



Research and Development

HANDBOOK FOR PERFORMING EXPOSURE ASSESSMENTS

Prepared for

PROGRAM OFFICES OF THE U.S. ENVIRONMENTAL
PROTECTION AGENCY

Prepared by

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HANDBOOK FOR

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PERFORMING

1201 Shattuck Avenue / Seattle, WA 98101

EXPOSURE ASSESSMENTS

Compiled by

Exposure Assessment Group

Office of Health and Environmental Assessment

Office of Health and Environmental Assessment

Office of Research and Development

U.S. Environmental Protection Agency

Washington, D.C. 20460

NOTICE

This document is a preliminary draft. It has not been formally released by EPA and should not at this stage be construed to represent Agency policy. It is being circulated for comment on its technical accuracy and policy implications.

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DISCLAIMER

This report is an internal draft for review purposes only and does not constitute Agency policy. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

FOREWARD

The Exposure Assessment Group is a newly formed office in EPA whose function is to provide expert scientific oversight of the assessments made by the various Agency programs of the exposure of humans to toxic substances. These assessments are critical to the evaluation of the public health risks that are presented by these toxic substances, to the development of regulations to protect against the hazards they present, and for the establishment of research priorities.

In order to define the qualitative and quantitative aspects of an exposure assessment, Guidelines have been formulated by which the Agency will conduct assessments in the future. Because these Guidelines fulfill the various needs of all the Program Offices, they contain general policy/procedure statements. The following Handbook has been constructed by the Exposure Assessment Group to provide more specific details of how exposure assessments are to be performed. Thus, the Handbook can be viewed as directly related to the Guidelines with both documents helpful for understanding the Agency approach in conducting exposure assessments.

James W. Falco, Director
Exposure Assessment Group

ABSTRACT

This Exposure Assessment Handbook was constructed to provide specific details of how the Agency conducts exposure assessments. The Office of Pesticide Programs, Office of Air Quality Planning and Standards, Office of Radiation Programs, Office of Toxic Substances, and the Office of Water Regulation and Standards have all described their exposure assessment procedures plus have provided recent examples of their exposure work.

The Handbook also contains a glossary of terms routinely employed, standard factors used in calculations, examples of modeling and monitoring studies, and a discussion of how to calculate the uncertainties or errors. Since the Handbook was designed to expand upon the concepts of the Exposure Assessment Guidelines, the Guidelines are also included in an appendix to the Handbook for reference.

ACKNOWLEDGMENTS

The original ideas for the Handbook were suggested by the Director of the Office of Health and Environmental Assessment, Dr. Elizabeth Anderson. Ms. Jennifer Craig, a summer intern student, compiled available exposure information into a rough draft. Dr. Alan Senzel constructed the Glossary, plus did technical editing. Mr. Frank Letkiewicz headed an effort by JRB, Inc., to complete the first draft, working extensively on the Models and Uncertainty Sections.

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I. INTRODUCTION

Under the authorities provided by such statutes as the Toxic Substances Control Act; the Clean Air Act; the Federal Water Pollution Control Act; the Safe Drinking Water Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and the Atomic Energy Act, the U.S. Environmental Protection Agency (EPA) is responsible for identifying, evaluating, and regulating a variety of chemical and radiological hazards to human health and the environment. Exposure assessments are an essential component of the regulatory decision-making process for understanding and quantifying the nature and magnitude of the hazards presented by environmental agents and for discerning the most suitable control options both from a technological and regulatory standpoint.

Although there is a substantial history of exposure assessments conducted by the various EPA program offices to support both programmatic and regulatory decisions, there is, at the present time, no clear consensus on how exposure assessments should be conducted. The recognition of the importance of exposure assessments to the Agency's mission and the need for a more coordinated and consistent approach to conducting them by the various program offices led to the formation of the Exposure Assessment Group within the Office of Research and Development's Office of Health and Environmental Assessment. The role of the Exposure Assessment Group is to provide overall guidance and procedures to the Agency for conducting exposure assessments, to ensure the quality of the exposure assessments conducted by EPA, and, when needed, to provide independent assessments of exposure to specific agents. An Agency-wide Exposure Assessment Work Group was also formed to provide for the full input of the various EPA program offices to the development of the Exposure Assessment Group.

The initial product of the Exposure Assessment Group and the Exposure

Assessment Work Group is a document entitled "Guidance for the Preparation of Exposure Assessments" (see Appendix A). This guidance document provides an overview of the kinds of data that should, in most cases, be considered in an exposure assessment. The guidance document also suggests a format for organizing and presenting those data. It is intended that the guidance document will promote consistency in EPA's exposure assessments by providing a uniform approach.

The present document -- "The Exposure Assessment Handbook" -- was created to accompany the guidance document. Whereas the guidance document addresses the requirements of exposure assessments in general terms, this Handbook provides more practical guidance for the preparation of exposure assessments through the presentation of specific examples and detailed discussion of some key aspects of exposure assessments. It must be recognized that exposure assessment is a rapidly evolving area that will certainly undergo significant changes over the ensuing months and years. This Handbook and the guidance document that accompanies it will necessarily be revised to reflect the changes and developments that occur.

This Handbook begins with a discussion of exposure assessment needs and procedures of the key EPA program offices: Toxic Substances, Pesticides Programs, Water Regulation and Standards, Air Quality Planning and Standards, and Radiation Programs. Examples of current exposure assessments from these offices are provided in Appendix B, with brief discussions of their content. There is also a brief discussion on exposure assessment activities of the other regulatory agencies that comprise the Interagency Regulatory Liaison Group.

The next section provides summary level information on models that may be of interest in planning exposure assessments. Included is information that could apply to modeling needs of the user of the Handbook. For example, mathematical

descriptions of commonly used elements (e.g., Gaussian dispersion, Briggs plume behavior, liquid to vapor phase mass transfer, laminar and turbulent flow, etc.) could be readily appended to this section of the Handbook.

The Handbook also contains a listing and description of some data bases that contain useful data on the monitoring and measurement of substances in the environment. The ensuing section elaborates on uncertainty in exposure assessment, and the different types of deficiencies apparent in the input data or the assumed values. A discussion of the utility of sensitivity analysis in bracketing estimates is also included.

In an attempt to standardize definitions of terms used in exposure assessments, a glossary has been constructed. Similarly, an attempt has been made to establish a set of standard (numerical and other) factors for use in present and future exposure assessments. The use of a basic set of factors would facilitate assimilation of the quantitative components of an exposure assessment and the cross-comparison and cross-utilization of the results.

II. ORGANIZATION OF EXPOSURE ASSESSMENTS

A. OUTLINE OF TYPICAL EXPOSURE ASSESSMENT PROCEDURES FROM VARIOUS PROGRAM OFFICES

Each Program Office contributed to the development of the Exposure Assessment Guidelines (Appendix A) which suggest methods for conducting exposure assessments for ideal situations. For those readers who are not familiar with these Guidelines, it is suggested that they be read first.

In this section, the Program Offices were asked to describe their typical exposure assessment procedures. It is evident that each Program Office has its own goal with the particular end use and the availability of data dictating the scope of the assessment.

A thorough review of how each Program Office performs hazard, exposure, and risk assessments was recently conducted by a contractor (Clement Associates, Inc.) for OPTS. This report is still in draft form under the title "Review and Analysis of Hazard, Exposure, and Risk Assessment as practiced by EPA and other Federal Regulatory Agencies." When finalized, the report will present a critical analysis of the exposure assessment activities of the Agency.

Office of Pesticide Programs

Purpose--

The following discussion gives the purpose of and procedures used for preparing exposure assessments for pesticides as part of regulatory activity under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These assessments are prepared by the Environmental Fate Branch of the Hazard Evaluation Division, Office of Pesticides and Toxic Substances.

The overall goal of a pesticide exposure assessment is to provide the input necessary for risk assessment. The requirement for exposure assessments is

stated in the FIFRA regulations describing the Rebuttable Presumption Against Registration (RPAR) process, at 40 CFR 162.11. The "Interim Guidelines for Cancer Risk Assessment," published in May 1976, also specify exposure information needed for risk assessment. The exposure assessments are used to prepare risk assessments for chronic human health effects such as cancer, and also for potentially single-dose toxic effects such as teratogenicity, reproductive effects, and neurotoxicity.

Exposure assessments prepared under the mandate of FIFRA are limited to the use of chemicals as pesticides. Exposure from other types of uses, or from manufacture, formulation, transportation, and disposal, are not generally considered. In practice, the assessments have been concerned with several categories of exposed persons:

- o the general population exposed through pesticide residues in the food supply, as well as exposure through air and drinking water contamination
- o agricultural applicators, mixer/loaders, and flaggers exposed as a result of their direct contact with the pesticide
- o fieldworkers, harvesters, and others exposed upon re-entering treated areas
- o bystanders or nearby populations exposed as a result of pesticide drift from the target area
- o industrial and institutional users of pesticides
- o home users of pesticides and residents of homes in which pesticides have been used

Procedure--

The information required for a pesticide exposure assessment is of two general types: information about the use pattern of the pesticide and actual data on dose of chemical received. The first of these is outlined in Table II-1. This information is generally received from the Benefits and Field Studies Division of OPP.

Actual field data on pesticide exposure is obtained from several sources: the published literature; specific studies submitted by pesticide registrants; field studies conducted by EPA; monitoring studies for food, water, air, human blood, urine, or adipose tissue; etc. The Environmental Fate Branch (EFB) maintains an extensive file of pesticide exposure data, and continuously scans the current literature for new information on exposure methodology and results. Worldwide literature searches are also conducted for each pesticide exposure assessment. In some cases, the Hazard Evaluation Division (HED) will fund specific field studies designed to answer more general questions relating to pesticide exposure. The EFB staff may advise registrants regarding the types of exposure information needed and on methods and field procedures for measuring exposure.

The basic residue data used for a human dietary exposure analysis of a pesticidal chemical compound are the pesticide tolerance; Food and Drug Administration and U.S. Department of Agriculture compliance, market basket, and surveillance data; data from controlled field studies submitted with petitions for tolerances under the Federal Food, Drug, and Cosmetic Act; company conducted market basket survey data; EPA monitoring survey data; and the open literature.

The data base of pesticide exposure information is currently expanding very rapidly. In the near future the entire data base will be abstracted into a storage and retrieval system which will accommodate it in a more accessible format.

TABLE II-1. USE/USAGE INFORMATION REQUIRED FOR PESTICIDE EXPOSURE ASSESSMENT

Assessment of exposure of pesticide applicators, fieldworkers, and nearby populations to pesticides requires information on use practices and extent of use. The following is a general list of the kinds of information that contribute to this assessment.

For each use to be analyzed for exposure:

1. Pesticide label
2. Types of pesticide formulations used (emulsifiable concentrates, dusts, granules, etc.)
3. Packaging information (for example, 5 lb sack of 25% dust, 55 gal drum of 4% emulsifiable concentrate, etc.)
4. Methods of mixing and loading (such as open or closed system transfer to application equipment, pouring dust into hopper, etc.)
5. Application rates and dilutions (for example, 1 lb per acre active ingredient in 500 gal water)
6. Application schedules (when applied during growing season; how often)
7. Application techniques
 - description of apparatus used (such as air blast sprayer, hi-boy rig, backpack sprayer, indoor aerosol spray, etc.)
 - common practices during application (spray pressure, speed of spray rig, soil incorporation practices, type of spray coverage, etc.)
8. Number of personnel involved in application and their identity (farmers, commercial applicators, homeowners, etc.)
9. Extent of use (total acres treated per year, total pounds used, etc.)
10. Description of associated personnel used in application (mixer/loaders, flaggers, etc.)
11. Estimates of duration of exposure including any patterns of exposure (for example, 10 hours per day for 15 days in March or April; acres per hour that can be treated)
12. Information on protective clothing in common use

TABLE II-1 Continued

13. Percent of crop treated, consumed on farm, exported, etc.
14. Brief description of important activities at the site following application (cultivation, application of other agricultural chemicals, harvest schedules, etc.)
15. History of past incidents which indicate propensity for non-adherence to label directions and frequency of accidental exposure.

A number of methods have been developed to measure actual exposure to pesticides under field conditions. The EFB maintains a separate file of descriptions of these methods as well as examples of field study designs for specific exposure monitoring situations. Although there is no single best method for all exposure situations, the best current practice appears to be as follows:

dermal: Pads made from alpha-cellulose (for dermal exposure to sprays) or layers of gauze (for exposure to dusts or particulates) are attached to the forearms, chest, back, thighs, and perhaps the forehead or a combination pad made by placing gauze over alpha-cellulose (for exposure to dry formulation while being mixed into a liquid solution) are attached to the forearms, chest, back, thighs, and perhaps the forehead. The efficiency of protective clothing might be determined by placing pads under as well as over any protective equipment. These are collected for pesticide residue analysis after the period of exposure. The results can be converted to a milligram-per-square-centimeter dermal dose; when multiplied by standard body surface areas, the rate of dermal contact may be estimated. For the hands, which generally receive the highest dermal exposure during actual operations with pesticides, both measurement of residues on cotton or nylon gloves and hand washing with 95% ethanol have been used.

inhalation: Both respirators and personal air sampling devices have been used to sample air in the breathing zones of exposed persons. The former give a direct measure of the amount of pesticide that would have been inhaled, while the latter result in an air concentration that must be multiplied by an assumed breathing rate in order to obtain a value of the inhalation exposure. A number of studies are available which evaluate absorbents available for use in air sampling devices. In situations where it is important to measure air concentrations of pesticides that may be present at very low levels, high-volume air samplers should be employed to ensure the collection of an adequate sample volume. For both dermal and inhalation exposure measurements, the Office of Research and Development has prepared detailed reviews of the methods used by their laboratories.

oral: The goal of the oral (dietary) exposure assessment is to predict the pesticide residues in or on food as consumed. Projections of pesticide residues in food as consumed can be made if it is known where the pesticide was applied; the amount applied; what residue losses in commerce, processing, cooking, etc., are expected; and the time interval from application until consumption. Tables of food consumption and data on the extent to which crops are currently treated with the pesticide of interest are used to calculate the contribution of residues to the diet for each crop treated. The results of such calculations are summed over all the foods bearing residues of the pesticide to yield, for a national average, a rate of ingestion (mg/person/day).

urine: The above routes of exposure are all direct; that is, they result in measurement of the actual amount of pesticide residue with which a person may

come into contact. The appearance of pesticide residues and/or metabolites in human urine, however, is prima facie evidence of exposure; when data on the metabolism and the efficiency of excretion is available, the exposure may be calculated from the amount excreted. This indirect method of exposure measurement can be more precise than the above direct methods; however, it cannot identify the route of exposure.

other body tissues: Pesticide residues in blood, adipose tissue, or other body tissues are often available as evidence of exposure. Adipose tissue residues are generally limited to lipid-soluble and stable pesticides such as the chlorinated hydrocarbons, which tend to accumulate in these tissues. Since these residues may be stored over a long period of time, they indicate continuous exposure rather than the more instantaneous type of exposure that is measured by the direct methods discussed above. Blood levels of pesticides are sometimes available; these indicate an immediate type of exposure since blood is rapidly circulated and cleared by the kidneys.

The exposure estimates for the three routes of exposure are combined to produce the total exposure assessment. Alternatively, urinary excretion data might be used to back-calculate the total exposure by all routes, if adequate information on the pharmacodynamics of the pesticide in humans or animals is available. For dermal exposure, an estimate of skin absorption is necessary to arrive at the actual dose by this route; very little data on human skin penetration rates are available. The units of the dermal and inhalation exposure are usually expressed in milligrams per hour of exposure-related activity; when multiplied by the estimated duration of the activity (obtained from the use data in Table II-1) and divided by a standard body weight, the units become milligrams per kilogram per day or per year, depending on whether the risk assessment addresses single-dose or chronic effects.

Considerable judgment is necessary in order to complete a pesticide exposure assessment. The evaluation of limited field monitoring data, the influence of varying meteorological conditions, the use and efficiency of protective clothing, the use and efficiency of closed mixing/loading/transfer systems, the largely unknown absorption rates of chemicals through the skin, varying particle size which affects respiratory exposure, the sporadic but potentially enormous

exposure resulting from pesticide leaks and spills, and varying human activity patterns are all matters of judgment that influence the numerical outcome of the assessment. A primary requirement of the assessment is to state clearly all assumptions used to derive the calculated exposure, and, if possible, to give an estimate of the numerical variability.

Numerical assessments of exposure will often be requested in situations for which actual field monitoring data are not available. In such cases, a search of the EFB's exposure data base may reveal data for other similar pesticides applied under similar circumstances. If the use practices associated with these measurements are sufficiently similar to those for the pesticide in question, then a reasonable estimate of exposure may possibly be made, based on the "surrogate" data.

Procedures for estimating environmental mobility of the pesticide when experimental data are lacking are available. Computer models for calculating estimated environmental concentrations (EEC's) from known physical chemical parameters, along with hydrologic, and meteorological data provide information on the potential movement of pesticides from the site of application via spray drift, leaching, surface runoff, and unscheduled field flushings. The EEC's are relevant to human exposure in that potential concentrations of pesticides in groundwater and surface potable water supplies can be estimated.

Alternatively, exposure may perhaps be calculated from basic physical properties, such as vapor pressure, by assuming reasonable values of volatility rates, air circulation patterns, or other information necessary to make a calculation. These types of procedures clearly call for additional levels of judgment; such assessment procedures might or might not be attempted, depending on the nature of the regulatory question.

The general format of pesticide exposure assessments is given in Table II-2.

TABLE II-2. FORMAT OF THE EXPOSURE ASSESSMENT

1. Include the common name, important trade names, the structure, relevant physical properties (generally volatility, solubility, and perhaps partition coefficient), and other pertinent information such as important metabolites or degradation products, common impurities, significant inert ingredients in formulations, etc.

A brief review of the environmental fate and transport of the pesticide (typically the more important conclusions from the environmental fate profile).

A brief overview of common formulations and use patterns.

Established tolerances.

2. Exposure through use: For each use, this section contains estimated values of dermal and inhalation exposure, either from actual field monitoring studies or derived from data obtained for other pesticides under the same use conditions. These estimated values are then combined to produce a unit exposure, as discussed above under Procedure. In general, some estimate of the possible range of the values should be included. In some cases, no useful data whatsoever may be available; in such cases, the exposure assessment should so indicate, and, if possible, suggest how data might be obtained. No exposure estimate would be prepared in these cases.

The total exposure is then computed by multiplying the unit exposure by the duration of exposure and then adding in the dietary contribution. Information on the number of people exposed, and, if appropriate, some indication of the sporadic or chronic nature of the exposure should also be included. Thus, the exposure assessment ideally includes the levels at which people are exposed, the number of people so exposed, and the duration of the exposure.

3. Summary table: Lists the use patterns, the unit exposures, the number of people, and the total daily and annual exposure. The specific dietary burden for each crop is listed, as well as the total residue contribution.
4. Bibliography

Office of Air Quality Planning and Standards

Pollutant Assessment Branch--

Purpose--In the Office of Air Quality Planning and Standards (OAQPS), the Pollutant Assessment Branch of the Strategies and Air Standards Division is responsible for performing exposure assessments for hazardous pollutants under the authority of Section 112 of the Clean Air Act. Hazardous pollutant standards are health-based, using "ample margin of safety to protect the public health" as the criterion. Procedures in the proposed Airborne Carcinogen Policy (44 FR 58642) further define and elucidate exposure assessment needs for hazardous pollutants.

In regulating hazardous pollutants, exposure assessments are necessary to show public health impact. Ambient air is the medium of concern, so the general population is the group surveyed. Sources of air pollution fall into three categories: point sources, area sources which are generally small but numerous and of a specified location, and sources which are numerous but of unspecified location (generally called prototypical sources).

Procedures--Exposure assessments are performed by gathering available data on source locations and emissions, applying diffusion modeling techniques to these, and then calculating population exposure to the emissions. Source location and emission data are gathered through literature search, trade/technical journals, state/local agencies, and industry contact. Local meteorology is used where possible, and most recent census data are used to determine population profiles.

Monitoring is undertaken as an integral part of the exposure assessment only on a selected basis because of the time and expense involved, and the vagaries of meteorology. Furthermore, when monitoring is performed, it generally is to provide confirmatory information supporting regulation rather than to serve as

the basis for regulation.

The exposure assessments done by the Pollutant Assessment Branch are most commonly level I types. Their purpose is to estimate the number of persons exposed to various concentration levels of a pollutant. This information, along with input from the Carcinogen Assessment Group, is presented as evidence for the Administrator's decision whether to list the substance as a hazardous pollutant or not.

Ambient Standards Branch--

Purpose--Section 109 of the Clean Air Act pertains to the establishment of National Ambient Air Quality Standards (NAAQS). In setting primary ambient air quality standards, it should be the judgment of the EPA that the attainment and maintenance of such standards, "allowing an adequate margin of safety, are requisite to protect the public health." The most meaningful indicator of margin of safety is a risk assessment of alternative ambient air quality standards. This risk assessment explicitly accounts for uncertainty of scientific information concerning adverse health effects and population exposures. An exposure assessment is an inherent component of a risk assessment.

The exposure assessments relevant to Section 109 of the Clean Air Act are conducted by the Ambient Standards Branch of the Strategies and Air Standards Division of OAQPS. These exposure assessments serve two major purposes: 1) to support ongoing NAAQS reviews (e.g., for substances such as SO₂, CO, NO₂), and 2) to develop an exposure assessment capability to be a part of a risk assessment methodology currently under development. (The models employed become more refined with increasing experience in exposure assessment; thus, the overall quality of exposure assessments improves with time.)

In general, the exposure assessment is intended to estimate the distribution

of expected number of human exposures in a given geographical area to any desired time-averaged ambient pollutant concentration (up to a one-year time period) at any specified air quality level. The exposure model can be used to estimate exposures at base year ambient concentrations or future year levels when an area is in compliance with a given alternative national ambient air quality standard.

