United States
Environmental
Protection Agency

Science Advisory Board
Washington DC

EPA-SAB-EEC-97-012
September 1997

AN SAB REPORT: REVIEW OF THE SECTOR FACILITY INDEXING PROJECT (SFIP)

PREPARED BY THE ENVIRONMENTAL ENGINEERING COMMITTEE (EEC)

September 30, 1997

EPA-SAB-EEC-97-012

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

Subject: An SAB Review: Review of the Sector Facility Indexing Project (SFIP)

Dear Ms. Browner:

On April 29, 1997 a Subcommittee of the SAB's Environmental Engineering Committee met to review the technical aspects of the Agency's Sector Facility Indexing Project (SFIP). The SFIP incorporates the emissions data from the Toxics Release Inventory (TRI) and couples them with toxicity weighting factors to obtain an index which not only takes into account the reported quantities of the chemical but also takes into account the chronic human health hazards associated with this chemical, without considering exposure. The SAB was asked to examine the technical underpinnings of the use of toxicity weighting factors in the SFIP.

The Subcommittee applauds the Agency in its efforts to use existing data in moving away from simple total mass releases in the TRI data base to something that makes more sense from a toxicological and risk point of view. Clearly, using the modified Hazard Ranking System (HRS) scoring methdology is a step in the right direction. It is also apparent -- to the SAB and to the Agency -- that the resulting procedure falls short of generating estimates of actual risk, since it does not consider ecological effects, acute effects, or anything about exposure. And yet, for some screening purposes, the procedure might be helpful in a limited way. A scientific risk-based approach would have to include consideration of these other factors as well.

In short, the Subcommittee concluded that by adopting the SFIP, the Agency was taking only the first step that would get to actual risk. Members generally agreed that it is important to use available scientific information to transform the limited facility release data into toxicity-weighted data in order to get closer to assessing the risks involved. Members disagreed on whether this transformation, by itself, was sufficient progress to establish a firm scientific basis for the use of the SFIP.

The review of the SFIP was the first chance that the SAB has had to interact with the Office of Enforcement and Compliance Assistance (OECA). We accommodated

their request by including it in an already tightly scheduled meeting. As a result, looking at the matter in retrospect, the Board did not have the opportunity to fully explore the context and plans that the Agency has for using the SFIP. Therefore, our conclusions are somewhat more circumspect than they otherwise might have been, as evidenced by these quotations from the report:

a) "The SFIP is a process that is getting to risk, but it is not there yet."

b) "Whether the SFIP is sufficiently useful for the limited purposes to which the Agency wants to put it...is a policy call that the Agency must make."

We enjoyed the opportunity to review this project and to interact with a new office. We are grateful to the OECA Staff for their preparation, presentation, and patience in helping us understand the project. It was reassuring to see that they were fully aware of the related projects being conducted elsewhere in the Agency.

We look forward to interacting with OECA again and look forward to the response of the Assistant Administrator of the Office of Enforcement and Compliance Assistance (OECA).

Sincerely,

/signed/
Dr. Genevieve Matanoski, Chair
Science Advisory Board

/signed/
Dr. Ishwar Murarka, Chair
Environmental Engineering Committee

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ABSTRACT

On April 29, 1997 a Subcommittee of the SAB's Environmental Engineering Committee met to review the technical aspects of the Agency's Sector Facility Indexing Project (SFIP). The SFIP incorporates the emissions data from the Toxics Release Inventory (TRI) and couples them with toxicity weighting factors to obtain an index which not only takes into account the reported quantities of the chemicals but also takes into account the chronic human health hazards associated with these chemicals, without considering exposure. The SAB was asked to examine the technical underpinnings of the use of toxicity weighting factors in the SFIP. The charge consisted of two questions:

a) "...Does the modified Hazard Ranking System (HRS) scoring methodology used by the indicators reflect accepted scientific procedures and evidence regarding the relative ranking of chemical toxicity?"

b) "...is it acceptable to use toxicity weights to provide additional contextual information regarding the human health hazards associated with pollutant releases?

The Subcommittee applauded the Agency's efforts to move beyond the total mass emissions in an attempt to characterize facilities by using the modified Hazzrd Ranking System scoring methodology. They agreed that the SFIP is a process that is "getting to risk," but it is not there yet. Whether or not the SFIP is sufficiently useful for the limited purposes to which the Agency wants to put it, in the light of the limitations identified in Subcommittee's discussion, is a policy call that the Agency must make.

A number of the members of the Subcommittee prepared written material to capture their views. These extensive comments are included in an Appendix to this report and are commended to the Agency:

a) As a demonstration of the breadth of views on these issues.

b) For their individual, not Subcommittee-endorsed, insights and suggestions for improving the current SFIP.

KEYWORDS: Sector Facility Indexing Project, SFIP, Toxics Release Inventory, TRI, weighting factors

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U.S. Environmental Protection Agency
Science Advisory Board
Environmental Engineering Committee
Special Topics Subcommittee
Use of Toxicity Weighting Factors in the OECA/SFIP Review
April 29, 1997

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1. EXECUTIVE SUMMARY

On April 29, 1997 a Subcommittee of the SAB's Environmental Engineering Committee met to review the technical aspects of the Agency's Sector Facility Indexing Project (SFIP). The SFIP incorporates the emissions data from the Toxics Release Inventory (TRI) and couples them with toxicity weighting factors to obtain an index which not only takes into account the reported quantities of the chemicals but also takes into account the chronic human health hazards associated with these chemicals, without considering exposure. The SAB was asked to examine the technical underpinnings of the use of toxicity weighting factors in the SFIP. The charge consisted of two questions:

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a) As a demonstration of the breadth of views on these issues.

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2. INTRODUCTION

2.1 Background

Many aspects of the Agency's activities center around risk and reduction of risks to human health and the environment. The so-called "risk assessment/risk management (RA/RM)" paradigm articulated by the National Research Council (NRC) (1) has served as a valuable tool for focusing the Agency's regulatory program (2), its outreach program (3), and its science program (4).

In its quest to identify and reduce risks, the Agency continues to analyze many of its existing data bases. One particularly large data base relating to chemicals in manufacturing industries is the Agency's Toxics Release Inventory (TRI)(5). For the past decade certain industries have submitted estimates of releases of chemicals from their facilities.

