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Environmental
Protection Agency

Science Advisory
Board (1400)
Washington DC

EPA-SAB-EEC-98-007
April 1998

AN SAB REPORT: REVIEW OF THE TOXICS RELEASE INVENTORY (TRI) RELATIVE RISK-BASED ENVIRONMENTAL INDICATORS METHODOLOGY

A REVIEW BY THE ENVIRONMENTAL ENGINEERING COMMITTEE (EEC)

April 30, 1998

EPA-SAB-EEC-98-007

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

Subject: An SAB Review: Review of the Toxics Release Inventory Relative Risk-Based Environmental Indicators Methodology

Dear Ms. Browner:

The Office of Pollution Prevention and Toxics (OPPT) asked the Science Advisory Board (SAB) to evaluate its Toxics Release Inventory (TRI) Relative Risk-Based Environmental Indicator Methodology. The SAB's Environmental Engineering Committee (EEC) met on July 2, 1997 at the National Risk Management Research Laboratory in Cincinnati, Ohio, to review the technical merits of the methodology, including toxicity weighting, exposure modeling, and exposed populations. The EEC's Subcommittee on TRI Relative Risk-Based Environmental Indicators subsequently prepared this report, which the EEC approved in November 1997 and the SAB's Executive Committee approved on March 31, 1998.

We commend Agency representatives for their detailed understanding of the indicator methodology, their clear presentation to the Subcommittee, and the preparation of thorough reports that allowed the Subcommittee to grasp the toxicity, exposure and population elements, assumptions and limitations that were employed in the calculation of the indicators. The Agency's diligent preparation facilitated the SAB review.

The attached report presents in detail the Subcommittee's findings and recommendations. The Subcommittee would like to highlight the following points.

a) The methodology's consideration of exposure and populations in its estimation of risk is an improvement over estimates of risk based solely on the mass of annual releases or the toxicity-weighted releases as proposed for the Sector Facility Indexing Project (SFIP) which was recently reviewed by the Environmental Engineering Committee (SAB, 1997).

b) The Subcommittee agrees with OPPT that the TRI Relative Risk-Based Environmental Indicator, as presently structured, is developed to calculate chronic human health risk but not ecological risk. The Subcommittee therefore, encourages the Agency to implement its plans to include ecological impacts in a separate indicator.

c) The Subcommittee concurs with the Agency's decision to reduce the number of carcinogen categories from three to two.

d) The Subcommittee finds that the Agency's use of weights for binning is inappropriate, because binning can result in inaccuracies of nearly an order of magnitude and create artificial distinctions between chemicals having similar toxicity values that fall on different sides of the cut point. We, therefore, recommend that the Agency use the actual toxicity values in the TRI Relative Risk-Based Environmental indicators methodology and bin, if at all, at the end.

e) The Subcommittee recommends that separate indicators be considered for cancer and non-cancer chronic health end-points, and that these indicators be constructed in a manner that will allow them to be combined into a single chronic human health indicator.

f) The Subcommittee recommends that actual population numbers be used rather than the default minimum of 1000 because the default rural population value will artificially increase relative risks for remote facilities.

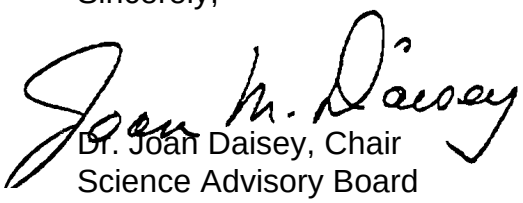
g) The Subcommittee recommends that OPPT replace or modify the deficient exposure models presently incorporated into the TRI Relative Risk-Based Environmental Indicators with others that are presently used within the Agency. The Subcommittee recommends that the Agency review all exposure models but in particular focus on those for surface water, land and POTW releases. The use of more appropriate exposure models with region-specific data (and, when available, site-specific data) will improve the precision and accuracy of the relative risk-based indicators. The Subcommittee believes these improvements will be most important when applying the methodology on a regional or site-specific basis.

h) The Subcommittee disagrees with OPPT's position that the selection of toxicity weights offers an opportunity to consider policy issues. The Subcommittee recommends that the introduction of any Agency policy should be transparent and reserved until after calculation of the TRI indicators.

i) The Subcommittee recommends that the Agency subject the TRI Relative Risk-based Environmental Indicators methodology to additional sensitivity and uncertainty analyses and also portray uncertainty in the final results. This will enable users of this methodology to assign proper levels of confidence when using the outputs.

The Subcommittee appreciates the opportunity to review the TRI Relative Risked-Based Environmental Indicators methodology and looks forward to a written response from the Office of Pollution Prevention and Toxics.

Sincerely,



Dr. Joan Daisey, Chair
Science Advisory Board

Dr. Ishwar P. Murarka, Past Chair
Environmental Engineering Committee

Dr. John P. Maney, Chair
Subcommittee on TRI Relative Risk-Based
Environmental Indicators

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ABSTRACT

The Science Advisory Board (SAB) assessed the technical merits of the Toxics Release Inventory (TRI) Relative Risk-Based Environmental Indicator methodology developed by the Office of Pollution Prevention and Toxics (OPPT). The methodology employs the same toxicity weighting for chemical releases as the Sector Facility Indexing Project previously reviewed by the SAB. The TRI Relative Risk-Based Environmental Indicator methodology also considers fate, transport, and the exposed population.

The methodology's consideration of exposure and populations in its estimation of risk is an improvement over estimates based solely on the mass of annual releases or solely on toxicity-weighted releases.

To improve the methodology, the Subcommittee recommends that the methodology: a) use actual, rather than binned, toxicity values; b) use more appropriate exposure models with region-specific data (and, when available, site-specific data); and b) use actual population numbers rather than rural population default value of 1000.

The Subcommittee recommends that the EPA subject the TRI methodology to sensitivity and uncertainty analyses and portray uncertainty in the final results. This will allow potential users the ability to use the output with the proper confidence.

Keywords: Toxic Release Inventory, modeling, relative-risk, toxicity weights

U.S. ENVIRONMENTAL PROTECTION AGENCY
Science Advisory Board
Environmental Engineering Committee
Subcommittee on TRI Relative Risk-Based Environmental Indicators-July, 1997

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CONSULTANTS

Mr. Terry Foecke, Waste Reduction Institute, St. Paul, MN

Dr. Wayne Kachel, MELE Associates, Brooks AFB, TX

Dr. Michael J. McFarland, Utah State University, Department of Civil and Environmental Engineering, Logan, UT

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Science Advisory Board Staff

Kathleen W. Conway, Designated Federal Official, U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC 20460

Dorothy M. Clark, Staff Secretary, U.S. Environmental Protection Agency, Science Advisory

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[1]Chair during the TRI review.; serving as Past Chair for FY 1998.

[2]Appointed to the EEC after the TRI review.

[3]Rotated of the EEC for FY 1998.

Board, Washington, DC 20460

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1. EXECUTIVE SUMMARY

This section of the report summarizes the Subcommittee responses to the Charge. The structure of this section closely follows that of the Charge, using the Charge questions as section heading. At the request of the Agency, the Charge questions were responded to in depth and with detailed suggestions. Although this section of the report summarizes the Subcommittee's responses, a more detailed discussion of the our responses and suggestions is presented in Section 3.

1.1 Response to General Charge :

1.1.1 General Charge Question 1

Charge Question 1 asked the Subcommittee to assess the technical merits of the methodology in order to evaluate whether appropriate approaches have been selected to assess hazard, exposure and population parameters.

The Subcommittee found the methodology's consideration of exposure and populations in its estimation of risk to be an improvement over estimates of risk based solely on the mass of annual releases or the toxicity-weighted releases as proposed for the Sector Facility Indexing Project (SFIP).

The Subcommittee agrees with OPPT's position, that the TRI Relative Risked-based Environmental Indicator, as presently structured is solely an indicator of chronic human health and does not address ecological impacts. The Subcommittee encourages the Agency to achieve a balance between human health and ecological issues by implementing its plans to include ecological impacts in a separate indicator.

The Subcommittee disagrees with OPPT's position that the selection of toxicity weights offers an opportunity to consider policy issues. The Subcommittee recommends that the introduction of any Agency policy should be transparent and reserved until after calculation of the TRI indicators.

The Subcommittee found the methodology, after incorporating some recommended changes (i.e. regarding binning, rural population default values and separate indicators for cancer and noncancer impacts) could be employed to develop scientifically defensible relative risk indicators for chronic human health at the national level. However, limitations in the exposure component of the methodology would still result in significant uncertainty for relative risk indicators at the regional or facility level.

1.1.2 General Charge Question 2 :

The second Charge item asked the Subcommittee to assess the technical merits of the methodology in order to determine if these elements have been properly integrated within the methodology.

1.1.2.1 Hazard

To improve integration of the hazard components, the Subcommittee recommends that toxicity values be used directly; carcinogenic potency values be converted to Risk Specific Doses; and indicators be reported to only a few significant figures. The TRI model has incorporated a number of approaches from the Hazard Ranking System (HRS). In the past, commenters have stated that because the HRS toxicity weighting scheme was developed for a different purpose, it should not be used in the TRI Indicators Project. However, the HRS and TRI indicator objectives are not sufficiently different to invalidate the use of the HRS system, especially if the Subcommittee's recommendations for improvement are utilized. Both HRS and the TRI indicators were developed with the intent of using surrogate measures of toxicity to arrive at conclusions that relate to risk. SAB comments on the HRS emphasized the need for risk-based rankings, and changes to the old HRS were made to improve that relationship, making the HRS suitable for integration into the TRI Relative Risked-based Methodology.

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 facility with several chemicals will usually be more deserving of attention than one with only one chemical with a similar component score. Regarding summing over different media, the underlying (unstated) assumption is that the exposure weights are roughly in the same proportion to risk for all of the media calculations, after consideration of route-specific toxicity differences and the application of exposure modeling uncertainty factors. That assumption is critical to the whole TRI indicator toxicity-weighting scheme, and therefore, the Subcommittee believes that summing adds no additional difficulties.

The Subcommittee believes that basing the hazard component on actual toxicity values and incorporation of the above suggestions for risk-specific doses and the number of reported significant figures offer a mechanism for properly integrating hazard with exposure and population elements

1.1.2.2 Exposure

The Subcommittee believes that there are superior exposure models available within the Agency and the scientific community at large. The Subcommittee believes that if the TRI methodologies are employed to generate disaggregate indicators (e.g., regional, facility specific indicators) the use of these models, regional-specific data and when available, site-specific data should improve the relative risk-based indicators.