In practice, exposure to a particular pollutant (such as CO) is estimated for several selected U.S. cities. A typical study area consists of a city and several suburbs. The findings are then extrapolated to the entire U.S. urban population of roughly 140 million people. Exposures to rural populations are not analyzed, as insufficient data from rural areas are available.

Procedure--

Sources of information--Some important sources of information for exposure assessments are listed below.

Census Bureau.	Population data, including age and occupation data
Storage and Retrival of. . .	Monitoring data
Aeromatric Data (SAROAD)	
Stanford Research Institute, International (SRI). . . .	Time budget studies
Project Engineering Development Company (PEDCO).	Analysis of pollutant concentration data

Three major data bases contribute to the exposure assessment. These are identified below:

1. Pollutant Concentration Data Base

A year is selected for which adequate data are available relevant to the study area of concern. The SAROAD network (administered by the states)

is the source of hourly pollutant concentration data for a one-year period. A monitoring network exists throughout the study area in order to measure legal compliance to existing standards. (It is recognized that the monitoring network does not measure air quality in between monitor locations. Various mathematical interpolation techniques are used to fill in data gaps.)

Human dosimetry is not employed, as this technique is not yet adequately developed. The monitoring data is convenient to obtain, as the networks are in place and are collecting data on an ongoing basis.

2. Human Activity Data Base

Time budget studies (provided by SRI) are conducted to learn how people spend their time. Currently, people in the study area are considered to be distributed among five microenvironments:

- indoor work
- other indoors
- inside transportation vehicles
- other transportation along roads
- other outdoors

The concept of microenvironments is being further refined, and in the near future ASB expects to be working with approximately 20 microenvironments for the populations of interest.

The age and occupation data from the Census Bureau is used to generate 12 age and occupation categories. Using the time budget information and urban transportation planning data, the fraction of people in each of the 12 categories is determined for the five microenvironments for each hour of the day.

Furthermore, an estimate is made of the fractions of people at each of three levels of activity: low (e.g., sitting, lying down), medium (walking), and high

(jogging, tennis, etc.). Thus, a person is considered to be in 1 of 15 possible situations at any given time (5 microenvironments x 3 levels of activity). Some of these situations are null categories (e.g., being inside a transportation vehicle at a high level of activity).

For longer averaging periods (such as 8 hours), it is not sufficient to estimate fractions of people in various microenvironments and activity levels; rather it becomes necessary to follow various types of people through their activities during the period of interest.

In organizing the data, there are separate sets of data for the three climatologic regions of the U.S. and for weekdays versus weekends.

3. Population Data Base

This information consists of the number of people living in the study area, the number in each sector, and the numbers in the 12 age and occupation categories.

The monitoring network provides base values for pollutant concentrations. These base values are transformed for each microenvironment depending upon its relationship to the nearest monitoring station(s). For example, if the pollutant is carbon monoxide and the microenvironment is the interior of an automobile, the base value is multiplied by a factor greater than one. Such a transformation follows from the fact that the monitoring stations are located at fixed points outdoors and that the carbon monoxide levels are higher within vehicles and along roads. Alternatively, a pollutant concentration value may be obtained by interpolation between values taken from two monitoring stations.

Another important consideration is transportation patterns. People will not only pass between microenvironments in a given sector, but will also move from one sector into another where different base values will be obtained. For instance, many people will commute from the suburbs or countryside into the

heart of the city during the course of a day. In addition, they are likely to be in a number of microenvironments within each geographical sector.

Using the model described above, it is the task of the Ambient Standards Branch to determine the present exposure of urban populations to air pollutants and to determine how exposure changes under various alternative control standards that may be implemented.

In addition, the data for a one-year period are used to project ambient air concentrations for future years. This area contains considerable uncertainty as the air concentrations of pollutants are highly dependent upon meteorological conditions. The data base over the one-year period is used to develop a probability distribution for future concentrations of air pollutants.

Office of Radiation Programs

Purpose--

The overall goals of radioactive exposure assessments conducted by the Office of Radiation Programs are to determine the health effects that result from radioactive emissions, and to determine whether it is cost effective to introduce control measures to reduce those emissions in the interest of protecting the public health.

Although the problems of reactor safety are handled by the Nuclear Regulatory Commission (NRC), authority over radioactivity in the environment is within the jurisdiction of the EPA under the National Environmental Policy Act (NEPA) of 1969. In addition, the Clean Air Act amendments enacted in August 1977, gave the EPA authority to establish standards to control emissions of radioactive pollutants into the atmosphere and to regulate radioactive pollutants.

The scope of the environmental exposure assessments performed by the Office of Radiation Programs is 1) to determine the isotopic composition of the radioactive source term, the physical states in which those radionuclides are emitted, the rates at which they are emitted, the models by which they diffuse and are absorbed in the environment, the pathways of exposure, individual and population exposures; 2) to make risk and health effects analyses; and 3) to perform assessments of the requirement for controls in the interest of public health.

Procedure--

Sources of information--Although the overall scope of environmental assessments is essentially the same for all source terms, the details of developing the data for these broad areas often differ widely. For example, solid, liquid, and gaseous radioactive effluents containing many radionuclides

are emitted from nuclear reactors and expose populations through the pathways of inhalation, ingestion, and direct radiation. On the other hand, the mining, storage, and combustion of natural gas are concerned with radon and its daughter products, which expose the population to radioactivity essentially through the inhalation pathway. In the development of an environmental assessment, data are drawn from the following sources:

Nuclear Regulatory Commission.	reactor emission data
Bureau of Mines.	mineral and energy production data
Mine Safety & Health Administration.	radon concentration & ventilation data
Oak Ridge National Laboratory.	dose conversion factors
National Academy of Sciences	health risk data
Department of Energy	energy and environmental data
Corps of Engineers, Dept. of Army	waterways impoundment data
Weather Bureau	meteorological data
Nuclear Reactor Facilities	environmental, dose, and source data
State Health Departments	environmental data

In addition, the following data are obtained from field and laboratory measurements (see reference 1 for analysis methods):

- o stack gas velocity and volume flow rate by EPA method 2
- o integrated gas sampling for radon emission from sources by EPA method 3
- o particulate emission rate by EPA method 5
- o particle size analysis of particulate emissions by Sierra Cascade Impactor
- o sample process emissions, including after the last control device - EPA method 5
- o stack height for diffusion estimates
- o stack temperature and pressure
- o area and volume of tailings piles
- o radionuclide concentrations at various points of emissions, e.g.,

nuclear reactor fission products

uranium	234	235	238
radium	226		
lead	210		
thorium	228	230	232
polonium	210		

o radionuclide concentrations in air, water, and food

Development of the environmental assessment--The computer code described in Airdos (2) represents a method for estimating radionuclide concentrations in air, ground surface, water, and in such foods as meat, milk, and fresh produce. Doses to 11 human organs from these pathways are computed from the rates of inhalation, ingestion, and dose conversion factors. Individual doses (rem/y) are converted to population doses (person-rem/y) which, in turn, are converted to health effects from risk factors (health effects/person-rem/y) (3-5).

The assumptions used in this assessment are as follows:

1. Health effects calculations are based upon the linear non-threshold hypothesis that the number of cancers that may occur per unit dose at low doses and dose rates is the same as observed at higher doses and dose rates and also that all radiation is harmful.
2. A modified Gaussian plume equation is used to estimate both horizontal and vertical dispersion (6-7).
3. In the calculation of an airborne external immersion dose at ground level, a semi-infinite cloud was assumed.
4. Ingestion doses are based upon the assumption of uniform daily consumption rates for each type of food.
5. Other assumptions peculiar to the particular source exposure assessment, e.g., the size of the tailings pile for radon emission assessment or the size of a nuclear reactor for assessing the exposure from fission products.

As indicated previously, the broad scope of an exposure assessment is essentially the same for all sources, the end result being an estimate of the number of health effects resulting from a radioactive source and a determination

of which emission control devices are cost effective. However, different source terms make it necessary to alter the structure of the format in the interest of making an orderly presentation. A good example of the format, style, and composition of an exposure assessment is the report "Assessment of Potential Radiological Health Effects from Radon in Natural Gas" by Raymond H. Johnson et al., EPA-520/1-73-004.

References--

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Office of Toxic Substances

Purpose--

The Toxic Substances Control Act (TSCA) directs the EPA to identify and appropriately regulate chemical substances and mixtures that present an unreasonable risk of injury to health or the environment. Sections 4, 5, and 6 of TSCA specifically apply to the work of exposure assessment for toxic substances.

Section 4 of TSCA gives the EPA the authority to require that testing be conducted on a chemical substance or mixture for which insufficient data is available with respect to health and environmental effects or exposures.

Section 4(f) requires the EPA to act within 180 days of receipt of test data or other information that indicates a chemical may present a significant risk to health or the environment. Under this subsection the EPA must "initiate appropriate action ... to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable."

Section 5 of TSCA requires the EPA to consider human and environmental exposure and potential risk to new chemical substances or mixtures for which a premanufacturing notice has been filed.

Section 6 of TSCA concerns the regulation of existing chemical substances and mixtures. An exposure assessment is specifically required for substances falling under this section.

Within the Office of Pesticides and Toxic Substances (OPTS), the Office of Toxic Substances (OTS) is responsible for preparing risk assessments to support regulatory decision making. The Exposure Evaluation Division (EED) is responsible for most of the exposure assessments pursuant to sections 4, 5, and 6. The Economics and Technology Division is responsible for a part of some of the assessments.

The Assessment Division combines the exposure assessment with the assessment of adverse effects of the chemical substance in order to generate a risk assessment. The Chemical Control Division then utilizes the risk assessment in the process of generating a Control Options Document.

The exposure assessments performed for OTS will meet different goals depending upon the applicable section of TSCA. For instance, under Section 6, the exposure assessment will have a rather broad scope with regard to consideration of pathways of exposure and populations exposed. In contrast, for a substance falling under Section 4(f), the exposure assessment may be limited to the particular exposure pathway and/or exposed population indicated by the test data or other information received by the Agency.

Procedure--

Sources of information--In conducting an exposure assessment, information gathering is directed toward the five major areas described in the Guidelines document: (1) Sources (Materials Balance), (2) Exposure Pathways, (3) Population or Target Studies, (4) Monitoring or Concentration Levels, and (5) Integrated Exposure Analysis.

Information and data are obtained through worldwide literature searches, from industry, through EPA monitoring studies, and from other U.S. Government Agencies. Exposure information is often obtained from sources such as the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC). Population data are often obtained from the Bureau of the Census and the Worker Population Studies produced by National Institute for Occupational Safety and Health (NIOSH).

Sources (materials balance)--For exposure assessments on existing chemicals, the materials balance studies are performed. The information needed to perform a materials balance study may be found in the Guidelines document in the

"Suggested Outline for an Exposure Assessment." Usually the entire United States during a particular calendar year is chosen as a boundary for the system being balanced, but other geographical or time boundaries can be used for specific purposes. The environmental releases are reported as amounts and rates of release to the various media, listed by geographical location and physical-chemical form of the substance at the point of release.

Exposure pathways and environmental fate--The principal pathways of exposure are identified and environmental distribution is predicted using models. When available, monitoring data is compared to the predicted environmental concentrations.

Population studies--Normally, population characteristics studies will be done only for those locations where potential exposure exists based upon information provided by chemical release, environmental fate, or monitoring studies. For abiotic receptors, population characteristics are replaced by studies of the receptor (e.g., ozone layer).

Monitoring--Monitoring data are generally obtained from the published literature or from reports provided by industry. OTS may also perform monitoring studies for some substances under TSCA.

Integrated exposure analysis--Exposure scenarios and profiles are provided by subpopulation, and provide information on frequency, duration, and intensity of exposure.

Exposure projections for new chemicals--Making an exposure projection for a new chemical (under Section 5 of TSCA) involves developing much of the same kind of information as for existing chemicals, i.e., materials balance information, environmental fate information, and population characteristics. In most cases, however, since the chemical is not yet being produced, monitoring as a verification tool is limited to follow-up studies. The information developed

for exposure assessment for new chemicals depends to a large degree upon estimates, data on chemicals similar to the one being studied, and the data provided by the potential manufacturer.

Format--The format for exposure assessments for toxic substances closely resembles that suggested in the Guidelines document. The basic outline is presented below.

- I. Introduction and Executive Summary
- II. General Information
- III. Sources (Materials Balance)
- IV. Exposure Pathways and Environmental Fate
- V. Population Studies
- VI. Integrated Exposure Analysis
- VII. Bibliography
- VIII. Appendices

Office of Water Regulation and Standards

Purpose--

The Clean Water Act (as amended, 1977) set forth a national objective "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." To accomplish this end, several general goals were established, which include the following:

1. That the discharge of pollutants into navigable waters be eliminated by 1985.
2. That an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983.
3. That the discharge of toxic pollutants in toxic amounts be prohibited.

The requirement for risk assessment for toxic pollutants (and thereby exposure assessment) is indicated in sections 307(a) (1) and (2) of the Clean Water Act. Section 307(a) (1) establishes that a list of toxic pollutants (priority pollutants) be published, to which the EPA may add or delete any pollutant. In revising the list of priority pollutants, the EPA is required to take into account the following factors: "the toxicity of the pollutant, its persistence and degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms, and the nature and extent of the effect of the toxic pollutant on such organisms." Section 307(a) (2) states that each priority pollutant shall be subject to effluent limitations, and that the EPA may publish effluent standards for pollutants, after considering the factors listed above as well as "the extent to which effective control is being or may be achieved under other regulatory authority."

In accordance with the 1977 amendments to the Clean Water Act, the EPA listed 129 priority pollutants which it agreed to evaluate. Within the Office

of Water Regulation and Standards (OWRS), the Monitoring and Data Support Division (MDSD) is responsible for evaluating the exposure and risks to human and nonhuman species resulting from the occurrence of the 129 priority pollutants in the water environment.

In general, the exposure assessments carried out under the mandate of the Clean Water Act are specifically focused in terms of exposure media and populations exposed. Exposures via water media are analyzed, and attention is directed to both human and nonhuman-exposed populations.

Although the exposure assessments conducted by MDSD are limited to exposure via water media, an attempt is made to put all routes of exposure into perspective. Where water media are the predominant routes of exposure, MDSD makes recommendations of ways to reduce water exposure after performing a risk assessment. When it becomes apparent that other media are important routes of exposure to a toxic pollutant, the information is directed to the appropriate program office(s) within EPA for follow-up study.

An important goal of exposure assessments for OWRS is to aid in the decisions to add to or delete from the list of priority pollutants required by Section 307(1) (a) of the Clean Water Act.

Another function of exposure assessments is to assist other program offices in risk assessment of imminent hazards presented by toxic wastes (e.g., spills and other emergencies). In these situations, the MDSD provides input into the risk assessment regarding possible alternatives for clean-up or other corrective measures.

Procedure--

In the MDSD, the entire staff is responsible for all aspects of each exposure assessment with which they are involved. Specific division of labor in a particular exposure assessment may exist between contractors hired for the

project.

The initial stage in preparing an exposure assessment consists of a cursory review of the available information on a toxic pollutant. This activity is valuable in giving direction for in-depth analysis of exposure by identifying target populations, pathways of exposure, and other important parameters. It is at this stage that an exposure assessment may be referred to another program office if it becomes apparent that water media are not significant routes of exposure.

Information and data are obtained from worldwide searches of the published literature, from unpublished reports, from industry, and from other Federal or State agencies and organizations. The Food and Drug Administration is a helpful source of information on levels of toxic pollutants in foods. Much information is gathered through the assistance of contractors.

Monitoring is conducted by the MDSD and by states, EPA Regions, universities, and contractors. Currently all monitoring data obtained by the MDSD are stored in a computerized data base, STORET (Storage - Retrieval system for water quality data). All states, contractors, universities, and other organizations receiving Federal funds are required to enter their monitoring data into STORET; many independent researchers have entered data into STORET on a voluntary basis. This computerized data base allows rapid access to the existing monitoring data on a given toxic pollutant under consideration. More information concerning the monitoring data storage and retrieval system may be obtained from the STORET User Assistance Branch of the MDSD.

A detailed exposure assessment will include a materials balance, i.e., a study of sources, production, uses, destruction/disposal, and environmental release of a substance. The materials balance analysis includes the entire United States for a particular calendar year as the boundaries of the system

being analyzed. Often the materials balance will be studied for several calendar years with special attention directed to any changes from one year to the next. Projections may be made for future years from observed trends.

Studies of population characteristics are made with particular attention to the identification of subpopulations which may be at highest risk. Human populations may be subdivided on the basis of age, geographic location, and other parameters. Less is known about the characteristics of aquatic populations, but subdivisions may be made within aquatic systems if the exposure data permits such differentiation.

Finally, exposure scenarios are devised for a typical individual in each subpopulation identified above. Commonly used assumptions are employed concerning daily intake of drinking water, diet, and other parameters in order to facilitate comparisons between exposure calculations for different substances. A value for exposure to each subpopulation is estimated, particularly for groups at highest risk. One then estimates the number of individuals within the high-risk subpopulation.

The exposure assessment for a toxic pollutant is then incorporated into the risk assessment with the outline of such a document dictated by the nature of the pollutant. A general outline is presented below:

- I. Executive Summary
- II. Materials Balance
- III. Environmental Pathways/Fate
- IV. Routes of Exposure
- V. Integrated Exposure Assessment
- VI. Toxicological Data
- VII. Risk Assessment
- VIII. Conclusions
- IX. Bibliography
- X. Appendices

B. EXPOSURE ASSESSMENT ACTIVITIES OF OTHER FEDERAL REGULATORY AGENCIES

Consumer Product Safety Commission (CPSC)

The Commission's mandate includes assessment of chemical as well as mechanical injury. The Commission has thus taken steps to develop the means to conduct comprehensive exposure assessments and has begun to develop assessments utilizing these evolving techniques.

In the past year, CPSC has supported the development of assessments of consumer exposure to formaldehyde, indoor air pollutants, and bisazobiphenyl (i.e., benzidine and some of its congeners) dyes. It has also supported the development of a comprehensive report on exposure assessment status and principles. Many procedures, approaches, and problems are discussed in this report on status and principles. Included are human ecology, dose-time functions, uncertainty, entropy, non-equilibrium systems, susceptible populations, and the use of decision logic tables in exposure assessment.

Exposure assessment modeling on benzidine-based dyes follows the sequence of first establishing exposure scenarios and then estimating corresponding exposure estimates using composition data, stoichiometric considerations, and mass balance methods. This approach permits ranking of exposure scenario estimates in order of perceived severity. Severity depends on chemical nature (e.g., reduced or oxidized form), route of entry, quantity or concentration, duration, outdoor or indoor use, size and sensitivity of the population, and other factors peculiar to individual scenarios. The emphasis in the approach is on using professional judgment to determine exposure scenarios and the best data sources and models to use to estimate exposure. Limitations are described and suggestions for improving the data base or the models are suggested at appropriate points throughout the report.

Reports on exposure to formaldehyde and indoor air pollutants begin similarly with identification of sources and scenarios. Source strength data is used in an air pollution model based on environmental parameters.

In indoor exposure modeling there are as many scenarios as there are exposed populations, pollutants, sources, and environmental conditions. For example, source strength data for formaldehyde emission from plywood, particleboard, textiles, gas combustion, cigarette smoke, aerosol products, outdoor air pollution, and insulation must be evaluated in relation to probable values of many environmental parameters. These parameters include temperature, humidity, area and/or volume of generation, specific rate of decomposition, smoking rate, forced filtration and decay effects, and air mixing factors. Probable single and multiple source scenarios can be obtained as characteristic exposure (concentration X time) data points by integrating the concentration vs. time graphs obtained by using a simple programmable calculator.

Health effects are summarily discussed in the formaldehyde and indoor air pollutants reports, but damage or risk assessment is not attempted.

Food and Drug Administration (FDA)

The broad scope of FDA's responsibilities leads to a spectrum of exposure assessment needs. Exposure assessments range from the relatively well-defined problem of evaluating the probable use of specific prescription drugs to complex exposure assessments, such as exposures resulting from environmental contaminants (e.g., polychlorinated biphenyls and aflatoxins); food animal additives/drugs (e.g., diethylstilbestrol); or migrants from food packaging (e.g., dioctyl adipate and vinyl chloride migration from certain polyvinylchloride food wraps).

The FDA, often in collaboration with other Federal agencies, has in the past

been involved in various types of exposure assessments on chemicals of significant concern, i.e., saccharin, nitrites and nitrates, selenium, PCB's, chlorofluorocarbons, and lead acetate, and is currently involved in exposure assessments on formaldehyde and the phthalates.

The FDA assesses exposure on at least two different levels. The first level relates directly to FDA's mandate to ensure that foods, feeds, drugs, cosmetics, biologics, medical and radiological devices are safe and/or effective for humans or specific target animals. These exposure assessments often involve mass balance, dose-type calculations.

Estimates prepared on the safety/efficacy level are generally developed in terms of the intake of a substance, usually presumed to be a bioactive agent, e.g., a chemical substance, form of radiation, microorganism, etc., associated with the use or consumption of foods, drugs, or other carrier vehicles. Intake normally occurs via ingestion and absorption within the gastrointestinal tract, passage through the skin, or by inhalation.

On a second level, related to the National Environmental Policy Act (NEPA), FDA is developing and applying exposure assessment methodology for assistance in the preparation of environmental assessments and environmental impact statements. These environmental documents often include exposure assessments containing both materials balance analysis and estimation of multimedia and multispecies exposures through prediction of the introduction and fate of FDA-regulated substances in the environment.

The requirement for assessment of environmental impact relates directly to the influence of manufacture, use, and disposal of foods, feeds, drugs, cosmetics, biologics, and medical and radiological devices on environmental quality. Such efforts by the FDA are being coordinated with other government agencies, primarily through the Interagency Regulatory Liaison Group.

Department of Agriculture (USDA)

The USDA is responsible for assuring the safety of meat products. Estimates of the amounts of toxic substances in foods that are included under USDA's mandate are prepared by standard mass balance methods.

