

# AN SAB REPORT: REVIEW OF THE SOURCE RANKING DATABASE

PREPARED BY THE INTEGRATED HUMAN EXPOSURE COMMITTEE (IHEC)

#### February 3, 1998

#### EPA-SAB-IHEC-98-004

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

Subject: Review of the Office of Pollution Prevention and Toxics

Source Ranking Database

Dear Ms. Browner:

At the request of the Office of Pollution Prevention and Toxics, the Integrated Human Exposure Committee (IHEC) of the Environmental Protection Agency's Science Advisory Board (SAB) reviewed the Agency's Source Ranking Database (SRD). The Committee met on July 21-22, 1997 at the EPA's Waterside Mall Complex in Washington DC. The IHEC approved the Subcommittee's report on December 17, 1997 and the SAB's Executive Committee approved this report on January 9, 1998.

The Source Ranking Database was developed under the U.S. EPA Indoor Air Source Characterization Project. The EPA developed the Source Ranking Database (SRD) in order to have a mechanism to conduct a systematic screening-level review of a large number of indoor sources to identify high-priority product and material categories for further evaluation. The SRD produces risk-based rankings by multiplying an indoor-air concentration by a hazard score for each chemical in a given product or material. The SRD was developed to be used internally by EPA staff as a tool for setting priorities for additional testing and review. The Agency requested the IHEC review of the SRD in order to incorporate the IHEC recommendations into the SRD prior to its full implementation by the Agency.

The Office of Pollution Prevention and Toxics requested that the IHEC review the assumptions and methodologies used in scoring product/material categories in the SRD in order to rank them for further characterization and possible risk management attention. The IHEC was charged to respond to the following specific questions:

- a) What is the general impression of the completeness and quality of the data included? Does the Committee know of any additional data that should be added?
- b) Is the chemical formulation/emissions data adequate to meet the goals of the overall project?
- c) Are the assumptions for each environment (e.g., building volume and air exchange rate) reasonable? Should more environments or subcategories of the listed environments be added?
- d) Are exposed populations accounted for in an appropriate manner? Do the subcategories of people in each environment represent an adequate accounting of potentially exposed populations?
- e) Do the four scenarios for estimating room concentrations from formulation/emissions data adequately cover the range of products/materials and their uses? Are the procedures for estimating emission rates and indoor-air concentrations accurate enough for the intended purpose?
- f) The SRD can perform rankings at various levels of aggregation in terms of product categories (i.e., at 4-digit Standard Industrial Classification (SIC) codes, 5-digit SIC codes, 7-digit SIC codes) and environments. What is the SAB's view about the appropriate levels of aggregation for ranking: Is the weighted-average approach currently employed the most appropriate way to aggregate scores across environments?
- g) Does the ranking algorithm make sense? Is this the appropriate level of detail for making the decisions on what products we will characterize further? Should other criteria be included?

The Source Ranking Database (SRD) may be considered to have two components, a relational database and a ranking algorithm. The Committee commends the agency for developing the unique and highly valuable database that is an essential component of the SRD. Given the importance of indoor environments in determining human exposures, this is a very worthwhile effort and will be of substantial value in helping the Agency set risk-based priorities. The database could be of considerable value to the scientific community at large, as well as to the

Agency for its source ranking exercise. Given its importance for achieving the Agency objectives and other potential uses by the indoor air community, it is essential that a strong effort be made to ensure the quality of the SRD.

The Agency should also begin to consider the future of the relational database, that is, the EPA should decide whether it will regularly update the database and whether the SRD will be made accessible to the scientific community at large and/or the public. A regular update of the SRD would require commitment of some resources.

The second component of the SRD, the algorithm for ranking products, has been specifically developed for Agency use to help identify those products likely to pose the highest health risks. In the review of the SRD, the IHEC focused much of its attention on whether or not the algorithm is sufficiently robust so that products are not misranked. For example, the Committee was concerned that a product that should be ranked "high" would be missed due to some underlying problems with the algorithm. The Committee has identified several components, which might lead to this problem, such as:

- a) Use of the volume of the whole house rather than a room or "breathing zone" volume for products used by individuals.
- b) Omission of dermal and certain inadvertent ingestion exposures.
- c) The overall sensitivity of the algorithm to variabilities in the component factors, and in the hazard scale in particular.

We recommend that the Agency address a) and c) immediately. The Committee makes some specific recommendations with respect to how to proceed and suggests a simplified method for screening and ranking products with respect to dermal exposures that could be used immediately. For example, with respect to the algorithm, the IHEC found that the rating scheme probably does not generate a scale to reflect the toxicity of all chemicals being evaluated because a range of toxicity that probably varies over four or five orders of magnitude is compressed into a narrow range of only two orders of magnitude. IHEC recommends that the Agency use a scale that provides a better reflection of the underlying toxicity data in the Chemical Use Clustering Scoring Methodology (UCSS).

The Committee also recommends that the Agency evaluate the appropriateness of the levels of aggregation and recommends two methods for doing so:

- a) Consider conducting a sensitivity analysis to identify the impact of different aggregation schemes.
- b) Validate the current approach for ranking by using the current methodology on specific examples before approving the SRD for implementation.

The IHEC also recommends that the Agency include several additional exposure sources in the SRD, specifically, office machines, air ionizers, and indoor combustion sources, and include the criteria air pollutants that are emitted by such sources i.e.,  $O_3$ ,  $NO_x$  fine particulate matter, and carbon monoxide. A short introduction should also be added to the document, *Source Ranking Database, Volume 1: Guide and Documentation*, to explicitly state the underlying assumptions and the uses for which the SRD is intended and to provide an overview of the methodology.