The mere existence of the TRI has helped to galvanize actions to reduce waste generation and releases that might otherwise not have been taken. For example, when confronted with the TRI data, certain industries were energized, for a variety of motives, to commit to reducing those emissions; cf., the 33/50 program (6) and the Project XL (7). In addition, the availability of the data in the TRI, coupled with citizens right-to-know programs (8), has also informed and empowered local citizens to become more involved in identifying and reducing risks in their own communities.

Recently (9), the TRI program has been expanded by the Agency to cover more chemicals, more industries, and more facilities. Therefore, the data base will become even broader and more complete in the future. Consequently, the Agency and others are exploring new ways in which these data can be used to help fulfill the mission of the Agency. For example, the Office of Pollution Prevention and Toxics is developing a technique that combines TRI release data , chronic human health effects (but not ecological effects) information, and exposure data (including analysis and generic computer transport and fate models) to generate "risk indicators" that would be useful to a number of Agency programs. This technique, the TRI Relative Risk-Based Environmental Indicators Project, was the subject of a July, 1997, Environmental Engineering Committee review that will result in a separate report by the Committee later this year.

The subject of this EEC report is the Office of Enforcement and Compliance Assistance's (OECA) somewhat less extensive effort, the Sector Facility Indexing Project (SFIP). The SFIP incorporates the TRI emissions data and toxicity weighting factors (taken from the TRI Relative Risk-Based Environmental Indicators Project) in a system designed to generate an index which not only takes into account the reported

quantities of the chemicals but also takes into account the chronic human health hazards associated with those chemicals, without considering exposure. The SAB was asked to examine the technical underpinnings of the use of toxicity weighting factors in the SFIP.

2.2 Charge to the Science Advisory Board

In general, the charge is a set of specific questions that guide--but do not confine--the SAB's review of an issue. That is, the SAB will provide answers to the charge questions, to the degree that it can. At the same time, the SAB may include additional comments/insights in their report, depending upon the dynamics of the particular review panel and the topic under review.

In this case, the SAB Staff worked with OECA Staff and the Chair of the EEC to develop a focused charge of two questions to guide the review:

a) "The SFIP uses chronic human health toxicity weights adopted from the TRI Relative Risk Environmental Indicators. Does the modified Hazard Ranking System (HRS) scoring methodology used by the indicators reflect accepted scientific procedures and evidence regarding the relative ranking of chemical toxicity?"

b) "EPA currently uses unweighted TRI pounds to evaluate pollutant releases from individual facilities. As a first step towards incorporating relative risk in this evaluation, is it acceptable to use toxicity weights to provide additional contextual information regarding the human health hazards associated with pollutant releases?**"**

The Subcommittee developed consensus responses to these charge questions (Section 3), provided additional perspective on the SFIP (Section 4 and associated Appendix I, and submitted individual insights that may help the Agency in dealing with the SFIP (Section 5 and associated Appendix II).

2.3 Response to Specific Charge Elements

2.3.1 First Charge Element

"The SFIP uses chronic human health toxicity weights adopted from the TRI Relative Risk-Based Environmental Indicators. Does the modified Hazard Ranking System (HRS) scoring methodology used by the indicators reflect accepted scientific procedures and evidence regarding the relative ranking of chemical toxicity?"

The HRS scoring system is simply a crude tiering/grouping/"binning" of chemical toxicity information that was useful in screening abandoned waste sites. The procedure can be used in a related way here in this instance, but there are underlying limitations of which the user must be aware; e.g.,

a) Only chronic human effects are considered.

b) There is no consideration of multiple effects.

c) There is no consideration of severity of effect.

d) There is no consideration of ecological effects.

e) There is no consideration of exposure.

A more technically defensible approach would be to deal with the hazard information for each chemical separately and group/bin the materials at the end of the analysis. The Subcommittee did not have time to explore how grouping/binning would affect the results of a screening application.

2.3.2 Second Charge Element

> "EPA currently uses unweighted TRI pounds to evaluate pollutant releases from individual facilities. As a first step towards incorporating relative risk in this evaluation, is it acceptable to use toxicity weights to provide additional contextual information regarding the human health hazards associated with pollutant releases?**"**

The application of toxicity information to release amount estimates in order to transform them into some type of toxicity emission data is a step towards getting to, but falling short of, risk. The procedure does provide some additional information regarding chronic health hazards associated with pollutant releases. At the same time, it is important to note that the procedure does not get to risk (i.e., generate risk numbers) and care must be taken lest the results be interpreted as such.

In reaching the policy judgment as to whether or not to utilize this product in the SFIP, a number of factors should be kept in mind:

a) Only chronic human effects are considered.

b) There is no consideration of multiple effects.

c) There is no consideration of severity of effect.

d) There is no consideration of ecological effects.

e) There is no consideration of exposure.

2.4 Overall Response to the Issue behind the Charge Questions

The Subcommittee appreciated the Agency's interest in using available information to make decisions that are more risk-based than would otherwise be the case. Using toxicity information in some appropriate fashion is a step in the right direction. At the same time, the Subcommittee agreed that the approach used in the SFIP does not address risk, *per se.* (The reasoning leading to this conclusion is laid out explicitly in Appendix I).

The Subcommittee concluded that by adopting the SFIP, the Agency was taking only the first step that would get to actual risk. Members generally agreed that it is important to use available scientific information to transform the limited facility release data into toxicity-weighted data in order to get closer to assessing the risks involved. Members disagreed on whether this transformation, by itself, was sufficient progress to establish a firm scientific basis for the use of the SFIP.

The question remains, however, "Where does taking this first step get the Agency?" There was a range of views expressed among the Subcommittee members. Some argued that it is better not to take a step until a more fully risk-based approach is available. Other members felt that it is better implement the first step now as a part of a screening procedure than to continue to deal with the raw mass emission data.

In the end, the Subcomittee agreed that the issue of whether or not to take the single first step is a policy question, not a technical question. Issues impacting the Agency's policy decision include factors such as

a) The availability, suitability, and viability of the OPPT TRI Indicators project.
b) The level of support provided by any submerged rock; for example, in any particular case, physical-chemical considerations could provide rough estimates as to whether exposure considerations would be likely to reverse toxicity-based estimates of potential risk or not.

c) The usefulness of a stand-alone hazard product for some additional purposes.