The Department's recent exposure/risk assessment on nitrosamines in bacon illustrates a direct approach for determining human exposure to nitrosamines that can, in turn, be used to estimate cancer risk.

Using knowledge of the average national consumption of bacon per day and data on the types and amounts of nitrosamines in bacon, it was possible to estimate average daily exposure (as a dose) to nitrosamines in bacon. Sensitive, state-of-the art analytical chemistry methods were used to secure quantitative composition data.

Carcinogenicity response data were reviewed and evaluated in conjunction with the exposure data with the objective of estimating the increase in human cancers associated with this national average type of exposure scenario. Other possible minimum (best case) and maximum (worst case) exposure scenarios were not considered. These could have been used to bracket the national exposure average, thus constituting one aspect of a sensitivity analysis related to exposure and risk.

Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH)

At OSHA, exposure assessments are used to support rule-making activities and thus, are not in themselves generally anticipatory. These assessments are based on comprehensive evaluation and assimilation of very large quantities of onsite monitoring data. Exposure data are compared to standards already in place, i.e., 8-hour, time-weighted average concentrations. Since concentration data are available, there is no need to develop or assume concentration-time data

prior to preparing an exposure assessment of this type.

The anticipatory (research) side of occupational exposure assessment is performed by the National Institute for Occupational Safety and Health (NIOSH). Assessment of the health and safety effects of exposure to workplace chemicals is a component of many NIOSH documents. For example, a recent document on the benzidine-based dyes illustrates the role of NIOSH in exposure assessment. The NIOSH report to OSHA assesses the impact of workplace exposure to these dyes and suggests that exposure be further decreased.

III. MODELS EMPLOYED IN EXPOSURE ASSESSMENTS

Some general exposure assessment principles of use in this Handbook have been presented in a review of the state-of-the-art in exposure assessment (1). An ideal model is described as providing for multiple emission sources; conversion of emission rates to contaminant concentrations in all media (air, water, soil, food); exposure to humans, plants, and animals (we would add materials); multiple routes of exposure to humans (inhalation, ingestion, dermal absorption); and allowing for interactive effects (synergistic or antagonistic) of multiple pollutants. Although the ideal model is not available, components can be assembled into useful models tailored to specific problems. Adequate characterization and central filing of existing model components, in conjunction with a decision logic approach, could facilitate the assembly of case-specific models (2). In the meantime, such synthesis must be left to the reader with a need to assess exposure.

In this Handbook, the intent is to provide the reader with a general overview of some of the existing models, with an emphasis on both physical and biological aspects of exposure assessment. Basic information on a variety of models is provided in Table III-1, including a model acronym, carrier vehicles, exposure routes, suitability for estimating the integral of the product of concentration and the derivative of time (Cdt), basis and summary features, and contacts and references for further details. No attempt has been made to critically evaluate the models, provide comparisons between them, or to include only those models that have been validated.

EPA's catalog of environmental models (3) is an extensive compilation of modeling information. Water quality, water runoff, air quality, economic, and some other specialized models are described in a consistent summary format. For

each model, concise statements of overview, capabilities, assumptions, input data requirements, output calculations, resource requirements, applications, contacts for further information, and key references are provided.

Along with other documents, the catalog of environmental models was reviewed with the objective of selecting models that are useful, either in whole or in part, for estimating exposure. The objective of this Handbook is to provide the reader with a broad view of existing concepts with which to plan and structure his or her own action plan. The exercise of prudent professional judgement is the most important ingredient in exposure assessment at the present state of development of this field. The information in this Handbook is a basic framework for displaying possibilities that can be structured and connected by the reader to meet case-specific requirements.

Table III-1 displays information that can be scanned to reveal key features of existing models with components that may be useful in the conduct of exposure assessments. The reader can select items of interest and proceed through the columns of information to the summarized descriptive material. Follow-up activities include contacting key individuals and reviewing the literature.

Although individual requirements may sometimes be met by a single model, a particular case may necessitate identification and use of a component feature of a complete model, or sequential application of discrete parts of two or more models. For example, the equation for time dependence of pollutant concentration at the coordinates of a home some distance from the source can be coupled with an indoor air pollution model to provide a hybrid model that may better meet the needs of a particular user of the Handbook than any single model. Similarly, an evaporation model can be used as the generation term or function in a conservative type, air pollution model incorporating various physical and chemical decay rates.

For the reader who wishes to relate dose to exposure, a very useful chapter on exposure and resultant toxic effect models can be found in a comprehensive report on mathematical models for atmospheric pollutants (4). Compared to the state of development and application of air pollution source and pathway models, the state of development of exposure and toxic effect models is lagging. Source and pathway models can be used to relate emission or generation of pollutants and ambient concentrations. Exposure models also incorporate attempts to link concentrations and durations with affected persons, other animals, plants, and objects in the environment.

Source models provide an estimate of the temporal and spatial variation of emission increases and decreases. Pathway process models consider physical and chemical decay of the concentration through the action of physical and chemical processes along the path between the source and the potentially affected subject. There is at present no substitute for specific knowledge and decision logic in assessing exposure and toxic effect.

Multimedia considerations apply to comprehensive exposure assessments consisting of diverse, yet interrelated, exposure scenarios. For example, airborne pollutants can be diluted and dispersed by the wind, undergo coagulation or chemical reactions, settle to the ground, be absorbed in cloud elements or precipitation, be absorbed on the ground, enter groundwater, or be washed out in precipitation. Humans, animals, plants, and materials can be exposed directly and indirectly. Entry can occur through surface contact, ingestion, or inhalation according to the spectrum of exposure scenarios applicable to a given system.

Streng, Watson, and Droppo (5) surveyed radiation exposure models and classified them according to atmosphere, surface water, ground water, and terrestrial pathways. Included in information on the 22 models that were

selected were internal and external doses, susceptible organs, and type of computer program. Key features of some of these exposure models are summarized in Table III-2.

EPA has prepared the Guideline on Air Quality Models (10) which recommends air quality modeling techniques that may be applied to air pollution control evaluations. The Guideline makes specific recommendations concerning air quality models, data bases, and general requirements for concentration estimates. The appendix of the Guideline contains summaries of the recommended models, several of which are listed here in Table III-1.

TABLE III-1. FEATURES OF MODELS WITH EXPOSURE COMPONENTS

Model Acronym ¹	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
EPA/ GEOMET	Air	Inhalation	Direct	Mass balance, conservative type, deterministic equation. Applicable to indoor/outdoor air. Generation term and two types of decay. Suitable for hand calculator.	6
CPSC/ JRB	Air	Inhalation	Direct	Mass balance, conservative type, deterministic equation. Generation term and three types of decay for indoor use with outdoor air infiltration. Suitable for developing tailored exposure profiles by user interaction with a programmable calculator.	7,8
CPSC/ JRB	Consumer Products	Inhalation, Skin absorp- tion, GI tract	Direct (but requires knowledge of use duration and frequency)	Mass balance, conservative type analyses of discrete scenarios with case-by-case analysis. Suitable for hand calculator.	2
CPSC/ ABERDEEN	Air	Inhalation	Indirect (re- quires coup- ling with time- dependent model)	Mass balance. Models evaporation from a liquid surface. Provides generation output that can be used with conservative indoor/outdoor models to obtain concentration-time exposure profiles.	9

¹See key to Acronyms at end of table.

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
SEM	Water	All determin- able from knowledge of concentration	Integration possible	Handles only point source inputs to streams, rivers, and shallow non- stratified lakes. 1st order decay. Simulates dilution, advection, and temperature effects. 1-dimensional. Considers uncoupled chemical re- actions. Suitable for hand calculator.	3(p.6)
ES001	Water	All determin- able from knowledge of concentration	Integration possible	Mass balance. Can be used for sequential reactions of two substances having 1st order kinetics. Tidally averaged, steady- state model. Suitable for complex water networks (100 junctions, 50-100 sections). Requires computer.	3(p.12)
DEM	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Real-time, link node model simulating unsteady tidal flow and dispersion in an estuary. Two-dimensional flow. Hydraulic and quality (pollutant concentration) model components. Mass balance checks at each junction. Predicts time varying concentrations. Requires computer.	3(p.15)
TIM	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Derivative model of DEM. Handles up to 4 constituents with coupled or noncoupled reactions with 1st order decay. Used for networks (300 junctions, 300 channels). Requires computer.	3(p.20)
HAR03	Water	All determin- able from knowledge of concentration	Indirect: Steady State	Mass balance. Multidimensional, steady- state model for two reacting substances. Handles 1st order kinetics. Incorporates convective-diffusive mass transport with source and decay terms. Requires computer.	3(p.23)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
FEDBAK03	Water	All determin- able from knowledge of concentration	Indirect: Steady State	Mass balance. Handles consecutive reactions and 1st order kinetics. Assumes that steady state conditions apply. Requires computer.	3(p.27)
PLUME	Water	All determin- able from knowledge of concentration	Indirect: Steady State	Considers only mixing and dilution with no water flow in a steady state stratified environment. 3-dimensional output. Provides concentration data along plume centerline. Requires computer.	3(p.32)
QUAL-II	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Simulates dynamic behavior of constituents subject to dispersion, flow, nutrient cycles, and algal growth. 1-dimensional for networks. Considers 1st order decay. Only point discharges and constant inflows are considered. Instantaneous mixing is assumed. Requires computer.	3(p.36)
EII	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Simulates near shore currents and exchange processes. Sophisticated treatment of dispersion, advection, and dynamic plumes. Requires computer.	3(p.48)
REDEQL	Water	All determin- able from knowledge of concentration	Indirect: Kinetics not considered	Computes equilibria for up to 20 metals and 30 anions in a system. Includes complexa- tion, precipitation, redox, and pH depen- dent reactions. Requires computer.	3(p.52)
RECEIV-II	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Two-dimensional model representing advec- tion, dispersion and dilution. Used on networks. Can simulate coupled and non- coupled chemical reactions. 1st order decay considered. Assumes instantaneous mixing. Requires computer.	3(p.62)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
EXPLORE-1	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Handles 1-dimensional flow in streams and rivers, 2-dimensional flow in shallow lakes and estuaries. Capable of handling constant or time-varying point or diffuse sources of substances. Requires computer.	3(p.66)
MS CLEANER	Water	All determin- able from knowledge of concentration	Direct: Dynamic	Sophisticated model with use in determining bioaccumulation of toxic substances. Re-quires computer.	3(p.70)
DIURNAL	Water	All determin- able from knowledge of concentration	Indirect: Steady State	Used to predict diurnal fluctuations during periodic steady-state conditions. Useful when algal oxygen production is related to concentration of affective agent. Requires computer.	3(p.77)
AGRUN	Runoff Water	All determin- able from knowledge of concentration	Direct: Dynamic	Simulates hydrology and channel pollutant loads for agricultural watersheds. Uses the universal soil loss equation and Horton's equation to compute infiltration rates. Requires specification of soil parameters. Requires computer.	3(p.80)
ARM-II	Runoff Water	All determin- able from knowledge of concentration	Direct: Dynamic	Mass balance. Assumes all runoff water from locations in the watershed. Pollutant transformations are approximated by a series of 1st rate expressions. Arrhenius equation used to adjust rates to different temperatures. Partitioning between phases assumed to be instantaneous. Requires computer.	3(p.83)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
GWM1	Ground Water	All determin- able from knowledge of concentration	Direct: Unsteady State	Based on convective-dispersive mass trans- port equation modified for 1st order decay. 1-dimensional treatment. Surface concentra- tion can be constant or exponentially varying. Vertical seepage constant. Soil saturated or unsaturated. Requires computer.	3(p.97)
GWM2	Ground Water	All determin- able from knowledge of concentration	Direct: Unsteady State	Describes concentration distribution in 2 underground dimensions. Advection and dispersion in 2 dimensions with 1st order decay and an exponentially decaying Gaussian boundary condition. Useful for sanitary landfills, wastewater lagoons, and chemical dumps. Requires computer.	3(p.99)
EPAURA	Runoff Water	All determin- able from knowledge of concentration	Indirect	Assumes accumulated pollutants are all carried off in rainfall on an area of impervious surface. Requires computer.	3(p.101)
EPARRB	Runoff Water	All determin- able from knowledge of concentration		Assumes all rural areas have slope per- centages allowing erosion to take place. Calculates delivered sediment to a water body based on the universal soil loss equation. Pollutant loads are outputted. Requires computer.	3(p.103)
NPS	Runoff Water	All determin- able from knowledge of concentration	Direct: Various time	Used to estimate nonpoint source pollutant loads in urban and rural settings. Requires computer.	3(p.112)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
HIWAY 2	Air	Inhalation	Direct: Hourly values outputed	Applies to uniform wind conditions and level 3(p.120) terrain. Based on Gaussian plume. No physical removal or consideration of chemical reac- tions. Requires small computer.	
APRAC 1-A	Air	Inhalation	Direct: Only for CO	Computes hourly averages of CO concentra- tions at any urban location. Plume rise not treated. Requires small computer. Could input carboxyhemoglobin model for determination of effective dose.	3(p.122)
APRAC 2	Air	Inhalation	Direct: Only for CO, HC, and NO _x	Makes use of historical CO concentration records. Useful for hydrocarbons, CO, oxides of nitrogen. Requires computer.	3(p.127)
PSM'S	Air	Inhalation	Indirect: Only for maximum, short-term levels	Based on Briggs plume rise methods and Pasquill-Gifford dispersion methods. Assumes Gaussian spreading both horizon- tally and vertically. Requires computer.	3(p.133)
TEM	Air	Inhalation	Direct: Depends on updating	Based on an emissions data inventory and a set of meteorological parameters over over a grid. Gaussian plume, Briggs plume rise. Available as a computer program.	3(p.138)
TCM	Air	Inhalation	Direct: Depends on updating	Similar to CDM, but requires less computer time. Gaussian plume, Briggs plume rise. Requires computer.	3(p.140)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
ISC	Air	Inhalation	Direct: Dynamic	Similar to CRSTER except multiple source separation, polar or cartesian coordinates. Gravitational settling and dry deposition of particulates. Simulates line area and volume sources. Evaluates building wake effects. Exponential decay of pollutants. Concentration estimates for 1-hour to annual average. Requires computer.	
PAL	Air	Inhalation	Direct: One-hour concentration increments	For small-scale point, line, and area sources of pollutants. Flat terrain assumed. Briggs plume behavior, Gaussian plume dispersion. No provision for chemical reactions. Requires small computer.	3(p.147)
CRSTER	Air	Inhalation	Direct: Dynamic	Provides concentrations for each hour of a one year period. Handles up to 19 colocated elevated stack emissions. Employs modified form of Gaussian plume equation. Average emission rates assumed. Horizontal and vertical dispersion considered. Requires small computer.	3(p.151)
AQDM	Air	Inhalation	Indirect: Steady State	Used to evaluate area sources in urban areas. Treats physical processes of transport and diffusion. Limited to SO ₂ and suspended particulates. Assumes Gaussian diffusion and homogeneous diffusion. CDM/CDMQC is preferred model. Requires computer.	3(p.156)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
RAM	Air	Inhalation	Direct: Concentrations determined hourly	Employs hourly meteorological data. Based on Briggs plume rise and the Pasquill-Gifford dispersion equations with parameters valid for urban areas. Constant emission rates assumed for each point and area source. Chemical decay half-life can be inputted. Requires computer.	3(p.159)
VALLEY	Air	Inhalation	Direct: Concentrations determined daily or yearly	Model is a steady-state, univariate Gaussian plume algorithm. Provides ground level concentrations at 112 receptor sites in a radial grid. Incorporates plume rise and limited mixing. Chemical reactivity and physical decay can be introduced (both exponential). Requires computer.	3(p.166)
NRRM	Air	Inhalation	Direct	Model only for ozone/oxidants and single precursor hydrocarbons. Requires concentration data. Does not require computer.	3(p.172)
SAI	Air	Inhalation	Direct: Dynamic	Three-dimensional model for area sources in urban areas. Simulates transport, diffusion, and photochemical oxidation reactions. Outputs hourly concentrations of photochemical oxidants and ozone. Requires computer.	3(p.174)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- grating Cdt	Basis and Summary Features	References
CDM/CDMQC	Air	Inhalation	Direct (but provides long- term concentra- tion values only)	Used to determine seasonal or annual quasistable concentrations at ground level receptors. Treats one or two pollutants simultaneously. Briggs formula for plume behavior. Gaussian plume for vertical dis- persion. Permits exponential decay for chemical half-life considerations. CDMQC out- put allows source contribution table. Requires computer.	3(p.177)
REPS	Air	Inhalation	Indirect: (This is a projection model)	Used to determine the impact of changes in national characteristics and parameters on future air quality. Covers five of the criteria pollutants for the 243 Air Quality Control Regions in the U.S. Requires computer.	3(p.182)
SEAS	Air, Water, Solids	All reducible to concen- trations	Indirect: (This is a projection model)	Used to determine environmental, economic, and energy effects of differing growth patterns and policies. Forecast from 1 to 50 years into future. Would require study to determine applications in exposure assessment. Requires computer.	3(p.185)
COPMOD1	Poten- tially Air, Water, Solids	?	?	Used to estimate the impact on copper producer's costs from pollution abate- ment expenditure. The model requires study to determine applications in exposure assessment. Requires computer.	3(p.192)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- Grating Cdt	Basis and Summary Features	References
CONMOD	Poten- tially Water	?	?	Econometric model. Used for estimating the economic impact resulting from EPA's sewer and sewer treatment plant expenditure program. Requires computer.	3(p.195)
PTM	Poten- tially Air, Water, Solids	?	?	Provides economic outputs (income statement, flow of funds summary, balance sheet) from production and pollution control cost inputs. Model would require study to determine applications in exposure assessment. Requires computer.	3(p.198)
CARMOD	Air, Water	?	?	Econometric model for estimating long run levels of automobile demand. Connection with automobile induced pollution is not apparent. Would require study to determine suitability for inputting exposure assessments. Requires computer.	3(p.204)
ABTRES	Air, Water	Inhalation, Others depend- ent on con- centration	Indirect: (This is a projection model)	Forecasts costs associated with pollution control systems. May be useful in exposure assessment work because specific types of pollutants can be studied. Residual levels of pollutants provided as output data. Useful for "what if" questions relating cleanup extent with associated costs. Requires computer.	3(p.211)

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TABLE III-1. (continued)

Model Acronym	Carrier Vehicles	Exposure Routes	Ease of Inte- Grating Cdt	Basis and Summary Features	References
WRAP	Solids	?	?	Used to determine the most efficient regional system design for resource recovery system. Requires study to determine if useful for exposure assessment inputs. Requires computer.	3(p.214)
MMMSPT- EPM	Air	Inhalation	Direct for CO ₂ : (This is a dose model by proxy)	Based on the effects of pollutants on the rate of CO ₂ excretion from the lungs, which is a measure of efficiency of respiratory function. Often reduces observation period for an effect of a pollutant to minutes instead of hours. Effects of pollutants are based on the difference of integral $C_{CO_2} V_{CO_2} dt$ between control animals and exposed animals. Calculator can be used.	3(p.219)
NRM	Elec- tro- magnetic Radia- tion	Body/Organ	Direct: (Converts to dose)	Used for predicting thermal load to animal organ when animal is exposed to radiation converted to heat within the organ. Applies to microwave radiation. Requires small computer.	3(p.222)

KEY TO ACRONYMS

<u>Model Acronym</u>	<u>Name of Model</u>
Water Quality Models	
SEM	Simplified Estuary Model
ES001	Estuarine Water Quality Model
DEM	Dynamic Estuary Model
TTM	Tidal Temperature Model
HAR03	Water Quality Model
FEDBAK03	Water Quality Feedback Model
PLUME	Outfall Plume Model
QUAL-II	Stream Quality Model
REDEQL.EPA	Computer Program for Chemical Equilibria in Aqueous Systems
RECEIV-II	Receiving Water Model
EXPLORE-I	Water Quality Model
MS.CLEANER	Multi-Segment Comprehensive Lake Ecosystem Analyzer for Environmental Resources
DIURNAL	Receiving Water Model
Water Runoff Models	
AGRUN	Agricultural Watershed Runoff Model
ARM II	Agricultural Runoff Model (Version II)
GWMTM1	One Dimensional Groundwater Mass Transport Model
GWMTM2	Two Dimensional Groundwater Mass Transport Model
EPAURA	Non-Point Runoff Model for a Single Storm Even in an Urban/Suburban Setting
EPARRB	Non-Point Runoff Model for a Rural Setting
NPS	Non-Point Source Pollutant Loading Model
Air Quality Models	
HIWAY 2	EPA HIWAY Model
APRAC-1A	Air Pollution Research Advisory Committee Model 1A
APRAC-2	Air Pollution Research Advisory Committee Model 2
PSM'S	Point Source Models
TEM	Texas Episodic Model
TCM	Texas Climatological Model
LIRAQ	Livermore Regional Air Quality Model
PAL	Point, Area, Line Source Algorithm

Model AcronymName of Model

Air Quality Models (Cont.)