Future expansions of the SRD should include dermal and inadvertent ingestion exposures, preschool children in daycare settings, and the analyses of potential exposures of special populations such as children, the elderly, asthmatics, and those with chronic obstructive pulmonary disease (COPD). Processes such as sorption, desorption and chemical reactions for certain compounds, can be added when it becomes feasible and appropriate to do so, if these are likely to have a significant overall impact on the ranking. The SRD is designed to accommodate inclusion of these processes. We also recommend adding the octanol/water partition coefficient and Henry's Law ratio as part of the database so that sorption/desorption and volatilization processes can be better addressed.

The Committee appreciates the opportunity to review the SRD, and looks forward to a written response from the Assistant Administrator, Office for Prevention, Pesticides and Toxic Substances to its recommendations for the Source Ranking Database.

Sincerely,

/signed/ Dr. Joan M. Daisey, Chair Executive Committee and Past Chair, Integrated Human Exposure Committee

# **NOTICE**

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

#### **ABSTRACT**

The Integrated Human Exposure Committee (IHEC) reviewed the EPA's Source Ranking Database (SRD) including the assumptions and methodologies used in scoring product/material categories in order to rank them for further characterization and possible risk management attention. Given the importance of indoor environments in determining human exposures, the SRD project is a very worthwhile effort.

The SRD includes an algorithm for ranking products. This algorithm has been developed for Agency use to help identify products that are likely to pose the highest health risks. The overarching concern is that the algorithm must be sufficiently robust so that products are not misranked. For example, the Committee was concerned that a product that should be ranked "high" is not missed due to some underlying problems with the algorithm. Several components of the algorithm may lead to this problem such as: a) use of the volume of the whole house rather than a room and or "breathing zone" volume for products used by individuals; b) omission of dermal and certain inadvertent ingestion exposures; and c) the overall sensitivity of the algorithm to variabilities in the component factors, and in the hazard scale in particular. The Committee recommends that the Agency address: a) and c) immediately, and makes some specific recommendations with respect to how to proceed. The IHEC also suggests a simplified method for screening and ranking products with respect to dermal exposures that could be used immediately.

The IHEC makes several additional recommendations including: a) The Agency should add several additional exposure sources to the SRD, including indoor combustion sources and the criteria air pollutants that are emitted by such sources. Future expansions should include dermal and inadvertent ingestion exposures, as well as inclusion of analyses of potential exposures of special populations such as children, the elderly, asthmatics and those with chronic obstructive pulmonary disease (COPD), b) The Agency should add the octanol/water partition coefficient and Henry's Law ratio as part of the database so that sorption/desorption and volatilization processes can be better addressed, and c) the Agency should consider whether the database will be regularly updated and whether the database will be made accessible to the public.

**<u>Keywords</u>**: Source Ranking Database (SRD), algorithm, ranking, scoring, breathing zone, aggregation

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**Mr. Ron White**, Deputy Director, National Programs and Director, Environmental Health, American Lung Association, Washington, DC

#### Consultants

**Dr. Jonathan M. Samet**, Chairman, Department of Epidemiology, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, MD

#### **Science Advisory Board Staff**

- **Ms. Roslyn Edson**, Designated Federal Official, USEPA, Science Advisory Board, (1400), 401 M Street SW, Washington, DC 20460
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- **Mrs. Dorothy M. Clark**, Staff Secretary, USEPA, Science Advisory Board, (1400), 401 M Street, SW, Washington, DC 20460

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#### 1. EXECUTIVE SUMMARY

The EPA developed the Source Ranking Database (SRD)(USEPA, 1997a,b) in order to have a mechanism to conduct a systematic screening-level review of a large number of indoor sources to identify high-priority product and material categories for further evaluation. The Source Ranking Database produces risk-based rankings based on the magnitude of the estimated pollutant concentrations in indoor air from these products, the size of the potentially exposed populations and the potential health hazards from inhalation of the emitted chemicals. The SRD was developed to be used internally by EPA staff as a tool for setting priorities for additional testing and review.

On July 21 - July 22, 1997, the Integrated Human Exposure Committee met at the EPA's Waterside Mall complex in Washington, DC to review the SRD. The charge was to review the assumptions and methodologies used in scoring product/material categories in order to rank them for further categorization and possible risk management attention by responding to the following questions:

- a) What is the general impression of the completeness and quality of the data included? Does the Committee know of any additional data that should be added?
- b) Is the chemical formulation/emissions data adequate to meet the goals of the overall project?
- c) Are the assumptions for each environment (e.g., building volume and air exchange rate) reasonable? Should more environments or subcategories of the listed environments be added?
- d) Are exposed populations accounted for in an appropriate manner? Do the subcategories of people in each environment represent an adequate accounting of potentially exposed populations?
- e) Do the four scenarios for estimating room concentrations from formulation/emissions data adequately cover the range of products/materials and their uses? Are the procedures for estimating emission rates and indoor-air concentrations accurate enough for the intended purpose?
- f) The SRD can perform rankings at various levels of aggregation in terms of product categories (i.e. at 4-digit SIC, 5-digit SIC, 7-digit SIC) and environments. What is the SAB's view about the appropriate levels of aggregation for ranking: Is the weighted-average approach currently employed the most appropriate way to aggregate scores across environments?

g) Does the ranking algorithm make sense? Is this the appropriate level of detail for making the decisions on what products we will characterize further? Should other criteria be included?

The Source Ranking Database (SRD) may be considered to have two components, a relational database and a ranking algorithm. The Committee commends the agency for developing the unique and highly valuable database that is an essential component of the SRD. Given the importance of indoor environments in determining human exposures, this is a very worthwhile effort. The database could be of considerable value to the scientific community at large, as well as to the Agency for its source ranking exercise. Given the importance of this database for achieving the Agency objectives and other potential uses by the indoor air community, it is essential that a strong effort be made to insure the quality of the SRD. The Agency should also begin to consider the future of the relational database, that is, the EPA should decide whether it will regularly update the database and whether the SRD will be made accessible to the scientific community at large and/or the public. A regular update of the SRD would require commitment of some resources.