The Subcommittee articulates some of the specific shortcomings and opportunities for improving the SFIP in Section 5 below and its associated Appendix II.

As a bottom line, the Subcommittee agreed that the SFIP is a process that is getting to risk, but it is not there yet. Whether or not the SFIP is sufficiently useful for the limited purposes to which the Agency wants to put it, in the light of the Subcommittee's discussion, is a policy call that the Agency must make.

2.5 Other Technical Comments

A number of the members of the Subcommittee prepared written material to capture their views. These extensive comments are included in the Appendix II to this report and are commended to the Agency: a) as a demonstration of the breadth of views on these issues; and b) for their individual, not Subcommittee-endorsed, insights and suggestions for improving the current SFIP.

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APPENDIX A

CONCEPTUAL BACKGROUND TO RESPONSE TO THE CHARGE

In order to understand the SAB's response to the charge, it is important to understand first a) the components that are contained in the assessment of risk and b) the goal and process of the SFIP.

1 Components of Risk Assessment

As defined by the NRC, risk assessment consists of four parts, each of which addresses a particular question:

a) Hazard Identification (HI):
"Is this material toxic; i.e., what, if any, types of toxicities are associated with exposure to the material?"

b) Dose-Response Assessment (DRA):
"How toxic is it?

c) Exposure Assessment (EA):
"Who is exposed to this material, how often, to how much, and for how long?"

d) Risk Characterization (RC):
"So what; i.e., what are the estimates of risk (and uncertainties) to exposed populations?"

The TRI data base provides some--but certainly not all--information that is needed to answer these risk questions about "the material". This acknowledged limitation results because the TRI only provides a simple estimate of annual amounts of releases of chemicals to air, water, and land, To consider risk fully, there are many other issues that would have to be considered. For example, the HI question of a full risk assessment covers not only the identity and amount of the material but also all adverse effects (both human health and ecological; both acute and chronic), all toxic endpoints (e.g., cancer, reproductive effects, and population impacts), and all data sources (e.g., *in vitro, in vivo*, epidemiological, and field data).

To make the point in another way, performing a risk assessment requires key pieces of information including toxicity information **ti**; cf., HI and DRA above) and exposure information, which, in this case, includes amount released (**ar**) and other

important exposure information (ei), such as environmental transport and fate, as well information about populations exposed:

RISK = F[(**ti**) x (**ar**) x (**ei**)] [1]

In this construct, it is clear that in addition to the **ar** information that is provided by the TRI data base, both **ti** and ei, must be evaluated in order to say anything definitive about risk. It is also clear that if either **ti** or **ei** is zero, then the RISK is zero.

It is important to understand that, in addition to the given **ar** information, SFIP focuses only on the **ti** factor for human health in the RISK equation, gathering information found in the Agency's Integrated Risk Information System (IRIS), Health Effects Assessment Summary Tables (HEAST), and similar sources. Therefore, by explicitly not considering **ei**, the SFIP cannot--nor does it purport to--say anything definitive about the risk involved with a particular facility. Instead, the SFIP is taking some toxicity information and using it to convert the TRI mass emission data into some crude measure of toxicity-weighted emission. In order to estimate the actual risk, one would have to gather and evaluate ei, which the SFIP deliberately does not do. (However, the OPPT TRI Relative Risk-Based Environmental Indicators Project subsequently reviewed by the EEC does address the question of exposure.)

The SFIP deliberately constrains the scope of its considerations by focusing solely on human chronic effects. While the TRI data could arguably be amenable to some level of treatment for chronic ecological consequences, the yearly estimate format precludes consideration of acute effects for both human and ecolgoical receptors.

Table I summarizes the "what's in and what's out" of the SFIP regarding risk.

TABLE I

INFORMATION NEEDED TO EVALUATE RISK
(Information considered in SFIP is underlined)

1. Amount emitted (ar)

2. Toxicity information on the emissions
    a. Human (ti)
        1) Acute
        2) Chronic
    b. Ecological
        1) Acute
        2) Chronic

3. Exposure information on the emissions (ei)
    a. Who is exposed
    b. To how much, how often

2. The Goal and Process of the SFIP

If so few components of risk assessment are included in the SFIP, one might question the motive behind the SFIP exercise in the first place. Simply put, the SFIP seeks "to go part way toward risk "rather than wait for a more complete estimate of the risk.

By way of explanation, consider that the goal of the SFIP is to identify--through an admittedly rough screening procedure--those facilities that may be posing the greatest human health risks, when only information about toxicity and amounts of released material are available. For example, consider the case of hypothetical Plants A and B releasing equal quantities of different materials, Chemical X and Chemical Y, each year; cf., Table II

TABLE II

HYPOTHETICAL TRI DATA FOR TWO HYPOTHETICAL FACILITIES

FACILITY	EMISSION	ANNUAL RELEASE
A	Chemical X	1000 tons/yr

On its face, it might appear that the two facilities are equal in their potential for posing a risk, in that each of them is releasing 1000 tons of material each year. And yet, as noted above, there is not enough information upon which to reach such a final judgment. For example, there is no definitive nor distinguishing **ei**. In addition, the identity of the materials as Chemical X and Chemical Y might lead to information on relative toxicity of the two compounds and, therefore, the relative potential for risk. For example, if Chemical X were a persistent, bioaccumulative, high potency carcinogen while Chemical Y were a comparatively short-lived, low potency carcinogen, one might anticipate that Facility A would likely pose a greater chronic risk than would Facility B. However, the actual risks presented would depend on the specific exposure conditions in the two cases.

That is, one could imagine a case in which

a) Facility A is releasing Chemical X in a remote area with a very low population, and

b) Facility B is releasing Chemical Y in a more populated area.

Under these conditions, the potential risk posed by Facility B might be greater than that for Facility A; i.e,. the reverse of what might have been anticipated from toxicity considerations alone. (To be more definitive, we would have to have additional information, such as the environmental transport and fate of the Chemicals X and Y and the activity patterns and susceptibility of the respective populations.)

In short, if one were willing to set the exposure issues aside in this case, one could use toxicity information (e.g., cancer potency values and reference doses) to transform the TRI data into some type of toxicity-weighted index for screening purposes that could be used as an indicator of risk potential, accepting the fact that the missing site-specific exposure information--if known--could significantly alter the validity of the conclusions from the screen.