1.1.2.3 Population

The present model takes into account the total population for a model-specified cell, area, reach or other zones of influence. Although the population estimates are likely to contribute little to the uncertainty of national indicators, as the TRI model is applied to smaller geographical areas, the contribution of population estimates to indicator uncertainty is likely to be more significant. It is also recognized that population changes in the zone of influence of a facility would increase or decrease its component scores even though no change in its releases occurs. TRI documentation should clearly explain this impact of population on TRI indicators and how local population changes could result in misleading conclusions regarding a facility's environmental management practices (Refer to Section 1.4.1).

The Subcommittee believes that actual population data, if available, should be used in estimating risk(s) (Refer to Section 1.4.2).

1.1.3 General Charge Question 3

Because the Subcommittee felt most comfortable by not trying to discriminate between general Charge issues 3 and 4, both of these issues are addressed together in Section 1.1.4 below. Issue 3 is, “assess whether this screening-level tool will provide reasonable results for relative risk- based analyses” and issue 4 is, “consider whether the overall methodology accomplishes OPPT's objective to provide a measure of risk-related impacts pertaining to TRI chemical emissions.”

1.1.4 General Charge Question 4

As detailed above, Charge 4 addressed the overall methodology in the light of the OPPT's objective.

According to the Executive Summary of the TRI Indicators document, "the objective of [the indicators methodology] is to calculate a unitless value that reflects the overall risk-related impacts of releases and transfers of all included TRI chemicals from all reporting facilities to each environmental medium for a given year or years." With one major exception and a number of minor ones discussed below, the methodology

should serve this narrow objective. It will not serve as well the subsidiary uses that are mentioned as possibilities: geographic analyses, chemical-specific analyses, industry sector analyses, environmental justice analyses, and so on, principally because any inaccuracies or biases will be magnified at lower levels of aggregation. Because the temptation to apply the indicators methodology to such other uses will be strong, the document should supply further cautions about its applicability.

A great strength of the TRI documentation is its clarity of presentation. The Subcommittee found little trouble in understanding how the methodology was developed or how it would operate. In particular, the document makes it clear that the definition of risk, which it has adopted is the public health definition: simulating the likely magnitude of impacts on the population, rather than the potential risks to highly exposed persons. A minor exception occurs because the methodology establishes a minimum size for the population at risk for a given facility's releases.

The Agency also has correctly chosen an approach that uses "proportional" weights, such that the algorithm for calculating the indicator combines and scores the weights in the same way they would be in a more complete risk assessment, again with one glaring exception - the binning of toxicity values. In many respects, the current indicator methodology for chronic human health amounts to a crude risk assessment that should produce component scores roughly proportional to risk, albeit with substantial uncertainties and conservative biases, which may not be consistent for different components of the methodology. Because the Agency seemed to recognize the virtues of the proportional approach, it is curious that it chose to use a severely constrained version of that approach for the toxicity weight by binning toxicity values and truncating their range. The Subcommittee recommends using toxicity values directly rather than binning them and believes that incorporation of this recommendation will result in more reasonable risk-based analyses.

The reliability of the indicators may depend strongly on the coverage of the TRI list of reportable releases. If the Agency has any way of characterizing the effect of omitted substances, it should present that information. Although this problem may not have a strong effect on the reliability of a national chronic health risk indicator, it is more likely to make comparisons on a smaller scale, such as interfacility or environmental justice, unreliable. Similarly, the Agency should attempt to consider the impact of not considering releases from facilities excluded from the TRI reporting requirements and the impact of chemicals not presently listed by the TRI. The Subcommittee recommends that the Agency identify the TRI slice of the universe of environmental risks and clearly present these limitations in its hard copy and electronic documentation and reports. The TRI relative risks indicators should be presented in the context of non-TRI chemical releases, exposures from other pathways such as indoor air, and the selective consideration of human populations at the exclusion of others such as avian and terrestrial animals.

The description of how the indicator methodology will be modified to accommodate changes in TRI reporting requirements is not very specific. Although the document states that it will continue to calculate a set of indicators based only on the original list of facilities and chemicals, it is not clear whether that list is the 1987 or 1994 version, or what additional indicators might be constructed. The flexibility of the TRI model makes it imperative that the Agency develops a means of ensuring that all assumptions, defaults, bases of comparisons and changes from previous models or reports are obvious to the potential user of the data.

The Agency has wisely recognized that the TRI indicators are ripe for intentional and unintentional misuse. This recognition has resulted in the repeated declarations found in the TRI documentation that the indicators are relative and should not be used to measure risk. In conflict with this recognition is a tool that has so much ability for displaying facility-specific information and comparisons among chemicals using exposure and risk estimates as a sort. The Agency has to be realistic with regard to the continuum of applications to which the TRI indicators are likely to be applied and continue to incorporate even more prominent warnings into all new documentation and reports, and where appropriate, into its computer program to decrease unintentional misuse and to discourage intentional misuse.

1.1.5 General Charge Question 5

The fifth Charge issue requested an assessment of the technical merits of the methodology in order to identify research needs that could influence future enhancements and improvements of the methodology.

Although the Subcommittee recognizes that considerable work has already been done to develop the indicator methodology, there is disagreement among the Subcommittee members as to whether more development is required before the indicator methodology can be credibly and reliably used for its intended purposes. To decrease controversy regarding the relative risk indicators, the Subcommittee recommends that the Agency subjects the methodology to sensitivity and uncertainty analyses and where possible validate the outputs.

1.1.5.1 Sensitivity and Uncertainty Analysis

As currently presented, the output from the methodology (numbers as well as graphs) implies an accuracy that is far greater than the quality of the input data and the models used to generate it. The developers must address the uncertainty question as a high priority and take steps to portray uncertainty in the final results. The Subcommittee believes this will be a valuable and necessary exercise that will allow potential users the ability to use the output with the proper confidence.

The TRI indicators documentation as well as presentations during the review imply that the developers of the methodology have not performed a sensitivity analysis, with the exception of a stack height analysis, that relates variations in the final results to variations in the value of input parameters and assumptions. The Subcommittee believes it is critical to understand the internal sensitivities of the model as a means, not only of understanding its limitations, but also focusing effort on improving the accuracy of those input parameters that make the most difference. Sensitivity analysis can result in numerous benefits, one of which is the ability to focus future research to minimize uncertainty in the resulting indicators.

Sensitivity analysis will explain the relative influence of model components (i.e., hazard, exposure-dose, and population) on the final indicators. This kind of analysis would provide some comfort level as to whether population size alone or some other component or assumption had undue influence on the final indicator. It would be useful for the developers to develop a summary table of the direction of bias in the default parameters and assumptions to provide a basis for the up/down adjustment of indicators. This summary table could facilitate future uncertainty analyses as default parameters are replaced with more realistic values.

In summary, uncertainty and sensitivity analyses can overcome the present lack of error bounds that make it difficult to distinguish "noise" levels from real changes in risk. This problem is likely to be exaggerated at the disaggregated level, because at this level the "noise" may be relatively large, requiring a sound understanding of uncertainty before lower tier indicators could be used to support environmental decision-making.

1.1.5.2 Validation of Output

The Subcommittee believes the model's output should be validated or "ground-truthed" by applying the methodology to a series of cases for which exposure concentrations were estimated using other accepted exposure models. The Subcommittee recognizes that any validation is complicated by the relative nature of the indicators and the uncertainty of the TRI release data, but in most situations at least exposure model components should be capable of validation. Lacking some sort of validation, questions will remain about the applicability of the model.

1.2 Specific Charges Regarding Toxicity Weighting

1.2.1 Compressing the Carcinogen Categories

The Subcommittee supports the approach for similar weighting of EPA Category A, B1 and B2 carcinogens. The Subcommittee agrees that it is appropriate to treat Category C carcinogens differently by reducing their potency value. The extent of the

reduction (one order of magnitude in the current Indicator methodology) is a policy judgment to be made by EPA; there is no scientific rationale for using a factor of ten.

For the long term, this approach to incorporating current weight of evidence evaluations of carcinogens into the Indicator will need to be revised to accommodate the new EPA carcinogen classification system that will emerge from the Agency's revision of its cancer policy guidelines. This classification abandons the alphanumeric categories used by the current Indicator methodology and establishes narrative categories that are less likely to support quantitative adjustment factors.

1.2.2 Comparing Severity and Number of Effects

1.2.2.1 Severity of Effects

The Subcommittee noted that toxicity values are currently not derived using factors to account for severity of endpoint, and that there is no generally accepted weighting scheme for increasing or decreasing the value of a RfD or RfC based on severity evaluations. [How to account for severity of endpoints is an important issue, but the Agency cannot be expected to deal with it in the TRI indicator methodology. It should be handled by the Agency in some other arena such as the Agency's Risk Assessment Forum with input from outside parties.] Given the Indicator project's need to rely on authoritative toxicity data and the value of having a quantitative hazard component in the Indicator, the Subcommittee believes it is reasonable to assess hazard based on most sensitive effect, without severity adjustments.

1.2.2.2 Multiple Effects

The Subcommittee noted that toxicity values are currently not derived using factors that account for a chemical's ability to cause multiple organ effects, and that there is no generally accepted approach to modifying the value of a RfD or RfC based on multiple effects. The Subcommittee agrees with the Agency's position of not incorporating a weighting mechanism for multiple effects into the present TRI methodology.

1.2.3 Binning of Toxicity Values

Although the project's general approach to hazard assessment is appropriate, the Subcommittee unanimously objected to the use of binning and truncation of toxicity values rather than actual toxicity values in indicator calculations. The Subcommittee believes that the binning of toxicity values is inappropriate, because it results in the loss of information and can make artificial distinctions between chemicals that have similar toxicity values that fall on different sides of the cut point. The Subcommittee consensus is that binning, if done at all, should be done at the end of the process,

when the final indicator is calculated, perhaps by presenting only one or two significant figures and if binning is discarded, the Subcommittee indicated a preference against truncating the lower and higher ends of toxicity values.

1.2.4 Toxicity Data Gaps

The Subcommittee recommends that chemicals without toxicity values that have been assigned binned toxicity scores via EPA's disposition process remain in the Indicator model. Assigned binned scores should be converted to interim toxicity values (RfDs, RfCs, or potencies) based on the log midpoint of the dose scales that define the bin responsible for a compound's toxicity scores. The Subcommittee also recommends that the Agency should more actively explore the possibility of an expedited process in which use of approved information from other reliable sources could result in Agency adoption of toxicity numbers.