The second component of the SRD, the algorithm for ranking products, has been specifically developed for Agency use to help identify those products likely to pose the highest health risks. The overarching concern here is that the algorithm must be sufficiently robust so that products are not misranked. For example, the Committee was concerned that a product that should be ranked "high" would be missed due to some underlying problems with the algorithm. The Committee has identified several components, which might lead to this problem, such as:

- a) Use of the volume of the whole house rather than a room and or "breathing zone" volume for products used by individuals.
- b) Omission of dermal and certain inadvertent ingestion exposures.
- c) The overall sensitivity of the algorithm to variabilities in the component factors, and in the hazard scale in particular.

We recommend that the Agency address a) and c) immediately. The Committee makes some specific recommendations with respect to how to proceed and also suggests a simplified method for screening and ranking products with respect to dermal exposures that could be used immediately.

The IHEC has several recommendations for the evaluation and improvement of the ranking algorithm. The IHEC recommends that EPA:

a) Expand the range of the health hazard scoring scale to a larger range than the 100-fold range of 0.01 to 1, to better reflect the underlying toxicity data of the Chemical Use Clustering Scoring Methodology (UCSS), a rating of human health

- effects which classifies chemicals into one of three potential health hazard categories (i.e., high, medium, and low).
- b) Select several products and go through the calculations step by step. This can be done using a computer to print out the results of each step. The basis for this recommendation is that the ranking algorithm only makes sense when every step of the calculations makes sense and this can best be determined by going through some of the calculations systematically.
- c) Carry out a limited sensitivity analysis in order to understand the driving forces of the whole ranking algorithm and identify the factors that have the greatest impact on the ranking.
- d) Treat the chronic and the acute scores separately and differently. The scoring and ranking scheme for acute hazard should be designed with consideration of the mechanism of acute toxicity in mind.
- e) Finally, the Committee strongly supports the plan to have EPA staff members with expertise in indoor air pollution conduct a review of the final ranking results in order to spot anything that seems out of line.

The IHEC also recommends that the Agency add several additional exposure sources to the SRD, specifically, office machines, air ionizers, and indoor combustion sources, and that it include the criteria air pollutants that are emitted by such sources, i.e., O<sub>3</sub>, NO<sub>x</sub>, fine particulate matter and carbon monoxide.

A short introduction should also be added to the report, *Source Ranking Database*, *Volume 1: Guide and Documentation* (USEPA, 1997a), to explicitly state the underlying assumptions and the uses for which the SRD is intended and to provide an overview of the methodology. An explicit statement should also be added, to the introduction to the *Source Ranking Database*, that the methodology is intended for relative ranking and is not intended nor appropriate for quantitative calculation of exposure.

Future expansions of the SRD should include dermal and inadvertent ingestion exposures, preschool children in daycare settings, and analyses of potential exposures of special populations such as children, the elderly, asthmatics and those with chronic obstructive pulmonary disease (COPD). Processes such as sorption, desorption and chemical reactions for certain compounds, can be added when it becomes feasible and if it is appropriate to do so, if these are likely to have a significant overall impact on the ranking. The SRD is designed to accommodate inclusion of these processes. We also recommend adding the octanol/water partition coefficient and Henry's Law ratio as part of the database so that sorption/desorption and volatilization processes can be better addressed.

The Committee recommends that the Agency evaluate the appropriateness of the levels of aggregation in the model and recommends that the Agency:

- a) Consider conducting a sensitivity analysis to identify the impact of different aggregation schemes.
- b) Validate the current approach for ranking by using the current methodology on specific examples before approving the SRD for implementation.

#### 2. INTRODUCTION

# 2.1 Background

The Source Ranking Database and associated algorithms were developed by EPA to rank products and materials that affect indoor air quality and to identify high priority products and materials for further evaluation with respect to potential health risks. The ranking is based on the magnitude of the estimated pollutant concentrations in indoor air from these products, the size of the potentially exposed populations and the potential health hazards from inhalation of the emitted chemicals. The SRD was developed to be used internally by EPA staff as a tool for setting priorities for additional testing and review. The SAB Integrated Human Exposure Committee was briefed on this project in 1994 by Office of Radiation and Indoor Air Staff.

The SRD contains formulation and emissions data on the chemical constituents in consumer/commercial products including building materials. In order to estimate indoor-air concentrations to which selected populations may be exposed in different environments, the formulation/emissions data are used along with parameters such as building volumes, air exchange rates, the amount of product use, the duration of product use, and materials loadings. The SRD defines nine indoor environments and four standard scenarios, which are based on how products/materials are used indoors, to estimate peak and average indoor-air concentrations in each applicable environment for each chemical in the formulation.

The risk score for a chemical is derived by multiplying the average air concentration by the hazard score for the chemical. A summary score for the chemical is obtained by weighting the risk scores across the environments in proportion to total person-hours of potential exposure, based on population activity patterns. The score for a product/material formulation is simply the sum of the scores across all the major chemicals in the formulation where:

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Formulation score = [chemical<sub>1</sub>score + chemical<sub>2</sub>score + ...]
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where chemical<sub>1</sub>score =  $[\text{envt}_1\text{score x envt}_1\text{weight} + \text{envt}_2\text{score x envt}_2\text{weight} + ...]$  and  $\text{envt}_1\text{score} = \text{chemical's air concentration in environment}_1$  x chemical's hazard score.

The score for a product (7-digit SIC Code, e.g., ceiling tile) is the average score across all the formulations for that product. Scores can also be determined at higher levels of aggregation, such as the average score for all products in a product class (5-digit SIC Code) or the average score for all product classes in an industry (4-digit SIC Code).

Once a ranking is completed, the underlying data for the highest ranked product/material categories will be evaluated by a panel of EPA managers and staff prior to selecting the top candidates for further analysis review and data development. The information generated by this review and data development will assist in risk assessment and risk management activities.