This approach is the one utilized by the Agency in the SFIP. The TRI reported quantities are transformed by applying modified scores first used in the Agency's Hazard Ranking System (HRS) for screening potential candidates for the National Priority List of Superfund sites.

APPENDIX B

COMMENTS BY INDIVIDUAL SUBCOMMITTEE MEMBERS

These comments, ideas, and suggestions are those of the individual Subcommittee members who authored them and should not be construed as representing Subcommittee-endorsed positions. The Subcommittee consensus is contained in the body of the report per se.

1. DR. WILLIAM ADAMS

1.1 Response to question #1

Scoring and ranking procedures are by their very nature subjective. There are now more than 100 different scoring techniques for prioritizing and screening chemicals for different purposes. Recently, many of these procedures were reviewed and some principles developed which lay the groundwork for developing and assessing scoring or ranking approaches (SETAC Scoring workshop, 1996). The value of a given methodology is often determined by its ease of use, its ability to help interpret masses of data, and its broad scale acceptance. This presumes that the approach has a good scientific basis. The SFIP Toxicity Weighting approach has significant limitations both in the design of the toxicity ranking factors and in the data which are obtained from the TRI data base.

The following describe some of the limitations associated with the proposed toxicity weighting factor approach.

The Hazard Ranking System (HRS) and the Toxicity Release Inventory (TRI) form the basis for the current approach. Neither of these systems were designed to be used for human health or ecological risk assessment. The HRS is a screening level tool and the data collected and used in that system are designed for screening level decisions. It is an approach which is based primarily on exposure estimates, not risk or relative risk. The TRI reports chemical release on an annual basis for the purpose of informing the community on chemicals used and released into the on a facility-to-facility basis. The data most often are not collected and reported in a way that is useful for accurate risk-based decisions, even at the screening level.

The current approach confuses risk, relative risk, and hazard. Risk estimates are based on the relative relationship between exposure concentrations and effect concentrations and require both components. The current approach uses release amounts data weighted by a toxicity factor (hazard) in an effort to provide a relative risk-based score for each facility of interest. The information for both exposure and

effects are unknown in this procedure and, hence, one would have to conclude that the (relative) risk is therefore unknown. The current approach is not transparent relative to the assumed population at risk, the assumed effects, or the assumed exposure. Without clearly stating the assumptions and providing sufficient validation to support them it is impossible to determine the accuracy of the approach. For screening level approaches to be effective there has to be some level of confidence that the approach provides a degree of confidence in the screen. Additionally, no information is provided on the uncertainty or accuracy of the scores generated in the weighted scoring procedure.

The question as to whether or not TRI release data are more informative when multiplied by a toxicity factor has not been adequately addressed. In some cases this appears to be true, in other it does not. The weighting approach is a subjective ranking system and it lacks sufficient depth to provide an accurate scoring approach.

The weighting approach for carcinogens assumes that thresholds are not appropriate for any of the chemicals. This is not consistent with the state-of-the-science and does not reflect the Agency's position on all chemicals. Clearly this is inappropriate for essential metals which may also cause cancer at high doses.

1.2 Response to question #2

The proposed toxicity weighting approach to evaluating TRI data has significant limitations as a first step towards incorporating relative risk in the evaluation. Pounds released multiplied by a toxicity factor does not constitute a risk index. Agency risk assessment guidelines for both human health and the environment are based on the premise that risk is a measure of the potential for exposure concentrations to exceed known effect concentrations. Both components must be measured and used with some degree of accuracy to develop reasonable risk statements. This is true even for screening level assessments. The current approach does not measure or estimate exposure in a meaningful way.

Additionally, the effects data (toxicity weighting factors) also have serious limitations. The methodology handles the scores in an additive manner. Scores for both non-carcinogens and carcinogens are added together and scores for non-carcinogens that have different modes of action are also added. This approach makes it difficult to sort out where the real hazards exist. The proposed approach also ignores the fact that some carcinogens clearly appear to have thresholds, it uses only the most sensitive endpoint, and it uses weighting factors for some chemicals which appear to be excessively large. It was noted during the SAB review that the weighting factors for sulfuric acid and ammonium sulfate appear to be considerably overstated.

In summary, the weighted hazard information gives the appearance of providing risk-based information which aggregates and presents data in a way which is easily understood, when in fact it does not present risk information at all. The hazard scoring numbers have the potential to be very misleading in many cases. The use of TRI information in a way that assumes that the reported poundage somehow equates to risk is not providing the public with accurate information on risk.

I recommend that the Agency develop an alternative procedure that accurately estimates or measures both exposure and effects and which allows for quantitative risk estimates associated with chemical releases to the environment. Such an approach will be defensible, will provide the public with information that is factual, and will assist industry to focus its pollution prevention efforts in the proper place. The ability to develop such an approach is well within the Agency's grasp. The Toxicity Indicators Program is nearing completion and may be useful towards that end. Finally, in my view, the Agency should incorporate additional stakeholder review in the process of interpreting the TRI data and IRIS effects data for risk assessment purposes. This will ensure the accuracy of the data and utility of the final overall methodology.

2. DR. STEVE BROWN

The HRS methodology was designed to help decide whether hazardous waste sites should be placed on the National Priorities List for Superfund status. Due in part to earlier SAB input, EPA restructured the procedure so that both the carcinogenic potency and chronic toxicity scales would be stepwise proportional to risk (presuming the input toxicity information was reasonably accurate, at least in a relative sense). This change was an improvement from the old HRS system in which the steps were unevenly related to risk.

Although the HRS methodology is not seriously flawed, I recommend that EPA consider three further improvements. First, the toxicity values from IRIS, HEAST, and the disposition process should be used directly rather than rounded by assigning them to bins an order of magnitude wide. Second, the carcinogenic potency values should be converted to "Risk Specific Doses" (RSDs) by dividing the potency into the risk value selected to be equivalent to exposure at the Reference Dose (RfD) - currently one in ten thousand or 10^{-4}. Then both the RSDs and RfDs can be divided into the TRI release figures to yield indexes, obviating the need to use two different scales for indexing. The units would be lbs-kg-day/(mg-yr), which could be converted to lbs or kg by using appropriate conversion factors. Third, the final indexes should be shown to no more than one significant figure; EPA should consider using categories at that point rather than specific values for the toxicity-weighted releases. For example, "A" could include any facility indexed above 10^{11} lbs-kg-day/(mg-yr), "B" indexes between 10^{10} and 10^{11}, and so on.