1.2.5 Separate Indicators for Cancer and Noncancer Impacts

Based on its review of the Indicator's approach to human health hazard assessment, the Subcommittee recommends that separate indicators be considered for cancer and noncancer chronic health impacts. The use of a toxicity scoring system that assigns the same weights to both cancer and noncancer toxicity values enables the project to generate a summary indicator of chronic human health impacts that integrates across these different endpoints. While there are advantages to the current TRI methodology's single summary chronic health indicator, it hides important value judgments about the relative importance of these endpoints that cannot be defined based on scientific considerations. A single summary indicator also precludes independent evaluation of cancer and noncancer endpoints. The Subcommittee recommends that separate indicators be considered for cancer and noncancer chronic health impacts, and that these indicators be constructed in a manner that will allow them to be combined into a single summary chronic human health indicator.

1.2.6 Introduction of Policy into Toxicity Weighting

The Agency has stated that the "selection (of) toxicity weights provide EPA with an opportunity to consider important policy issues in determining final weights" (Page 30 of *Toxic Release Inventory Relative Risk-Based Environmental Indicators: Interim Toxicity Weighting Summary Document* (EPA, 1997). The Subcommittee believes that the introduction of policy, especially in a non-transparent manner, into a model that needs to be scientifically defensible is inappropriate and will negatively impact the credibility of the TRI indicators. The Subcommittee recommends that consideration of the severity of endpoints and the introduction of Agency policy should be transparent and reserved until calculation of the TRI indicators are completed.

1.3 Specific Charges Regarding Exposure Modeling

The Subcommittee found the methodology, after incorporating some immediate changes (*i.e.,* regarding binning, rural population default values and separate indicators for cancer and noncancer impacts) could be employed to develop scientifically defensible national relative risk indicators for chronic human health. However, even after incorporation of these immediate changes, the Subcommittee determined that limitations and deficiencies in the exposure component of the methodology would result in significant uncertainty for disaggregated relative risk indicators at the regional or facility level.

1.3.1 Improving the Media- and Pathway-Specific Approaches Used for Exposure Modeling

The Subcommittee believes that there may be more appropriate fate and transport models than those employed by the TRI methodology. The EEC has previously provided comments on such models, including where and how they should be applied. The Agency should review alternative models to determine if they would be more appropriate alternatives to those presently incorporated into the TRI methodology.

The Subcommittee recommends that the Agency evaluate all potential exposure pathways before excluding any from consideration. For example, the surface water pathway with potential exposures through recreational use or bathing are pathways that should be considered for inclusion in the TRI model. Another main route of exposure to environmental contaminants, the dietary pathway, is not adequately accounted for in the TRI model. For example some chemical releases through the air pathway can result in more human exposure/risk via the diet than via inhalation. The Agency should document the logic for including or excluding a pathway as well as the ramifications of these decisions on the accuracy and uncertainty of the TRI model.

1.3.2 Adjustment Factors and Uncertainty in Evaluating Exposure

Due to the conservative assumptions made in some exposure models, adjustment factors of 5 or 10 are used to adjust down "surrogate" doses. Nevertheless, in certain situations, default assumptions may not be as conservative as suggested. For example, the fish consumption value (6.5 g/day) in the surface water pathway is based on the per capita mean for the U.S. population, yet the exposed population who fish and eat fish are probably consumers in the upper percentile range. [If the 6.5 g/day figure is retained, it should probably apply to all the people in an area; otherwise a higher consumption figure is probably appropriate and/or the adjustment factor should be less.] The Subcommittee recommends that the Agency review adjustment factors in light of the following discussion of pathway assumptions in Section 3.

1.3.3 Alternate Values for Exposure Modeling Assumptions

The Subcommittee believes that the Agency should review its assumptions for groundwater and air releases from land disposal units, population estimates, surface water discharges and air dispersion models. A more detailed discussion of these issues is presented in Section 3.

1.4 Specific Charge Issues Regarding Exposed Populations

1.4.1 Filling Data Gaps for Interim Years Between Primary Census Dates

The majority of the Subcommittee believes that an accepted method to address population changes over time is to use the latest intercensual rate of change (i.e., average annual rate of change between 1980 census and 1990 census) to project population size for postcensual years (Shrycock *et. al, 1976)*. A dissenting Subcommittee member voiced concern over this approach because it was perceived as encouraging the extrapolation of data, a policy that the EEC has often opposed.

1.4.2 Approaches for Weighting Data on Rural Populations

Population considerations are a significant component of the TRI model, such that population change could influence the indicator for regional and site-specific applications. An increase or decrease of population will elevate or lower the indicator even when no change in releases occurred.

Members of the Subcommittee had concerns regarding the 1000 exposed persons minimum for air exposure for rural areas and recommend the use of actual population numbers as opposed to this default minimum of 1000. Presently, the default rural population value of 1000 may artificially increase relative risks for remote facilities and remove the incentive to locate facilities in areas removed from adjacent populations.

2. INTRODUCTION

2.1 Background

The Emergency Planning and Community Right to Know Act of 1986 established the requirement for the Toxics Release Inventory (TRI). Since 1987, implementation of the TRI regulations has resulted in one of the Agency's largest and longer-term databases. EPA's need to track changes in the environment and to set priorities naturally led to the consideration of the TRI database as a means to measure risk and changes in risk over time.

The TRI database is not a meaningful indicator of risk, because the annual mass data ignores key components of risk. Risk is specific to those exposed and varies in magnitude according to the degree of exposure and the toxicity of the chemical. OPPT designed the TRI Relative Risk-Based Environmental Indicators methodology to ameliorate these limitations and to calculate an indicator of relative risk-based impacts on the nonworker, general population.

2.2 Review and Charge

The Office of Pollution Prevention and Toxics (OPPT) asked the Science Advisory Board (SAB) to evaluate the TRI Relative Risk-Based Environmental Indicator methodology. The Environmental Engineering Committee formed a Subcommittee on TRI Relative Risk-Based Environmental Indicators, consisting of EEC members, members of other relevant SAB committees, and consultants. Drs. Brown, Kimerle, Maney, and Murarka had also participated in the related April 29, 1997 Special Topics Subcommittee review (SAB, 1997) of the use of toxicity weighting factors in the Office of Enforcement and Compliance Assurance's Sector Facility Indexing Project (SFIP). The SFIP employed the toxicity weights as established by the TRI Relative Risked-based Environmental Indicators Methodology. The EEC and the Subcommittee met on July 2-3, 1997 at the National Risk Management Research Laboratory in Cincinnati to address the following Charge:

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a) General Charge: To assess the technical merits of the methodology to:

   1) evaluate whether appropriate approaches have been selected to assess hazard, exposure and population parameters;

   2) determine if these elements have been properly integrated within the methodology;

3) assess whether this screening-level tool will provide reasonable results for relative risk-based analyses;

4) consider whether the overall methodology accomplishes OPPT's objective to provide a measure of risk-related impacts pertaining to TRI chemical emissions; and

5) identify research needs that could influence future enhancements and improvements of the methodology.

b) Specific Charge Issues Regarding Toxicity Weighting:

1) Does the SAB have any comments regarding the recommendation to compress the carcinogen categories to two (one for A and B, and one for C) with only a single factor of ten separating the categories?

2) Can the SAB offer any recommendations as to how severity or number of effects be compared?

c) Specific Charge Issues Regarding Exposure Modeling:

1) Does the SAB have any suggestions on how to improve the media- and pathway-specific approaches used for exposure modeling?

2) Are there more appropriate adjustment factors, which may be incorporated in the uncertainty categories used for evaluating exposure?

3) Can the SAB suggest alternate values for these assumptions which would be more appropriate?

d) Specific Charge Issues Regarding Exposed Population

1) At various levels (state, county, city, block group) could SAB suggest potential approaches to filling data gaps for interim years between primary census dates?

2) Can SAB recommend any other approach which would more appropriately weight rural populations?

The EEC and the Subcommittee reviewed materials sent in advance of the meeting,[4] listened to overview presentations, discussed the documentation accompanying the presentations, and provided a verbal synopsis of findings and recommendations to Agency staff before adjourning. The Executive Summary presents the Subcommittee's findings and recommendations for each of the Charge questions. In response to OPPT's request for a more detailed response to the Charge questions, a detailed presentation of the Subcommittee's findings, recommendations and references are presented in Section 3.

[4]Materials reviewed by the Subcommittee are listed in Appendix B.

3. RESPONSE TO THE CHARGE

Detailed responses to the Charge issues are presented in this section. The Charge identified general and specific issues and did not emphasize their close relationship. While this format is constructive for a Charge, it can lead to unnecessary redundancy within a report. This chapter has been structured to re-establish the relationship between the general and specific issues. For example, questions regarding the binning of toxicity values or the compression of carcinogenic categories are considered in subsections under the section on hazard.

In addition, the Subcommittee determined that it was best not to discriminate between two of the General Charge issues:

> General Charge Question a)3) - assess whether this screening-level tool will provide reasonable results for relative risk-based analyses; and
>
> General Charge Question a)4) - consider whether the overall methodology accomplishes OPPT's objective to provide a measure of risk-related impacts pertaining to TRI chemical emissions;

Both of these Charge issues are addressed together in Section 3.3. To facilitate consistency throughout the document and efficient perusal, the major findings are summarized at the beginning of each subsection, with more detailed discussion, comments and findings following.

3.1 Are Approaches for Hazard, Exposure and Population Appropriate for Stated Objectives?

3.1.1 Appropriateness of Approach for Assessing Hazard

The assumptions underlying the hazard assessment component of the Chronic Human Health Environmental Indicator are consistent with current scientific practice. That is, the cancer and noncancer toxicity values developed by EPA to provide a measure of inherent toxicity for indicator calculations. The TRI Indicators document emphasizes that the current indicator addresses relative chronic health effects only. This focus is appropriate given that the limitations of the TRI release data prevent construction of an analogous quantitative indicator for acute health effects. The Subcommittee agrees with the overall approach and provides, in the following subsections, suggestions that can improve the mechanism for assessing hazard for incorporation into the TRI indicator.

3.1.1.1 Binning

Finding: The Subcommittee found that the binning of toxicity values is inappropriate because binning may introduce more significant artifacts to the Indicator than use of actual toxicity values. If a toxicity value should change and move across a cut point, binning can improperly exaggerate the change by an order of magnitude.

Recommendation: The Subcommittee consensus is that binning, if done at all, should be done at the end of the process, when the final indicator is calculated, perhaps by presenting only one or two significant figures.

Recommendation: If binning is discarded and actual toxicity values are used, the Subcommittee recommends that the Agency not truncate the lower and higher ends of toxicity values.