A methodology for determining hazard scores for individual chemicals (i.e., high, medium, and low) was developed by the U.S. EPA for the Use Cluster Scoring System. This hazard ranking system was evaluated by the SAB's Environmental Engineering Committee (SAB, 1995). This ranking system is used in the SRD with the addition of a scoring element for acute effects. Since the hazard-scoring component of the SRD is almost identical to that of the previously reviewed Use Cluster Scoring System, the EPA did not request that the IHEC review the underlying data and criteria for the SRD's hazard scores in its review of the SRD. However, the Agency did request IHEC to comment on how the SRD integrates the hazard scores with predicted indoor-air concentrations in developing the overall product rankings.

#### 2.2 The Review and Charge

On July 21-22, 1997, the IHEC Committee met at the EPA's Waterside Mall Complex in Washington, DC to review the Source Ranking Database. The Committee was charged to review the assumptions and methodologies used in scoring product/material categories in order to rank them for further characterization and possible risk management attention, and to respond to the following questions:

- a) What is the general impression of the completeness and quality of the data included? Does the Committee know of any additional data that should be added?
- b) Is the chemical formulation/emissions data adequate to meet the goals of the overall project?
- c) Are the assumptions for each environment (e.g. building volume and air exchange rate) reasonable? Should more environments or subcategories of the listed environments be added?
- d) Are exposed populations accounted for in an appropriate manner? Do the subcategories of people in each environment represent an adequate accounting of potentially exposed populations?
- e) Do the four scenarios for estimating room concentrations from formulation/emissions data adequately cover the range of products/materials and their uses? Are the procedures for estimating emission rates and indoor-air concentrations accurate enough for the intended purpose?
- f) The SRD can perform rankings at various levels of aggregation in terms of product categories (i.e. at 4-digit SIC, 5-digit SIC, 7-digit SIC) and environments. What is the SAB's view about the appropriate levels of aggregation for ranking: Is the weighted-average approach currently employed the most appropriate way to aggregate scores across environments?

g) Does the ranking algorithm make sense? Is this the appropriate level of detail for making the decisions on what products we will characterize further? Should other criteria be included?

A complete reference for review documents provided prior to and during the meeting can be found in the References Cited section.

#### 3. RESPONSE TO THE CHARGE

#### 3.1 Some General Comments

The Committee commends the Agency for developing the Source Ranking Database (SRD). This is a very worthwhile effort given the importance of indoor environments in determining exposure and will be of substantial value in helping the Agency set risk-based priorities. The database could be of considerable value to the scientific community at large, as well as to the Indoor Air Division for its source ranking exercise.

Given the importance of this database for achieving Agency objectives and other potential uses by the indoor air community, it is essential that a strong effort be made to insure the quality of the SRD. The Agency should also begin to consider the future of the relational database, that is, the EPA should decide whether it will regularly update the database and whether it will be made accessible to the scientific community at large and/or to the public. A regular update of the SRD would require commitment of some resources.

The IHEC recommends that the Agency add a short introduction to its report, *Source Ranking Database*, *Volume 1: Guide and Documentation*, to explicitly state the underlying assumptions and the uses for which the SRD is intended. The report would also benefit from the addition of a section that gives an overview of the entire methodology and its components to the reader. Some of the viewgraphs used by the Agency at the Committee meeting might be incorporated for this purpose.

#### 3.2 Completeness and Quality of the Data

What is the general impression of the completeness and quality of the data included? Does the Committee know of any additional data that should be added?

The SRD database is very comprehensive and EPA has utilized most of the key references of which the Committee is aware. This is an impressive database that should be further supported and expanded to include several additional indoor sources as well as several criteria pollutants:

- a) office machines and air ionizers or air "purifiers" because some of these products emit ozone,
- b) indoor combustion sources such as environmental tobacco smoke, kerosene heaters, and ventless gas heaters,
- c) the criteria air pollutants i.e., fine particulate matter, ozone, nitrogen oxides, and carbon monoxide.

Emissions of criteria pollutants as well as organic pollutants emitted from office machines, air ionizers, and sources of indoor combustion can be very high. They may far outweigh the health effects of many of the other sources that are already addressed in the Source Ranking Database. Their addition to the SRD will provide a basis for a more comprehensive ranking of indoor air pollutant sources.

The Committee recommends that the Agency consider the following as potential sources of additional data for inclusion in the Source Ranking Database:

- a) The U. S. Department of Energy's Office of Building Technology, State, and Community Programs Core Databook which contains statistical data on the U.S. building stock (residential and commercial) including square feet of floor space by building categories.
- b) The Toxic Exposure Surveillance System (TESS), which is a database of millions of human poison exposure cases reported by poison control centers in the United States. The American Association of Poison Control Center (AAPCC) maintains the TESS database and publishes an annual report on the TESS. This annual report is available in the September issues of the *American Journal of Emergency Medicine*. The most recent annual report can be found in the September 1997 issue of the *American Journal of Emergency Medicine* (AAPCC, 1997).
- c) The CHEMTREC (The Chemical Transportation Emergency Center) database, which is sponsored by the Chemical Manufacturers Association).
- d) The European Union System for the Evaluation of Substances (EUSES) 1.00 User Manual (RIVM, 1997), a computer model system database which is available from the RIVM (the National Institute of Public Health and Environmental Protection in The Netherlands). It contains some information on indoor-sources and consumer exposures and would be useful as a quality assurance tool.
- e) ConSEXPO van Veen (RIVM, 1995), a program to estimate consumer product exposure and uptake.
- f) The Cosmetic Ingredient Review (CIR) (The Cosmetic Ingredient Review is an endeavor by industry to conduct safety assessments of the ingredients used in cosmetics. Their safety assessments are published in the *International Journal of Toxicology* which was formerly entitled *Journal of the American College of Toxicology*. CIR is funded by the Cosmetic, Toiletry, and Fragrance Association in Washington, DC).

