf, root, and so forth, depending on the nature of the receptor). In addition, the approach does not take full and correct account of mass balance. For these reasons, the Subcommittee concludes that the current approach is not technically reasonable but that a scientifically defensible approach can be developed in practice. The Subcommittee recommends that a revised method of calculation be used, one that is designed to integrate exposures occurring via the various pathways. See Sections 3, 5, and 7.

3) Is it scientifically reasonable to use oral toxicity data in the absence of dermal toxicity data for dermal routes of exposure? Are the dermal exposure equations applied reasonably?

SUBCOMMITTEE RESPONSE: No. While there are some relationships between risks from dermal and oral exposures, they cannot be addressed with the simplistic approaches suggested in the draft HWIR document. See Section 7.5.

Fate and Transport Issues

4) The OSW methodology examines many pathways of exposure to human and ecological receptors. Are the equations and models appropriate and suitable for the available data and the scenarios developed for analysis? Are the equations, models, and assumptions properly integrated into an overall assessment methodology?

SUBCOMMITTEE RESPONSE: No. The Subcommittee is concerned that many models or equations used in the calculation were not validated and/or peer-reviewed. In addition, the total construct of models and equations represents a physically untested, unvalidated whole. The Subcommittee recommends that OSW actively seek the substantive participation, input and peer review of Agency scientists, and outside peer review groups as necessary, in order to: 1) ensure the scientific defensibility of the individual elements of the proposed methodology, and 2) compare calculated exit values with readily accessible, published sources of data on observed values in the field under similar conditions. See Sections 3, 5, 6, 7, and 12.

5) The mass balance issue was addressed through simple equilibrium-based release equations. Is this approach scientifically reasonable, given resource constraints?

SUBCOMMITTEE RESPONSE: No. The Subcommittee concludes that the absence of

a mass balance approach in the proposed methodology engenders lack of confidence in any resulting exit criteria. An overall mass balance can be maintained, however, if a revised method of calculation is used that simultaneously considers all pathways and the several possible routes of exposure to externally delivered contaminants by the receptors. The mass balance calculation should consider not only terms associated with transport, but those terms representing loss or elimination (e.g., biodegradation and sorption) as well. See Sections 3 and 5.

6) Certain parameters were grouped for the analyses. Were the assumptions of this parameter dependency reasonable? Are there other correlated parameters that should be treated as related?

SUBCOMMITTEE RESPONSE: Neither the written nor oral Agency presentations clearly articulated the approach taken to grouping parameters for analysis. Thus, the Subcommittee did not discuss in any detail the question of parameter dependencies. However, given that most of the equations used in the HWIR analysis are linear constructs and that often the input values used were at most two numbers (i.e., a central-tendency value and a high-end value), the Subcommittee finds that the grouping of parameters can be adequately addressed if the Agency implements the recommended sensitivity analysis and changes in calculational approach. See Sections 5 and 10.

7) Due to resource and time constraints, this analysis was performed in a deterministic manner with the use of extensive sensitivity analyses to guide the selection of parameter values. Is this approach reasonable? What would be the value added to this analysis by a probablistic approach such as Monte Carlo analysis? Would it produce any greater assurance of comparability given the lack of full underlying probability distributions for many key parameters?

SUBCOMMITTEE RESPONSE: The Subcommittee recommends that the Agency: 1) use mass balance constraints to identify and correct problems with the accounting of constituent mass; 2) conduct a systematic and complete evaluation of the analysis as applied to a specific site(s) to establish the consistency in use of all equations and input data; 3) conduct a systematic evaluation of the "true" sensitivity (numerical estimates of first partial derivatives) of the numerous parameters used in the HWIR approach to develop the scientific defensibility of deterministic calculations within the domain of available data; 4) compare forward and backward calculations with real data sets; and 5) consider using a Monte Carlo approach or multiple sites for forward calculations to identify the variability and uncertainty in back-calculated exit values. Monte Carlo or other methods should be used to assess the overall sensitivity of the fate and transport models used in the assessment methodology. However, care should be taken in developing input parameter distributions in the absence of data. See Sections 6 and 10.

8) Given the generic nature of the analysis, is it scientifically appropriate to assume that soil concentrations within a depositional area are uniform and can be estimated through the key parameters (i.e., average dry deposition rates, soil dissipation rate, soil bulk density, and soil mixing depth)?

SUBCOMMITTEE RESPONSE: Yes. While soil concentrations may not be uniform within a depositional area, the use of average concentrations is reasonable for this type of simplified generic analysis in which a pseudo-steady state is assumed, provided mass balance is correctly considered.

9) Is the use of the Jury model for volatilization from soil when the system is at or below soil saturation reasonable? Are the equations used to handle saturated soils reasonable?

SUBCOMMITTEE RESPONSE: No. Jury's volatilization model is inappropriately applied in the HWIR analysis. See Section 7.2.

10) One of the waste management units examined by OSW is the land treatment unit. A major function of the land treatment unit is to degrade organic materials. OSW was unable to account for this degradation in its analysis of the unit. Does the SAB have any suggestions on how to incorporate this on-site degradation into the analysis?

SUBCOMMITTEE RESPONSE: The Subcommittee recommends that the HWIR methodology account for biodegradation and other loss terms and suggests an approach for so doing. See Section 7.1.

<u>Ecological Exposure Issues</u>

11) Of the 400 constituents of concern under RCRA, 200 were used for the human health analyses and only about 50 were used for the ecological analyses. Should ecological analyses be conducted for additional constituents?