CRSTER	Single Source Model
AQDM	Air Quality Display Model
RAM	Gaussian Plume Multiple Source Air Quality Algorithm
VALLEY	Gaussian Plume Dispersion Algorithm
- - -	Nonlinear Rollback/Rollforward Model
SAI	Systems Applications, Inc., Model
CDM/CDMQC	Climatological Display Model
REPS	Regional Emissions Projection System
ISC	Industrial Source Complex Model

Economic Models

SEAS	Strategic Environmental Assessment System
COPMOD1	U.S. Copper Industry Model
CONMOD	Construction Model
PTM	Steel Industry Model
CARMOD	Automobile Demand Model
ABTRES	Abatement and Residual Forecasting Model

Other Models

WRAP	Waste Resources Allocation Program
MMMSPT-	Mathematical Model for Fast Screening
EPM	Procedure for Testing the Effects of Pollutants in Mammals
NRM	Nonionizing Radiation Models

TABLE III-2. EXPOSURE-EFFECTIVE DOSE MODELS

Fluid Flow Regions	Compartments	Compatibility with Modeling of Stable Gases and Particles	Reference
Air: Nose, Throat, Lungs	Lung	Compatible	T.G. Hatch and P. Gross. Pulmonary Deposition and Retention of Inhaled Aerosols. New York: Academic Press, 1964.
Blood	Blood	Compatible	Robert T. Jones. "Blood Flow." Annual Review of Fluid Mechanics, 1. Palo Alto, CA: Annual Reviews, Inc., 1969. pp. 223-244.
Air, Surface and Ground Water	Atmosphere, Water, Humans; Aquatic Plants	Compatible	Dale D. Huff and Paul Kurger. "Simulation of the Hydrologic Transport of Radioactive Aerosols." Radionuclides in the Environment. Washington, D.C.: Adv. in Chem. Ser. American Chemical Society, 93, 1970. pp. 487-505.
Air, Water	Air, Soil, Plants, Animals, Humans	Compatible (also includes transfer coefficients for inhalation, direct radiation, and ingestion of food)	A. Cardinale, V. Gervasio, A. Marxocchi, and E. Nardelli. "A Proposed Approach on Modeling Techniques for Ecological Purposes Using Dynamic Criteria." In Proceedings of the Second Meeting of the Expert Panel on Air Pollution Modeling. Paris, France: NATO Committee on the Challenges of Modern Society, July 26-27, 1971. Chapter II, pp. II-1 to II-20.

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TABLE III-2. (continued)

Fluid Flow Regions	Compartments	Compatibility with Modeling of Stable Gases and Particles	Reference
Air: Nose, Throat, Lungs	Air, Pulmonary Region, Blood, Lymph Nodes, Bone, GI Tract	Compatible	U.S. Nuclear Regulatory Commission. Reactor Safety Study, An Assessment of Accident Risk in U.S. Commercial Nuclear Power Plants. 1975. NUREG-75/014, WASH 1400.
Air, Surfaces, Liquid and Solid Foods	Target population growing at an exponential rate, Susceptible organs	Compatible (and most comprehensive radiation model)	J.L. Rider and S.K. Beal. A Model to Estimate Radiation Dose Commitments to the World Population from the Atmospheric Release of Radionuclides. West Mifflin, PA: Bettis Atomic Power Laboratory, February 1978. WAPD-TM-1274.
Air	Human as a single compartment	Compatible (but assumes even distribution over whole body)	Robert Handy and Anton Schindler. Estimation of Permissible Concentrations of Pollutants for Continuous Exposure. Research Triangle Park, N.C. Research Triangle Institute for U.S. Environmental Protection Agency, EPA-600/2-76-155, June, 1976.
Air, Water	Plants: Many compartments and environmental variables	Compatible	W.W. Heck and C.S. Brandy. "Effects on Vegetation: Native, Crops, Forests." Air Pollution. Third Edition, II. New York: Academic Press, 1977. Editor A.C. Stern. pp. 157-229. S.B. McLaughlin and D.S. Shriner. "Plant Pollutant Interactions and the Oak Ridge Approach to Air Pollutant Impact Analysis." Oak Ridge, TN: Oak Ridge National Laboratory 1976.

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TABLE III-2. (continued)

Fluid Flow Regions	Compartments	Compatibility with Modeling of Stable Gases and Particles	Reference
Air, Water	Plants: Atmosphere, vegetative canopy, soil, root system, leaf, stomatal zone, plant tissues and cells.	Compatible	J.H. Bennett and A.C. Hill. "Interactions of Air Pollutants with Canopies of Vegeta- tion." Response of Plants to Air Pollution. New York: Academic Press, 1975. pp. 273-306.

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IV. MONITORING EMPLOYED IN EXPOSURE ASSESSMENTS

This chapter consists of three sections: monitoring methods, data bases, and monitoring activity.

Part A gives some examples of the available methodologies for monitoring chemical, biological, and physical parameters. It is designed as a compendium, referring the reader to referenced texts and reports.

Part B, which is a listing of some of the available computer files, should serve as a reference to the reader who desires access to past or current data generated from monitoring studies. By examination of the various data bases one may decide which would be likely to contain the desired information. No attempt has been made to report whether or not the data contained in these data bases has been validated.

Part C is a listing of past or ongoing monitoring activity. The purpose of this presentation is to make the reader aware of other monitoring studies. This may be helpful in providing more references on certain methodologies as well as examples for examination and possible application to future studies.

A. MONITORING METHODS

This section includes the monitoring of chemical, biological, and physical data. For details of the procedures and instruments used, refer to the referenced reports.

Chemical Data Monitors

Concentrations of substances in the following media may be monitored with available methodology.

Air--

Aliphatic Aldehydes 1
Ammonia 1
Carbon Dioxide 1
Carbon Monoxide 1,3

Elements of Atomic No. 16 - 35 and 82 1
Lead 1
Metals 2
Methane 1
Nitrogen Oxides 1,3
Organic Vapors 1
Ozone and Oxidants 1,4
Polynuclear Aromatic Hydrocarbons 2
Respirable Particles 1,3
Sulfur Oxides 1
Total Hydrocarbons 1
Total Suspended Particles 1

Water, Blood, Urine²--

Halogenated Hydrocarbons and Benzene
Metals
Pesticides and PCB's
Polynuclear Aromatic Hydrocarbons

Hair--

Arsenic, Cadmium, and Lead
Polychlorinated Biphenyls
Polynuclear Aromatic Hydrocarbons

Biological Data Monitors

Personal Cardiopulmonary Electrode Monitors 4

Physical Data Monitors

The following parameters may be monitored using available methodology.

Air--

Wind Speed 1
Wind Direction 1
Temperature 1
Relative Humidity 1

Water--

Sedimentation--

B. DATA BASES

Listed below are the available data bases generated from monitoring studies.
(Source: Enviro-Control, Rockville, MD)

SAROAD (Storage and Retrieval of Aeromatic Data System)

EPA data base with ambient air quality data from over 4000 active air monitoring sites across the country.

HATREMS (Hazardous and Trace Emissions System)

EPA emissions data base for pollutants not regulated by the Primary Ambient Air Standards.

NEDS (National Emissions Data System)

EPA data base on emissions of pollutants for which there are Primary Ambient Air Standards. Collection is from about 75,000 point sources and 3,200 area sources.

EHIS (Emissions History Information System)

EPA data base containing reports of U.S. pollutant emissions estimates for previous years.

AEROS (Aerometric and Emissions Reporting Systems)

EPA data base of pollution data.

STORET (Storage and Retrieval for Water Quality Data)

EPA data base on water quality.

NPDES (National Pollutant Discharge Elimination System)

EPA data base with information on the quantity and quality of discharges which have been permitted under the National Discharge Permit Program for all point source discharges into U.S. water.

NAWDEX (National Water Data Exchange)

U.S. Geographical Survey data base of water monitoring data from federal, state, and local programs.

WATERDROP (Distribution Register of Organic Pollutants in Water)

EPA data base of organics in water.

EDAS (Environmental Data Analysis System)

EPA data bases on fine particle emissions, liquid effluents, solid wastes, and gaseous emissions.

Environmental Contaminant Monitoring Program

Department of Interior data base with pesticide monitoring data for fish, ducks, and starlings. Twenty pesticides, organics, and heavy metals are included.

Pesticides Soils Monitoring Program

Results of EPA monitoring programs to measure levels of pesticides in soil.

C. ONGOING MONITORING ACTIVITY

Beaumont - Lake Charles Environmental Study

This is a multimedia study of air, food, and drinking water in the Texas-Louisiana Gulf Coast. Body burden measurements will be studied by taking blood samples. The target pollutants that will be investigated are halocarbons, benzene, vinyl chloride, cadmium, and mercury. This study will be performed by the Office of Research and Development, Region VI, and the National Enforcement and Investigative Center.

The first phase of this investigation has now been completed. A number of monitoring methods were tested in the field, including personal air quality monitors to measure direct human exposure to 15 volatile organic compounds (VOC), a method of collecting and analyzing human breath samples for VOC levels, an analytical protocol for determining VOC levels in blood, and a collection method and fractionation scheme for bioassay of particulate organics. Eight sampling trips between August 1978 and March 1980 resulted in determining levels of 10 to 20 toxic substances in about 40 air samples, 20 water samples, 12 food composites, and 22 blood and urine samples taken from local non-occupationally exposed individuals. Major conclusions to date are as follows:

1. Use of personal monitors coupled with breath analysis appears to be a promising technique for field monitoring studies.
2. Individual exposures at Lamar University in Beaumont and ambient concentrations at Lake Charles, LA are high for many organic species.
3. Investigations of sources identified several industrial or waste disposal sites of concern.

Southern Ohio Integrated Exposure Assessment Study

This study is an effort to establish outdoor gradients in concentrations of several pollutants: benzo(a)pyrene, arsenic, cadmium, and benzene. There are

plans to extend the monitoring to indoor and personal exposures. This study is being performed by the EPA Environmental Monitoring and Support Laboratory in Las Vegas, Nevada.

Carbon Monoxide Studies

In this study 1,000 vehicles in Denver and Boston including schoolbuses, police vehicles, and taxicabs, are being tested for carbon monoxide (CO) levels inside passenger compartments. Stain tubes and personal monitors in conjunction with CO analyzers are being used. Commuting pathways and other activity patterns are also to be studied. This study is being performed at EPA's Environmental Monitoring and Support Laboratory, Research Triangle Park.

World Health Organization (WHO) Air Quality Monitoring Project

There are two goals of this project. The first is to establish and develop air monitoring systems, and the second is to exchange information on the levels and trends of air pollution. There are currently about fifty countries participating in this project, and a supporting monograph, "Analyzing and Interpreting Air Monitoring Data" (WHO 1980), has been published.

Total Exposure Assessment Methodology (TEAM) Study

The goal of this research program is to provide field tested methods for estimating total human exposure to selected toxic or hazardous substances. All major pathways contributing to human exposure for a geographical area are to be investigated simultaneously for each individual in the study. A comparative analysis is to be made on the air each person breathes, the water he/she drinks, and the food he/she eats. Concurrently, the same chemicals or their metabolites will be measured in each person's biological fluids. The program will attempt to establish, for each chemical, the relative importances of certain routes of exposure as well as to determine whether a predictable correlation exists between exposure and body burden.

This initial study, with a duration of about 6 months, will be conducted on nine individuals selected from the communities of Elizabeth and Bayonne, New Jersey. The specific aims of this pilot study are as follows:

1. To develop, test, and apply portable or personal air quality monitors capable of determining ambient air concentrations of selected toxic chemicals in the microenvironment of an individual.
2. To develop and/or field test sampling and analytical protocols and questionnaires for measuring the toxic chemicals of interest in air, food, drinking water, and human body fluids.

Subobjectives include the following:

1. To determine which substances are important in terms of exposure.
2. To determine biological variability within and between individuals.

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3. Selected Methods of Measuring Air Pollutants. WHO offset publication No. 24, World Health Organization, Geneva, Switzerland, 1976. 112 pp.
4. Mage, D.T., and L. Wallace. Proceedings of the Symposium on the Development and Usage of Personal Monitors for Exposure and Health Effects Studies. EPA-600/9-79-032, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 1979. 525 pp.

V. TREATMENT OF UNCERTAINTY IN EXPOSURE ASSESSMENTS

Uncertainty in exposure assessments arises because frequently such assessments are derived from limited monitoring data, simulation models, and assumptions about parameters for approximating actual exposure conditions. Both data based on estimated parameters and assumptions about parameters are likely to contain uncertainties which affect measurements introduced in exposure assessments. It is true that good and ample monitoring data and realistic assumptions will reduce, to a large extent, the magnitude of uncertainty associated with exposure assessments. However, quality data for various elements of exposure assessments are rare, and this is one area where future efforts need to be directed to improve exposure assessment analysis.

In general, two approaches are available for dealing with uncertainties in exposure assessments. The first, a parametric approach, is usually based on a mathematical model which links the output and input variables. The model itself can range from simple to complex. Using the most probable input values as estimates, the estimate of output is derived through the specified model. Uncertainties in the input variables or parameters are expressed as likely ranges for the variables and estimates of the variables. The variation in output variable due to perturbations in input values or parameters can be evaluated by partial derivatives or by a simple method of calculation, substituting new values of the variables or parameters.

The above treatment of uncertainty, conducted through sensitivity analysis of exposure assessments due to parametric variations, is based on a mathematical model and ranges of input values, and uses partial derivatives as the principal tools. In the second approach, which can be termed a statistical approach, parameters are estimated statistically from the data. The uncertainties of the

parameters in this case can be expressed by statistical confidence intervals, which are ranges in which the true values of the parameters are expected to lie with a certain level of confidence. Furthermore, uncertainties associated with individual parameters can be progressively combined by the method of error propagation of certainty to obtain the confidence interval or uncertainty of the output variable. The model in this case can be considered as statistical rather than mathematical. Further explanation of the above two approaches follows.

A. PARAMETRIC APPROACH

Johnson (1) has given a good example of one approach for thoroughly investigating uncertainties in exposure assessments. The approach is a parametric analysis of the numerical effects of possible variations in input terms on the estimated dose of radiation from radon in natural gas. This is just one example of how to deal with uncertainty and is far from a complete treatment of how to quantitate uncertainty in all types of exposure assessments.

A schematic diagram of the overall assessment of the exposure from radon contamination is depicted in Figure 1. This sort of graphical representation is very helpful, as it presents an organized approach to the assessment and shows all its major components, including a listing of the important parameters involved. Following this schematic diagram, a table showing the most probable input values or parameters used for analysis and their possible variations (ranges) seems useful and needs to be given. The input term values are first selected and defended or justified as being representative of a probable, well-defined scenario. In the analysis given by Johnson, these information bits include the radon concentration in the gas at the point of use, the type of appliance, and parameters related to gas use, such as degree days, house size, air exchange rate, mode of exposure, critical organ, and other factors.

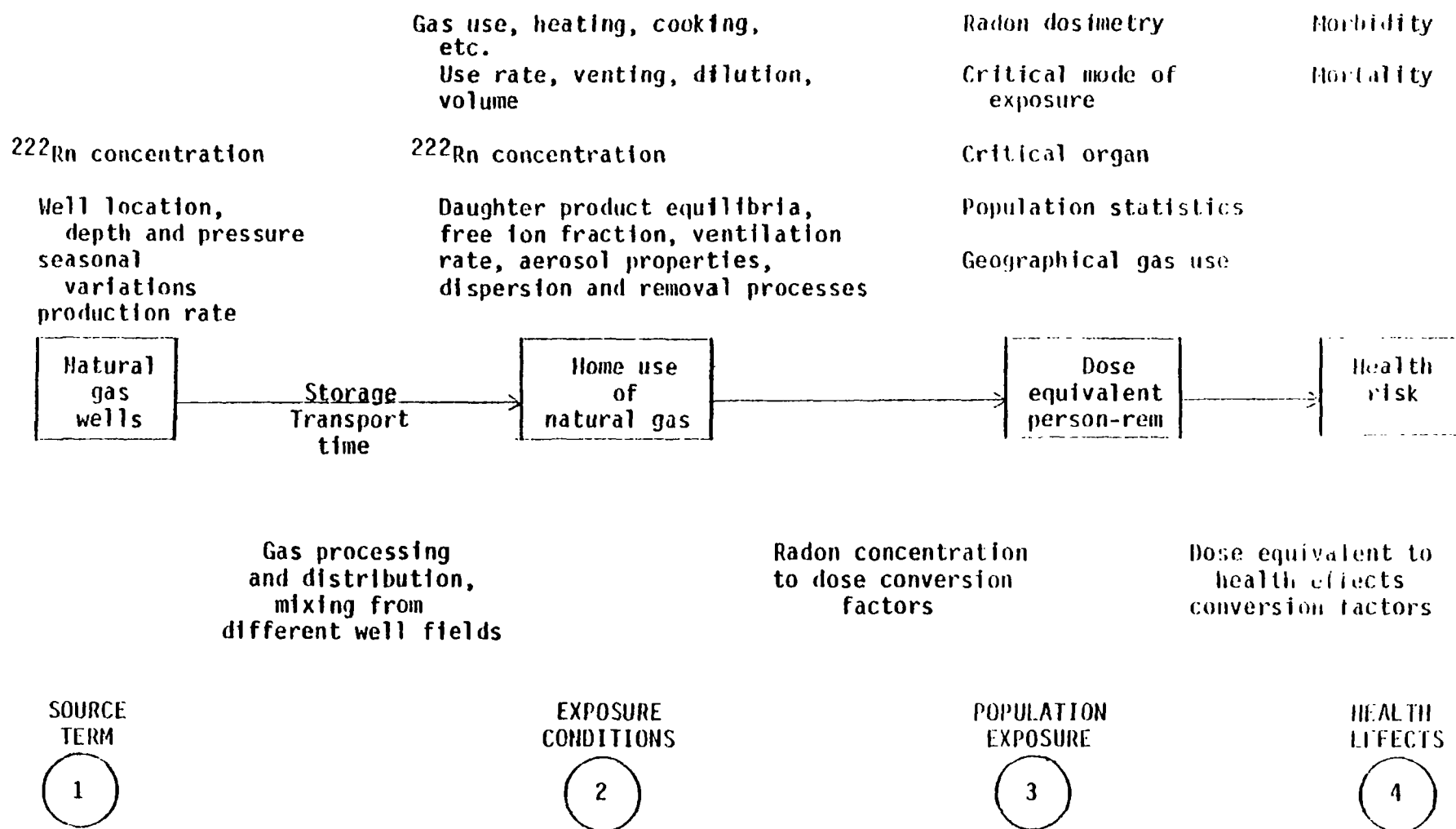


Figure 1. Model for estimating potential health effects from radon in natural gas.

SOURCE: Johnson, R.H., Jr., D.E. Bernhardt, H.S. Nelson, and H.N. Calley, Jr. November 1973. Assessments of potential radiological health effects from radon in natural gas. EPA 520/1-73-004.

Possible variations in each of the above parameters are then listed, e.g., although the radon concentration used in the assessment was 20 pCi/liter, the possible variation is 10 to 100 pCi/liter. A table (Table V-1) is used to provide representative values of the parameters and their possible variations.

A second table (Table V-2) is then used to provide simple, one-at-a-time factors for use in estimating the effects on the assessment of output value for variations in the input terms. To facilitate such "what if" analyses by the reader, correction multipliers are provided for each value. For example, since the exposure decreases exponentially with increasing air exchange rate, and 1.0 air exchanges per hour is the reference level, multipliers at 0.25 and 2.0 air exchanges per hour are given. The correction at 0.25 air exchanges per hour is 6.01, i.e., the exposure is 6.01 times as great at 0.25 than at 1 air exchange per hour. The correction multiplier at 2.0 air exchanges per hour is 0.339, which is 0.339 of the dose at 1 air exchange per hour. Also, the dose at 2 air exchanges per hour is 1/18th of the dose at 0.25 air exchanges per hour, thus showing the pronounced influence of air exchange rate on radon-related dose to the bronchial epithelium.

TABLE V-1. EXPOSURE CONDITIONS AND POSSIBLE VARIATION IN PARAMETERS FOR ANALYZING DOSE FROM RADON IN NATURAL GAS

Parameter	Condition for this analysis ^a	Possible variations ^b
Radon concentration in gas at point of use	20 pCi/l	10-100 pCi/l
Gas appliances	Cooking ranges Space heaters	Could include refrigerators, clothes dryers, etc.
Gas use: Ranges Heaters	0.765 m ³ /day 0.354 m ³ /degree-day	Up to 1.19 m ³ /day 0.28-0.42 m ³ /degree-day
Degree-days	Average for each state	± 25% within states
Appliance venting	Unvented	Ranges could be partly vented
House size	226.6 m ³	142-425 m ³
Air change rate	One per hour	0.25-5 per hour

^aThese are intended to be typical average conditions, although some of the less well understood parameters were chosen to give a higher or more conservative dose estimate.

^bThese are reasonable variations which could be encountered for a large fraction of the exposure conditions or population at risk.

^cSee original document for average annual degree-days and for variation with degree-days/day.

^dRatio of R_n, R_{aA}, R_{aB}, R_{aC} (R_{aC'}).

^eThis factor includes assumptions for daughter equilibria, critical mode of exposure, lung model, and other dosimetry factors.

(continued on following page)

TABLE V-1. (continued)

Parameter	Condition for this analysis ^a	Possible variations ^b
Radon concentration in home from ranges from heaters ^c	0.0028 pCi/l 0.01 pCi/l	0.001-0.05 pCi/l 0.005-0.3 pCi/l
Radon daughters: in gas in home	No daughters 1, 0.8, 0.6, 0.4 ^d	1, 1, 1, 1 ^d 1, 1, 1, 1 to ^d 1.0, 0.5, 0.25, 0.1
Percent free RaA	8.5 percent	5-25 percent
Critical mode of exposure	Inhalation of radon daughters	Radon alone gives < 1% of dose
Critical organ	Bronchial epithelium	Some exposure also to nasopharynx, lung, and whole body
Dose conversion factor ^e	100 rads/year for continuous exposure at 1 WL (100 pCi/l)	50-125 rads/year
Quality factor	10	3-10

^aThese are intended to be typical average conditions, although some of the less well understood parameters were chosen to give a higher or more conservative dose estimate.

^bThese are reasonable variations which could be encountered for a large fraction of the exposure conditions or population at risk.

^cSee original document for average annual degree-days and for variation with degree-days/day.

^dRatio of R_n, RaA, RaB, RaC (RaC').

^eThis factor includes assumptions for daughter equilibria, critical mode of exposure, lung model, and other dosimetry factors.