- g) The Pesticide Product Label System, which is a set of pesticide product label images that is available on CD ROM. This database is published quarterly and is maintained by the EPA Office of Pesticide Programs (USEPA, 1997c).
- h) EPA's Office of Research and Development chamber testing data.
- i) EPA's Draft Exposure Factors Handbook which was reviewed by the IHEC in 1996 (SAB, 1997). In particular, Chapters 14 and 16 in Volume III lists a number of references and sources for ventilation rates and time-activity information.
- j) Additional sources of ventilation measurements for residences including those performed by the EPA as part of the Particle TEAM (Total Exposure Assessment Methodology) study in California (USEPA, 1996).
- k) For office buildings, the ventilation rates and volumes from the on-going EPA Building Assessment, Survey and Evaluation (BASE) project.

The Committee emphasizes the need for QA/QC (quality assurance/quality control) as well as the recommendation that sufficient resources be made available for this effort. Additionally, the Committee notes that some of the data on product formulations were generated before 1984 and, consequently, the formulations for some of the products may be very out of date. The Agency should be aware that the Source Ranking Database is a moving target because companies are constantly changing the formulas of their products and are adding new products to the market. Thus, the SRD must be regarded as a decision guidance *support* tool to be used in combination with expert technical judgment. In addition, the Agency must decide whether the SRD will be issued for a limited time or if the SRD will be updated and supported over time.

#### 3.3 Chemical Formulations/Emissions Data

Are the chemical formulation/emissions data adequate to meet the goals of the overall project?

There was consensus among the Committee members that, overall, the Agency had done an acceptable job in obtaining and evaluating formulation/emissions data for the Source Ranking Database (SRD) to meet the goals of the overall project given the very limited data available. The IHEC has some concerns regarding the chemical formulations/emissions data used in the SRD. The IHEC recommends that the Agency seriously consider adding certain chemical properties such as the octanol-water partition coefficient ( $K_{ow}$ ) and the Henry's law ratio (H) to the CHEMICALS data file. These properties play an important role in the classification of potential exposures and ultimately, if not in the short-term, these properties will be important factors for the exposure algorithms. For example, the use of  $K_{ow}$  and the Henry's law ratio in a simple algorithm for the volatilization of chemicals from consumer products, such as detergents, in place of a default assumption, would improve the basis for ranking these types of products. The

addition of these data would also enable the Agency to make a preliminary ranking of the potential consequences from the dermal exposure pathway. This may be important for certain types of products (see section 3.4). The IHEC also recommends that the Agency consider several potential sources of additional data for inclusion in the SRD (See section 3.2).

#### 3.4 Assumptions for Each Environment

Are the assumptions for each environment (e.g., building volume and air exchange rate) reasonable? Should more environments or subcategories of the listed environments be added?

For many products, the Committee found that the assumption of a whole building single-compartment exposure scenario appropriate and useful for source ranking. However, this could lead to some mis-classification when the product is used in a confined space or when dermal and/or inadvertent ingestion are important pathways.

More specifically, the Committee was concerned about the assumption of dilution throughout the volume of the residence or building for products that are typically used in a small room of a house such as a bathroom or for personal products, such as hair spray. This may lead to too low a ranking for some products, particularly for acute exposures. The Agency should consider using the "effective volume" of dispersion as a means of avoiding misclassification.

The Committee also suggests that the Agency think of exposure in terms of a transfer ratio or a transfer factor, which can be constructed as follows:

Transfer ratio or = (emission fraction) x (exposure time)
transfer factor (dilution volume) x (effective lifetime)

The transfer ratio is the ratio of personal air concentration experienced by the product user to the quantity of product used. In its most simple form, this ratio can be estimated from the product of the emission fraction (the fraction of the mass of the product used emitted to air per use, in mg emitted per mg used) and the exposure time (the duration the user is in the residential volume in which the product is used, in min) divided by both a dilution volume (the volume of air in which the product is most likely to be initially distributed, in m³) and the effective lifetime (how long the chemical persists in the initial dilution volume, in min). The effective lifetime accounts for dilution by advection and dispersion and removal by deposition and reaction. This approach has been applied by EPA to radon emissions from water to indoor air and by Cal-EPA to volatile organic compounds transferred from tap water to indoor air.

With respect to the assumptions for air exchange rates for different indoor environments, there is a substantial body of measured air exchange rates for residential buildings and selection of the median value of the distribution of these measurements, 0.5 air exchanges per hour, is a reasonable assumption. For other types of buildings, (e.g., commercial, schools, hospitals) the

ASHRAE Standard 62, Ventilation for Acceptable Indoor Air Quality (ASHRAE, 1989) for the air exchange rate is used because of the scarcity of measured data. ASHRAE Standard 62 was published by the American Society of Heating, Refrigerating and Air Conditioning Engineers.

Given that the ASHRAE design standard for ventilation rates is applied uniformly across most of the building environments, and that the median of the measured air exchange rate data for residential buildings is close to the ASHRAE design standard (0.35 h<sup>-1</sup>), the air exchange rates used for the various building environments should not result in any major mis-rankings of products. However, the Committee recommends that the Agency compare any existing measured air exchange rates for these other types of buildings to the ASHRAE standards to identify any information that might imply major discrepancies between the recommended standard and actual practice. For example, there is some evidence, such as a 1995 report by Lagus Applied Technology, to suggest that ventilation rates in some schools may be below the recommended ventilation rates (Lagus Applied Technology, 1995).

Deposition to and re-emission from indoor surfaces and materials are not currently considered in the Source Ranking Database, but they can alter the effective lifetime of a product in the indoor environment. However, since scientific understanding of these processes is still very limited, it is not yet feasible to include these processes in the algorithm for estimating indoor air concentrations in a scientifically defensible way.

