UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-EHC-LTR-94-003

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

Subject: Review of the Health Benefits for the proposed RIA for the RCRA Corrective Action Plan Rule by the Environmental Health Committee

Dear Ms. Browner:

At the October, 1992 meeting of the SAB's Executive Committee (EC) the Board was asked by the Office of Solid Waste and Emergency Response (OSWER) to review the methodology for the draft Regulatory Impact Analysis (RIA). This cost/benefit analysis is required prior to promulgation of the Agency's final Resource Conservation and Recovery Act Corrective Action Rule. The EC, recognizing the importance, complexity, and novelty of OSWER's work and its multi-disciplinary character, established an ad hoc RCRA-RIA Steering Committee (RRSC) to assure that certain aspects of the RIA -- in both methodology and application --received appropriate attention from the relevant SAB committees.

At a public meeting on January 29, 1993, the RRSC concluded, on the basis of presentations by and discussions with OSWER personnel, that four SAB individual committees should review the major segments of the RCRA-RIA. Specifically, the RRSC agreed to review: a) the contingent valuation (CV) methodology used in the RCRA RIA analysis (CV-1, by the Environmental Economics Advisory Committee (EEAC)); b) the application of CV in the RCRA-RIA (CV-2, by the EEAC); c) the principal fate and transport model (MMSOILS), used in the RCRA-RIA (by the Environmental Engineering Committee (EEC)); d) the ecological risk assessment portion of the RCRA-RIA (by the Ecological Processes and Effects Committee (EPEC)); and f) the human health risk assessment portion of the RCRA-RIA (by the Environmental Health Committee (EHC)).

This letter was prepared by the SAB's Environmental Health Committee following the circulation (by mail) of initial comments prepared by a Committee Member, and a public teleconference held on September 24, 1993. The report focuses on the risk assessment methodology used to generate the estimated impacts on human health resulting from proposed corrective action at RCRA facilities. The March 23, 1993 memorandum from Richard Guimond to Dr. Donald Barnes described the Charge for the SAB's review expresses an interest (page 4) in the implications of the fate and transport model assumptions on the ecological and human health risk assessments. Before such an interest can be addressed, the risk assessments must be reviewed to determine whether they are sound, and to suggest improvements where they are not; otherwise comments on the implications of fate and transport assumptions may not be meaningful.

Our report is organized into two sections -- some overall strategic comments which follow in the body of this letter, and detailed technical points, keyed to specific sections of the draft RIA, which are incorporated in an Appendix enclosed with this letter.

Based on our understanding of OSWER's goals, the Committee views the draft methodology as a screening analysis, as opposed to a more detailed and definitive analysis. We have therefore reviewed the material with the following question in mind as our Charge: "Is this the best that can be done to provide a method for conducting a screening analysis?"

The screening analysis methodology produced by the Agency was a very ambitious undertaking. It is also of great potential importance since implementing the proposed RCRA Corrective Action regulation could cost many billions of dollars and, in the future, these techniques for estimating and comparing costs and benefits may well find application to other important cases as stated in the document.

In general, the methods used are well known and correspond to "much-used" guidelines, methods and practices (GMP). These GMP have, for the most part, been developed for use in setting prudently protective standards of exposure to individual substances in specific regulatory situations. In the proposed RCRA/RIA methodology the GMP are being applied to a large set of complex cases involving multiple exposures to make calculations of total impact not contemplated when the GMP were first derived. Determining whether the GMP can be so applied, whether they are adequately applied, whether their application to determine overall health impacts is reasonable, whether the important assumptions and limitations have been clearly

identified, and what reasonable and feasible improvements can be suggested has been an objective of our review.

The methods developed in Chapter 7 and Appendix E are obviously the result of much careful and thoughtful work. Care has been taken to lay out and define the risk assessment process used and its components. The basic assumptions used in each of the steps are clearly stated, (including the way in which numerical values were chosen to bring in as much realism as possible at each step through the use of site specificity where possible). Alternatives considered and different ways used to calculate the end results are set forth so as to give an idea of sensitivities or possible alternative results (e.g., the decision to analyze a "less than 100 percent effectiveness" corrective action scenario). Lastly, possible biases and uncertainties inherent in the whole procedure are identified.