Several related issues were raised in the statements by the public and in our discussions. My findings on them are presented below.

2.1 *Issue*: Because the HRS toxicity weighting scheme was developed for a different purpose, it should not be used in the OECA SFIP.

Finding: Although I agree with the premise that the objective must be considered in determining the scientific validity of a procedure, the HRS and SFIP objectives are not sufficiently different to invalidate the use of the HRS system, especially if our recommendations for improvement are accepted.

2.2 *Issue*: The toxicity weights should be binned rather than derived directly from the toxicity values because the latter would imply more accuracy than justified and because a small change in toxicity values would usually not change the bin assignment.

Finding: Neither argument is sound. Binning the toxicity values loses information and can make artificial distinctions between chemicals that fall just on either side of a cut point. Binning, if done at all, should be done at the end of the process. Presenting up to 11 significant figures in Attachment (5) is unwarranted when the input information has been binned to less than 1 significant figure. If a toxicity value should change and move across a cut point, binning can improperly exaggerate the magnitude of the change. Reindexing will be done no more than annually, when the new TRI data become available. At that time, all the toxicity numbers will have to be re-checked for changes. It is little additional work to change the weighting factors accordingly.

2.3 Issue: The discounting of Category C carcinogens relative to Categories A and B is arbitrary.

Finding: I do not disagree with the idea behind discounting the potencies of Category C carcinogens: the probability that the substance will be carcinogenic in humans at the potency derived from animal studies is likely less than for Category A or B carcinogens. Therefore, it may be appropriate to discount them. However, the magnitude of the discount factor is not derivable from any current scientific data and must be a policy decision.

2.4 *Issue*: Reference Doses are derived for substances that are presumed to have thresholds of toxicity, whereas carcinogenic potency factors are derived under the assumption of linear, no-threshold risk. Therefore, they must be treated differently.

Finding: The contention is certainly true if the SFIP indexes were to be construed as risks. EPA maintains that they will not, and are for priority-setting and information purposes only. For the latter purpose, one can argue that the magnitude of the RfD is

an indicator not of risk but of the likelihood that the RfD will be exceeded in some person if a release of a fixed magnitude occurs, all else equal. In this sense it is equivalent to the likelihood that the release will create a cancer risk in some person in excess of the benchmark risk (now 10^{-4}).

2.5 *Issue*: The equivalence risk level of 10^{-4} is arbitrary and may be inappropriate.

Finding: I agree that the level is a policy call and not a scientific decision. It is similar in many respects to the Superfund action criteria, which recommend remediation if total cancer risk exceeds 10^{-4} or exposure to non-carcinogens exceeds a Hazard Index of 1.0. Lowering the equivalence level to 10^{-5} or 10^{-6} would have the effect of focusing more attention on facilities with carcinogens, while raising it would focus more attention on sites with non-carcinogens.

2.6 *Issue*: Summing indexes over chemicals or media of release may be inappropriate.

Finding: It is true that toxicologists generally advise against summing Hazard Quotients (estimated dose/RfD) over chemicals that do not have the same endpoint and mechanism of action. However, if one adopts the probability viewpoint about the significance of the indexes, then a site with several chemicals is more deserving of attention than one with only one chemical with a similar index. Regarding summing over media, the underlying (unstated) assumption is that a release is just as likely to result in a dose of a given magnitude, independent of medium of release. That assumption is critical to the whole SFIP toxicity weighting scheme, and therefore summing adds no additional difficulties. I doubt that summing or simply reporting the highest index will be much different if EPA adopts my suggestion to bin the output indexes.

2.7 *Issue*: The toxicity weights derived from the disposition process (DP) are less reliable than those from IRIS and HEAST.

Finding: Lacking a good description of the DP (or, for that matter, of the HEAST process), I am unable to conclude much about the validity of the toxicity weights derived from it. I do not disagree with the idea of supplying toxicity values for the chemicals in TRI but not evaluated in IRIS or HEAST, but I was surprised at several of the weights shown in Attachment (3). The Agency should provide a description of the DP and indicate on Attachment (3) the source of the toxicity information (IRIS, HEAST, or DP). Moreover, it should review the values with an independent group of toxicologists (within or outside the Agency) to identify any that seem unusual and verify whether the interpretation of the base information was appropriate. Some of the

substances worthy of review are sulfuric acid, ammonium sulfate, aluminum, lead, manganese (inhalation), and zinc.

2.8 *Issue*: The use of inhalation toxicity values for releases to air and oral toxicity values for all other releases may not be justified.

Finding: While intermedia transfers can greatly affect the correct toxicity factor(s) to use for a medium of release, the Subcommittee has no quarrel with EPA's decision to divide the weights in this manner as a first step.

2.9 *Issue*: Particularly with respect to RfDs, the severity of the endpoint can differ substantially from one chemical to another.

Finding: This problem is acknowledged, but is endemic to the current process of developing RfDs, and OECA cannot be expected to deal with it in the SFIP.

Relative to Charge Element #2

I agree with the premise that risk is a better indicator of priorities for enforcement attention or for informing the public about facilities in their communities than is the simple use of release estimates from the TRI. The use of toxicity weights is a step in the right direction, but the Agency could be even more forceful in its explanation that the resulting indexes may have little to do with risk even in a relative sense.

As with the first charge, several related issues were raised. My findings on them are presented below:

2.9 Issue: The assumptions behind the indexing project are not well explained.

Finding: In producing the toxicity-weighted TRI release information as a means of informing the public and setting OECA priorities, EPA is implicitly making some assumptions about the facilities. Essentially, EPA assumes that, save for the identities of the chemicals released and the amounts released to different media, all facilities are the same. For example, the emissions to air are released at the same height and with the same buoyancy, the meteorological conditions are identical, the temporal pattern of release is the same, the most exposed person is located at the same distance and downwind direction, and that person has identical patterns of activity that influence his or her exposure. Such assumptions need to be explained in greater detail and their influence on relative risk rankings needs to be honestly revealed.

2.10 *Issue*: Towards which definition of "risk" the indexing project is attempting to advance is not clear.