Dermal and certain inadvertent ingestion pathways are not considered in the SRD because the focus is on indoor air and inhalation. For some of the products in the SRD, however, dermal exposures may be significant. Preliminary estimates of dermal uptake potential could be made based on the dermal exposure guidance document that the EPA's Office of Research and Development has issued (USEPA, 1992). An algorithm based on  $K_{ow}$  and exposure time could be used to make preliminary estimates of dermal uptake potential and to rank products for which this exposure pathway might be significant.

Certain types of chemicals may also be inadvertently ingested, particularly by young children. Some chemicals deposit and sorb on indoor surfaces and objects, e.g., toys. The chemicals can be ingested when young children pick up the surface deposited chemicals with their hands and put their hands in their mouths. Toys with chemical contaminants can also be put in children's mouths. This is the subject of ongoing research. When scientific understanding is more fully developed, the Agency may wish to address this exposure pathway.

A two-category assumption, based on vapor pressure, is made in the exposure model for chemicals that can volatilize from a product such as a liquid detergent. Some products with a low vapor pressure will be over-ranked based on this assumption. How significantly this assumption will affect the rankings is not completely clear but this should be evaluated.

Although school children are included in the SRD ranking algorithms, pre-school children are not explicitly addressed. Pre-school children in day care centers probably spend more time in school settings than do school-age children, i.e., more hours and summer months. Given the Agency's concerns about children's health, there should be some consideration of modifying the algorithms to take this into account.

# 3.5 Exposed Populations

Are exposed populations accounted for in an appropriate manner? Do the subcategories of people in each environment represent an adequate accounting of potentially exposed populations?

The SRD incorporates time-activity information from a national survey designed for purposes other than exposure analysis and from the California Time-Activity Study. The latter was designed for exposure analysis in indoor environments and was employed because of the greater level of detail in the data. The Committee believes that this is an appropriate choice. However, there is now or soon will be a more recent EPA national survey of time-activity patterns. Once this is available, the Agency should consider using these newer data as appropriate. The national data probably do not differ significantly from the California survey data in most instances, but there may be additional types of survey data that were not included in the California survey that will be useful for the SRD.

The IHEC is also concerned that susceptible populations, e.g. children, the elderly, asthmatics, those with heart problems, and individuals who have chronic obstructive pulmonary disease (COPD), were not explicitly considered. IHEC recommends the inclusion of an analyses regarding exposures to susceptible populations and exposures at daycare facilities into any subsequent updates of the SRD.

#### **3.6** Scenarios for Estimating Room Concentration

Do the four scenarios for estimating room concentrations from formulation/emissions data adequately cover the range of products/materials and their uses? Are the procedures for estimating emission rates and indoor-air concentrations accurate enough for the intended purpose?

The four scenarios for estimating room concentration cover potential exposures for many types of products, but not all. First, as discussed above, exposures from the use of some types of products will be substantially underestimated if the dilution factor is assumed to be the volume of the residence in which the product is used, rather than the volume of the room in which the product is used or the even smaller volumes that are relevant for human exposure, such as the volume of the personal breathing zone. Many consumer products, such as detergents or personal products are of this type. Thus, the Committee recommends adding one or more scenarios for these types of products.

Second, scenarios for dermal exposures should be included in the second phase of SRD development for products whose use would likely result in dermal exposure. Dermal exposures can be addressed in a preliminary way in the current version of the SRD by adding an algorithm based on  $K_{ow}$  and exposure to rank products for which this exposure pathway might be significant (see section 3.3 above).

Certain types of ingestion exposures should also be considered for inclusion in the future. For example, some chemicals deposit and sorb on indoor surfaces and can then be ingested by infants and toddlers who touch these surfaces and put their hands and toys into their mouths.

Procedures for estimating emissions rates and indoor air concentrations in the SRD are generally accurate enough for ranking purposes. However, for product releases from water, the assumption of 50% release is likely to overestimate indoor air exposure by an order of magnitude, in some cases. For example, Wooley and colleagues have reported that only a few percent of the ethanol contained in liquid dishwashing and laundry detergents is released into air during use (Wooley et al., 1990). The release of chemicals from water will be a function of vapor pressure and solubility. The Committee recommends that a simple algorithm of fractional assumptions based on Henry's Law constants for different compounds, be developed to provide a better estimate of these losses. The concern is that, in the ranking process, some products which are likely to pose a higher "risk" when used and/or released from water will be ranked too low.

The sorption and desorption of chemicals from indoor surfaces are not yet sufficiently well understood to include in a scientifically defensible way within the algorithm. However, as better scientific understanding develops, these processes can be included in algorithm since the database has been set up to allow the addition of this information.

## 3.7 Appropriate Levels of Aggregation for Ranking

The SRD can perform rankings at various levels of aggregation in terms of product categories (i.e. at 4-digit SIC, 5-digit SIC, 7-digit SIC) and environments. What is the SAB's view about the appropriate levels of aggregation for ranking: Is the weighted-average approach currently employed the most appropriate way to aggregate scores across environments?

The Committee generally endorses the levels of aggregation for ranking in the SRD, but recommends quality control and some refinement. Since the most appropriate criteria for aggregating the rankings may depend upon the particular situation, the IHEC did not recommend a generalized approach nor did it offer modifications to the proposed weighted-average approach. The analyst who uses the SRD should use his/her professional expertise to determine the most appropriate way to aggregate scores, especially when aggregating scores across environments. The Integrated Human Exposure Committee recommends that the Agency consider conducting a sensitivity analysis to identify the impact of different aggregation schemes. Finally, the IHEC

highly recommends that the Agency validate the current approach for ranking by using the current methodology on specific examples before the Agency approves the SRD for implementation.

# 3.8 The Ranking Algorithm

Does the ranking algorithm make sense? Is this the appropriate level of detail for making the decisions on what products we will characterize further? Should other criteria be included?