Although the methodology's general approach to hazard assessment is appropriate, the Subcommittee unanimously determined that the use of binning and truncation of toxicity values rather than actual toxicity values in indicator calculations was scientifically flawed. The Agency asserted before, during and after the review that the indicator should be calculated using toxicity bins (assigned on the basis of categorical ranges of toxicity values defined by the Hazard Ranking System) rather than derived directly from the toxicity values. Four arguments have been offered by Agency Staff to support the use of toxicity bins:

a) use of actual toxicity values would imply more accuracy than justified;

b) small changes in toxicity values should not be allowed to change overall indicator scores (toxicity scores based on bin assignments would be more unlikely to change);

c) use of weights will prevent the indicator tool from being misused to produce risk estimates that might be misinterpreted as predictions of the incidence of adverse health effects in exposed populations; and

d) that toxicologists are more confident in assigning order-of-magnitude toxicity weights (even though the disposition process generates a point estimate toxicity value that is later assigned to a bin) to TRI chemicals missing toxicity values than to develop the actual values themselves through EPA's disposition process.

The Subcommittee believes that the first three arguments (a, b, and c above) are unsound, and that there are solutions to the problems posed in the fourth (d). Binning the toxicity values creates inaccuracies of up to an order of magnitude resulting in

artificial distinctions between chemicals of similar toxicity. Binning to account for uncertainties, if done at all, should be done at the end of the process, when the final indicator is calculated, perhaps by presenting only one or two significant figures. While there are legitimate concerns about the uncertainty associated with toxicity values, these concerns are not unique; there are also uncertainties associated with the other major components, including reported release data, exposure and population assumptions.

The Subcommittee is not persuaded by the rationale for the third argument (c above): "toxicity weights cannot be easily manipulated mathematically to convert indicator values from unitless numbers to precise (although probably inaccurate) estimates of the number of cases of health effects associated with various chemical emissions". This rationale is not persuasive because it is always possible for a person of modest technical skill to replace weights with the actual toxicity values (included in the data section) and then generate individual and population risk estimates for carcinogens (or hazard indices and population exceedance for noncarcinogens). To prevent people from using the methodology to generate risk estimates, the Agency would have to make the methodology non-transparent and prevent public access to the data elements required by its indexing algorithms.

Because the Agency is concerned about potential misuse of the screening-level assessments, the Subcommittee recommends the Agency describe the limitations of screening-level assessments and advise against misinterpreting risk estimates as actual body counts. If the Agency wants to be sure that the public cannot misinterpret the outputs as actual risk estimates, the Agency could also bin indicator *results* at the end of the calculation process, by focusing on the exponents of the calculated indicator values or by converting the exponent to letter scores that convey ordinal ranking without any risk interpretation.

The fourth argument (d above) -- the concern regarding the assignment of toxicity scores to TRI chemicals missing toxicity value s-- is addressed in the following subsection. Options for calculating indicators with actual toxicity values are presented in Section 3.1.1.3.

3.1.1.2 Toxicity Data Gaps

The Agency does not have data with which to develop toxicity values for all TRI chemicals. Several strategies exist to deal with these data gaps. Currently the Agency employs a disposition process by which experts assign these chemicals to “bins”.

Recommendation : The Agency should more actively pursue development of an expedited process which uses approved information from other reliable sources to generate actual toxicity values.

Recommendation: If, as recommended, the Agency uses actual toxicity values instead of bins, there will be a subset of chemicals which lack actual toxicity values and were assigned "bins" using the disposition process. The Subcommittee recommends that the Agency convert the assigned binned toxicity scores for these chemicals to interim toxicity values. Such values (RfDs, RfCs, or potencies) can be based on the log midpoint of the dose scales that define the bin responsible for a compound's toxicity scores.

The Subcommittee agrees that lack of IRIS and HEAST values, especially for such important substances as lead and copper, creates a great impediment to the successful implementation of the TRI Relative Risk-based Environmental Indicators Methodology. Therefore, the Subcommittee agrees, in concept, with developing toxicity values for those TRI chemicals not evaluated in IRIS or HEAST. However, the Subcommittee recommends that the Agency establish a continuing process for reviewing and updating the toxicity values to be consistent with best toxicological practice in values used elsewhere in the Agency.

Presently 372 of the 600 chemicals covered by TRI have toxicity values that can be used to create the chronic human health indicator. The Subcommittee encourages the Agency to develop values for the remaining TRI chemicals. The Subcommittee consensus is that it is better to use alternative approaches for filling toxicity data gaps, than to ignore the chemical(s) because the alternative approaches have fewer undesirable implications for the integrity of the overall indicator system.

The Subcommittee supports the hierarchy of data sources for toxicity values utilized by the project (first IRIS, then HEAST, then the disposition process), *plus* currently unutilized sources of credible toxicity values that could enrich the data supporting the Indicator.

If the Agency accepts the SAB's advice to use actual toxicity values, there will remain a subset of chemicals lacking actually toxicity values which were binned using the disposition process. An short-term approach is to convert assigned binned scores into interim toxicity values (RfDs, RfCs, or potencies) based on the log midpoint of the dose scales that define the bin responsible for a compound's toxicity score.

In the medium term, the Agency should evaluate whether compounds without IRIS or HEAST values do have toxicity values that have been generated other organizations using procedures similar to EPA's risk assessment practice (e.g., the California EPA). Where such toxicity values exist, EPA should promptly substitute them for the current toxicity values based on the disposition process. Consistency in methods used to derive toxicity values, is important, however, and some organizations that derive toxicity values using different practices (e.g., ACGIH, ATSDR) may not be appropriate sources.

Outside organizations may also be valuable sources of toxicity values on exposure scenarios that EPA has not developed values for, but would like to address in future enhancements of the Indicator (e.g., CalEPA acute inhalation exposure guideline limits).

The Agency should first adopt an explicit approach to setting priorities for those chemicals that lack toxicity values and then define a structured approach for establishing toxicity values for the higher priority chemicals. In the short term, the summary Indicator is appropriately derived using just those compounds that can be modeled based on available data. An additional subset of "missing data/unmodeled" compounds could be indexed using default toxicity values for sensitivity analyses. These default toxicity values could be based on various cut points observed in the distribution of existing toxicity values (median, and some upper bound percentage). Sensitivity analyses could then be run to examine whether addition of default-based Indicators to the summary modeled Indicator has a significant impact. More resource intensive approaches to developing "expedited" toxicity values could be explored in the future as an effort to reduce the number of TRI chemicals excluded from the Indicator because of toxicity data gaps. Alternatives to be explored include estimating cancer potency based on the relationship between acute toxicity and carcinogenic potency, and by estimating toxicity values based on structure activity relationships.

The Subcommittee also had the following recommendations regarding IRIS and HEAST toxicity data;

a) Do not remove existing toxicity values from these data bases, because it is disruptive to a variety of Agency programs among which the TRI project is an example.

b) Make a commitment to improve the IRIS and HEAST databases by completing work on important chemicals (e.g., lead and copper).

c) Facilitate the creation and use of interim toxicity values for specific purposes such as the TRI Risked-based Environmental indicators. The Subcommittee is mindful that proliferation of potentially inconsistent and less reliable toxicity numbers is undesirable. However, properly qualified toxicity numbers should be available for specific and limited purposes.

d) Explore more actively the possibility of an expedited process in which use of approved information from other reliable sources could result in Agency adoption of toxicity numbers based on the latest research without feeling the need to defend the older numbers.

3.1.1.3 Separate Indicators for Cancer and Noncancer Impacts

Recommendation: The Subcommittee recommends that separate indicators be considered for cancer and noncancer chronic health impacts, and that these indicators be constructed in a manner that will allow them to be combined into a single summary chronic human health indicator.

Based on its review of the Indicator's approach to human health hazard assessment, the Subcommittee recommends that separate indicators be considered for cancer and noncancer chronic health impacts. The use of a toxicity scoring system that assigns the same weights to both cancer and noncancer toxicity values enables the project to generate a summary indicator of chronic human health impacts that integrates across these different endpoints. While there are advantages to the current summary chronic health indicator, it also obscures important value judgments about the relative importance of these endpoints. A single summary indicator also precludes independent evaluation of cancer and noncancer endpoints.

The Agency's toxicity weighting system establishes an equivalency of cancer and noncancer impacts: a cancer risk of 10^{-4} is scored as equivalent to a noncancer hazard index of 1. While this equivalency has always been implicit in the HRS scoring system, it has never been publicly advertised as Agency policy and involves value judgments that may vary substantially among stakeholders in risk debates. Lowering the equivalence level to 10^{-5} or 10^{-6} would have the effect of focusing more attention on carcinogens, while raising it would focus more attention on noncarcinogens. The Subcommittee suggests that separate indicators be considered for cancer and noncancer impacts and that these indicators be constructed in a manner that will allow them to be combined into a single summary chronic human health indicator.

The Agency may require a scoring system that generates a single summary chronic human health indicator. If so, there are approaches that use actual toxicity values (not binned weights); these approaches can be designed such that they do not predict the incidence of adverse health effects. These approaches are not very susceptible to misuse or misinterpretation. To use this approach, the Agency would first develop "benchmark" levels of acceptable exposure based on actual toxicity values. These benchmarks would be established by Reference Concentrations/Doses for noncarcinogens. Benchmarks for carcinogens would be established by converting carcinogenic potency values to "Risk Specific Doses" (RSDs) by dividing the potency into the risk value selected to be equivalent to exposure to the Reference Dose, currently 10^{-4}. Two examples of summary scoring systems are discussed in Appendix A.

3.1.1.4 Compression of Carcinogenic Categories

Finding: The Subcommittee supports the approach employed for the compression of the carcinogenic categories.

The Subcommittee supports the approach for similar weighting of EPA Category A, B1 and B2 carcinogens. The Subcommittee agrees that it is appropriate to treat Category C carcinogens differently by reducing their potency values. The extent of the reduction (one order of magnitude in the current Indicator methodology) is a policy judgment to be made by EPA; there is no scientific rationale for using a factor of ten.

For the long term, this approach to incorporating current weight of evidence evaluations of carcinogens into the Indicator will need to be revised to accommodate the new EPA carcinogen classification system that will emerge from the Agency's revision of its cancer policy guidelines. This classification abandons the alphanumeric categories used by the current Indicator methodology and establishes narrative categories that are less likely to support quantitative adjustment factors.

3.1.1.5 Accommodation of Severity

Finding: The Subcommittee supports the approach employed for accommodating the severity of endpoints.

The Subcommittee noted that toxicity values are currently not derived using factors to account for severity of endpoint, and that there is no generally accepted weighting scheme for increasing or decreasing the value of a RfD or RfC based on severity evaluations [How to account for severity of endpoints is an important issue, but the Agency cannot be expected to deal with it in the TRI indicator methodology. It should be handled by the Agency in some other arena such as the Agency’s Risk Assessment Forum with input from outside parties.]. Given the Indicator project's need to rely on authoritative toxicity data and the value of having a quantitative hazard component in the Indicator, the Subcommittee believes it is reasonable to assess hazard based on most sensitive effect, without severity adjustments.