The net effect of the effort was to produce a construct formed of many carefully selected parts with which a formal estimate of cancer population risk can be made, both before and after corrective action, and with which a formal estimate can be made of the numbers of persons exposed to contaminant levels which have some probability (extent unknown) of producing adverse, non-carcinogenic effects , also before and after corrective action. Thus, at least formally, the effect of the regulation can be measured in two different ways, one for cancer and one for non-cancer effects.

Although those responsible for developing this construct can be congratulated on their achievement, another group of workers might have made different specific choices at various junctures (for example, some other length of time than the 9 year exposure period, or the 128 year timeframe). However, it is doubtful if, given the state of science, a more "rigorous" method with greater certainty of giving "right" answers is possible at the present time.

As a construct, given both the state of science and the impossibility of validating the calculations through any realistically achievable, actual measurements, the results reported must be regarded as coming from an enormously complex, logically consistent, but mainly hypothetical calculation -- as must the results of most low exposure-level risk assessments. We do not use the term "hypothetical" in a negative sense; rather, as carefully devised as it is, the construct cannot give, at best, more than a rough estimate of the actual situation. Using these results in any kind of cost-benefit balancing must be done with this ambiguity firmly in mind. **We suggest that in the final RIA, this point be made abundantly clear to avoid even the possibility that the results will be treated as definitive by anyone.**

There are some areas where we suggest possible improvements. i It would be very useful to include a way to estimate, even crudely, the fraction of the population presumably exposed to significant levels of contaminants (HI > 1) who actually manifest adverse, non-cancer effects. Without some attempt at providing such estimates for the most important cases, the cost/benefit calculation remains seriously incomplete. By including such estimates, the monetization of both cancer and non-cancer effects avoidance benefits can be done in a formal sense, and that portion of the cost/benefit calculation would at least be present in the overall screening analysis.

The Committee suggests that there is a methodology available to estimate the size of the population affected at a specified level of effects. We suggest (and this is probably the most significant revision we propose) a change in the basic approach used for relating toxicant exposure and effects. The proposed methodology can be expanded to include use of the *benchmark dose concept* for determining adverse effects, including reproductive and developmental toxicity, as described by Crump (1984) and Kimmel and Gaylor (1988), and offered as a suggestion in the EHC's report (EPA, 1990) reviewing proposed revisions to the EPA Guidelines for Developmental Toxicity. From this benchmark dose, a straight line can then be drawn to the dose level that represents a 100-fold margin-of-safety, plus any relevant uncertainty factors, i.e., the reference dose for developmental toxicity. The reference dose is considered to be an exposure level unlikely to cause human developmental effects. At the beginning of the low-dose extrapolation below the benchmark dose, the actual probabilities of adverse effects may be close approximations of the linear extrapolation. As the extrapolation progresses toward the reference dose, the calculated probability of adverse effects may exceed reality to some unknown extent due to the presumed threshold phenomena operative for most developmental toxicants.

Use of this model would allow both pre- and post-remediation quantification of reduction of risk in a manner markedly consistent with that for low-dose extrapolations for carcinogenesis. This calculation could be used to monetize remediation efficacy. The example given here has been for developmental toxicity, but it is suggested that the report also attempt similar type calculations for reproductive toxicity and other non-carcinogenic toxicologic endpoint assays. (It should be noted that this method does not lend itself to quantification of effect severity, e.g., cleft lip verses auricular tags, but it does permit quantification of classes of adverse effects.)

Addressing other areas, we note that the term "population risk" (and related terms in connection with both cancer and non-cancer adverse effects) is employed correctly *vis-a-vis* cancer, but not with non-cancer effects. As discussed in more detail

in the Appendix, the population risk for cancer is correctly given as an estimate of the number of people affected by cancer within the exposed populations. In contrast, for non-cancer effects, estimates of the number of people who are exposed at levels exceeding the Hazard Index (HI > 1) do not necessarily coincide with the numbers presumed affected; indeed, the fraction of those actually expected to be affected by non-cancer effects among the numbers cited is likely to be very small, possibly zero. Also, within the cancer/non-cancer dichotomy, consideration might be given in some way to those autoimmune diseases such as lupus, and certain genetic diseases whose causes may be related to environmental factors. The Agency should be more explicit in distinguishing cancer and other disease conditions with respect to risk and "population at risk." The SAB's Environmental Engineering Committee, in its review of the RCRA MMSoils model (EPA-SAB-EEC-94-002) had similar concerns about the EPA practice of using different approaches to cancer and non-cancer risk assessment (as well as on some misidentification of critical endpoints for some common landfill constituents).