The ranking algorithm, when applied across the many products, environments and scenarios, is quite complex. However, the final score is essentially a product of two components, the hazard rating and a year-long cumulative exposure, weighted by the fraction of time spent by various subpopulations in different environments. The former is a rating of human health effects adapted directly from the Use Cluster Scoring System (UCSS), which classifies chemicals into one of three potential health hazard categories (i.e., high, medium, and low). The latter is an estimate of average population exposure involving concentration, time, population, and environment.

The health hazard rating of the UCSS categorizes chemicals as high, medium and low hazard based on their toxicological properties. To adapt the UCSS for use in the SRD ranking algorithm, a score of 1, 0.1 or 0.01 was assigned to each chemical based on its categorization of high, medium, or low hazard, respectively. The cutpoints are chosen in a way that a ratio of approximately 1:2:1 of the chemicals are distributed in the high, medium, and low categories. The question is "can this rating scheme meet the EPA's objective to generate a scale to reflect the toxicity of all chemicals being evaluated?" The answer is "probably not," because a range of toxicity that probably varies over four or five orders of magnitude is compressed into a narrow range of only two orders of magnitude.

For example, chronic health effects are generally estimated by relating the cumulative population exposure to the chronic reference dose (RfD) or the slope of a dose-response curve. A hazard rating of one quarter of the chemicals grouped into one single "high" category actually loses the most important toxicity information. For the large number of products and chemicals to be evaluated and ranked, collapsing toxicity data into three categories sacrifices the differentiability that is essential in developing a scoring and ranking scheme. To evaluate and rank hundreds of chemicals and products, IHEC recommends that the Agency use a scale that provides a better reflection of the underlying toxicity data in the UCSS.

The exposure assessment is determined by the concentration and person-time weight for each of the nine environments. The peak and integrated concentrations are functions of mass used, weight fraction, air exchange rate, indoor volume, and frequency of use. Calculations are carried out to estimate the average population exposure. In reviewing the algorithm, the IHEC considered these various components and has addressed them under other sections of this report.

A second way to examine the ranking algorithm is to take one product and go through all the major steps to see if all the calculations involved with these steps make sense. The Committee chose household soap as an example to go through the major steps and discovered some problems with the algorithm. The concentration of a chemical in a given environment (e.g., a hospital) is calculated using the average volume (13,075 m³) and air exchange rate (1.0 air change per hour) of that environment. Soaps are most frequently used in a bathroom. When a person takes a shower or washes his or her hands, the door of the bathroom is usually closed and the exhaust fan usually is on. Thus, only a small fraction of the chemicals emitted from the soap is generally distributed throughout the entire building, although the person using the soap product may receive a relatively high exposure because of proximity and the "effective" volume.

As shown in Appendix E-10 of the *Source Ranking Database*, *Volume 2: Appendices* (USEPA, 1997b) the average frequency of using household soaps (Product ID#28413000) in hospitals is 554,800 times. The high frequency of soap used in hospitals leads to a high chronic score of 1255 and a high acute score of 706. This consequently puts household soaps at first and third position of the ranking lists of chronic and acute hazard respectively. The Committee recommends that for those products which are ranked "high," that this procedure of carefully going through the steps of the algorithm be used to check for any discrepancies.

There are also some potential problems in the steps chosen to average across formulations to get a product score and to average across products to get a category score. When the score of a specific product is calculated by averaging all formulations of that product, equal market share is assumed. We know that usually only few formulations dominate the market of a product. For household soaps, the chronic hazard scores of different formulations range widely from 4.2 to 9724.6. The average score based on the assumption of common market share could be highly biased if there are few uncommon formulations with extraordinary high scores.

A third way to examine the ranking algorithm is to check the final scores and ranks to see if they make sense, i.e., professional judgment. The results of the scores and ranks for 20 product categories appear on page 7-26 of the SRD Report (Table 7-20). Contrary to what would be expected, household soaps rank the second highest on the list, while household pesticides rank the last of the 20 product categories. The ratios between household soaps and pesticides for both chronic and acute scores are as high as 140. Some explanations of these results can be found in the detailed output of all formulations. The most obvious difference that can be found is the length of the lists of formulations for pesticides and soaps. The list of pesticides has only three items, while the list of soaps consists of formulations well over 50. Thus, we are comparing two product categories, which are not equally represented by the number of formulations and products. When we examine the chronic scores of formulations for household soaps, high scores of some formulations are the results of specific chemicals and environments. Looking at the details, one notices that final scores of formulations are generally dominated by only few chemicals and environments.

It is important to examine the major forces driving the SRD. The values of hazard rating only vary 100-fold (from 0.01 to 1), while the average volume of environments vary from 2 to 13,075; the average frequencies of use vary from 0 to 554,800; and the average quantities used vary from 0 to 378,158. It is important to understand how these values affect the final scores.

Another important factor that plays an uncertain role in determining the final score is the unknown value. If a chemical has not been assigned a high, medium or low hazard value, the chemical will be given an arbitrary value of 0.0099. In fact, approximately half of the chemicals in the database have not been assigned into any of the three groups. In the absence of hazard information, we might have compared unknowns with unknowns.

It is reasonable to derive the cumulative exposure of chronic hazard over a year, but for acute hazard, peak exposure is the determinant of immediate physiological reactions. The mechanisms of chronic and acute toxicity are usually different, therefore the chronic and acute ranks are generally not in agreement. Thus, averaging acute hazard over a year is not recommended. The close similarity between chronic and acute ranks as shown in Table 7-20 (page 7-26) of the *Source Ranking Database*, *Volume 1: Guide and Documentation Revised Draft Report* indicates that final scores are not functions of their chronic and acute toxicity, but that they are determined by some common driving forces not related to toxicity.

In summary, the SRD has two major objectives, as indicated on page 1-1 of the Introduction of *Source Ranking Database (SRD) - Volume 1: Guide and Documentation Revised Draft Report.* The first objective is to provide a means for the systematic review of a large number of consumer products, building materials and furnishings that are potential sources of indoor exposures to airborne chemicals. The second objective is to provide a mechanism for grouping products, materials, and furnishings into classes and assigning priorities for further evaluation by class.