3.1.1.6 Accommodation of Multiple Effects

Finding: The Subcommittee supports the approach employed for accommodating multiple effects for the present version of the indicator methodology.

The Subcommittee noted that toxicity values are currently not derived using factors that account for a chemical's ability to cause multiple organ effects, and that there is no generally accepted approach to modifying the value of a RfD or RfC based on multiple effects. The Subcommittee agrees with the Agency's position of not

incorporating a weighting mechanism for multiple effects into the present TRI methodology.

In the short term, the Agency could consider supplementing a core noncancer impact indicator (which is a quantitative function of RfD/RfC, surrogate dose and population) with qualitative indicators summarizing the mass release of compounds affecting distinct endpoints/organ systems (e.g., pounds released of developmental/reproductive toxicants). This would represent a first step towards addressing concerns regarding the need to track trends of chemicals with multiple effects. The *Federal Register* documentation supporting the listing of TRI compounds identifies specific endpoints of concern for TRI chemicals (e.g., neurotoxicity, immunotoxicity). These endpoints could be utilized to organize health endpoint subsets of TRI chemicals. California's Air Toxics program has also classified a large number or toxic air contaminants by the endpoint affected. Since the toxicity values underlying the quantitative noncancer index are based on a compound's most sensitive effect and are unlikely to be appropriate for scaling a compound's capacity to affect multiple, different endpoints, it will not be possible to generate toxicity-weighted releases or relative-risk adjusted releases for these subsets.

3.1.1.7 Introduction of Policy into Toxicity Weighting

Recommendation: The Subcommittee recommends that Agency introduce policy in a transparent manner and do so only after completing calculation of the TRI indicators.

The review document, *Toxic Release Inventory Relative Risk-Based Environmental Indicators: Interim Toxicity Weighting Summary Document*, states that the "selection (of) toxicity weights provide EPA with an opportunity to consider important policy issues in determining final weights". The document explains further that lead is a priority chemical that the Agency may want to "highlight" and "target".

The Subcommittee believes that the introduction of policy, especially in a non-transparent manner, into a model that needs to be scientifically defensible is inappropriate and will detract from the credibility of the TRI indicators. Because the present model is not designed to address severity of endpoints, an attempt to address this limitation for selected chemicals is not only arbitrary but also compromises the relative nature of the indicators and comparisons across chemicals. The Subcommittee therefore recommends that both consideration of the severity of endpoints and the introduction of Agency policy be transparent and reserved until calculation of the TRI indicators are completed.

3.1.2 Appropriateness of Approach for Assessing Exposure

Recommendation: The Subcommittee recommends that OPPT replace or modify the deficient exposure models presently incorporated into the TRI Relative Risk-Based Environmental Indicators with others that are presently used within the Agency. The Subcommittee recommends that the Agency review all exposure models but in particular focus on those for surface water, land and POTW releases. The use of more appropriate exposure models with region-specific data (and, when available, site-specific data) will improve the precision and accuracy of the relative risk-based indicators. The Subcommittee believes these improvements will be most important when applying the methodology on a regional or site-specific basis.

The TRI indicator methodology is a screening level tool whose proposed use is for identifying trends and for prioritizing. Due in large part to its attempt to model exposure, the Subcommittee finds the TRI indicators to be an improvement over ranking and trending based on pounds alone. The following are comments regarding the exposure approaches employed to calculate the TRI indicators. The comments are categorized into three somewhat overlapping classes according to the nature of the comments: general comments, comments pertaining to pathways, and comments regarding assumptions.

3.1.2.1 General Comments

The Subcommittee believes there are more appropriate fate and transport models than those employed by the TRI methodology. The EEC has previously provided comments on such models, including where and how they should be applied. The Agency should review alternative models (including Cal TOX) to determine whether they would be more appropriate than those presently incorporated into the TRI methodology.

The TRI indicators methodology is designed to accommodate various types of analysis, such as aggregation and de-aggregation; various model options from pounds alone in the model to the full model of hazard; surrogate dose and receptor population; and modification of default parameters. However, uncertainty in the exposure-dose approach increases as the analysis moves from a larger-scale, more aggregated level (national) to smaller-scale more disaggregated levels (local/site-specific). With this loss of resolution, the ability to say something meaningful about the indicators at the local/site-specific level is compromised. Therefore, the Agency should provide some guidance to users about the level of confidence in the indicators at different levels of analysis/application, and at what level of analysis, site or regional-specific data are preferable and should be used in place of default assumptions.

Although the TRI indicator is a first step toward assessing trends and prioritizing environmental impacts, the methodology offers little insight concerning actual impact(s) of the TRI chemicals on community health. Community health is commonly assessed through epidemiology, which is the study of factors of health and disease in human populations. Epidemiological studies often rely heavily on more sophisticated analyses of exposure and effects information. Individualized exposure and effects information is especially useful in such analyses. Because the TRI release data are often estimates based on crude mass balance calculations rather than actual monitoring, it is difficult to determine what they mean in terms of individual exposures. Because assessment of community health requires monitoring, surveillance, and sophisticated analyses beyond that which the TRI Environmental Indicators methodology provides. Therefore the Agency should repeatedly inform the users of the methodology about these limitations and of the proper uses of the TRI indicators. Two special cautions follow.

a) First, although TRI is one the most extensive databases on environmental releases, the TRI data are limited because they capture only a small percent of actual releases and transfers of all chemicals from all sources. For example, only manufacturers with ten or more employees who either use 10,000 pounds or manufacture 25,000 pounds of one of the listed chemicals must report. In the South and Southwest regions of Philadelphia, only 11 of approximately 250 facilities listed in federal and state environmental regulatory databases are required to submit TRI data (Burke *et. al*, 1997). Interpretation of TRI indicators should reflect this limitation.

b) Secondly, the lack of error bounds make it difficult to distinguish "noise" levels from changes in environmental quality or true difference between chemicals and facilities. Particularly at the smaller, disaggregated scale, the "noise" levels may be quite large.

3.1.2.2 Comment Regarding Pathways

The Subcommittee recommends that the Agency evaluate all potential exposure pathways before excluding any from consideration. Then the Agency should document the logic for including or excluding a pathway and also state the ramifications of these decisions on the accuracy and uncertainty of the TRI model. For example, the surface water pathway should be considered for inclusion in the TRI model because of the potential for exposure through recreational use. The TRI model does not adequately account for the dietary pathway because some chemical releases through the air pathway can result in more human exposure/risk via the diet than via inhalation. Vegetation, fruits and vegetables can become contaminated directly by atmospheric deposition or indirectly through uptake from contaminated soil and this may be passed

on to farm animals and poultry. Similarly, dietary exposure can occur when contaminated surface water is used for irrigation.

3.1.2.3 Comments Regarding Assumptions

Due to the conservative assumptions made in some exposure models, *adjustment factors* of 5 or 10 are used to adjust down "surrogate" doses. Nevertheless, in certain situations, default assumptions may not be as conservative as suggested. For example, the fish consumption value (6.5 g/day) in the surface water pathway is based on the per capita mean for the U.S. population, yet the exposed population who fish and eat fish are probably consumers in the upper percentile range [If the 6.5 g/day figure is retained, it should probably apply to all the people in an area; otherwise a higher consumption figure is probably appropriate.].

For the *air dispersion model*, a steady-state model is used to estimate concentrations of pollution in each of the 441 cells surrounding a particular facility. However, it is not clear in the TRI documentation whether this model is predicting the maximum concentration in the cell (e.g., centerline concentration) or some other parameter (e.g., maximum ground level concentration). During the review, Agency personnel indicated that, for sparsely populated rural areas, the number of people needed to reach 1000 were distributed evenly across the 441 100-hectare cells. The Agency should document its chosen method of distribution for heavily or sparsely exposed populations and provide an explanation for its choice.

EPA's choice of air modeling parameters minimizes plume rise. This choice will generally predict higher ground-level concentrations close to the facility and lower concentrations further away than would be the case if the plume rose higher. For the air pathway, stack height is currently set at 10 meters. The actual range in stack heights can be wide. Information from one set of air emission data showed stack height can range from 6 to 76 meters. Perhaps, distribution of stack heights could be empirically derived from existing data and the high, mid, and low values can be identified, or possibly stack heights could be correlated with SIC or facility type. The choice of stack heights is further complicated by the fact that the same model is employed to model fugitive emissions. The Agency should comment on the rationale and impact of their choice.

The Subcommittee believes that the Agency should review its assumptions for *groundwater releases from land disposal units*. For the groundwater pathway, the simplified TRI methodology for quantifying contaminant releases is prone to significant errors because it does not accommodate the diversity of waste management facilities and subsurface disposal schemes used for TRI wastes. A general assessment of the configurations, designs, and construction materials used by industry for the land disposal of TRI wastes would improve understanding of the source term(s).

The methodology could be improved by establishing a subcategory for exposure for groundwater contaminated by landfill leachate that accounts for the wide range of landfill conditions actually seen. The current landfill model does not account for the depth to groundwater when evaluating releases to land, instead the model sets groundwater exposure concentration equal to a hundredth of the leachate concentration. This does not fit with actual experience. In the west and southwestern US, depths to groundwater in subtitle D landfills may be on the order of 100 to 400 feet. Also, because of the high evapotranspiration rates in these areas, leachate may never reach groundwater.

One approach would be for the TRI indicators methodology to employ one of the several landfill models currently used by US EPA to evaluate landfill leachate, for example the Hydrologic Evaluation of Landfill Performance (HELP) Model. The HELP model uses publicly accessible data from sources such as the National Oceanagraphic and Atmospheric Administration, the Natural Resources Conservation Service; and the U.S. Department of Agriculture.

HELP is one of the most robust and popular landfill leachate generation and migration models. Developed by the US Army Waterways Experiment Station, HELP has undergone several revisions since it was first released in 1984. The latest documentation of HELP is contained in an USEPA publication for HELP version 3.0.[5]

Other sources of subsurface data for the United States can be found in *Guide to Technical Resources for the Design of Land Disposal Facilities* (EPA, 1988). Although site-specific data would be the most desirable to use as input to any model, reasonable ground water model outputs can be obtained using data supplied by the Natural Resources Conservation Service (NRCS).[6]

The conservative nature of estimated leachate concentrations resulting from wastes deposited in "non-hazardous" landfills, can be evaluated by comparisons to the toxicity characteristic criteria. If the estimated leachate concentrations exceed the criteria for hazardous waste, which are not allowed to be disposed in non-hazardous landfills, the model may be too conservative.