The benefits of abating disease are not monetized in the RIA document. At some point, the decrease in cancer cases and the decrease in numbers exposed to possible risks of non-cancer adverse effects may need to be balanced, along with other benefits (either monetized or not) against the dollar costs of corrective action. This is a difficult if not impossible aim to achieve in any objective way. Alternatively, using existing methodologies, the results of the calculations could be used to estimate direct monetary benefits of cancer avoidance (medical costs avoided, lost productivity, etc...) as well as indirect costs (pain and suffering, damage to family relations, damage to quality of life, etc...). However, a similar calculation cannot be made for non-cancer effects based on the results of the proposed screening method. (The SAB's Environmental Economics Advisory Committee, as part of its review of the RCRA/RIA, is considering the monetization of health benefits.) Another consideration which might be taken into account in estimating impact or monetizing effects is age of onset of a fatal and/or disabling disease; i.e., cancer in an 80-year old will have different societal and personal impacts than cancer in a 24-year old person.

It would be useful to estimate for cancer, the number of individuals "at risk" (already done for non-cancer effects) so as to have comparable numbers of people at risk for cancer and non-cancer effects. An estimate of the population exposed at levels of exposure of concern for cancer (i.e., levels leading to a lifetime individual risk of 10^{-6} or greater) would yield such estimates recognizing the fact that what is of concern is not identically defined in the two cases.

Lastly, we urge increased emphasis on the collection and management of good exposure data as a foundation for this, and other efforts by the Agency. The importance of good exposure data can not be underestimated. From what we now understand, concentrations predicted via the MMSOILS model (as reviewed by the Environmental Engineering Committee) are subject to large uncertainties, affecting exposure estimates significantly, and thereby affecting the results of the risk assessment. Moreover, the screening methodology will produce results which are completely useless and inaccurate if chemicals released from the subject facilities are not included in the assessment. We note that several chemicals which have caused problems around municipal landfills are not included in Table E-1 – particularly methane and hydrogen sulfide. These chemicals may well also be generated at solid waste management units at RCRA facilities. Although not generally considered a toxic problem, methane has accumulated in houses and caused explosions; this is indeed a public health problem. Hydrogen sulfide is produced when sulfur containing compounds such as gypsum are buried and become wet. Hydrogen sulfide releases from several landfills have produced documented health effects in people living in nearby communities. Although the importance of exposure data is discussed in the Appendix, we believe that it is such a basic and important consideration that it needs to be highlighted in our comments especially since some problematic chemicals have not been included in the assessment.

We look forward to receiving your response to our comments.

Sincerely,

Raymond C. Loehr

Dr. Raymond C. Loehr, Chair
Science Advisory Board

Arthur C. Upton

Dr. Arthur C. Upton, Chair
Environmental Health Committee

ENCLOSURE

APPENDIX

SPECIFIC COMMENTS: CHAPTER 7

-- Page 7-7, last para.: The SAB/EEC, in its review of the MMSOILS transport model as part of the RCRA/RIA review, apparently has reservations about the use of such a general model to predict concentrations for a wide variety of different, specific cases, along with other reservations about it. It would be desirable to contact the SAB/EEC (and the liaison members) to determine what bias or uncertainty this might introduce into the risk assessment, what might be done instead, and under what criteria MMSOILS might not be adequate, with suitable precautionary considerations, for a screening analysis.

-- **Page 7-15, references 17 and 18**: It would be useful to review the SAB's reviews of these documents, which took place subsequent to the dates on them, to ensure that the comments therein are adequately taken into account in this proposed methodology; perhaps the SAB's review should be added as a reference.

-- **Page 7-22, top Of the page**: The selection of the nine-year period needs more justification or explanation.