SUBCOMMITTEE RESPONSE: Yes. The screening technique used to flag the 50 or so chemicals provides no assurance that, for the remainder of the chemicals, human health-based criteria will protect ecological resources. This is a predictable result of the nature of the screen, the way in which the screen was arbitrarily constrained, and the lack of relevant data for most chemicals. Moreover, many of the flagged chemicals received inadequate ecological analysis because of incomplete data. The Subcommittee recommends that the Agency discard the proposed screening procedure for selecting the initial subset of chemicals for ecological analysis and instead require that a minimum dataset be satisfied before ecologically based exit criteria are calculated. For those chemicals for which the minimum dataset cannot be satisfied, the Agency should indicate clearly that the exit criteria are based solely on human health considerations. The exit criteria should be re-evaluated when and if additional data on ecological effects become available. See Section 9.

12) Do the equations for ecological exposure adequately address both chemicals that bioaccumulate or bioconcentrate and those that do not? Are these equations adequately linked to the fate-and-transport equations? Are the BAF and BCF models being used appropriately?

SUBCOMMITTEE RESPONSE: The equations for ecological exposure omit consideration of significant factors such as behavior and life history characteristics and chemical transformations that take place in the environment. The ability to address these characteristics, where known, should be included in the exposure analysis. See Section 8. The limitations of available BAF/food web models are discussed at length in a recent SAB commentary (EPA-SAB-EPEC/DWC-COM-95-006) and were not evaluated by the Subcommittee. Exposure characterization issues are discussed further in an SAB advisory on developing wildlife criteria (EPA-SAB-EPEC-ADV-94-001).

Ecological Effects Issues

13) The OSW ecological analyses were at the community level for aquatic, sediment, and soil communities. Is the approach used for these community effects reasonable?

SUBCOMMITTEE RESPONSE: The development of the toxicity benchmarks for the aquatic, sediment, and soil communities seems justified in the context of current practices. However, what the document terms "community-level" assessments are really population-level or species-level assessments. The HWIR document should clearly indicate that the current methodology does not address community-level effects. See Section 8.

14) OSW developed benchmarks for terrestrial ecological receptors using a NOEL approach rather than a specified effect level approach. Is this approach for setting terrestrial ecological benchmarks appropriate? Is the approach of extrapolation across terrestrial species appropriate? Is the LOEL-to-NOEL extrapolation approach appropriate?

SUBCOMMITTEE RESPONSE: Given the scope of the charge, the Subcommittee did not discuss these issues in any detail and instead refers the Agency to a previous SAB advisory on developing wildlife criteria (EPA-SAB-EPEC-94-001).

15) OSW used either the ambient water quality criteria approach (when there were sufficient data) or the Great Lakes Initiative Tier II approach (when there were insufficient data) to select aquatic ecological benchmarks. Is this approach for selection of aquatic ecological benchmarks appropriate?

SUBCOMMITTEE RESPONSE: Given the scope of the charge, the Subcommittee did not discuss these issues in any detail and instead refers the Agency to a previous SAB

advisory on developing wildlife criteria (EPA-SAB-EPEC-ADV-94-001) and a review of the Great Lakes Water Quality Initiative (EPA-SAB-EPEC/DWC-93-005).

16) Bird and mammal population-level effects were inferred using physiological-level endpoints, including reproductive, developmental, and growth endpoints. Is this approach reasonable? Are the appropriate endpoints being used?

SUBCOMMITTEE RESPONSE: Yes. The approach to developing population-level effects for birds and mammals seems reasonable. The emphasis on ingestion as the major pathway for contaminant input seems justifiable. The protocol for selecting from available toxicity data on growth, reproduction, and mortality - with emphasis on reproduction - seems consistent with assessing population-level effects. There is some question regarding the practice of dividing a "lowest effects level" (LEL) by 10 to generate a "no effects level" (NEL), but this is recognized in the HWIR document. Similarly, the allometric scaling of toxicity data across species is questionable, yet this is also recognized as a potential weakness by the authors. While the development of toxicity data for birds and mammals emphasizes the oral ingestion pathway for exposure, the overall pathway analysis in the assessment framework appears to ignore the direct ingestion of contaminated water or food from surface impoundments. This omission needs to be corrected by adding the necessary pathways for birds and mammals. See Sections 7 and 8.

17) OSW developed a generic aquatic ecosystem and a generic terrestrial ecosystem since the analysis is for a nationally-applicable regulation. Is this a reasonable approach to assessing ecological effects at the national level? Are the generic ecosystems developed by OSW appropriate? Are the necessary at-risk components of aquatic and terrestrial ecosystems adequately addressed by these generic ecosystems?

SUBCOMMITTEE RESPONSE: The generic ecosystems described in the report really are generalized terrestrial and aquatic food chains without any consideration of constraints and feedbacks between biotic and abiotic system components. Further, the use of two generic ecosystems does not define the most at-risk of the wide range of ecosystems. Nonetheless, use of the generic systems is probably acceptable for an initial iteration of the methodology. See Section 8.

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AN SAB REPORT: REVIEW OF A METHODOLOGY FOR ESTABLISHING HUMAN HEALTH AND ECOLOGICALLY BASED EXIT CRITERIA FOR THE HAZARDOUS WASTE IDENTIFICATION RULE (HWIR)

PREPARED BY THE HWIR SUBCOMMITTEE OF THE EXECUTIVE COMMITTEE