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[5]Since the release of the 1994 USEPA publication, HELP has undergone additional modifications. The latest version of HELP is version 3.07. To obtain this latest version, either send two (2) 3.5", high density DOS formatted diskettes to Dr. Paul Schroeder, EE-P, USAEWES, 3909 Halls Ferry Road, Vicksburg, MS 39180-6199, or get into the FTP site:

Host: 134.164.99.52
Username: help3
Password: lloyd
(note: all files from the D:\HELP3 subdirectory should be transferred)

[6]The NRCS is an Agency of the US Department of Agriculture, 817-334-5292 or pcole@ftw.nrcs.usda.gov). These data, which are publicly accessible, include estimations of: (1) soil types, (2) hydraulic conductivities, (3) depth to groundwater, (4) soil chemistry, etc. of the various geographical areas of the United States.

It is unclear as to why the *volatilization* of substances from wastes deposited in landfills must be mediated by leaching, as opposed to direct volatilization from the waste. The TRI documentation should clarify whether this choice was a calculational convenience or a statement of expected physical behavior.

The methodology documents do not clearly explain how the dilution volumes are specified for the *water discharges* from individual facilities. If they are related to reported river flow rates, then the averaging method should be explained (e.g., annual average vs. harmonic mean).

The assumption that people drink contaminated surface water without any benefit of water treatment may be excessively conservative, because most water systems meet maximum contamination limits (MCLs). The Agency should evaluate the scores to be sure they do not imply consumption at levels well above the MCLs.

The indicators methodology includes a component for individual public owned treatment wo (POTWs). The POTW release model assumes that all municipal sewage sludge is land filled. In Agency discourages the practice of land filling of sewage sludge (or biosolids) and promotes bene this material as a more environmentally attractive alternative as described in *Land Application of S Sludge and Domestic Septage* (EPA, 1995).

The practice of sewage sludge land application is regulated by the Clean Water Act under t requirements set forth in 40 CFR Part 503 (known as the sludge rules). These regulations specify conditions, sludge quality, sludge application rate, monitoring and sampling frequencies, record ke that a POTW must comply with to legally land apply sewage sludge. These regulations, which we by the USEPA, are risk- based and consider the effect of sewage sludge pollutants on highly expo individuals (human, plant and animal). Results of the human health and environmental risk assess land application of sewage sludge may be found in the following publications: *Technical Support Document for Land Application of Sewage Sludge* (EPA, 1993a) and *Standards for the Use or Disposal of Sewage Sludge* (EPA, 1993b).

In developing the sludge rules, the USEPA considered fourteen (14) exposure pathways, im nitrogen control for ground water protection, established surface water protection features, implem pathogen reduction and vector attraction control requirements and imposed metal concentration li conservative approach employed by the USEPA in developing the technical basis for the sludge ru reasonable to expect that a POTW that is legally land applying its sludge would not significantly in human health and/or environmental risk through this disposal practice.

Landfilling of sewage sludge is regulated by Subtitle D of the Resource Conservation and R (RCRA) if it is co-disposed with other solid wastes (*i.e*., sludge monofills are regulated by 40 CFR response to the Hazardous and Solid Waste Amendments of 1984, the USEPA promulgated a fina regarding new performance criteria for municipal solid waste landfills (EPA, 1993c). The new perf criteria include requirements related to facility location, design, operations, monitoring, corrective a and post closure care.

With regard to the impact of landfill leachate on ground water quality, it is important to reco the federal mandated performance standards require that a landfill design prevent the concentrati water pollutants from exceeding maximum contaminant levels (MCLs) at the point of compliance (v normally the uppermost aquifer at the landfill boundary). The US EPA requires that landfills attem the performance standard using alternative designs rely on site specific data collection and model conservative nature of the federal landfill performance standards, it is not unrealistic to expect that sludge that is landfilled in a permitted Subtitle D facility would present an insignificant human heal environmental risk. However, it can be argued that there are many landfills which presently are ei without a Subtitle D permit or are in various stages of acquiring a permit

The TRI Subcommittee does not believe that the Agency should attempt to identify the type sludge treatment processes employed at individual public owned treatment works (POTWs). Rath Subcommittee has suggested that the TRI relative risk model account for the technical difference b "landfilling" and "land application" (or beneficial use) of POTW sewage sludge.

3.1.3 Appropriateness of Approach for Assessing Exposed Populations

Finding: The present default value for minimum rural populations may artificially increase relative risks or show a risk when one actually does not exist for these remote facilities.

Finding: The majority of Subcommittee members believe that an accepted method to address population changes over time is to use the latest intercensual rate of change (i.e., average annual rate of change between 1980 census and 1990 census) to project population size for postcensual years.

Population considerations are a significant component of the TRI model, such that population change could influence the indicator. An increase or decrease of population will elevate or lower the indicator even when no change in releases occurred.

Members of the Subcommittee had concerns regarding the 1000 exposed persons minimum for air exposure for rural areas and favored the use of actual population numbers. The Members indicated that many government and industrial facilities were located in remote areas for the sole purpose of being removed from residential populations. Presently, the default rural population value of 1000 may artificially increase relative risks for remote facilities and remove the incentive to locate facilities in areas removed from adjacent populations. If facility-specific indicators are developed, a further step of properly assigning the rural populations to individual cells would also increase the accuracy of lower tier indicators. The Subcommittee is concerned that the present default value for minimum rural populations may artificially increase relative risks or show a risk when one actually does not exist for these remote facilities.

Although, population estimates are not usually significant contributors to overall uncertainty in the model, projection of population changes for non-census years may be important when the TRI indicators are applied to smaller geographical areas. For example, population changes can be significant in urban environments. The population in the south/southwest Philadelphia has decreased by 25% within the last 20 years. (Burke *et. al,* 1997. The majority of the Subcommittee believes that an accepted method to address population changes over time is to use the latest intercensual rate of change (i.e., average annual rate of change between 1980 census and 1990 census) to project population size for postcensual years (Shrycock *et. al, 1976).* A dissenting Subcommittee member voiced concern over this approach because it was perceived as encouraging the extrapolation of data, which the EEC has often opposed.

3.2 Are Hazard, Exposure and Population Elements properly integrated?

3.2.1 Hazard

Recommendation: To improve integration of the hazard components, the Subcommittee recommends that toxicity values be used directly; carcinogenic potency values be converted to Risk Specific Doses; and indicators be reported to only a few significant figures.

The TRI model has incorporated a number of approaches from the Hazard Ranking System (HRS). Some observers have stated that because the HRS toxicity weighting scheme was developed for a different purpose, it should not be used in the TRI Indicators Project. The Subcommittee agrees with the premise that the objective must be considered in determining the scientific validity of a procedure. However, the HRS and TRI indicator objectives are not sufficiently different to invalidate the use of the HRS system, especially if the Subcommittee's recommendations for improvement are utilized. Both HRS and the TRI indicators were developed with the intent of using surrogate measures of toxicity to arrive at conclusions that relate to risk. SAB comments on the HRS emphasized the need for risk-based rankings, and changes to the old HRS were made to improve that relationship.

Although the HRS methodology is not seriously flawed, the Subcommittee recommends that the Agency consider the three improvements discussed in Section 3.1.1. First, the toxicity values from IRIS, HEAST, and the disposition process should be used directly rather than rounded by assigning them to bins of an order of magnitude wide. Second, the carcinogenic potency values should be converted to "Risk Specific Doses" (RSDs) to allow use of a single index scale for both cancer and noncancer toxicities. Third, the various indicators should be reported to only a few significant figures. Although changes in the third significant figure could be meaningful for the national level indicators, most of the lower tier component scores would be subject to significant levels of uncertainty. The computer implementation of the

indicator methodology should actively discourage use of inappropriate numbers of significant figures.

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 facility with several chemicals will usually be more deserving of attention than one with only one chemical with a similar component score. Regarding summing over different media, the underlying (unstated) assumption is that the exposure weights are roughly in the same proportion to risk for all of the media calculations, after consideration of route-specific toxicity differences and application of exposure modeling uncertainty factors. That assumption is critical to the whole TRI indicator toxicity-weighting scheme, and therefore, the Subcommittee believes that summing adds no additional difficulties.

The Subcommittee believes that basing the hazard component on actual toxicity values and incorporation of the above suggestions for risk-specific doses and the number or reported significant figures offer a mechanism for properly integrating hazard with exposure and population elements.

3.2.2 Exposure

Recommendation: The Subcommittee recommends that the Agency identify and evaluate more appropriate exposure models to be used with region-specific data (and, when available, site-specific data), to improve the relative risk-based indicators. Further, these models and regional data (and site-specific data when available) should be used to improve the relative Risk-Based indicator.

In general, the Subcommittee found that the exposure modeling presently used in the development of the TRI indicators constitutes a first step in identifying the critical human health exposure pathways. However, there were several major assumptions used in the model development that could potentially lead to significant errors in predicting the risk impact of TRI releases. The Subcommittee believes that many of the technical deficiencies in the exposure pathway models can be corrected using publicly available models and information such as climatic, soil and groundwater conditions from the various geographical regions of the United States. To maintain credibility of the models, the choice of model parameters should be transparent, well documented and scientifically based. Agency offices, such as the Office of Water, Office of Solid Waste, and Office of Air and Radiation, routinely use many of the modeling tools that could be easily imported into the TRI indicator model.

The Agency requested detailed information on modeling tools that might be imported into the TRI Indicator Model. The Subcommittee, therefore, is providing more detail here.

Mathematical models are useful tools that provide insight into the effects of solid waste facility design and operation on ground water quality. There are three basic types of mathematical models that the USEPA currently uses to evaluate Subtitle D facilities (*e.g.,* landfills, surface impoundments and land treatment facilities). These are: leachate generation models, leachate migration models, and geochemical models.

Leachate generation models predict the quantity and/or quality of leachate that will be released from the bottom of a waste disposal facility. Leachate migration models simulate the transport of contaminants from the source, through the unsaturated and/or saturated zones, by ground water. Geochemical models evaluate subsurface chemical processes that affect contaminant transformation and availability such as adsorption/desorption, precipitation/dissolution, oxidation/reduction, aqueous speciation and reaction kinetics. A thorough evaluation of the various mathematical models have been summarized by the USEPA in the following report: *Leachate Generation and Migration at Subtitle D Facilities - A Summary and Review of Processes and Mathematical Models* (EPA, 1993d). It should be noted that numerous models are described in this report which can be applied to the simulation of leachate generation and migration. The report describes: a) 27 mathematical models used to predict leachate generation; b) 39 mathematical models used to evaluate leachate migration and exposure assessment; and c) six mathematical models used to evaluate geochemical reactions. The models vary in complexity, from simple analytical solutions (which can be solved with a hand held calculator) to complex numerical models which require significant computer capabilities.[7]

Finally, some of the earlier (and simpler) mathematical models used to describe contaminant transport may be found in another USEPA publication *Ground Water Transport: Handbook of Mathematical Models* (EPA, 1984).