-- **Page 7-23, last sentence of 1st para.**: This is an inadequate risk descriptor (See comments re Page 7-41, 2nd para. and further related comments as to why).

-- **page 7-29, 1st paragraph**: the word "may" appears twice; delete the second occurrence.

-- **Page 7-41, 2nd para.**: The statement, " ... and 25,000,000 persons experiencing non-cancer health effects over the 128 year modeling period... " is an example of an inaccurate interpretation of the extent of the population whose exposure exceeds an HI of 1.0. (The next sentence is another example as is the wording in Exhibit 7-17). The 25,000,000 people correspond to the population exposed at levels yielding an HI of 1.0 or higher, not those "...experiencing non-cancer health effects... ". **Exposure at or above effect levels does not equal effect, only the probability of effect.** (Suppose a news story were to appear asserting that EPA estimates that 25,000,000 people suffer from etc...!) The number experiencing non-cancer health effects will actually only be a fraction of the 25,000,000 -- 25, 250 or maybe as many as 2,500. The number of people exposed at an HI of 1.0 or greater is therefore not a measure (or a descriptor) of population risk: the number of such people who do actually experience non-cancer health effects is (as in the case of cancer,population risk is the number of people adversely affected). The numbers of people so exposed and the numbers actually experiencing non-cancer health effects can, in fact, easily be in reverse order for different cases so that the figure of 25,000,000 is, again, not a measure of risk. This wording should be changed (as should similar wording elsewhere in the text) to reflect

this fact and to emphasize it so that the user/reader will not be misled. As mentioned above, one of the matters the SAB's Environmental Economics Advisory Committee is addressing in their portion of the RCRA/RIA review is the question of monetizing the health risks so as to calculate the benefits obtained directly from reducing the risks through regulation. Use of the 25,000,000 figure in such monetization under the impression that it measures the number of people experiencing non-cancer health effects would lead to grossly high dollar values.

-- ***Page 7-42, 1st para.:*** This paragraph is a most important observation. It could imply that most of the cost and most of the benefit of Corrective Action could be attributed to this one site. It would be highly desirable to quote the site population figures in this paragraph, compared to the relevant totals, and to underline or highlight the paragraph to help ensure that its importance for the rest of the analysis is not missed by the reader.

-- **Page 7-42, 2nd para,. last two sentences**: The last of the two sentences corrects the statement of the first one; I suggest eliminating the first one and using the sense of the second one, instead, to give a correct impression in the first place.

-- **Page 7-42, section entitled " Number of Facilities..'Exhibit 7-18 and all other sections of the material under review where this comment applies:** The cancer and non-cancer population "risk" figures should not be combined in any way and indicated to be somehow of the same type since they are intrinsically differently defined; they should preferably be presented separately. The cancer figures represent an estimate (however uncertain) of the *number of cancer cases* whereas the non-cancer figures represent the *number of individuals who merely might* become non-cancer *health effects cases.* Any kind of "sum" or statement of "jointness" is meaningless unless very carefully labelled. Stating the number or percentage of sites where the number of cancer cases is expected to be insignificant (less than one in a million, say) and in which the HI is less than one (and therefore the number of people in which non-cancer health effects might not occur in significant numbers if at all) is a not-misleading statistic that might be helpful to the reader/user. The text and Exhibits need to be modified to not mix the two types of estimates in a misleading way. For example, in Exhibit 7-18, the wording No Risk might be changed to **'No' Risk** and the wording **__% Risk** might be changed to **__% Risk and Possibly At Risk**. Other examples abound; for example, in Exhibit 7-24 (a very useful Exhibit), even though the non-cancer ordinate has a parenthetical statement defining what is really meant, the title of the chart should be changed to CUMULATIVE NON-CANCER POPULATION POSSIBLY AT RISK and the title of the ordinate should be changed accordingly.

Throughout the entire text the distinction between the two types of population estimates should be carefully maintained: population risk, in the case of cancer, and population at risk,in the case of non-cancer effects. There are many such instances and I suggest the text be carefully edited to find and change each and every one of

them (for example, where the term "risk/effects" is used one might use, instead "risk/at risk," or "risk/concern" or "effects/possible effects," etc.