Finding: The term “risk” is interpreted differently in different contexts. By creating an index that uses only release quantities and toxicity weights, EPA is implicitly moving toward a ranking based on individual risk to a highly exposed individual, a definition that is probably appropriate from an environmental equity perspective. By not including population as another weighting factor, EPA is implicitly moving away from a population risk or incidence definition that might be more appropriate from a public health perspective.

2.11 *Issue*: The public may be confused or misled by the toxicity-weighted release calculations and the indexing project results should not be released.

Finding: I heard contrasting views on this subject which I do not have the expertise to resolve. Although EPA has offered many caveats regarding the information, it could do more to reduce the possibility of misinterpretation, for example by including the caveats on Attachment (5). It also might consider using a focus group to see how the public interprets the results.

2.12 Issue: EPA should not issue a toxicity-weighted release index but should wait for an index that better approximates risk.

Finding: I agree that toxicity-weighting is a step in the right direction, but note that it may be a small step. The Subcommittee was not unanimous in recommending for or against release of the indexes at this stage of development. Why OECA is taking a somewhat different approach from the OPPT TRI Indicators project and attempting an earlier completion was not clear to me.

2.13 *Issue*: TRI and toxicity information should not be used to target enforcement activities.

Finding: The Subcommittee was not charged with such policy issues. However, I do not disagree with the premise that facilities posing the most *risk* might be the best place to start when enforcement and compliance resources are limited.

2.14 *Issue*: The TRI data, not just the toxicity data, may be substantially inaccurate.

Finding: The Subcommittee did not specifically address this issue. Binning the output estimates as suggested above under the response to Charge (1) would help to alleviate concerns about the TRI.

2.15 *Issue*: The units used to report the results in Attachment (5) are incorrect or misleading.

Finding: It would be more accurate to label the column of Total Toxicity Weighted Release as being in lbs, because the toxicity weights are alleged to be dimensionless. The proposal to use toxicity information directly would also result in numbers with a dimension of mass, but the numerical values would be different. Choosing the actual unit (lbs vs. tons, for example) can make the numbers seem smaller or larger to the unwary.

3. DR. LINDA GREER AND MR. TOM NATAN

These written comments supplement the discussion held on April 29, 1997 in a special Topics Subcommittee meeting of the Environmental Engineering Committee of the Science Advisory Board. At that meeting, EPA staff presented a component of its Sector Facility Indexing Project – the use of toxicity weighting – for SAB review and comment. Both of us work extensively with the publicly available information provided in the Toxic Release Inventory as well as with the lay public concerning pollution around facilities in their neighborhoods. This topic is of great importance to the public's right to know, and we are pleased to have this opportunity to highlight our thoughts in writing.

When a community becomes concerned about an industrial facility in its midst, or, for that matter, when we in the national environmental community begin research on a particular plant or industry, our line of inquiry is approximately the following:

a) How many pounds of waste and emissions are reported from this facility?

b) How "bad" are these chemicals and their releases for human health and the environment?

c) How would these releases affect people in the area?

TRI has, to date, been an invaluable resource in answering our first important question, which concerns simple environmental loading.

Beyond loading, however, it has been difficult to systematically assess the level of hazard of releases in reported TRI, because we have lacked any sort of scoring mechanism that indicates relative hazard of the reported compounds. The toxicity weighting factor project developed in the Office of Enforcement and Compliance Assurance (OECA) responds to this gap by providing methods to evaluate the potential hazard of TRI wastes and releases in an objective and methodologically transparent way. It thus allows us to answer the second question about TRI emissions important to communities and environmental groups.

Several participants commented during our meeting that reporting on hazard alone, without taking exposure into account, was not desirable. Their primary concern was that the public would be confused about hazard information that was presented in the absence of information about exposure. We strongly disagree with these comments. First of all, many people are interested in pollutant loading per se, and not in a risk calculation, because they distrust exposure calculations. Others are interested in waste and emissions per se because they are concerned with pollution prevention

opportunities at the plant. In both of these cases and several others, information on hazard distinct from “risk” is valuable.

Furthermore, as evidenced in the string of questions most commonly raised by the public, people will not be confused with information on hazard. To the contrary, the sophisticated public, which includes many of those who currently use TRI data, understand very well the difference between hazard and risk and would find the information more useful in a disaggregated state than combined. For the lay public not experienced in TRI and pollution issues, we are confident that EPA can explain the limitations of hazard data in a way that is readily comprehensible, as it has explained the limitations of simple environmental loading in the TRI to date. We should not under-estimate the ability of the public to come to grips with technical information such as this, especially if the information is accompanied by an explanation of its usefulness and limitations. The public has proved itself fully capable of understanding these sorts of distinctions and, in fact, intuitively understands the differences between the terms “hazard” and “risk”. People know, for example, that rattlesnakes are dangerous but pose no threat to them if they are not in a rattlesnake habitat! In addition, the combination of hazard information and releases will provide another tool for communities to determine the impact of environmental improvements at facilities in their neighborhood where the potentially exposed populations don't vary much -- essentially providing a surrogate for the exposure piece not included in the indexing project.

Finally, it is not just the public and the environmental community that will find disaggregated hazard information useful. Industry itself, when trying to set priorities for voluntary reductions of its TRI wastes and emissions, undoubtedly often finds itself uncertain as to which of its chemicals most merit reductions from a human health and environmental perspective. The toxicity weighting factors will help those individuals in industry interested in reducing their company’s environmental “footprint” to select waste streams for pollution prevention assessment and emission control. Certainly they would want to understand the environmental fate, transport, and ultimate risk posed by their wastes. But they will also find useful information on the inherent hazard of these compounds, in order to consider occupational exposure scenarios as well as impact across diverse environmental media. The hazard information will thus add an important component to waste minimization and pollution prevention planning which is currently based almost exclusively on savings in raw material costs.

The dangers in waiting until the exposure piece is done before releasing this valuable hazard weighting scheme are thus two-fold. First, it will unnecessarily delay transmission of a valuable EPA work product. Second, it will obfuscate some of the important differences between hazard and risk which we all are concerned to highlight. Thus, we strongly urge the issuance of the Toxicity Weighting Factors without delay.