TABLE V-2. CORRECTIONS TO ADJUST ESTIMATED HEALTH EFFECTS FOR DIFFERENT EXPOSURE CONDITIONS

Parameter	Correction multiplier
Air changes per hour	
0.25	6.01
1.0	1.0
2.0	0.339
Radon activity	Linear ^a
Quantity of gas used	Linear
House size	Linear
Daughter equilibria	
Ratio 1, 1, 1, 1	1.9
1, 0.9, 0.8, 0.7	1.3
1, 0.8, 0.6, 0.4	1.0
1, 0.75, 0.5, 0.3	0.84
1, 0.5, 0.25, 0.1	0.39
Percent unattached RaA	
3	0.75
8.5	1.0
10	1.3
25	2
Dose conversion factor	Linear
Quality conversion factor	Linear
Health effects conversion factor	Linear

^aA linear correction means the correction is proportional to the variation in the parameter.

Finally, no exposure assessment should be considered complete without a review of uncertainties. This review should include a qualitative evaluation of the significance of pertinent assumptions in light of reasonable variations which could be encountered for actual exposure conditions. If possible, special emphasis should be placed on evaluating extremes in each assumption. For example, have parameters been chosen to evaluate extreme or average exposure conditions? Is the final assessment likely to be an overestimate or underestimate? In addition, the review of uncertainties could also include a comparison of exposure estimates with actual monitoring data (if any exists), and a mathematical/statistical propagation of errors for each of the assessment parameters.

The approach outlined above is a simple one based on calculating results after substituting the new values of the parameters. To summarize, this simple approach has four basic components:

1. A schematic diagram of the overall assessment.
2. A table listing the main assumptions and possible quantitative variation of each parameter.
3. A sensitivity analysis of the effects of the output variable(s) with variations of the input variables or parameters.
4. A review of uncertainties.

This approach provides answers to "what if" questions identical to those that can be generated by partial derivatives. An elegant exposition of the partial derivative approach was given in the GEOMET Indoor-Outdoor Air Pollution Model (2). The model estimates indoor air pollutant concentrations as a function of outdoor pollutant levels, indoor pollutant generation source rates, pollutant chemical decay rates, and air exchange rates. Sensitivity studies on the model parameters were conducted with partial derivatives indicating change

in outdoor pollutant levels for variations in input variables or parameters. The main advantage of the partial derivative approach is that formulas for evaluating partial derivatives can be provided. Simple graphs of output vs. input parameter variations, taken one at a time, can be used to show the forms and strengths of the various dependencies.

Mathematically, for a given general model $y = f(X,P)$, model sensitivity is defined as:

$$\frac{\partial f(X,P)}{\partial p_i} | (X_0, P_0)$$

where

f = the function defining the mathematical model,

$X = (X_1, X_2, \dots, X_n)$ = the vector of independent variables,

$P = (P_1, P_2, \dots, P_n)$ = the vector of parameters,

$X_0 = (X_{10}, X_{20}, \dots, X_{n0})$ = fixed value of X , and

$P_0 = (P_{10}, P_{20}, \dots, P_{n0})$ = fixed value of P .

The term $\frac{\partial f(X,P)}{\partial p_i} | (X_0, P_0)$ is the partial derivative of the function f with respect to the parameter p_i at fixed values of the input and parameter vectors X_0 and P_0 . The partial derivatives can be considered as sensitivity coefficients. The change in the function f due to perturbations of several parameters is given by the following equation:

$$df = \sum_{i=1}^k \frac{\partial f}{\partial p_i} dp_i \quad (1)$$

Equation (1) indicates that the approximate uncertainty (df) of f is a linear combination of the uncertainties in the individual parameters (dp_i , $i=1, \dots, k$), where the coefficient of each dp_i is the sensitivity coefficient. The

approach can be used for error or sensitivity analysis when Δf , the actual change in the function, can be approximated by df .

B. STATISTICAL APPROACH

In the parametric approach, the effects of the variations of the input values on the output value is either determined numerically through the substitution of the new values of the input variables or through evaluation of the partial derivatives. Statistical methods are not used directly for analysis of uncertainty but the ranges of the input variables can be determined indirectly through statistical analysis.

In the statistical approach, uncertainty is analyzed through more rigorous use of statistical methods. Essentially, in this approach uncertainty of an unknown parameter is given by a confidence interval where the true value of the parameter will lie. The level of confidence can be set accordingly as desired by the analyst. Furthermore, uncertainties associated with individual parameters can be propagated, and the manner in which they are propagated will depend on the functional relationships between variables and upon the type of uncertainty (random or systematic) involved.

The uncertainty or error in the estimate of a parameter can be broken down into two components known as random error and systematic error. Random error results from imprecision of measurements, which is indicated by the scatter of the independent measurements on a parameter. Systematic error, on the other hand, results from the inherent bias in the measurement process and cannot be eliminated even if the sample size is greatly increased. Failure to measure something that is intended results in bias. If bias is zero, then uncertainty will consist solely of random error.

R.W. Serth et al. (3) have provided practical and useful formulas for

evaluation of uncertainty or errors when random or systematic errors are present. Tables V-3 and V-4 give error propagation formulas for various operations of variables for random and systematic errors. In the case of random errors, uncertainty is expressed by confidence intervals determined from samples. For example, consider two independent variables X_1 and X_2 whose measurements are subject to random errors. The true means \bar{X}_1 and \bar{X}_2 are unknown and are estimated from samples n_1 and n_2 . The errors of measurement for X_1 and X_2 are assumed to be normally distributed with zero means and variances σ_1^2 and σ_2^2 . The sample means A and B are the estimates of true means. With these assumptions, $(1-\alpha) \times 100\%$ confidence intervals for \bar{X}_1 and \bar{X}_2 are given by $A \pm a$ and $B \pm b$. The terms a and b are evaluated by $z_\alpha \frac{\sigma_1}{\sqrt{n_1}}$ and $z_\alpha \frac{\sigma_2}{\sqrt{n_2}}$ where Z_α is the $(1-\alpha/2)$ percentage point of the normal distribution and can be obtained from the table of normal distribution. The propagation of error for addition of X_1 and X_2 can be obtained by considering $y = X_1 \pm X_2$. The confidence interval of $\bar{X}_1 + \bar{X}_2$ is given by $A + B \pm \sqrt{a^2 + b^2}$ (see Table V-3). Confidence intervals for other functions of X_1 and X_2 are given in Table V-3. In practice, the population variances σ_1^2 and σ_2^2 are not known, and they have to be estimated by sample variances. Where the variances σ_1^2 and σ_2^2 are not known and are replaced by sample estimates, the terms a and b are given by $t_\alpha \frac{s_1}{\sqrt{n_1}}$ and $t_\alpha \frac{s_2}{\sqrt{n_2}}$ where t_α is the $(1-\alpha/2)$ percentage point of 't' distribution and s_1^2 and s_2^2 are sample estimates of σ_1^2 and σ_2^2 . When the sample size is large, confidence intervals can be approximated well by using normal distribution.

The determination of confidence intervals and propagation of errors provides another possible approach to determine uncertainty associated with exposure assessments. The output variable related to exposure assessments usually depends on various input parameters whose estimates are needed to make sound exposure assessments. If sample data are available for estimating parameters, the uncertainty or confidence interval for each parameter can be constructed by the method discussed above. Furthermore, propagation of error formulas can be used for determination of uncertainty of any function of the parameters.

TABLE V-3. ERROR PROPAGATION FORMULAS FOR RANDOM ERRORS

Operation		Error Propagation Formula
Addition	$X_1 + X_2$	$A + B \pm \sqrt{a^2 + b^2}$
Subtraction	$X_1 - X_2$	$A - B \pm \sqrt{a^2 + b^2}$
Multiplication	$X_1 X_2$	$AB \pm \sqrt{B^2 a^2 + A^2 b^2}$
Division	X_1 / X_2	$(A/B) \pm \sqrt{\frac{a^2}{B^2} + \frac{A^2}{B^4} b^2}$
General case	$f(X_1 X_2)$	$f(A, B) \pm \sqrt{\left[\frac{\partial f(A, B)}{\partial X_1} \right]^2 a^2 + \left[\frac{\partial f(A, B)}{\partial X_2} \right]^2 b^2}$

Note:

$A \pm a$ and $B \pm b$ are confidence intervals for \bar{X}_1 and \bar{X}_2 , where \bar{X}_1 and \bar{X}_2 are the true average values and A and B are the sample means based on samples n_1 and n_2 . It is assumed that the variables X_1 and X_2 are statistically independent. The errors are assumed to be normally distributed with zero means and variances σ_1^2 and σ_2^2 . The error propagation formulas give $(1-\alpha) \times 100$ percentage confidence intervals for various operations of X and Y , where $a = Z_{\alpha} \frac{\sigma_1}{\sqrt{n_1}}$ and $b = Z_{\alpha} \frac{\sigma_2}{\sqrt{n_2}}$, and

Z_{α} is the $(1-\alpha/2)$ percentage point of the normal distribution. The formulas for multiplication, division, and the general case are only approximations, as they are based only on the first two terms in the Taylor Series expansion.

TABLE V-4. ERROR PROPAGATION FORMULAS FOR SYSTEMATIC ERRORS

Operation	Lower Bound	Upper Bound
Addition	$(A + B) - (a + b)$	$(A + B) + (a + b)$
Subtraction	$(A - B) - (a + b)$	$(A - B) + (a + b)$
Multiplication	$AB + \text{sgn}(AB)ab - (a B + b A)$	$AB + \text{sgn}(AB)ab + (a B + b A)$
Division	$\frac{A}{B} - \frac{a B + b A }{B^2 + \text{sgn}(AB)b B }$	$\frac{A}{B} + \frac{a B + b A }{B^2 - \text{sgn}(AB)b B }$

Note:

$A \pm a$ and $B \pm b$ are error bounds for X_1 and X_2 , where A and B are estimates. The formulas give lower and upper bounds of four basic mathematical operations of X_1 and X_2 . The formulas are valid only when X_1 and X_2 are functionally independent variables. $\text{Sgn}(AB)$ denotes the algebraic sign of the product AB .

As an example of the application of error propagation of uncertainty, consider that a certain pollutant is released to the air and that solid wastes are disposed of from a plant. It is required to estimate the mean emission factors of air and solid waste separately, as well as the total mean emission factor, which is the sum of the two individual emission factors. Consider that the following sample data are available for estimation.

TABLE V-5. HYPOTHETICAL DATA

	Air	Solid Waste
Number of observations, n	10	15
Sample mean emission factor, g/kg	0.403	0.760
Sample standard deviation, s, g/kg	0.318	0.540
$t_{0.975, n-1}$ (0.975 point of 't' distribution)	2.262	2.145

Following the notation of Table V-3, the estimates of mean emission factors for the pollutant to air and solid waste are as follows:

Estimate of mean air emission factor = $A = 0.403$ g/kg

Estimate of mean solid waste emission factor = $B = 0.760$ g/kg

The 95% confidence intervals for mean emission factors to air and solid waste are given as:

95% confidence interval of mean air emission factor = $0.403 \pm$

0.228 g/kg, $a = 0.228$ g/kg

95% confidence interval of mean solid waste emission factor = $0.760 \pm$

0.298 g/kg, $b = 0.298$ g/kg

The total emission factor is the sum of the air and solid waste emission factors. The confidence interval of the mean of the total emission factor is calculated by the error propagation formula for addition (see Table 3) as follows:

$$\begin{aligned}\text{Confidence interval of total emission factor} &= A + B \pm \sqrt{a^2 + b^2} \\ &= 1.163 \pm 0.375 \text{ g/kg}\end{aligned}$$

Though rigorous statistical analysis of uncertainty in exposure assessments is desirable, it might be difficult to adopt. The sampling data for estimation of various parameters are often unavailable or scanty, making them unsuitable for reliable statistical analysis. In these situations, a simpler parametric analysis or a combination of parametric and practical statistical analyses can prove to be useful.

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3. Serth, R.W., T.W. Hughes, R.E. Opferkuch, and C. Eimutis. Source Assessment: Analysis of Uncertainty Principles and Applications. EPA-600/2-78-004u, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 1978. 180 pp.

VI. GLOSSARY OF TERMS USED IN EXPOSURE ASSESSMENTS

This chapter of the Handbook contains many terms commonly used in the exposure assessments of the various program offices. It is important that these terms be defined since they are not universally understood as having only one meaning. It is hoped that the definitions presented here will be used by all program offices in future assessment reports.

abiotic: referring to nonliving elements of the environment.

absorption, chemical: the uptake of a pollutant by its penetration into living or nonliving material through a physical or biological process.

absorption, radiation: the process by which radiation imparts some or all of its energy to any material through which it passes.

acute: referring to exposure of short duration. Traditionally a general term used for serious adverse effects following brief exposure, such as "acute studies" referring to LD₅₀ estimates.

adsorption: the adhesion of pollutants to the surfaces of materials.

ambient: environmental or surrounding conditions.

area source: a pollutant source that releases emissions over a relatively large geographical area.

background, chemical: normal environmental concentrations of a pollutant resulting from non-specified sources.

background, radiation: radiation arising from radioactive material other than the one directly under investigation.

bioaccumulation: the ingestion and concentration of a substance (pollutant) by an organism.

bioassay: the determination of the biological effect of a substance on a test organism.

bioconcentration: the increase in concentration in tissues of aquatic organisms over that in water due to the water only, and not due to ingestion (see bioaccumulation).

biodegradation: the decomposition of a pollutant by organisms into more elementary compounds.

biomagnification: the total accumulation of a pollutant by a series of organisms in the food chain normally showing increasing concentrations of the pollutant in each succeeding trophic level.

biotransformation: the changing of a substance into other compounds; includes biodegradation.

burden: the quantity of a substance contained in a given constituent at a given time.

carcinogenicity: the capacity of a substance (pollutant) to cause or induce cancer.

CAS registration number: a number assigned by the Chemical Abstracts Service to identify a chemical substance unambiguously.

chronic: referring to adverse effects resulting from long term and/or frequently occurring exposure to a pollutant.

critical pathways: those pathways by which a significant amount of pollutant moves from the source to the receptors.

critical receptor: a designated segment of the human population or of the environment which is most adversely affected by exposure to a pollutant.

critical source(s): the pollutant source(s) that contributes significantly to the exposure of the critical receptor.

cumulative exposure: the summation of exposures of a receptor to a pollutant, over a period of time.

Curie: the unit used in measuring radioactivity amounting to a decay rate of 3.7×10^{10} disintegrations per second.

damage/response: the mathematical relationship between exposure and likelihood or extent of injury to the receptor.

decomposition: the reduction of net energy level and change in chemical composition of organic matter because of actions by microorganisms.

degradation: the chemical or biological transformation of a complex compound into simpler compounds.

dermal exposure: exposure of an organism's external membrane (generally the skin) to a pollutant.

diffusion: the movement of a pollutant in an environmental medium resulting in its dilution.

direct exposure: exposure resulting from occupational or consumer contact with a chemical.

dose, chemical: the quantity of a pollutant absorbed across the exchange boundaries of the receptor and available for interaction with metabolic processes.

dose, radiation: the quantity of radiation absorbed, expressed in units of rads.

dose commitment, radiation: the sum of doses to all individuals over the period a radioactive substance (pollutant) persists in the environment in a state available for interaction with humans; measured in person-rems.

dose equivalent, radiation: biologically effective radiation, expressed as the product of absorbed dose, a quality factor, and a distribution factor; measured in units of rems.

dose rate: the quantity of material (pollutant) absorbed across the exchange boundaries per unit of time.

dose response: the function relating dose to the likelihood of adverse effects to an organism.

dosimetry: (1) instrumentation to measure dose; (2) process of measuring dose.

ecological (or environmental) exposure: exposure of a nonhuman receptor to an environmental pollutant.

ecology: the interrelationships of living things to one another and to their environment or the study of such interrelationships.

ecosystem: the interacting system of a biological community and its nonliving environment.

effective stack height: the sum of the stack height and the plume rise.

effluent: gaseous or liquid outflow (including aerosols and particulates) of a pollutant from a source to the environment.

emission factor: a term relating the amount of a pollutant released to the environment by a source to the level of activity of the source.

emission rate: the amount of a pollutant released to the environment by a source per unit of time.

environmental fate: the destiny of a pollutant after release to the environment; it involves temporal and spatial considerations of pollutant transport, transfer, and transformation.

epidemiology: the science that deals with the incidence, distribution, and as the final outcome, control of disease.

exposure, chemical: a measure of the amount of a pollutant available at the exchange boundaries, i.e., lungs, gut, and skin of the receptor during specified times.

exposure, radiation: a measure of the ionization produced in air by X or gamma radiation; expressed in units of roentgens.

exposure assessment: an estimation of the magnitude of exposure to an environmental pollutant; it generally requires that an estimation be made of all of the pollutant's major features including sources, releases, fate, and contact.

foliar uptake: the uptake of a pollutant by plant leaves.

fugitive emissions: emissions which are not directly out of the stacks.
Fugitive emissions are leaks which aren't captured in the exhaust system.

fume: an airborne dispersion of minute solid particles commonly formed by the condensation of a volatilized solid, often molten metal, and frequently accompanied by oxidation.

gradient: the rate of change of a quantity with distance.

half-life: the length of time required for the mass, concentration, or activity of a pollutant to be reduced by one-half.

histogram: a bar chart depicting the frequency of occurrence of each of various outcomes of an experiment or series of events.

hydrolysis: The process by which a compound is degraded by reaction with water.

indirect exposure: exposure not resulting from either occupational or consumer contact with a chemical.

intake: that amount of pollutant inhaled, ingested, or absorbed dermally during a specified period of time.

integrated exposure assessment: a summation over time, in all media, of the magnitude of exposure to an environmental pollutant.

intermedia: concerning the transfer of a pollutant from one environmental medium to another.

leaching: the movement or removal of a pollutant by the action of a percolating liquid (generally water).

materials balance: an accounting of sources, production, uses, destruction/disposal, and environmental release of a substance.

metabolite: any product of metabolism, especially a transformed pollutant.

mobile source: a moving pollutant source such as an automobile.

mobilization: the physical, chemical or biological disturbance of chemicals that may be relatively harmless if left undisturbed in bones, adipose tissue, ore deposits, landfills, or bottom sediments of water bodies so that these chemicals can move into the general environment where exposures can occur.

modeling: the development of mathematical procedures to simulate real events and processes.

monitoring: measuring concentrations or behavior of pollutants in environmental media or in human or other biological tissue.

morbidity: (1) relating to diseases caused by exposure to environmental pollutants; (2) the rate of illness in a population caused by exposure to pollutants.

mortality: (1) relating to fatalities caused by exposure to environmental pollutants; (2) the rate of deaths in a population caused by exposure to a pollutant.

mutagenicity: (1) the ability of a substance (pollutant) to cause a permanent, hereditary change in an organism such that the affected characteristic will be transmitted to future generations of descendants; (2) the ability of a substance (pollutant) to cause a change in the genetic material of a cell.

particulates: finely divided solid or liquid particles in the air or in an emission. Particulates include dust, smoke, fumes, mist, spray, and fog.

pathogenic: causing or capable of causing disease.

pathways: the sequence of environmental interactions of a pollutant extending from its source to the receptor.

percolation: downward flow or infiltration of water through the pores or spaces of a rock or soil.

permissible dose: the dose of radiation or hazardous substance that may be received by an individual within a specified period with the expectation of no significantly harmful result.

person rem: the product of the average individual dose in a population and the number of individuals in the population.

pharmacokinetics: the dynamic behavior of chemicals inside biological (especially animal) systems; it includes the processes of uptake, distribution, metabolism, potentiation or detoxification, and excretion.

photochemical smog: air pollution associated with oxidants rather than with sulfur oxides, particulates, etc., and arising from the interaction of light with organic matter.

photolysis: the decomposition or dissociation of a molecule as the result of the absorption of light.

point source: a geographically small, stationary emission source.

population at risk: the population subgroup that is susceptible to the toxic effects of the pollutant in question at the exposed concentration levels.

prototype source: a source that is used as a typical example to represent other similar sources (of a certain size category) in lieu of individual modeling.

rad: the acronym for radiation absorbed dose. A dose of one rad equals the absorption of 100 ergs of radiation energy per gram of absorbing material.

radiation: the transmission of electric or magnetic energy through any medium, with or without matter. The term has been extended to include streams of particles, e.g., alpha particles, beta particles, and cosmic radiation. Examples of radiation are heat rays, sunlight, radio waves, X or gamma rays, and lightning discharges. (Alpha particles are helium nuclei and beta particles are electrons.)

receptor: a living or nonliving object that receives, may receive, or has received environmental exposure to a pollutant.

rem: acronym for roentgen equivalent man. The unit of dose of any ionizing radiation which produces the same biological effect as a unit of absorbed dose of ordinary X-rays.

reservoir: a place in the environment where a pollutant collects for possible later release.

risk: the potential for realization of unwanted negative consequences of an event.

risk assessment: a quantification of the environmental and/or health risk resulting from exposure to a pollutant; it combines exposure assessment results with dose/response and/or damage/response information to estimate risk.

root uptake: the absorption of a pollutant by a plant through its roots.

route of exposure: the nature of exposure to an organism; this includes inhalation, ingestion, dermal contact, and less frequently, injection and implantation.

runoff: the portion of rainfall, melted snow, or irrigation water that flows across ground surfaces and into streams, lakes, ponds, discharge basins, sewage treatment plants, etc.

sedimentation: the settling of solids under the action of gravity.

sink: a place in the environment where a pollutant collects more or less permanently.

sorption: the process of taking up and holding either by adsorption or absorption.

source: the origin of the emissions of a pollutant to the environment.

species, chemical: a specific kind of chemical molecule or radical ion, as opposed to a class, mixture, or unspecified substance; the helium atom, the benzene molecule, and the OH radical are chemical species.

stratification: (1) the division of a population into subpopulations for sampling purposes; (2) the separation of environmental media into layers as in lakes.

synergism: cooperative action of two or more agents such that the total effect is greater than the sum of the individual effects taken independently.

teratogenicity: the capacity of a substance (pollutant), to cause nonhereditary changes, e.g., birth defects, in a first-generation descendant.

threshold: the lowest dose at which a specified measureable effect is observed and below which it is not.

threshold limit value (TLV): the largest exposure at which no measurable adverse effects are expected to be produced; a list of values is published periodically by the American Conference of Governmental Industrial Hygienists for various chemical compounds.

time-weighted average: an average of a sample of observations weighted to represent time history, usually applied to environmental concentrations.

toxicant: a substance that kills or injures an organism through its chemical or physical action or by altering its environment.

toxicity: the quality or degree of being poisonous or harmful to plant or animal life.

transfer: the movement of a pollutant from one environmental medium to another.

transformation: the change in chemical state or structure of a pollutant.

transport: the movement of a pollutant from one environmental medium to another.

uncertainty: a range of values (probability estimates) or the statistical confidence limits associated with an estimated value.

uptake: See dose, chemical.