In addition to the Subtitle D facilities fate and transport models previously described in *Leachate Generation and Migration at Subtitle D Facilities - A Summary*

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[7]Examples of some of the USEPA models described in the report include the following:

Leachate Generation Models
Approximating Pollutant Transport to Groundwater 1982 - USEPA Ada, Oklahoma
Simulations of Leachate Generation from Municipal Solid Wastes EPA/600/2-87/059
Modeling Chemical Emissions from Lagoons and Landfills 1984 - USEPA Athens, Georgia

Leachate Migration Models
Multimedia Exposure Assessment Model (MULTIMED) for Evaluating the Land Disposal of Wastes - Model Theory 1990 - USEPA Athens, Georgia
A Subtitle D Landfill Application Manual for the Multimedia Exposure Assessment Model - (MULTIMED) 1990 - USEPA Athens, Georgia

and Review of Processes and Mathematical Models (EPA, 1993d), the USEPA has recently developed its own composite model for landfills (EPACML). The EPACML model is basically a contaminant fate and transport model which simulates both saturated and unsaturated subsurface flow under steady and nonsteady conditions. The model also simulates microbial and physico-chemical contaminant transformations by incorporating first order reaction kinetics, adsorption and dispersion algorithms.

The EPACML model, which was developed primarily for regulatory rule making purposes (*e.g.,* toxicity characteristic rule), allows the estimation of the probability distribution of contaminant concentrations at various exposure points. The model, which employs a Monte Carlo technique, is not designed for site specific application, rather, it uses general information including hydrogeologic parameters and relative positions of exposure points to the contamination source as model inputs.[8]

With regard to improving the media and pathway approaches for exposure modeling, the Subcommittee concluded that a sensitivity analysis be conducted as either part of the overall indicator evaluation or as part of a subindicator analysis on exposure pathway in order to determine the impact of the various components of the model on the outcome of the final TRI indicator. For example, comparison of the value of the TRI relative risk indicator using results from a simple groundwater model versus the value of the TRI relative risk indicator using the results from the present generic approach could be used to gauge the relative error involved in the present groundwater exposure modeling approach. The uncertainty adjustment factor should then be modified to reflect the magnitude of this error.

3.2.3 Population

The present model takes into account the total population for a model-specified cell, area, reach or other zones of influence. While the population estimates are likely to contribute little to the uncertainty of national indicators, as the TRI model is applied to smaller geographical areas, the contribution of population estimates to indicator uncertainty is likely to be more significant. It is also recognized that population changes in the zone of influence of a facility would increase or decrease its component scores even though no change in its releases occurs. TRI documentation should clearly explain this impact of population on TRI indicators and how local population changes could result in misleading conclusions regarding a facility's environmental management practices.

The Subcommittee determined that actual population data, where available, should be used in estimating risk(s).

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[8]Details of the EPACML model, including background documentation and model validation, may be obtained from the USEPA Office of Solid Waste (Dr. Zubair Saleem - Tel. no. 703-308-0467).

3.3 Will Methodology provide Reasonable Relative Risk-based Analyses and Impacts of TRI Chemical Emissions?

Finding: Relative uncertainties increase as one moves from a larger, more aggregated level (national) to smaller, more disaggregated levels, i.e., local/site-specific. With this loss of resolution, the ability to say something meaningful about the indicators at the local/site-specific level is compromised.

Recommendation: The Subcommittee recommends that the Agency identify and clearly present in its documentation the specific universe of environmental risks addressed by the TRI model.

Finding: The Subcommittee believes the Agency has to be realistic with regard to the continuum of applications to which the TRI indicators are likely to be applied and incorporate more warnings into its documentation and reports, and where appropriate, into its computer program to decrease unintentional misuse and to discourage intentional misuse.

Due to the similarity of its responses, the Subcommittee took the liberty of combining in this section, responses for both General Charge questions a)3) and a)4).

According to the Executive Summary of the TRI Indicators document, "the objective of [the indicators methodology] is to calculate a unitless value that reflects the overall risk-related impacts of releases and transfers of all included TRI chemicals from all reporting facilities to each environmental medium for a given year or years." With one major exception and a number of minor ones discussed below, the methodology should serve this narrow objective.

The methodology will not perform as well for the subsidiary uses that are mentioned as possibilities: geographic analyses, chemical-specific analyses, industry sector analyses, environmental justice analyses, and so on, principally because any inaccuracies or biases will be magnified at lower levels of aggregation. Because the temptation to apply the indicators methodology to such other uses will be strong, the document should supply further cautions about its applicability.

One great strength of the TRI documentation is its clarity of presentation. The Subcommittee found little trouble in understanding how the methodology was developed or how it would operate. In particular, the document makes it clear that the definition of risk that it has adopted is the public health definition: simulating the likely magnitude of impacts on the population, rather than the potential risks to highly exposed persons. A minor exception occurs because the methodology establishes a minimum size for the population at risk for a given facility's releases.

The Agency has correctly chosen a "proportional" weights approach. The algorithm for calculating the indicator combines and scores the weights in the same way they would be in a more complete risk assessment, again with one glaring exception - the binning of toxicity values. In many respects, the current indicator methodology for chronic human health amounts to a crude risk assessment that should produce component scores roughly proportional to risk, albeit with substantial uncertainties and biases, which may not be consistent for different components of the methodology. Because the Agency seemed to recognize the virtues of the proportional approach, it is curious that it chose to use a severely constrained version of that approach for the toxicity weight by binning toxicity values and truncating their range. As explained in Section 3.1.1.1, the Subcommittee recommends using toxicity values directly rather than binning them and believes that incorporation of this recommendation will result in more reasonable risk-based analyses.

The reliability of the indicators may depend on the coverage of the TRI list of reportable releases. Although the proposed methodology considers the majority of chemicals that have significant releases. If the Agency has any way of characterizing the effect of omitted substances, it should present that information. Although this problem may not have a strong effect on the reliability of a national chronic health risk indicator, it is more likely to make comparisons on a smaller scale, such as interfacility or environmental justice, unreliable. Similarly, the Agency should attempt to consider the impact of not considering releases from facilities excluded from the TRI reporting requirements and the impact of chemicals not presently listed by the TRI. The Subcommittee recommends that the Agency identify the TRI slice of the universe of environmental risks and clearly present these limitations in its hard copy and electronic documentation and reports. The TRI relative risks indicators have to be presented in the context of non-TRI chemicals releases, exposures from other pathways such as indoor air, and the selective consideration of human populations at the exclusion of others such as avian and terrestrial animals.

The description of how the indicator methodology will be modified to accommodate changes in TRI reporting requirements is not very specific. Although the document states that it will continue to calculate a set of indicators based only on the original list of facilities and chemicals, it is not clear whether that list is the 1987 or 1994 version, or what additional indicators might be constructed. The flexibility of the TRI model makes it imperative that the Agency develops a means of ensuring that all assumptions, defaults, bases of comparisons and changes from previous models or reports are obvious to the potential user of the data.

The Agency has wisely recognized that the TRI indicators are ripe for intentional and unintentional misuse. This recognition has resulted in the repeated declarations found in the TRI documentation that the indicators are relative and should not be used to measure risk. In conflict with this recognition is a tool that has so much ability for

displaying facility-specific information and comparisons among chemicals using exposure and risk estimates as a sort. The Agency has to be realistic with regard to the continuum of applications to which the TRI indicators are likely to be applied and continue to incorporate even more prominent warnings into all new documentation and reports, and where appropriate, into its computer program to decrease unintentional misuse and to discourage intentional misuse.

3.4 Identify Future Research Needs

Although the Subcommittee recognizes that considerable work has already been done to develop the indicator methodology, there is disagreement among the Subcommittee members as to whether more development is required before the indicator methodology can be credibly and reliably used for its intended purposes. The Subcommittee recommends that the Agency address these fundamental research needs and issues to verify the models scientific basis and decrease the uncertainties in the resulting indicators.

3.4.1 Sensitivity and Uncertainty Analysis

Recommendation: The Subcommittee recommends that the Agency subject the methodology to sensitivity and uncertainty analyses and portray uncertainty in the final results. The Subcommittee believes this will allow potential users the ability to use the output with the proper confidence.

As currently presented, the output from the methodology (numbers as well as graphs) implies an accuracy that is far greater than the quality of the input data and the models used to generate it. This is a typical problem with computational models that do not explicitly consider uncertainty. The developers should take steps to limit the number of significant figures in the final results to an appropriate number and to incorporate a level of uncertainty into the final results. It is not sufficient to caveat the limitations of the model in associated documentation. There should be an explicit indication of uncertainty in the reported results. The Subcommittee believes that lack of such qualifiers must be corrected if the results are to be used with confidence to draw conclusions and make meaningful comparisons. The developers must address the uncertainty question as a high priority item and take steps to portray uncertainty in the final results. The Subcommittee believes this will be a valuable and necessary exercise that will allow potential users the ability to use the output with the proper confidence.

The TRI indicators documentation as well as presentations during the review imply that the developers of the methodology, except for stack heights, have not performed a sensitivity analysis that relates variations in the final results to variations in the value of input parameters and assumptions. In the case where the model's sensitivity to certain parameters (i.e., variation in stack height) has been investigated,

the results led to a far better appreciation of the limits of the model. The Subcommittee believes it is critical to understand the internal sensitivities of the model as a limitations, but also focusing effort on improving the accuracy of those input parameters that make the most difference. Sensitivity analysis can result in numerous benefits, one of which is the ability to focus future research to minimize uncertainty in the resulting indicators.

Sensitivity analysis will explain the relative influence of model components (i.e., hazard, exposure-dose, and population) on the final indicators. This kind of analysis would provide some comfort level as to whether population size alone or some other component or assumption had undue influence on the final indicator. It would be useful for the developers to develop a summary table of the direction of bias in the default parameters and assumptions to provide a basis for the up/down adjustment of indicators. This summary table could facilitate future uncertainty analyses as default parameters are replaced with more realistic values.

In summary, uncertainty and sensitivity analyses can overcome the present lack of error bounds that make it difficult to distinguish "noise" levels from real changes in risk. This problem is likely to be exaggerated at the disaggregated level, because at this level the "noise" may be relatively large, requiring a sound understanding of uncertainty before lower tier indicators could be used to support environmental decision-making.