We have a few other “fine points” that merit attention, although none of them rise to a level of concern that should delay the issuance of this document.

a) Ecological hazard. As we noted at the meeting, we are concerned with the exclusive focus on human health and the absence of ecological hazard weighting factors. We understand that the ecological factors are on a slower track and will ultimately be a part of the toxicity weighting package. We urge that EPA continue to place high priority on this task, since there are several notable TRI compounds, such as copper and nickel, which are disproportionately toxic to some ecosystems.

b) “Binning”. Several commentors, including the Environmental Defense Fund, objected to the clustering of compounds into bins which reflect order of magnitude differences in the hazard they pose. However, there are pluses as well as problems associated with this approach. We believe that on balance, the “binning” should be maintained as in the draft presented, because the use of the actual toxicity number associated with a compound would give a false sense of accuracy to the hazard numbers. In our limited experience with risk assessments based on TRI data, it is rare that a change lower than one order of magnitude in toxicity numbers has any bearing on the outcome.

c) Non-IRIS compounds. The toxicity portfolios of a small number of chemicals on the TRI are not sufficiently mature for those chemicals to be found in the EPA IRIS data base. In response, EPA has made its best effort, using expert judgment, to assign a hazard score to that chemical. We are fully supportive of EPA’s decision in this area. It would not serve the public interest to simply “punt” on a chemical that is not in IRIS and would leave a false impression that chemicals with inadequate toxicity information are not as toxic as those that are found in the IRIS data base. Although we recognize that a full IRIS work-up is better than individual efforts for this project, the fact that the Sector Facility Indexing Project is only clustering chemicals into bins by order of magnitude, combined with the fact that gaping holes in the hazard data base would be misleading to the public, compels us to support EPA’s decision in this area. We urge that EPA make it a high priority to work on TRI chemicals that are not in the IRIS data base, especially those generated and emitted in large quantities, to resolve outstanding issues associated with their toxicity. In the meantime, this project should move forward and not wait.

In sum, we are very pleased with the work that was presented to us on the Use of Toxicity Weighting Factors in the Sector Facility Indexing Project and urge that the document be released expeditiously.

4. DR. RICHARD KIMERLE

4.1 Overall Comments

The Sector Facility Indexing Project (SFIP) and the use of the chronic human health weighting factors needs much improvement before it can be accepted as technically sound enough to provide any benefit to the public, regulatory agencies, and dischargers. However, we do need a tool to effectively sort out, priorities, and communicate potential human and ecological health risk associated with TRI discharges and all releases. Industry will then be able to focus their pollution prevention resources on the chemical discharges having the greatest potential adverse impact on ecological and human health.

I believe (and I hope the SAB review Panel can agree) the proposed Sector Facility Indexing Project must undergo a major revision incorporating better science. In its current form, SFIP cannot be defended as scientifically sound enough for use even as an "interim step toward the longer term goal of more complete risk-based modeling that will factor in chemical fate, transport and exposure". To draw any conclusions and communicate those conclusions to regulatory agencies and the public is not scientifically sound. The reasons the procedure is not acceptable is that only chronic human health factors are used without including the recognized factors of chemical fate, transport, exposure, ecological, other human health effects, exposure, and most importantly, risk assessment.

It would not be that difficult, nor should it take very long, to seek the input of other chemical scoring and ranking procedures found within and outside the EPA and develop the comprehensive risk based approach which is needed. Canada, Michigan DNR, EPA Indicators model, and the University of Tennessee under an EPA grant have already developed procedures that are more risk based than the current SFIP procedure. The Society of Environmental Toxicology and Chemistry (SETAC) held a workshop and will be publishing a book on the scientific practices of chemical scoring and ranking.

4.2 Specific Comments

a) The SFIP chemical scoring and ranking approach that is most likely to be accepted by the technical community is one that is risk based right from the start. That is, any and all decisions on chemicals would be founded in the accepted risk assessment paradigm where data on toxicological effects and potential for exposure are both available to derive at a risk characterization conclusion. To use only toxicity or only exposure leads to confusion and rejection by the scientific community. The results from

risk based assessment are easiest to explain to public and most helpful to the risk management decisions, both regulatory and industrial.

b) Ecological health effects were an obvious omission and I believe that this to be an essential part of any chemical scoring procedure. The above mentioned chemical scoring approaches all have a method to include ecological data and a manner similar to the human health approach.

c) I believe that the SFIP procedure should include commonly practiced chemical fate modeling procedures to appropriately modify the total TRI chemical releases. These procedures are quite routine and have been used in many of the published chemical scoring and ranking publications.

d) An overall algorithm should be considered that scores (1) acute and chronic toxicity for human health; (2) acute and chronic toxicity of aquatic and terrestrial organisms; (3) total pounds released; (4) chemical fate losses; and (5) potential for exposure to populations. Other factors can also be included. When the algorithm is "transparent", it is possible to generate a single score for each chemical at each discharge site and then look into the data base for a better understanding of the source of the scores and sub-scores.

e) Every chemical scoring and ranking procedure has numerous characteristics that make the procedure look to be arbitrary. It is not until some runs and sensitivity analyses are made on real data under real conditions that one can gain confidence that the scoring model provides useful data. Therefore appropriate real data analyses need to be a part of the development of an approach.

5. DR. JOHN MANEY

5.1 Charge Element #1

Does the Hazard Ranking System scoring methodology used by the indicators reflect accepted scientific procedures and evidence regarding the relative ranking of chemical toxicity.

5.1.1 HRS Model as applied to Operating Facilities

The Agency proposes to use the Hazard Ranking System (HRS) to calculate a proportional weighting factor for chronic human toxicity. The HRS has proven to be a useful tool for preliminary screening of abandoned hazardous waste sites. The HRS uses a conservative screening model that uses information from preliminary

assessments (PA) and rudimentary site investigations (SI) to determine if a site should be included on the National Priority List. The HRS is designed to favor false positives as opposed to false negatives. There is a key difference however, between the intended use and that of the proposed use of the HRS by the SFIP. The HRS was designed to estimate releases from abandoned waste sites, not operating facilities.

It is also important to note, that as described in the SAB review documents, the Agency is not proposing to employ the HRS model but is proposing to employ only that portion of the HRS model that pertains to chronic human toxicity and excludes those portions of the HRS that address acute toxicity, environmental effects, exposure routes and receptors.