VII. STANDARD FACTORS USED IN EXPOSURE ASSESSMENTS

This section of the Handbook contains some of the parameters used in the exposure assessments of the Program Offices. We have classified these parameters as biological, economic, chemical, and physical. The Program Offices reserve the right to exercise judgement in the use of these standard factors as mitigating circumstances (such as current data) may warrant the substitution of more appropriate numbers.

A. BIOLOGICAL PARAMETERS

Mass of Standard Humans¹

male adult: 70 kg

female adult: 60 kg

Skin Surface Area²

1.85 m² - totally exposed (man 180 cm high)

0.294 m² - assuming short-sleeved, open-necked shirts, pants,
shoes, with no gloves or hats

0.091 m² - assuming long sleeved shirts, gloves, pants, shoes.

Effective Pore Size of Skin and Other External Membranes³

4 Angstroms (0.4 nm)

Amount of Food Consumption⁴

1500 gm/day (excluding beverages)

Drinking Water Consumption⁵

2.0 liters per day

Respiratory Rate⁶

	Adult male	Adult female
resting	0.5 m ³ /hr	0.27 m ³ /hr
light work	1.2 m ³ /hr	1.0 m ³ /hr
medium or heavy work	1.8 m ³ /hr	1.5 m ³ /hr

Size of Respirable Particulates (aerodynamic diameter)³

- < 1 μm : 100% reach the alveoli; 0% retention in nasal passage
- 2 μm : 80% reach the alveoli; 20% retention in nasal passage
- 5 μm : 50% reach the alveoli; 50% retention in nasal passage
- >10 μm : almost complete retention in nasal passage
- mouth breathers can inhale particles up to 15 μm aerodynamic diameter

B. ECONOMIC PARAMETERS

1977 U.S. Population by Age and State (in thousands)⁷

STATE	Total	Under 5	5-13	14-17	18-24	25-34	35-44	45-54	55-64	65 and over
U.S.	210,322	13,115	22,227	16,771	12,703	22,019	25,777	22,121	12,121	122,049
New Eng.	12,212	723	1,307	941	721	4,012	2,573	1,121	3,122	3,122
Maine	1,074	76	126	87	64	340	221	120	120	120
N.H.	449	27	150	100	77	277	121	51	120	120
Vt.	481	31	78	78	51	163	121	51	120	120
Mass.	3,172	331	441	441	321	1,111	1,111	587	1,111	1,111
R.I.	933	43	127	127	127	221	121	121	121	121
Conn.	2,108	176	458	321	176	1,042	621	340	1,111	1,111
Mid. Atl.	27,228	1,111	2,111	1,111	1,111	11,111	8,111	1,111	1,111	1,111
N.Y.	17,221	1,111	2,111	1,111	1,111	8,111	5,111	1,111	1,111	1,111
N.J.	7,221	1,111	1,111	1,111	1,111	3,111	2,111	1,111	1,111	1,111
Pa.	11,786	721	1,111	1,111	1,111	5,111	3,111	1,111	1,111	1,111
E. No. Cent.	41,157	2,111	4,111	2,111	2,111	13,111	8,111	4,111	4,111	4,111
Ohio	10,221	1,111	1,111	1,111	1,111	3,111	2,111	1,111	1,111	1,111
Ind.	5,221	331	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Ill.	11,221	531	1,111	1,111	1,111	3,111	2,111	1,111	1,111	1,111
Mich.	9,221	531	1,111	1,111	1,111	3,111	2,111	1,111	1,111	1,111
Wis.	4,221	310	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
W. No. Cent.	16,221	1,111	2,111	1,111	1,111	5,111	3,111	2,111	1,111	1,111
Minn.	3,221	370	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Iowa	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Mo.	4,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
N. Dak.	621	40	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
S. Dak.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Neb.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Kans.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
S. Atl.	21,221	2,111	4,111	2,111	2,111	11,111	6,111	2,111	2,111	2,111
Del.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Md.	4,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
D.C.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Va.	5,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
W. Va.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
N.C.	5,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
S.C.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Ga.	5,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Fla.	8,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
E. So. Cent.	13,221	1,111	2,111	1,111	1,111	4,111	2,111	1,111	1,111	1,111
Ky.	3,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Tenn.	4,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Ala.	3,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Miss.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
W. So. Cent.	21,221	2,111	4,111	2,111	2,111	11,111	6,111	2,111	2,111	2,111
Ark.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
La.	3,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Okla.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Tex.	12,221	1,111	1,111	1,111	1,111	4,111	2,111	1,111	1,111	1,111
MT.	10,221	121	1,111	1,111	1,111	3,111	1,111	1,111	1,111	1,111
Mont.	721	59	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Idaho	821	73	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Wyo.	421	33	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Colo.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
N. Mex.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Ariz.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Utah	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Nev.	1,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Pac.	21,221	2,111	4,111	2,111	2,111	11,111	6,111	2,111	2,111	2,111
Wash.	3,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Ore.	2,221	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Calif.	12,221	1,111	1,111	1,111	1,111	4,111	2,111	1,111	1,111	1,111
Alaska	421	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111
Hawaii	121	121	1,111	1,111	1,111	1,111	1,111	1,111	1,111	1,111

1977 U.S. Population by Age and Sex (in thousands)⁷

	Male	Female	Total
Total, all years	105,240	111,092	216,332
under 5 years	7,790	7,446	15,236
5-13 years	16,438	15,789	32,227
14-17 years	8,553	8,228	16,781
18-21 years	8,436	8,361	16,798
22-24 years	5,740	5,811	11,551
25-34 years	16,312	16,677	32,990
35-44 years	11,433	12,047	23,480
45-54 years	11,319	12,062	23,382
55-64 years	11,319	12,062	23,382
65 years and over	9,599	13,925	23,491
16 years and over	76,756	83,768	160,521
18 years and over	72,460	89,629	152,089
21 years and over	66,060	73,270	139,320
median age (yrs.)	28.2	30.6	29.4

Number of People Exposed to the Chemical (exclusive of a workplace environment)⁸

Number of People	Examples
$> 20 \times 10^6$	<ul style="list-style-type: none"> - widely used household products - general air, food, and water contaminants - automotive products - products used widely in commercial environments
$2 - 20 \times 10^6$	<ul style="list-style-type: none"> - less widely used household products - regional air and water pollutants, farm chemicals (exclusive of pesticides)
$0.2 - 2 \times 10^6$	<ul style="list-style-type: none"> - specialty hobbies, specialty products - neighborhood air and water pollutants from local industries
$< 2 \times 10^5$	<ul style="list-style-type: none"> - chemical intermediates rarely found outside the workplace

Frequency of Exposure to the Chemical (exclusive of a workplace environment)⁸

Frequency	Examples
Daily or more often	<ul style="list-style-type: none">- general air, food, and water contaminants- household products in regular use- material used inside automobiles- clothing
Weekly	<ul style="list-style-type: none">- hobby crafts- household products used intermittently- bleaches- gardening products
Monthly	<ul style="list-style-type: none">- dry cleaning- certain solvents- house maintenance- automobile maintenance
Yearly or less frequently	<ul style="list-style-type: none">- application of household paints- specialty products

Intensity of Exposure to the Chemical (exclusive of a workplace environment)⁸

Intensity	Examples
High (10^{-1} or more grams per exposure)	plastics, fabrics, surface coatings, volatile solvents used in closed spaces, liquids contacting skin, high concentration gases
Medium (10^{-1} to 10^{-2} grams per exposure)	fabric additives, solvents in open spaces or outdoor, dusts, solutes, transitory exposures to vapors or aerosols
Low (10^{-3} to 10^{-4} grams per exposure)	low level indoor exposure, volatile substances from home furnishings and building materials (e.g. plasticizers, flame proofers), low volatility solvents, pigments
Very low (less than 10^{-5} gram per exposure)	environmental contaminants (low level air, food, and water contaminants), monomers in polymers

Time Spent in Various Activities⁹

activity budget for 8 hr workday:	6 hr light work
	2 hr heavy work
activity budget for 24 hr workday:	12 hr rest
	10 hr light work
	2 hr heavy work

Birth Rate⁷

1976: 14.8 per 1,000 population

Death Rate⁷

1976: 8.9 per 1,000 population

Average Life Expectancy⁷

Male - 69.0 years

Female - 76.7 years

Employment by Industry (1977)⁷

	Total (x 10 ³)	Percent Female
Agriculture, forestry, fisheries	3,383	18.5
Mining	814	8.5
Construction	5,504	6.4
Manufacturing	20,637	29.8
Transportation, communications, and other public utilities	5,833	22.3
Wholesale and retail trade	18,706	44.3
Wholesale trade	3,597	23.6
Retail trade	15,109	49.2
Finance, insurance, and real estate	5,038	54.1
Banking and other finances	2,061	63.2
Insurance and real estate	2,977	47.0
Services ^a	25,658	60.5
Business services	1,924	43.0
Automobile services	794	11.0
Personal services ^a	3,826	73.6
Private households	1,406	86.1
Hotels and lodging places	1,068	68.2
Entertainment and recreation	968	36.4
Professional and related services	17,644	64.5
Hospitals	3,645	76.0
Health services except hospitals	2,683	72.9
Elementary, secondary schools	5,106	70.6
Colleges and Universities	2,016	47.9
Welfare and religious agencies	1,429	57.5
Public administration ^b	4,972	32.9

^aIncludes industries not shown separately

^bIncludes workers involved in uniquely governmental activities, e.g.,
judicial and legislative

Farms⁷

number of farms in the U.S. - 2.7×10^6
total farm acreage in the U.S. - 1×10^9 acres
average farm size in the U.S. - 397 acres

Total Land in U.S.⁷

2.264×10^9 acres

Home Gardens¹⁰

average size - 750 ft^2
annual value of home grown produce - \$14 billion
percentage of U.S. household with gardens - 44%
total amount of land used as gardens - 6 million acres

House Size¹¹

142 - 425 m^3

Building Size for Typical Endosed Production Facility³

7,000 - 26,000 m^3 (250,000 - 925,000 ft^3)

C. CHEMICAL PARAMETERS

Chemical Composition of Dry Air¹²

Substances found in greater non-variable concentrations--

Nitrogen	$78.084 \pm 0.004\%$	(percent by volumes)
Oxygen	$20.946 \pm 0.002\%$	(percent by volumes)
Argon	$0.934 \pm 0.001\%$	(percent by volumes)

Substances found in lesser non-variable concentrations--

Neon	$18.18 \pm 0.04 \text{ ppm}$
Helium	$5.24 \pm 0.004 \text{ ppm}$
Krypton	$1.14 \pm 0.01 \text{ ppm}$
Nitrous Oxide	$0.5 \pm 0.1 \text{ ppm}$
Hydrogen	0.5 ppm
Xenon	$0.087 \pm 0.001 \text{ ppm}$

Substances found in variable concentrations; may depart significantly from normal, from time to time and place to place--

Carbon Dioxide	330 \pm 10 ppm
Methane	2.0 ppm
Sulfur Dioxide	0 - 1 ppm
Ozone	0 - 0.07 ppm (summer) 0 - 0.02 ppm (winter)
Nitrogen Dioxide	0 - 0.02 ppm
Iodine	0 - 0.01 ppm
Ammonia	trace
Carbon Monoxide	0 - trace

Chemical Composition Sea Water, Surface Water, and Ground Water¹³

See the CRC Handbook of Environmental Control, Volume III, Water Supply and Water Treatment.

pH Ranges for Various Water Quality Categories¹⁴

Category	Range
Recreation and Aesthetics	5.0 - 9.0
Public Water Supplies	6.0 - 8.5
Fish, Aquatic, and Wildlife	6.0 - 9.0
Marine and estuarine organisms	6.7 - 8.5
Wildlife	7.0 - 9.2
Fresh water organisms	6.0 - 9.0
Agricultural Use	5.5 - 9.0
Irrigation Water Supplies	4.5 - 9.0

D. PHYSICAL PARAMETERS

Air Change Rate (Home Dwelling)¹¹

0.25 - 5 per hour

Characterization of Production Emissions³

Emission Route	% of Total Emissions of Air
Process Vents	66 - 70%
Fugitive Emissions	15 - 20%
Storage and Transportation	8 - 10%
Solid and Liquid Waste	2 - 5%
Stream Emissions	

Average Wind Speed³
5.5 m/sec

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APPENDIX A

GUIDANCE FOR THE PREPARATION OF

EXPOSURE ASSESSMENTS

I. PURPOSE

The guidelines presented in this document provide the Agency with a general approach and framework for carrying out human or nonhuman exposure assessments for specified pollutants. The guidelines have been developed with the intention that they will assist in future assessment activities and encourage improvement in those EPA programs which require, or could benefit from, the use of exposure assessments. The guidelines are procedural and are not intended to usurp the substantive basis for regulatory standards or the data requirements for regulatory action under any statute. They should be followed to the extent possible in instances where exposure assessment is a required element in the regulatory process or where exposure assessments are carried out on a discretionary basis by EPA management to support regulatory or programmatic decisions. In some cases, the guidelines will be useful only as a rough template to help ensure that significant oversights do not occur. In other cases, the guidelines will serve more closely as a model.

The purpose of the guidelines is threefold. First, the document, by laying out a set of questions to be considered in carrying out an exposure assessment, should help avoid inadvertent mistakes of omission. EPA recognizes that gaps in data will be common, but the guidelines will nevertheless serve to assist in organizing the data that are available, including any new data developed as part of the exposure assessment. It is understood that exposure assessments may be performed at many different levels of detail depending on the scope of the assessment.

The second major purpose of the guidelines is to promote consistency, to the extent feasible, among the various exposure assessment activities that are carried out by the Agency. Consistency with respect to common physical,

chemical, and biological parameters, with respect to assumptions about typical exposure situations, and with respect to the presentation of the possible ranges of estimates, will enhance the comparability of results and enable the Agency to improve the state-of-the-art of exposure assessment over time through the sharing of common data and experiences.

Finally, the guidelines provide a format for organizing the contents of an exposure assessment document. This common approach to format will simplify the process of reading and evaluating the assessments and, thereby, increase the utility of exposure assessment documents.

As the Agency performs more exposure assessments, the guidelines will be revised to reflect the benefit of experience.

II. GENERAL GUIDELINES AND PRINCIPLES

A. EXPOSURE AND DOSE

Exposure is the contact between a subject of concern and a chemical, biological, or physical entity, hereafter designated as an agent. The magnitude of the exposure is determined by measuring or estimating the amount of an agent available at the exchange boundaries, i.e., lungs, gut, skin, during some specified time. Exposure assessment is the determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure. Exposure assessments may consider past, present, and future exposures with varying techniques for each phase, i.e., modeling of future exposures, measurements for existing exposure, and biological accumulation for past exposures. Exposure assessments are often combined with environmental and health effects data in performing risk assessments.

In considering the exposure of a subject to a hazardous agent, there are several related or subsequent processes. The contact between the subject of concern and the agent may lead to the intake of some of the agent. If absorption occurs, this constitutes an uptake (or an absorbed dose) which then may lead to health effects.

B. DECISION PATH TO DETERMINE SCOPE OF THE ASSESSMENT

The first step in preparing an exposure assessment should be the circumscribing of the problem at hand to minimize resource utilization by use of a narrowing process. This process could take the form of a decision logic path as shown in Figure II-1. The two phases of such a logic path would be the preliminary assessment phase and the in-depth assessment phase.

The preliminary assessment phase should commence by considering what risk

s under study and what law might regulate the exposure to the agent. Within this framework, a preliminary data base should be compiled from readily available scientific data and exposure information based on manufacturer, processor, and user practices. Next, the most likely areas of exposure (manufacturing, processing, consumer, distribution, disposal, ambient, water and food, etc.) should be defined. Many of these areas will have already been eliminated from consideration because of the risk under study and the regulatory law. Since a complete data search has not been conducted, well identified assumptions and "ball park" estimates are used to further narrow the exposure areas of concern.

Data from this preliminary exposure assessment can then be coupled with toxicity information to perform a preliminary risk analysis. As a result of this analysis, a decision will be made that either an in-depth exposure assessment is necessary or that there is no need for further exposure information. The organization and contents of an in-depth exposure assessment are given in Section III.

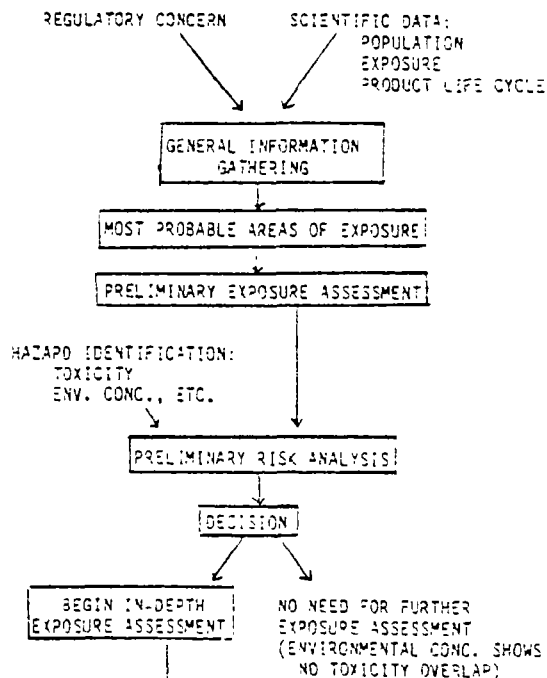
In assembling the information base for either a preliminary assessment or more detailed assessment, its adequacy should be ascertained by addressing the following considerations:

- availability of information in every area needed for an adequate assessment;
- quantitative and qualitative nature of the data;
- reliability of information;
- limitations on the ability to assess exposure.

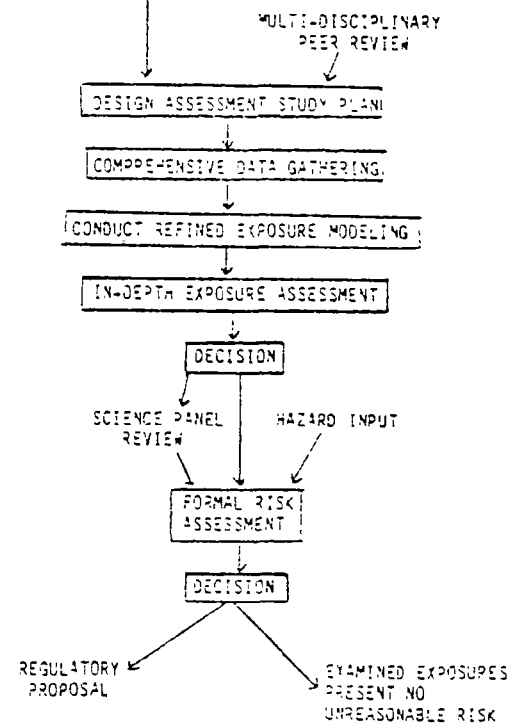
FIGURE II-1

EXEMPLARY DECISION PATH FOR EXPOSURE ASSESSMENT

PRELIMINARY EXPOSURE
ASSESSMENT



IN-DEPTH EXPOSURE
ASSESSMENT



REGULATORY
RESPONSE

C. UNCERTAINTY

Exposure assessments are often based on limited monitoring data, simulation models, and assumptions about parameters for approximating actual exposure conditions. Both data and assumptions contain varying degrees of uncertainty which influence the accuracy of exposure assessments. An evaluation of these uncertainties is important and may be helpful to program offices when the assessments are the basis for regulatory action. A rigorous statistical analysis of uncertainty is often impossible. However, there are simpler approaches which would be useful in describing generally the uncertainty inherent in an exposure assessment.

The elements of a simplified evaluation of uncertainty might include the following:

1. a schematic diagram of the overall assessment
2. a table listing the main assumptions and possible quantitative range for each parameter
3. a sensitivity analysis
4. a review of uncertainties

The schematic diagram may be helpful in several ways. It presents an organized approach to the assessment and shows all the major components of the assessment, including a listing of important parameters to be evaluated. Such a model enables technical and nontechnical persons to visualize quickly the overall scope of the assessment.

The table that lists all the parameters for the assessment is a place for specifying all the values or assumptions detailing the conditions of the exposure assessment. This table should correspond to the parameters identified in the schematic diagram. The table should also include a listing of possible variations in each parameter which would encompass a reasonable

range of actual exposure conditions that might be expected. The text accompanying this table should give reasons for each assumption.

Since actual exposure conditions may have parameters with values different from those chosen for the assessment, a table of correction factors could be helpful. This table would show how the overall exposure assessment can be varied by adjusting each parameter. With the table, one could quickly see the effect of an increase or decrease of any parameter on the overall assessment. This selective variation of parameters is called a sensitivity analysis. A properly utilized sensitivity analysis will provide an estimate of the possible variations in calculated exposure concentrations when relevant parameters and process rates are varied within pre-established ranges.

A review of uncertainties should include a qualitative evaluation of the significance of pertinent assumptions in light of reasonable variations which could be encountered for actual exposure conditions. If possible, special emphasis should be placed on evaluating extremes in each assumption. For example, have parameters been chosen to evaluate extreme or average exposure conditions? Is the final assessment likely to be an overestimate or underestimate?

In addition, the review of uncertainties could also include a comparison of exposure estimates with actual monitoring data (if any exists), and a mathematical/statistical evaluation based on propagation of errors for each of the assessment parameters.