-- **Sections 7.4.1, 7.4.2 and 7.4.3**: These two sections are well done and very welcome.

SPECIFIC COMMENTS: APPENDIX E

-- **page 5, first paragraph**: Too flat and sharp a distinction is made between carcinogens and non-carcinogens on the basis of the existence or nonexistence of thresholds. I would suggest the following words: **"It has been the custom to suppose that for non-carcinogenic or systemic effects protective physiological mechanisms exist that must be overcome before the adverse effect is manifested. This may not, in fact, be universally true and for the non-carcinogenic effects of lead, for example, it appears not to be true. Similarly thresholds are thought to be absent in the case of cancer, i.e., any level of exposure, however small, could result in cancer although there are a very few instances now known in which this assumption may not hold. Nonetheless, in this method, the existence of thresholds will be assumed as usual in the case of non-carcinogens (except for lead, as discussed below) and the lack of thresholds will be assumed for carcinogens, also as usual."**

These words describe just what is being done, and the real assumptions being made, for the user of the method.

-- **page 5, second paragraph**: The use of "benchmark" to describe RfDs could be confused with the term "benchmark dose," which quite different from and RfD. We suggest changing the subject sentence to read "For many chemicals the RfD approach has been used as a basis for regulatory decisions in relation to potential impacts on human health."

-- **Page 27, first paragraph**: This is an entirely sensible way to handle the aggregation of risks from exposures to multiple carcinogens. it should be mentioned here, however, that synergism (and/or antagonism) is possible (referring to section 7.4.3 of Chapter 7 where it is already mentioned).

-- **Page 27, second paragraph**: The second sentence, beginning "Ratios of contaminant level... " should be added to as follows: " ... non-carcinogenic health affect *for exposure* to a particular *contaminant.* The hazard *quotients for different contaminants,* even *If they* have equal *RfDs, do not necessarily indicate which substance poses* the greater *risk."* (the material in italics is the added material) - Also, regarding the HI, the SAB/EHC commented in considerable depth somewhat over a year ago on the limitations of the use of the Hi in its review of the **"Risk Assessment Guidelines for Superfund Sites"**. We suggest that the Agency needs to refer to the SAB/EHC review, especially its Appendix, and to include mention of the principal limitations of the use of

the HI, here, in Appendix E, since the HI is incorrectly used in identifying populations as being significantly exposed to contaminants having non-cancer adverse health effects.

– **page 27,last paragraph (E.3.3)**: Here, again, the comments made on Chapter 7 need to be taken into account on the subject of the difference between population risk and population at risk. The first sentence of this paragraph, as well as further statements within it, need modification.

The problem is that the estimates of population risks associated with carcinogens, despite their well known weaknesses, at least purport to make some kind of estimate, using a model which may or may not apply in a given case, of the number of people **affected** (true population risk) as a result of exposure whereas counting the number of people with HI > 1 for non-carcinogens estimates the number of people at exposure levels such that they are **potentially affected but not necessarily affected** (this is not population risk). Whereas the estimates for carcinogens at least attempt to get at the number of people affected, the method for non-carcinogens does not attempt to do so since it includes those exposed and affected, plus those exposed but not affected in its count. Unless some effort is made to reconcile the two methods, the result of the non-carcinogen procedure is inconsistent with that for carcinogens and the two results are not comparable. Moreover, as mentioned above, the "population-at-risk" result for non-carcinogens does not measure risk and should not be said or inferred to do so here or elsewhere in the report: it estimates only one factor in characterizing risk, namely, an estimate of whether an exposed population is exposed to possibly meaningful levels of the agents involved, but it takes no account of the probability of such a population actually exhibiting adverse effects. This point needs to be made and maintained clearly in the text to avoid any misunderstanding by users if the method.

REFERENCES

Crump, K.S. 1984. A new method for determining allowable daily intakes. *Fund. Appl. Toxicol.* (4):854-871.

EPA. 1990. Review of proposed developmental guidelines. EPA-SAB-EHC-90-013.

Kimmel, C.A. and Gaylor, D. W. 1988. Issues in qualitative and quantitative risk analysis for developmental toxicology. *Risk Analysis* (8):15-20.

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