3.4.2 Validation of Output

Recommendation: The Subcommittee recommends that the model's output should be validated or "ground-truthed" by applying the methodology to a series of cases, for which exposure concentrations were estimated using other exposure models.

The Subcommittee believes the model's output should be validated or "ground-truthed" by applying the methodology to a series of cases for which exposure concentrations were estimated using other accepted exposure models. The Subcommittee recognizes that any validation is complicated by the relative nature of the indicators and the uncertainty of the TRI release data, but in most situations at least exposure model components should be capable of validation. Lacking some sort of validation, questions will remain about the applicability of the model. Facilities/locations for which there are exposure monitoring data should be identified for this validation efforts. The EPA-NHEXAS exposure data are another potential source for validation. NHANES IV is in the planning phase at the current time; a consideration may be given to design into NHANES IV a component to validate the TRI indicators.

The issue of ground-truthing can be applied to model inputs and interim model results such as typical surface water contamination levels. Outreach efforts to other sources in the Agency, and in other parts of the government (such as the USGS and

NMFS and F&W service) as well as to NGO's such as the Nature Conservancy and the Audubon Society, to secure additional sources of data. Under certain circumstances, strategies to measure actual levels of key pollutants in the environment such as ambient monitoring, "fence line" monitoring, household measurements, and individual sampling may be appropriate.

The validation of model inputs can also be applied to the TRI reported releases. During the review it was suggested that the quality of TRI data may vary by industry segment or facility type. This variation reflects the different levels of sophistication in data collection and management that exists across industries. A review of the uncertainty in the reported releases and its impact on the relative ranking of indicators should be considered.

3.4.3 Unintended Consequences

Recommendation: The Subcommittee recommends that the Agency review the model to detect aspects of the model's algorithm that may result in unintended consequences.

Past tax laws encouraged personal debt and present tax laws can encourage businesses to make decisions for tax purposes, not for the sake of their long-term welfare. Environmental regulations can also encourage unwanted results. The Agency should consider the possibility that some companies may manage their environmental responsibilities for the sake of a favorable TRI rating as opposed to managing for the sake of the environment and the public health.

The TRI indicator model, because it addresses many of the factors that reflect the relative risks of releases, offers an opportunity to decrease unintended consequences by encouraging decision makers to make decisions that have the greatest chance of lowering risk. However, as presently constructed, the TRI methodology may not accurately reflect the relative risk and could result in unintended and unwanted consequences. An accurate allocation of relative risks to chemicals and facilities would reward a facility manager with greater credit when focusing on the greatest risk. The following model assumptions and structure do not accurately reflect actual risks and could discourage a facility manager from addressing the most significant risks.

The "severity-of-effect" is not considered when assigning toxicity weights, and the model could encourage a facility manager to focus on a chemical that displays less severe effects at lower concentration when the largest risk may be from a chemical with a less sensitive yet more severe endpoint [Due to the subjective nature of assigning values such as severity, the TRI model understandably does not address this contentious issue. However, the methodology documentation and repeated use of caveats should encourage decision-makers to consider severity when making

comparisons across different chemicals.].

Onsite and offsite management of hazardous waste are ranked differently (onsite air releases are incorporated into reported release estimates, while offsite air releases are considered negligible and are not accounted for) by the TRI model, possibly encouraging a facility manager to invest resources in a less ideal waste management alternative that improves his TRI standing.

As discussed in Section 3.1.3, the default rural population value of 1000 may artificially increase relative risks for remote facilities and remove the incentive to locate facilities in areas removed from adjacent populations.

The TRI indicators capture only a percentage of total chemical releases and, because releases from smaller businesses, utility power plants and transportation sources are not considered, reported releases of certain chemicals from a given facility could be a minor contributor to regional releases and not be recognized as such.

Recognizing that the complexities of the TRI regulations and the TRI indicators can result in unintended consequences when used to support lower tiered decisions, and that industry will consider its TRI ranking when making environmental-management decisions, the Subcommittee recommends that the Agency review the model to 1) ensure that its indicators reasonably reflect the relative magnitude of risks, and 2) to detect aspects of the model's algorithm that may result in unintended consequences.

3.4.4 Other Research

As additional evaluations, field-testing and validations are completed, the TRI indicators have the potential to lead toward a better understanding of environmental and human health risks from toxic releases. To better exploit the TRI database and the TRI indicators, the Subcommittee suggests that the Agency consider the following topics for future research:

a) EPA should review the toxicity rankings from the disposition process with an independent group of toxicologists (within and/or outside the Agency) to identify any that seem unusual and verify whether the interpretation of the base information was appropriate.

b) Evaluate alternative exposure models for the pathways presently addressed by the TRI indicators and complementary exposure models for pathways not presently addressed by the model (e.g., such as consumption of foods contaminated from deposition of air pollutants).

c) Research into better sources of data for the model should be a continuing

need that should be given continuing attention. In this search for better data, the Agency should consider existing sources of data that could be relevant to their work, such as facility monitoring data associated with air permits and wastewater discharges and CERCLA releases. The need for better data increases with the desire to disaggregate national level information and move down to the local or plant-specific level.

d) Estimate what percentage of total chemical releases are captured by the TRI database, because releases from smaller businesses, utility power plants and transportation sources are not considered.

e) Identify risks such as those resulting from exposure to indoor air pollution that are not captured by the TRI database and indicators so that the risk of TRI chemical releases can be placed in the proper perspective.

f) Evaluate whether the TRI methodology lends itself to visualization technologies such as Geographic Information Systems (GIS).

g) Elicit input and dialogue with local and state public health officials regarding the TRI indicator project as part of its ground-truthing and to devise means for local officials to better use the indicators and to better address public questions/concerns regarding the TRI indicators.

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APPENDIX A

Examples of Summary Scoring Systems Employing Actual Toxicology Values

Section 3.1.13 discusses the advantages of scoring system that support the creation of a summary chronic human health indicator that combines cancer and noncancer impacts. The remainder of this appendix discusses two options for constructing chronic human health indexes that utilize actual toxicity values and not binned weights. These options do not predict the incidence of adverse health effects, and are therefore not likely to be susceptible to misuse or misinterpretation. Both of these options require the Agency to develop "benchmark" levels of acceptable exposure based on actual toxicity values. These benchmarks would be established by Reference Concentrations/Doses for noncarcinogens. Benchmarks for carcinogens would be established by converting carcinogenic potency values to "Risk Specific Doses" (RSDs) by dividing the potency into the risk value selected to be equivalent to exposure to the Reference Dose, currently 10^{-4}.

Option 1: This option employs the measurement of potential health impact as population-weighted "exceedances" of chemical-specific benchmarks. Benchmark levels of "acceptable" exposure would be defined by RfCs or RfDs for noncarcinogens, and RSDs for carcinogens. The index would be a population-weighted count of when predicted surrogate doses for a chemical from a facility exceed applicable benchmark levels. In essence, this option extends the current practice of calculating hazard indices for noncarcinogens to carcinogens. It is also analogous to the conventional way of doing noncancer risk characterization for criteria air pollutants, where the population size exposed above a NAAQS standard is estimated. The ratio of predicted surrogate dose to RfC/RfD/RSD would be calculated and the population exposed to hazard indices greater than 1 would be estimated. This option would allow users to calculate separate cancer and noncancer indices, as well as an integrated chronic human health index that would be constructed by summing the population-weighted cancer and noncancer exceedance counts. The major assumption underlying this option is that exposure to less than the benchmark level is not considered to pose health risk and does not contribute to the index (i.e., hazard indices less than 1 are considered "safe"). While this is a standard assumption in noncancer risk assessment, not counting potentially carcinogenic exposures that pose risks lower than the benchmark RSD level is likely to be more controversial. There is considerable policy debate about what benchmark cancer risk level should be considered *de minimis*: some stakeholders might argue that the RSD/RfC equivalency should be set at 10^{-6} rather than 10^{-4}. Because the relative emphasis to be given to cancer vs. noncancer endpoints is a policy judgment and not a scientifically resolvable issue, the Subcommittee recommends that the TRI tool support user selection of a *de minimis* "equivalence" level for cancer and noncancer endpoints, even if EPA wants to establish as a matter of policy

the HRS 10^{-4} equivalence level for its default national indicator construction. This methodology is already being utilized to evaluate chronic human health impacts in the Office of Policy Planning and Evaluation's Cumulative Exposure Project, which has been reviewed positively by a different SAB Subcommittee. it is to EPA's advantage to be consistent in these risk indexing methods.

Option 2: This option employs the measurement of potential impact as toxicity-weighted population dose. This index could be derived by calculating chemical-specific total doses to a population (population x surrogate dose) and then dividing by a toxicity benchmark (RfC/D for noncarcinogens, or RSD for carcinogens). For any given population dose, a larger contribution to the index would be made by higher toxicity chemicals (because they will have lower benchmark levels). Like the Agency's current indexing method, this option is not entirely consistent with conventional noncancer risk assessment practice. Rather than presume there is a threshold dose below which there is no risk of deleterious adverse effects, these methods presume some potential for noncancer impacts at any dose. Release and exposure situations that result in an estimated surrogate dose that is less than the RfC/RfD still contribute to the index developed using these methods (i.e., the index is calculated by multiplying population exposed times chemical-specific hazard ratios of dose to benchmark, even if hazard ratios are less than 1). This inconsistency with conventional noncancer risk assessment practice might be warranted, however, in a screening level tool. Option 1 only includes people whose surrogate dose is above the benchmark dose, but none of those below. To the extent that surrogate doses are biased toward overestimation (as a result of generic model assumptions), Option 1 can make an artificial distinction between facilities producing doses just above the benchmark and those just below. For screening level assessments, Option 2 may better accommodate exposure-modeling uncertainties.

Although Option 2's index is harder to interpret than the "body" counts produced by risk assessment methods, or the "exceedance" counts produced by Option 1, this might actually limit the potential for misinterpretation of the TRI indicators. The Option 2 index is neither a population risk for cancer nor an estimate of the number of people potentially affected: it is an indicator of the relative probability of some adverse health effect occurring, in the sense of the chance that some level of concern will be exceeded. If the biases are reasonably uniform from facility to facility and chemical to chemical, resulting rankings will be reliable, even though the relationship to real risk may be exaggerated. Of course, the biases will not be uniform, and so there is a high likelihood of mischaracterizing the relative risks among facilities, chemicals, and so on. That is why the indicator will be most useful for discerning national trends, and much more uncertain when it is applied at the micro-level for comparing facilities or communities.

APPENDIX B
Documents Reviewed

Bouwes, N.W and S.M. Hassur. Toxic Release Inventory Relative Risk-Based Environmental Indicators: Interim Toxicity Weighting Summary Document. June 1997.

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