Some exposure assessments may be based largely on monitoring data. In these cases, the uncertainty in the exposure assessments will depend both on the sample collection and analysis errors and on the statistical variation associated with extrapolating the observations made for the sample to the assessed population and time frame.

When using models, several types of mathematical and statistical methods can be employed to calculate uncertainty in the exposure assessments from the uncertainties in the input components. Examples of input uncertainties are simulation models, emission rates, and evaporation rates. They can be combined to estimate the uncertainty in the exposure assessments through an analytical approach. This approach usually requires the expected values and variances, and sometimes requires the covariances of the variables, as input; the output is the variance of an estimated exposure. Simulation techniques (such as Monte Carlo techniques) may also be used to estimate uncertainty.

III. ORGANIZATION AND CONTENTS OF AN EXPOSURE ASSESSMENT

The structure of a specific exposure assessment will depend on its purpose, the sources of concern, and the exposure media evaluated. The actual order in which topics appear in the document is arbitrary, but the document should attempt to include some discussion of all five major topics listed below and should proceed in a logical order from sources to exposure estimates. A suggested outline for an exposure assessment document is given in Exhibit III-1.

Since exposure assessments are written at many different levels of detail, the extent to which any assessment contains the items listed as subheadings in Exhibit III-1 depends on the purpose, scope, and level of detail of the assessment. The outline is a guide to organizing the data whenever they are available, or organizing data developed as part of the exposure assessment.

The five major topics to address within most exposure assessments are as follows: (1) Source(s); (2) Exposure Pathways; (3) Exposed Population(s); (4) Monitoring or Estimated Concentration Levels; and (5) Integrated Exposure Analysis. Addressing a topic may be as simple as a single statement concerning a broad assumption made, or it may involve description of some or all of the data outlined in the subheadings of Exhibit III-1. These five topics are appropriate for exposure assessments in general, whether the assessments are of global, national, regional, local, site-specific, workplace-related, or other scope. The topics are appropriate for exposure assessments on new or existing chemicals and radionuclides. They are also applicable to both single media and multimedia assessments.

Exhibit III-1

SUGGESTED OUTLINE FOR AN EXPOSURE ASSESSMENT

- I. EXECUTIVE SUMMARY
- II. INTRODUCTION
 - A. Purpose
 - B. Scope
- III. GENERAL INFORMATION
 - A. Identity
 1. Molecular formula and structure, CAS number, TSL number
 2. Description of technical grades, contaminants, additives
 3. Other identifying characteristics
 - B. Chemical and Physical Properties
- IV. SOURCES
 - A. Characterization of Production and Distribution
 1. Production and processing
 2. Distribution in commerce
 - B. Uses
 - C. Disposal
 - D. Summary of Environmental Releases
- V. EXPOSURE PATHWAYS AND ENVIRONMENTAL FATE
 - A. Transport and Transformation
 - B. Identification of Principal Pathways of Exposure
 - C. Estimates of Environmental Concentrations (Distribution) Using Models
- VI. MONITORING OR ESTIMATED CONCENTRATION LEVELS
 - A. Summary of Monitoring Data
 - B. Comparison of Concentration Estimates with Monitoring Data
 - C. Estimation of Environmental Concentrations

VII. EXPOSED POPULATIONS

A. Human Populations (Size, Location, and Habits)

1. Population size and characteristics
2. Population location
3. Population habits

B. Nonhuman Populations (where appropriate)

1. Population size and characteristics
2. Population location
3. Population habits

VIII. INTEGRATED EXPOSURE ANALYSIS

A. Development of Exposure Profiles and Scenarios

1. Identification and characterization of the exposed populations and critical elements of the ecosystem
2. Pathways of exposure

B. Human Dosimetry and Monitoring

C. Calculation of Exposures

D. Evaluation of Uncertainty

IX. REFERENCES

X. APPENDICES

Detailed Explanation of Outline

I. EXECUTIVE SUMMARY

The "Executive Summary" should be written so that it can stand on its own as a miniature report. Its main focus should be on a succinct description of the procedures used, assumptions employed, and on summary tables or charts of the results. Some discussion of the uncertainties associated with the results should be included.

II. INTRODUCTION (Purpose and Scope)

This section should state the intended purpose of the exposure assessment and identify the agent being investigated, the types of sources and exposure routes included, and the populations of concern.

III. GENERAL INFORMATION

A. Identity

1. If appropriate, molecular formula and structure, synonyms, CAS number, TSL number
2. If appropriate, description of technical grades, contaminants, additives
3. Where appropriate (e.g., for radionuclides), other identifying characteristics

B. Chemical and Physical Properties

This is a summary description of the chemical and physical properties of the agent. Particular attention should be paid to the features that would affect its behavior in the environment. Examples of factors to be included, if available or appropriate, are molecular weight, density, boiling point, melting point, vapor pressure, solubility, pK_a , vapor density,

partition coefficients, and half-lives.

IV. SOURCES

The points at which a hazardous substance is believed to enter the environment should be described, along with any known rates of entry. [The environment includes the natural (outdoor) surroundings and indoor or anthropogenic surroundings.] A detailed exposure assessment will include a "materials balance," defined here as a study of sources, production, uses, destruction/disposal, and environmental release of a substance. The materials balance should include a description of man's activities with respect to the substance and the environmental releases resulting from those activities. It should account for the controlled mass flow of the substance from creation to destruction and provide estimates of environmental releases at each step in this flow. Seasonal variations in environmental releases should also be examined. All sources of the substance are balanced (as in accounting) with the sum of the uses, destruction, and the environmental releases. The environmental releases can be described in terms of geographic and temporal distribution and the receiving environmental media, with the form identified at the various release points.

A. Characterization of Production and Distribution

All sources of the substance's release to the environment, consistent with the scope of the assessment, should be included, such as production, extraction, processing, imports, stockpiles, transportation, accidental/incidental production as a side reaction, and natural sources. Where appropriate, the sources should be located, and activities involving exposure to the substance should be identified.

B. Uses

The substance is traced from its sources through various uses (with further follow-up on the products made to determine the presence of the original material as an impurity), exports, stockpile increases, etc.

C. Disposal

Where necessary, this section may involve an evaluation of disposal sites and destruction processes, such as incineration of industrial chemical waste, incineration of the substance as part of an end-use item in municipal waste, landfilling of wastes, biological destruction in a secondary wastewater treatment plant, or destruction in the process of using the end product. As necessary, hazardous contaminants of the substance may be included, and products containing the substance as a contaminant may be followed from production through destruction/disposal.

D. Summary of Environmental Releases

Estimates should be made of the quantities of the substance released to the various environmental media. Sources of release to the environment include production, use, distribution/transport, natural sources, disposal, and contamination of other products. Environmental releases should be presented at a reasonable level of detail. Extremely detailed exposure estimates would attempt to specify, to the extent feasible, for each significant emission source: location, amount of the substance being released as a function of time to each environmental medium, physical characteristics of the emission source, and the physical and chemical form of the substance being released. Some evaluation of the uncertainties associated with the emission estimates should be given.

V. EXPOSURE PATHWAYS AND ENVIRONMENTAL FATE

The exposure pathways section should address, wherever possible, how a hazardous agent gets from the source to the exposed population or subject. For a less detailed assessment, broad generalizations on environmental fate and pathways may be made. In the absence of data, e.g., for new substances, fate estimates may have to be predicted by analogy with data from other substances. Fate estimates may also be made by using models and laboratory-derived process rate coefficients. At any level of detail, certain pathways may be judged insignificant and not pursued further.

For more detailed assessments involving environmental fate, the sources (materials balance) analysis described previously should provide the amount and rate of emissions to the environment, and possibly the locations and form of the emissions. The environmental pathways and fate analysis follows the substance from its point of initial environmental release through the environment to its ultimate fate. It may result in an estimation of the geographic and temporal distribution of concentrations of the substance in the various contaminated environmental media.

A. Transport and Transformation

The substance, once released to the environment, may be transported (e.g., carried downstream in water or on suspended sediment, carried on air currents, etc.) or physically transformed (e.g., volatilized, melted, absorbed/desorbed, etc.); undergo chemical transformation such as photolysis, hydrolysis, oxidation, reduction; undergo biotransformation such as biodegradation; or accumulate in one or more media. These processes may yield an environmental distribution quite different from that associated with the initial environmental load. Thus, the environmental behavior of a substance should be evaluated before exposures can be assessed.

Factors that may be addressed include:

- o How does the agent behave in air, water, soil, and biological media? Does it bioaccumulate or biodegrade? Is it absorbed or taken up by plants?
- o What are the principal mechanisms for change or removal in each of the environmental media?
- o Does the agent react with other compounds in the environment?
- o Is there intermedia transfer? What are the mechanisms for intermedia transfer? What are the rates of the intermedia transfer or reaction mechanisms?
- o How long might the agent remain in each environmental medium? How does its concentration change with time in each medium?
- o What are the products into which the agent might degrade or change in the environment? Are any of these degradation products ecologically or biologically harmful? What is the environmental behavior of the harmful products?
- o Is a "steady state" concentration distribution in the environment, or specific segments of the environment, achieved? If not, can the non-steady state distribution be described?
- o What is the resultant distribution in the environment - for different media, different types or forms of the agent, for different geographical areas, at different times or seasons?

3. Identification of Principal Pathways of Exposure

The principal pathway analysis should evaluate the sources, locations, and types of environmental release together with environmental behavioral factors to determine the significant routes of human and environmental exposure to the substance. Thus, by listing the important characteristics of the environmental release (entering media, emission rates, etc.) and the agent's behavior (intermedia transfer, persistence, etc.) after release to each of the entering media, it should be possible to follow the flow of the agent from its initial release to its subsequent fate in the environment. At any point along these environmental flow lines, human or environmental exposure might occur. Points with sufficient concentration of

the agent and sufficient potential for human or environmental contact, including those pathways where no environmental fate is involved, are the principal exposure pathways.

C. Estimates of Environmental Concentrations (Distribution)

Where appropriate, models can be used to predict environmental concentrations. Many models are based on monitoring data, and the two are closely linked, as described in section VI below.

In this section an estimation is made, using appropriate models, of average or representative concentrations of the agent in different environmental media, and its time dependence in specific geographical locations (e.g., river basins, streams, etc.).

VI. MONITORING OR ESTIMATED CONCENTRATION LEVELS

A. Summary of Monitoring Data

As discussed in the previous sections, monitoring data are used throughout the materials balance and exposure pathways assessments to allow quantitative estimates of both sources (releases) and environmental concentrations. Some examples of monitoring data used in a materials balance would be: (a) sampling of stacks or discharge pipes for emissions to the environment; (b) testing of products for chemical or radionuclide content; (c) testing of products for chemical or radioactive releases; (d) sampling of appropriate points within a manufacturing plant to determine releases from industrial processes or practices; and (e) sampling of solid waste for chemical or radionuclide content. These data should be put into perspective as to accuracy, precision, and representativeness. If actual environmental monitoring data are unavailable, concentrations can be estimated by various means, including the use of fate models (see previous section), or in the case

of new chemicals, by analogy with existing chemicals.

B. Comparison of Concentration Estimates with Monitoring Data

Examination of monitoring data has often been considered a substitute for environmental pathways and fate analysis, since monitoring data directly provide the environmental distributions of pollutants. The analysis of monitoring data should be considered a complement to environmental pathway and fate analysis for the following reasons: (a) for most pollutants, particularly organic and new chemicals, monitoring data are limited ; (b) analysis of monitoring data does not often yield relationships between materials balance and environmental concentration distribution in media or geographic locations that have not been monitored; (c) analysis of monitoring data does not provide information on how and where biota influence the environmental distribution of a pollutant; and (d) monitored concentrations may not be traceable to individual sources that EPA can regulate. Monitoring data are, however, a direct source of information for exposure analysis and, furthermore, they can be used to calibrate or extrapolate models or calculations to assess environmental distribution.

C. Estimation of Environmental Concentrations

Where consistent with the purpose of the exposure assessment, it is necessary to estimate the environmental concentrations of the agent resulting from its release, behavior, and subsequent fate. Concentrations should be estimated for all environmental media that the release, behavior, and fate analysis indicate might contribute to significant exposures. Generally, the environmental concentrations are estimated from monitoring data, mathematical models, or a combination of the two.

The concentrations must be estimated and presented in a format consistent with available dose-response or damage-response information. In

some cases an estimate of annual average concentrations will be sufficient, while in other cases the temporal distribution of concentrations may be required. Future environmental concentrations resulting from current or past releases may also be projected. In some cases, both the temporal and geographic distributions of the concentration may be assessed. Moreover, if the agent has natural sources, the contribution of these to environmental concentrations may be relevant. These "background" concentrations may be particularly important when the results of tests of toxic effects show a threshold or distinctly nonlinear dose-response.

The uncertainties associated with the estimated concentrations should be evaluated by an analysis of the uncertainties of the model parameters and input variables. When the estimates of the environmental concentrations are based on mathematical models, the model results should be compared to available monitoring data, and any significant discrepancies discussed.

VII. EXPOSED POPULATIONS

Populations selected for study may be done a priori, but many times the populations will be identified as a result of the sources and fate studies. From an analysis of the distribution of the agent, populations and subpopulations (i.e., collections of subjects) at potentially high exposure can be identified, which will then form the basis for the populations studied. Subpopulations of high sensitivity, such as pregnant women, youth, chronically ill, etc., may be studied separately.

In many cases, exposed populations can be described only generally. In some cases, however, more specific information may be available on matters such as the following:

A. Human Populations

1. Population size and characteristics (e.g., trends, sex/age distribution)
2. Population location
3. Population habits - transportation habits, eating habits, recreational habits, workplace habits, product use habits, etc.

B. Nonhuman Populations (if appropriate)

1. Population size and characteristics (e.g., species, trends)
2. Population location
3. Population habits

Census and other survey data may be used to identify and describe the exposed population for the various contaminated environmental media. Depending on the characteristics of available toxicological data, it may be appropriate to describe the exposed population by other characteristics such as species, race-age-sex distribution, and health status.

VIII. INTEGRATED EXPOSURE ANALYSIS

The integrated exposure analysis combines the estimation of environmental concentrations (sources and fate information) with the description of the exposed population to yield exposure profiles and exposure pathway analyses. If available, significant data should be provided on the size of the exposed populations; duration, frequency, and intensity of exposure; and route of exposure. To the extent possible, consistent with the scope of the exposure assessment, exposures should be related to sources.

For more detailed assessments, the estimated environmental concentrations should be considered in conjunction with the geographic distribution of the human and environmental populations. To the extent

desirable, the behavioral and biological characteristics of the exposed populations should be considered and population exposures to various concentration profiles should be estimated. The results can be presented in tabular or graphic form, and an approximation of the uncertainty associated with them should be estimated.

A. Development of Exposure Scenarios and Profiles

Depending on the scope of the exposure assessment, the total exposure picture may be fractionated into one or more "exposure scenarios" to facilitate quantification of exposure. As an example, Table III-1 lists seven very broad scenarios: Occupational, Consumer, Transportation, Disposal, Food, Drinking Water, and Ambient. For each of the scenarios, the major topics necessary to quantify exposure, namely sources, pathways, monitoring, and population characteristics, are involved. Investigation of only one scenario may be necessary for the scope of some assessments. For example, a pesticide application exposure assessment may consider the occupational scenario, which would cover the exposure to applicators and populations in the vicinity of the site. An exposure assessment around a hazardous waste site may focus on the disposal scenario. The exposure assessment also may consider other scenarios. The more extensive and comprehensive the scope, the more scenarios are usually involved.

It will usually be advantageous in performing an exposure assessment to identify exposure scenarios, quantify the exposure in each scenario, and then integrate the scenarios for a total exposure picture. In this "integrated exposure analysis," the adding of independent exposures from different scenarios (keeping exposure routes separate) will often result in a breakout of exposure by subpopulations, since the individual scenarios usually treat exposure by subpopulation. Therefore, the integration of the scenarios,

TABLE III-1. EXPOSURE ASSESSMENT NEEDS FOR VARIOUS EXPOSURE SCENARIOS

Exposure Scenario	Sources Needs	Fate Needs	Population Characteristics Needs	Monitoring Needs
Occupational (chemical production processing, use)	site/plant locations, in-plant/on-site materials balance	chemical properties models?	workers, families, population around sites/ plants	in-plant/on-site levels, releases, ambient levels surrounding site/plants human monitoring
Consumer (direct use of chemical or inadvertent use)	consumption rates, distribution pattern amounts in products	chemical properties, shelf life, release rates, models?	consumers	levels in products, releases
Transportation/ Storage/Spills	patterns of distribu- tion & transportation; models for spills	chemical properties, environmental fate models	storage, transportation workers; general population in area	releases, ambient levels
Disposal (include incineration, land- fill)	materials balance around disposal method, efficiency, releases to environment	fate within disposal process; environmen- tal fate of releases; models	workers at site of disposal, general population around site	releases, levels at various points within process, ambient levels
Food	food chain, packaging, additives	food chain models, fate during prepara- tion or processing of food	general population, nonhuman populations	levels in food, feed- stuff; food chain sampling
Drinking Water	groundwater, surface water, distribution system	leach rates from pipes, chlorination processes, fate in water; models	general population	levels in drinking water; ground water, surface water; treat- ment plants
Ambient	releases to environ- ment; air, land, water	environmental fate models	general population; nonhuman populations	ambient air, water, soil, etc.; human monitoring

or integrated exposure analysis, will often result in an exposure profile such as that shown in Figure III-1.

For each exposed subpopulation (or group), exposure profiles should include, where relevant data are available, the size of the group, the source of the agent, the exposure pathways, the frequency and the intensity of exposure by each route (dermal, inhalation, etc.), duration of exposure, and the form of the agent when exposure occurs. The following discussion, and the discussion under Section B and C below, refers to calculating the exposures under each scenario.

1. Identification of the Exposed Population and Critical Elements of the Ecosystem

The estimate of environmental concentrations also should give the geographic areas and environmental media contaminated. The stated purpose of the assessment should have prescribed the human and environmental subjects for which exposures are to be calculated. If the subjects are not listed, the contaminated geographic areas and environmental media can be evaluated to determine major subjects. The degree of detail to be utilized in the exposed population distribution depends on the concentration gradient over geographic areas.

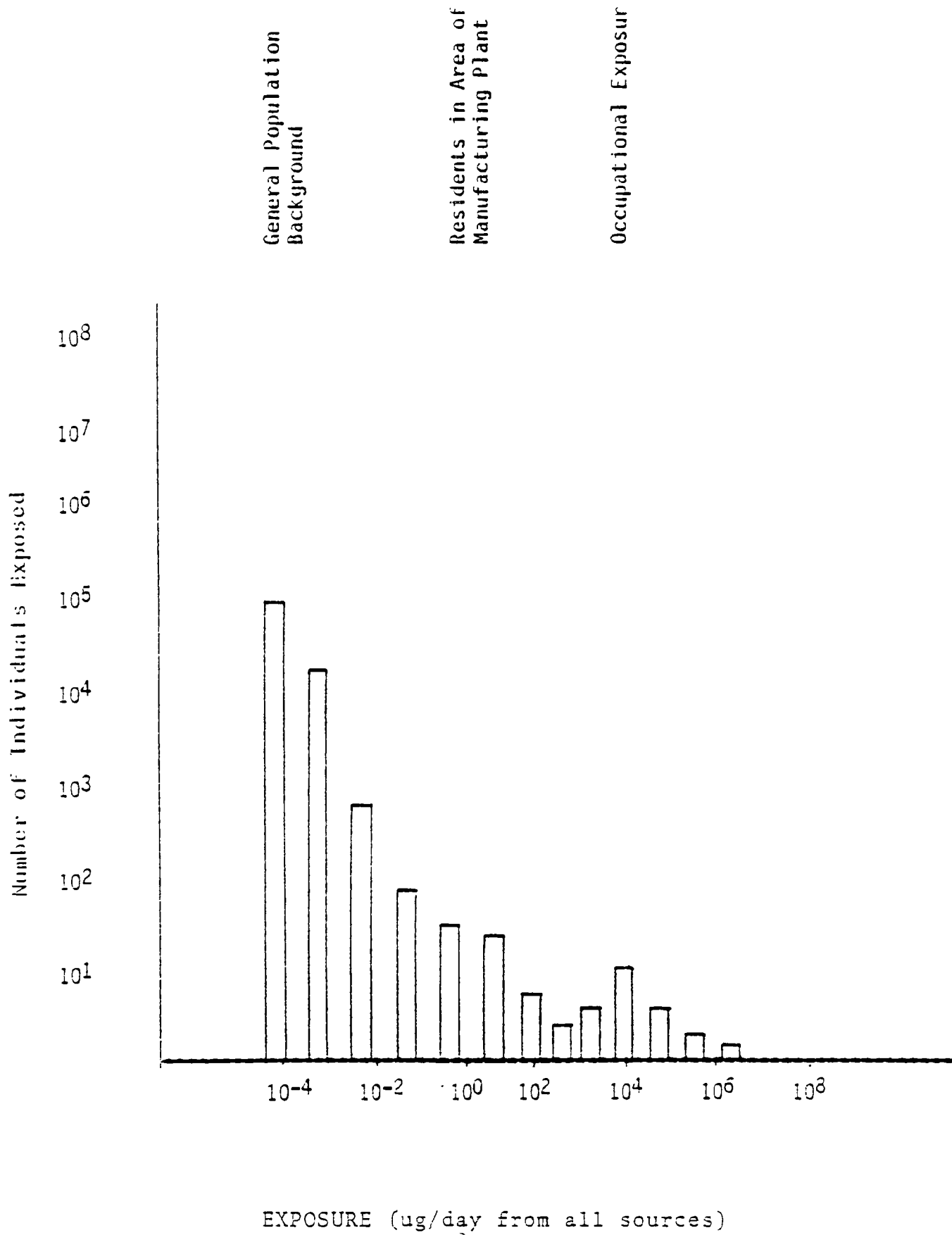


Figure III-1. Typical Exposure "Profile" of General Population

2. Pathways of Exposure

Where necessary for the regulatory purpose of the exposure assessment, some or all of the following should be provided:

- a. Qualitative - Identification and description of the routes by which the substances travel from production site, through uses, through environmental releases/sources, through transport and fate processes, if any, to the target population.
- b. Quantitative - Attaching available numerical values to the amounts of the chemical following each exposure pathway. Such estimates allow the various pathways to be put in the perspective of relative importance.