The Agency's decision to employ only a portion of the HRS and the fact that the HRS is applied to operating facilities leads one to conclude:

a) That the toxicity-weighted annual release numbers are not an accurate measure of hazard or toxicity, are at best relative and should only be used by those familiar with the assumptions of the HRS and the limitations of the data.

b) All data tables and reports should be properly qualified with legends and notations indicating that the toxicity-weighted data are not accurate representations of risk to the public or the environment and use of the data as a screen, to make comparisons or to establish priorities should be restricted to those familiar with the HRS model, underlying assumptions and the fact that the reported data only address the human chronic toxicity of releases for TRI-specified compounds.

5.1.2 Toxicity Values used to estimate Weighting Factors

Based on testimony presented at the SAB meeting, the Agency should review the validity of the slope factors and RfDs used to weight release data. This review should be initiated with an evaluation of the toxicity data for lead, zinc and aluminum.

5.1.3 Releases from Off-Site Shipments

The Agency's intention is to employ the SFIP toxicity-weighted data for a number of applications including the following:

a) Evaluate low and high toxicity chemicals within a given industry.

b) Compare across facilities

c) Focus pollution prevention

d) "identify high performing facilities that can be recognized under the Environmental Leadership Program"

e) "taking a more holistic, multi-media perspective"

The above uses conflict with the Agency's intention of only examining "on-site" releases. This on-site focus can result in data-use limitations, if significant amounts of chemicals are transferred off-site to POTWs or RCRA TSDFs and later result in releases. Section 40 CFR 372.85 (b)(16) of the EPCRA-TRI regulations require that facilities supply "information on transfers of chemicals in wastes to off-site locations". This information includes the annual amount of transferred chemicals, the concentration of the chemicals in the waste before treatment, and the type and efficiency of treatment. The SFIP needs to track these off-site transfers to properly perform intra-facility and inter-facility comparisons and to ensure a significant off-site release is not overlooked. The off-site transfers can be tracked in a column separate from on-site releases. To facilitate comparisons the off-site data could be corrected for treatment efficiency and subjected to fate and transport models to estimate a release. Although, this mechanism for including off-site shipments may not be ideal, it should increase the accuracy of comparisons and offer the data user additional information. Using this approach will still allow on-site releases to be tracked separately. However, the Agency must consider off-site shipments to use the toxicity-weighted data for the previously stated applications.

5.4.1 Issues Raised by Other Members of the Subcommittee

a) Other subcommittee members proposed inclusion of environmental effects into the weighting of the TRI data. I agree with this approach, but strongly recommend that the environmental effects not be combined with the human chronic toxicity factor. The TRI release data should be weighted twice, once for chronic toxicity and once for environmental effects and the data should be reported in separate columns. The separate columns would prevent loss of information and would facilitate use by those who may only be interested in human health or environmental effects. The presence of the two columns and possibly another two columns for off-site shipments would help to capture the true complexity of the data evaluation and minimize misuse.

b) I agree with the proposal to employ actual slope factors and RfDs as opposed to the use of order-of-magnitude bins. This procedure would not round-off until reporting the final toxicity-weighted value, which would then be rounded to 1 significant figure.

6. DR. LAUREN ZEISE

6.1 General Findings/Comments

The general approach, development of indicators of hazard by weighting dose surrogates by toxicity measures, is scientifically sound. The approach is a significant advance over the previous one of using pounds released, without regard to the relative toxicity of the chemicals released.

Further, the adoption by the Agency of the scoring methodology from the modified Hazard Ranking System is reasonable. Nonetheless I have reservations about some aspects of the methodology, and is therefore proposing improvements for the Agency's consideration. I believe these modifications can be made without substantial expenditure of additional resources or undue delay in implementation.

6.2 Specific Findings/Comments

a) Proportionality of Weights and Toxicity Measures

The toxicity weights assigned are roughly proportional to the degree of toxicity. To the extent feasible, this should be the case, with the caveat that severity of effect should be considered. For example, in cases where the RfD is based on an effect which is not life-threatening, a smaller toxicity measure should be considered than if the opposite were true. The Agency decided not to consider severity in its proposed procedure, indicating that a subjective evaluation of relative severity would be required. I believe this can be mitigated by clear criteria and by considering only two or three categories of severity, and by reviewing documentation serving as the basis for the addition of the chemical to the TRI.

b) Categorical weights

I agree with the Agency that dose response relationships are typically not known with accuracy, and that there are often significant uncertainties associated with RfDs and cancer slopes.

Nonetheless, the adoption of categorical weights, rather than toxicity weights directly proportional to cancer slopes and indirectly proportional to RfDs, introduces additional imprecision. The amount introduced in some instances may result in misleading rankings. The disadvantage of giving the impression of accuracy can be addressed farther downstream in the exercise by for example, rounding of the toxicity weighted releases.

c) Scheme for A, B and C carcinogens

The proposal of using cancer slopes to assign toxicity scores for C carcinogens, but reducing their score by an order of magnitude below A/B carcinogens having the same slope is, in my judgment, reasonable.

The same approach could be used in the event that the suggestion for a continuous, rather than categorical, toxicity weighting scheme is adopted.

d) Toxicity scores derived from data from secondary sources

When toxicity values are not available in IRIS or HEAST, the Agency derived toxicity weights from information in secondary sources. At least one of the secondary sources noted in the Agency documentation is not adequate for this purpose (Hazardous Substances Database). During the meeting on April 29 several examples were raised of toxicity weights that did not seem credible, particularly for some agents for which acute effects have been a concern.

Greater (internal) peer involvement and review of values derived from secondary sources is needed, and alternative approaches, including expedited approaches using primary literature, should be considered. Other arms of the Agency, such as the National Center for Environmental Assessment, could be of great assistance.

e) Harmonization across cancer and non-cancer endpoints

The development of a single scale on which to compare facilities is appealing, and the proposed procedure seems reasonable. It is difficult to endorse this approach without a better understanding of its implications. The comparability of values among non-carcinogens is unclear given the variety of uncertainty factors applied and of endpoints serving as the basis for the derivation. In addition, the current approach does not provide ways of accounting for periodic large releases versus low continuous releases in developing toxicity weighted release values. Until there is more experience and understanding of the toxicity weighted releases, the toxicity weighted scores for cancer endpoints should be totaled and reported separately whenever totals across cancer and non-cancer endpoints are reported.

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