The Source Ranking Database with its seven types of files, which contain comprehensive information on chemicals, products, materials, people and environments, is a valuable tool for reviewing consumer products, building materials and furnishings. The SRD software developed by Geomet and Versa has met the first objective which was to provide a means for the systematic review of a large number of consumer products, building materials and furnishings that are potential sources of indoor exposures to airborne chemicals. However, the values that have been entered into the SRD must be checked for accuracy, some information needs updating, and more data should be collected for the incomplete lists of products.

The ranking mechanism proposed in this report to assign priorities and meet the second objective, however, needs further evaluation and validation. Based on the previous discussion which identified some shortcomings of the algorithm, the IHEC has the following recommendations for the evaluation and improvement of the ranking algorithm:

- a) Select several products and go through the calculations step by step. This can be done using a computer to print out the results of each step. The basis for this recommendation is that the ranking algorithm only makes sense when every step of the calculations makes sense.
- b) Carry out a limited sensitivity analysis in order to understand the driving forces of the whole ranking algorithm and identify the factors that have the greatest impact on the ranking.
- c) Treat the chronic and the acute scores separately and differently. The scoring and ranking scheme for acute hazard should be designed with consideration of the mechanism of acute toxicity.

Finally, the Committee was informed during the review that once a ranking is completed, the underlying data for the highest ranked product/material categories will be evaluated by a panel of EPA managers and staff in order to spot anything that seems out of line. The Committee fully supports this plan.

#### 4. SUMMARY OF RECOMMENDATIONS

- a) The IHEC recommends that the Agency should add a short introduction to its report, Source Ranking Database, Volume 1: Guide and Documentation, to explicitly state the underlying assumptions and the uses for which the SRD is /intended. The report would also benefit from the addition of a section which gives an overview of the entire methodology and its components. Some of the viewgraphs used by the Agency at the Committee meeting might be incorporated for this purpose.
- b) The Committee recommends that the Agency include several additional exposure sources in the SRD, specifically, office machines, air ionizers, and indoor combustion sources, and also that the SRD include several of the criteria air pollutants which can be emitted by indoor sources.
- c) The Committee recommends that the Agency add one or more scenarios for products that are routinely used in the volume of a room or a smaller volume that is more relevant to human exposure, e.g. personal breathing zone volume.
- d) The IHEC recommends that the Agency consider adding the octanol-water partition coefficients and Henry's law ratios to the SRD and that a simple algorithm of fractional assumptions based on Henry's law constants for different compounds, be developed to provide a better estimate for the release of chemicals from water.
- e) Dermal and ingestion pathways are not considered in the SRD because the focus is on indoor air and inhalation. For some of the products in the SRD, however, dermal exposures may be significant. IHEC recommends that the Agency incorporate a simplified algorithm, based on K<sub>ow</sub> and exposure time, for ranking products which have the potential for significant dermal exposures. More detailed scenarios for dermal and ingestion exposure pathways should be included in a later phase of development of the SRD.
- f) The Committee recommends that the Agency include an analyses of potential exposures to susceptible populations, e.g. children, the elderly, those with heart problems, asthmatics and individuals who have chronic obstructive pulmonary disease (COPD), in any subsequent updates of the SRD. IHEC also recommends that the Agency include an analyses of potential exposures at daycare facilities in future versions of the SRD.

- g) The IHEC has several recommendations for the evaluation and improvement of the ranking algorithm. The IHEC recommends that EPA:
  - i) Expand the range of the health hazard scoring scale to a larger range than the 100-fold range of 0.01 to 1, to better reflect the underlying toxicity data of UCSS.
  - ii) Select several products and go through the calculations step by step. This can be done using a computer to print out the results of each step. The basis for this recommendation is that the ranking algorithm only makes sense when every step of the calculations makes sense and this best be determined by going through some of the calculations systematically.
  - iii) Carry out a limited sensitivity analysis in order to understand the driving forces of the whole ranking algorithm and to identify the factors that have the greatest impact on the ranking.
  - iv) Treat the chronic and the acute scores separately and differently. The scoring and ranking scheme for acute hazard should be designed in consideration of the mechanism of acute toxicity.
  - v) Finally, the Committee strongly supports the plan to have EPA staff members with expertise in indoor air pollution conduct a review of the final ranking results in order to spot anything that seems out of line.
- h) The Committee recommends that the Agency evaluate the appropriateness of the levels of aggregation for ranking by:
  - i) Conducting a sensitivity analysis to identify the impact of different aggregation schemes.
  - ii) Validating the current approach for ranking by using the current methodology on specific examples before approving the SRD for implementation.

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- \* These are the two EPA documents that were reviewed by the Committee.

# **APPENDIX A - ACRONYMS AND ABBREVIATIONS**

AAPCC - American Association of Poison Control Centers

ASHRAE - American Society for Heating, Refrigerating and Air-Conditioning

Engineers

BASE - Building, Assessment, Survey and Evaluation Study

CHEMTREC - Chemical Transportation Emergency Center

CIR - Cosmetic Ingredient Review

COPD - Chronic Obstructive Pulmonary Disease

CTFA - Cosmetic, Toiletry and Fragrance Association

EUSES - European Union System for the Evaluation of Substances

IHEC - Integrated Human Exposure Committee

PPLS - Pesticide Product Label System

QA/QC - Quality Assurance/Quality Control

RIVM - National Institute of Public Health and Environmental Protection in The

Netherlands (acronym is in Dutch)

SAB - Science Advisory Board

SIC - Standard Industrial Classification

SRD - Source Ranking Database

TEAM - Total Exposure Assessment Methodology

TESS - Toxic Exposure Surveillance System

UCSS - Use Cluster Scoring System

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