3. Human Dosimetry and Monitoring

After the exposure estimates are made, they can be checked by comparison with any available human dosimetry, human tissue monitoring, or non-invasive human monitoring.

C. Calculation of Exposures

From the geographic and temporal distribution of environmental concentrations, the exposed population, the behavioral characteristics, and the critical elements of the ecosystem, exposure distributions can be estimated. The way the exposure calculations are made should be consistent with the requirements of the dose-response or damage-response functions that may later be used in a risk assessment. Examples of requirements are annual average exposures, peak exposures, exposures that are greater than some threshold value, or the frequency and distribution of intermittent exposures. Many past exposure assessments have been based on the average exposure occurring over the exposure period. The range of possible exposures is

usually divided into intervals, and the exposures within each interval are counted. The results can be presented in tabular form or as a histogram (see Figure III-1).

The population residing in a specific geographic area may be environmentally exposed to a substance from several different sources and through several exposure routes. Exposures for individuals in these populations may be determined by summing over sources for the same exposure route, but exposures through different exposure routes should be kept separate. Combined exposures should be stated only if the metabolic fate processes are well understood. Because EPA regulates sources of releases, the contribution to exposures from each type of source with respect to which regulation is being considered should be displayed, if the information is available. Estimates should be presented for exposure from all relevant exposure routes (i.e., those routes consistent with the regulatory purpose), and the results should be tabulated in such a way that total exposures can be determined. (For example, see Table III-2 as one way of presenting the results.)

D. Evaluation of Uncertainty

See II. GENERAL GUIDELINES AND PRINCIPLES, section C.

TABLE III-2. EXAMPLE OF A PRESENTATION FOR MULTIROUTE EXPOSURES

Population Subgroup	Population Subgroup Size	Exposure Route		
		Inhalation (mg/yr)	Ingestion (mg/yr)	Dermal (mg/yr)
Manufacturing facility workers	200	40	5	0.5
General population in area around industrial or manufacturing facility	54,000	20	1	0.1
Farmers	3,000	5	2	0.2

IX. REFERENCES

The references should contain a listing of all reports, documents, articles, memoranda, contacts, etc. that have been cited in the report.

X. APPENDICES

The appendices may contain such items as memoranda and letters that are not readily accessible by others, tables of monitoring data, detailed lists of emission sources, detailed tables of exposures, process flow diagrams, mathematical model formulations, or any other item that may be needed to describe or document the exposure assessment.

APPENDIX B. EXAMPLES OF EXPOSURE ASSESSMENTS

Examples of typical exposure assessment are presented here from five EPA program offices. Because of space limitations, no attempt is made to discuss any example in depth. For more details about each of the examples, the reader should refer to the source documents themselves.

1. "Assessment of Potential Radiological Health Effects from Radon in Natural Gas." U.S. EPA Office of Radiation Programs, Washington, D.C. 20460. November 1973.

Release Estimates--

This document primarily covers the release of radon (^{222}Rn) in dwellings through use of natural gas in unvented cooking ranges or space heaters. Radon concentrations in natural gas at production wells and in gas processing, distribution, and storage systems are also presented and discussed.

Environmental Fate Estimates--

Environmental fate estimates for ^{222}Rn are not addressed directly in this document. The principal ^{222}Rn exposure pathway considered is to individuals in private residences.

Exposure Estimates--

The document contains a discussion of indoor human exposure to ^{222}Rn and its important daughter isotopes, ^{218}Po , ^{214}Pb , ^{214}Bi , and ^{214}Po . The primary concern for exposure to radon is from inhalation and retention of radon daughters which release their alpha decay energy to tissues of the respiratory system, especially the lungs. Various lung models are presented and discussed in an attempt to determine the relationship of exposure to radon daughters and the development of precancerous cells. Dose conversion factors for radon and radon daughters are tabulated for conditions in normal rooms representative of

typical dwellings. Exposure conditions are postulated on the basis of an average kitchen range use of 0.765 m^3 of natural gas per day in a home with a volume of 226.6 m^3 having an air change rate of once per hour (dilution volume = $226.6 \times 24 = 15,438 \text{ m}^3$).

The authors calculated the estimated annual dose to an individual at 0.028 rems/year in the following manner:

$$\frac{226.6 \text{ m}^3 \text{ house} \times 24 \text{ air changes}}{0.765 \text{ m}^3 \text{ gas used per day (in ranges)}} = 7111 \text{ (dilution factor)}$$

$$\frac{\text{Assumed natural gas } ^{222}\text{Rn concentration}}{\text{dilution factor}} = \frac{20 \text{ pCi/l}}{7111} = 0.0028 \text{ pCi/l}$$

$$0.0028 \text{ pCi/l} \times \frac{100 \text{ rads/year}}{100 \text{ pCi/l}} = 0.0028 \text{ rads/year}$$

$$0.0028 \text{ rads/year} \times \frac{10}{\text{quality factor}} = 0.028 \text{ rems/year}$$

Further assumptions and calculations are made to estimate the average tracheobronchial dose to individuals from unvented kitchen ranges and space heaters at 15 and 54 mrem/year, respectively, or 2.73 million person-rems per year for the entire United States population.

Discussion--

The tracheobronchial dose effect or risk of concern from radon daughter exposure is lung carcinoma. The authors calculated an absolute risk of 35 excess deaths/ 10^6 persons/year/rem from exposure to radon and its daughter isotopes. This factor is multiplied by the dose of 2.73×10^6

person-rem/s/year to obtain an estimate of 95 excess deaths per year. However, uncertainties in and corrections for loss of daughter products by plating out or deposition on surfaces; low ventilation rate; nose breathing instead of mouth breathing; a lower, more realistic continuous residence time in dwellings; and other factors lower this estimate to a more likely estimated excess mortality of 15 deaths/year, which represents only 0.03 to 0.08 percent of normal lung cancer mortality. Several methods for reducing exposure to ^{222}Rn through additional controls in production, processing, distribution, use, and storage of the gas are discussed. It is calculated that controls for reducing radon concentrations in natural gas by storage methods would cost over \$100 million for the elimination of each potential excess death. The authors concluded that controls would not be cost effective on a national basis and that the use of natural gas containing ^{222}Rn for average exposure conditions does not contribute significantly to lung cancer deaths in the United States. (For more details from the text of this report see pages V-5 - V-7.)

2. "DDVP/Trichlorofon/Naled Exposure Assessment." U.S. EPA Office of Pesticide Programs, Washington, D.C. 20460. February 1981.



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

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

03 MAR 1981

"DDVP/Trichlorofon/Naled: Exposure Assessment." US EPA Office of Pesticide Programs, Washington, D. C. 20460. February, 1981.

This document develops the human exposure assessment for three related pesticides: DDVP, trichlorofon, and naled, for possible inclusion in position document 1, the OPP preliminary risk assessment for these pesticides. Each pesticide is an organophosphorus insecticide used to control a number of different species of insects. These three insecticides show a similarity both chemically and metabolically.

This exposure assessment focuses on the interconversion possibilities of these three pesticides. A review of the literature leads to the conclusion that the conversion of naled and trichlorofon to DDVP is plausible in mammalian systems. In addition, the metabolism of DDVP by hydrolysis and/or demethylation has been shown to produce other degradates in many species including man.

The environmental fate of these three pesticides is incompletely understood. However, it appears that long-term persistence under natural environmental conditions does not appear to be a factor.

The quantitative non-dietary exposure data for affected populations represent the best currently available estimates of exposure occurring during the most important registered uses of these pesticides. The dietary burden was calculated by determining the rate of ingestion of food commodities bearing the legal tolerance limits.

DDVP/TRICHLOROFON/NALED

Exposure Assessment

Product Chemistry
Synthesis and Formulation
Environmental Fate
Physicochemical Degradation and Metabolism
Non-Dietary Exposure
Dietary Exposure

Prepared by:

Environmental Fate Branch
Hazard Evaluation Division
Office of Pesticide Programs

Richard V. Moraski, Ph.D.
Chemist
Review Section No. 4
February 12, 1981

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SUMMARY -- NON-DIETARY EXPOSURE

The numerical values generated in this summary are based on the analysis of the available literature and represent the best currently available estimates of exposure.

A. NaledI. Aerial Application for Mosquito Control

Urine concentration of dimethylphosphate = 0.80 ppm

B. TrichlorofonI. Warehouse Workers Exposed as a Result of Storage of TCPDaily Respiratory Exposure

exposure range: 0.06-1.391 mg/m³

exposure mean: 0.72 mg/m³

absorption factor: 100%

0.72 mg/m³ x 1.8 m³/hr x 8 hr/day x person/70 kg

= 0.15 mg/kg/day

II. Turf Applicatorsa) Boom ApplicationDaily Respiratory Exposure

N. D.

Daily Dermal Exposure

Trichlorofon detected: 2 ug/m² body surface

Body area exposed: 0.203 m² (hand and forearm)

Absorption factor: 10%

2 ug/m²/day x 0.203 m² x person/70 kg x 0.1

= 0.0006 ug/kg/day

b) Spray Gun ApplicatorsDaily Respiratory Exposure

0.002 mg/m³ x 1.8 m³/hr x 8 hr/day x person/70 kg

= 0.0004 mg/kg/day

Daily Dermal ExposureTrichlorofon detected: 0.83 ug/m^2 body surfaceBody area exposed: 0.6 m^2

Absorption factor: 10%

 $0.83 \text{ ug/m}^2/\text{day} \times 0.6 \text{ m}^2 \times \text{person}/70 \text{ kg} \times 0.1$ $= 0.0007 \text{ ug/kg/day}$ C. DDVPI. Workers in WarehousesAssumptions:

1. two insecticidal treatments per week
2. effective level of insecticide: 2 mg DDVP/ft^3
3. normal work day is 8 hours

Daily Respiratory Exposurea) Insecticide sprinkled on floor

<u>Time After Treatment</u>	<u>DDVP Concentration in Air</u>
4 hr	1.7 mg/m^3
24 hr	0.9 mg/m^3
48 hr	$<0.4 \text{ mg/m}^3$

Possible weekly exposure:

Exposure during first day after treatment:

 $1.7 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 8 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.35 \text{ mg/kg/day}$

Exposure during second day after treatment:

 $0.9 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 8 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.15 \text{ mg/kg/day}$

Exposure during third day after treatment:

 $0.4 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 8 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.1 \text{ mg/kg/day}$ Total for week (two treatments per week): $0.1 + 0.1 + 0.2$ $= 1.2 \text{ mg/kg/wk}$ Approximate average daily exposure $= 0.2 \text{ mg/kg/day}$ b) Aerosol Treatment

<u>Time After Treatment</u>	<u>DDVP Concentration in Air</u>
4 hr	2.2 mg/m^3
24 hr	0.14 mg/m^3
72 hr	0.07 mg/m^3

Possible weekly exposure:

Exposure during first day after treatment:

 $2.2 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 8 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.45 \text{ mg/kg/day}$

Exposure during second day after treatment:

 $0.14 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 8 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.03 \text{ mg/kg/day}$

Exposure during third day after treatment:

 $0.07 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 8 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.15 \text{ mg/kg/day}$ Total for week (two treatments per week): $0.9 + 0.06 + 0.03$ $= 0.99 \text{ mg/kg/wk}$ Approximate average daily exposure $= 0.2 \text{ mg/kg/day}$ II. Aircraft Personnel -- Disinsection of AirplanesRespiratory ExposureDDVP air concentrations, range, $0.15\text{--}0.25 \text{ mg/m}^3$ mean: 0.20 mg/m^3

Assumptions: 30 min/treatment, 3 treatments/day

 $0.2 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 1.5 \text{ hr/day} \times \text{person}/70 \text{ kg}$ $= 0.007 \text{ mg/kg/day}$

III. Householders with Resin Strips

Assumption: over the period of 90 days, the daily average amount of DDVP in the air is 0.03 mg/m^3

The maximum potential daily inhalation exposure to homeowner:

For 2 hours of moderate work:

$$0.03 \text{ mg/m}^3 \times 1.8 \text{ m}^3/\text{hr} \times 2 \text{ hr} = 0.1 \text{ mg}$$

For 10 hours of light work:

$$0.03 \text{ mg/m}^3 \times 1.2 \text{ m}^3/\text{hr} \times 10 \text{ hr} = 0.4 \text{ mg}$$

For 12 hours of rest:

$$0.03 \text{ mg/m}^3 \times 0.5 \text{ m}^3/\text{hr} \times 12 \text{ hr} = 0.2 \text{ mg}$$

$$\text{Total daily average exposure: } 0.7 \text{ mg/day} \times \frac{\text{person}}{70/\text{kg}} = \underline{0.01 \text{ mg/kg/day}}$$

It is recognized that DDVP concentrations in the air do not remain constant over a period of 90 days, the effective lifetime of the strip. Therefore, daily exposures to DDVP are also calculated for four different intervals from the time of installation of the strip: one day after the strip is hung and approximately one month, two months, and three months after installation. Based on the data of Collins and DeVries (1973) and on the same activity schedule used in the previous calculation, the daily exposures are estimated to be as follows:

A. 1 day after installation: 0.06 mg DDVP/m^3 of air

Total daily exposure: 0.02 mg/kg/day

B. 28 days after installation: 0.02 mg DDVP/m^3 of air

Total daily exposure: 0.005 mg/kg/day

C. 56 days after installation: 0.01 mg DDVP/m^3 of air

Total daily exposure: 0.003 mg/kg/day

D. 91 days after installation: $<0.01 \text{ mg DDVP/m}^3$ of air

Total daily exposure: $<0.003 \text{ mg/kg/day}$

IV. Householder with One Flea Collar on Pet

Concentration of DDVP in

A. Room (casual exposure) range: $0.00013 - 0.0011 \text{ mg/m}^3$ (1-77 days)

mean: 0.0016 mg/m^3

B. Breathing Zone range: $0.003-0.29 \text{ mg/m}^3$ (1-89 days)

mean: 0.15 mg/m^3

If casual exposure to the pet is for 8 hours/day and the average breathing rate is $1.2 \text{ m}^3/\text{hr}$ and in the breathing zone of the pet the exposure time is 1 hour/day, then the potential exposure is:

A. Casual exposure:

$$0.0016 \text{ mg/m}^3 \times 1.2 \text{ m}^3/\text{hr} \times 8 \text{ hour/day} = 0.015 \text{ mg/day}$$

B. Breathing zone:

$$0.15 \text{ mg/m}^3 \times 1.2 \text{ m}^3/\text{hr} \times 1 \text{ hour/day} = 0.18 \text{ mg/day}$$

Total potential daily exposure due to inhalation from pet wearing one flea collar is 0.2 mg/day or 0.003 mg/kg/day .

3. "Human Exposure to Atmospheric Concentrations of Selected Chemicals." U.S. EPA Office of Air Quality Planning and Standards, Research Triangle Park, N.C. 27711. May 1980.

Introduction--

Systems Applications, Incorporated, in conjunction with Hydrosience, Incorporated, and Minimax Research Corporation, estimated the atmospheric concentrations of, and magnitude of, populations exposed to 35 chemicals. Three different methodologies were employed to make exposure estimates. The methodology used depended on the type of source being considered. Sources were classified into three major categories:

1. Major, Specific Point Sources - Sources considered as specific point sources individually accounted for significant emission fractions and had enough information available to estimate emissions. Most specific point sources were chemical manufacturing facilities.

2. General Point Sources - General point sources were sources for which sufficient information to make emissions estimates was generally not available or which were too small or too numerous to consider practically as specific point sources. Estimates of exposure to chemicals released from general point sources were made by developing estimates for one or more prototypes and by multiplying those estimates by the number of sources the prototype(s) represents.

3. Area Sources - Sources that were even more numerous and widely distributed than general point sources were more conveniently treated as area sources. Examples of sources that are generally combined and treated as area sources are home chimneys and automobiles.

Estimates of Exposure to Chemicals Released from Specific Point Sources--

Estimates of emissions from specific point sources were made by multiplying emission factors (mass emitted/mass produced or used) by production or use data. Emission factors were developed by several different methodologies. A number of emission factors were estimated for model plants based on data obtained during onsite visits to chemical manufacturers "Emission Control Options for the Synthetic Organic Chemical Manufacturing Industry," (EPA 68-02-2577). Emission factors were also estimated from process monitoring data taken from state air emissions inventory questionnaires (EIQ). In addition, emission factors were obtained from various reports published by EPA. Finally, if no other information was available, the emission factor for a given process was either assumed to be equal to the emission factor estimated for another similar process or was taken as the average of emission factors estimated for several different processes.

Three types of emissions evolving from the production and intermediate use of a chemical were considered.

1. Process emissions - "discrete losses that occur at process vents from reactors, columns, and other types of plant equipment." Process emissions are often obtained by direct monitoring of process vents.

2. Storage emissions - losses from storage tanks as well as from loading and handling. Storage emissions estimates were generally obtained from AP-42 (Compilation of air pollutant factors," 2nd ed. US EPA, Research Triangle Park, N.C. 27711. Publication No. AP-42. April 1976) calculations.

3. Fugitive emissions - "losses that result from plant equipment leaks, visual openings, evaporation from waste products, and other nondiscrete sources." Estimates of fugitive emissions are generally obtained by material

balance. For most chemical manufacturing facilities, separate emission factors for process vent, storage, and fugitive emissions were estimated. However, in cases of insufficient information, an overall emissions factor was estimated.

For each specific point source, average annual atmospheric concentrations at ground level were estimated for 10 distances from the source in each of 16 wind directions. The concentrations were estimated by the use of a computer program which combined unidirectional Gaussian solutions for each combination of atmospheric stability classes and 6 wind speed categories with meteorological data on the annual frequencies of each of the 16 wind directions, 7 atmospheric stability categories and 6 wind speed categories for the geographical vicinity of the specific point source. The meteorological data used were modified STAR data, which are climatological frequency of occurrence summaries formatted for use in EPA Gaussian dispersion models and are recorded for numerous meteorological stations throughout the country. The estimated concentrations were not only functions of distance, wind direction, emission rates, and effective stack heights but were also modified to account for the chemicals' atmospheric reactivities.

Three major types of reactions were considered in estimating a chemical's average atmospheric reactivity: photolysis, reaction with the hydroxyl radical, and oxidation by ozone. Pseudo-first order rate constants were estimated based on assumed concentrations of hydroxyl radical and ozone.

Population exposure to various concentrations of a chemical were estimated by use of U.S. Census Bureau data at the level of finest resolution available: Enumeration District/Block Groups (ED/BG's). As mentioned above, concentrations were estimated for 160 points (receptors) around each specific point source (10 distances in each of 16 wind directions). At small radii from the point source (e.g., up to 2.8 km), a single ED/BG contained several neighboring receptors, so

the population within the ED/BG was apportioned among the receptors falling inside the ED/BG. At larger radii (e.g., >2.8 km), most ED/BGs contained no receptors, so concentrations that populations within those ED/BGs were exposed to were estimated from the estimated concentrations at surrounding receptors. The estimates were based on an approximately linear relationship between the log of concentration and the log of distance from the source for large distances and on interpolation between neighboring wind directions.

Estimates of Exposure to Chemicals Released from General Point Sources--

Exposure estimates were made for prototype point sources in each of nine geographical regions. The methodology employed was similar to that used to obtain exposure estimates for chemicals released from specific point sources. However, exposure estimates were generally made only for urban areas. The population exposed to a given concentration estimated at one of the 160 receptors was assumed to be equal to the area of the radial sector whose center is the receptor times the average urban density for the geographical region considered. The data from a STAR meteorological station that was representative of the geographical region being considered was used to estimate atmospheric concentrations. Exposure estimates for a prototype point source within a given geographical region were multiplied by the number of sources within the same geographical region represented by the prototype to be overall exposure estimates.

Estimates of Exposure to Chemicals Released from Area Sources--

Atmospheric concentrations of chemicals emitted from urban area sources were estimated by use of the Hanna-Gifford equation:

$$X = CQ_0/u$$

where

X = average atmospheric concentration,

C = coefficient dependent on city size,

Q_0 = effective emissions rate per unit area, and

u = average wind speed.

Specific values of C have been estimated by Hanna and Gifford (1973) for a large number of U.S. cities.

The effective emissions rate for a given city Q_0 was assumed to be the sum of emissions from mobile sources (e.g., automobiles), stationary heating sources (e.g., chimneys), and non-heating sources. The emissions from mobile sources for a specific city were estimated from the following equation:

$$Q_m = \left(\frac{EM}{A} \right) \left(\frac{a + t R}{a' + t' R} \right) ,$$

where

EM = national total mobile source emissions of the chemical,

A = land area of the city,

a = estimated number of autos in the city,

t = estimated number of trucks and buses in the city,

R = ratio of average truck-bus emissions to auto emissions,

a' = estimated national total of autos, and

t' = estimated national total of buses/trucks.

The emissions from heating sources for a specific city were estimated from the following equation:

$$Q_H = \left(\frac{EH}{A} \right) \left(\frac{P \cdot HR}{4633 P'} \right) ,$$

where

EH = national total heating source emissions of the chemical,

A = area of the city,

P = population of the city,

HR = heating requirements (degrees-days/yr),

P' = population of United States, and

4633 = population-weighted nationwide per capita heating requirement (degree-days/yr).

The emissions from non-heating stationary sources for a specific city was estimated from the following equation

$$Q_N = \left(\frac{EN}{A} \right) \left(\frac{P}{P'} \right) ,$$

where

EN = national total emissions from non-heating stationary area sources, and

A, P, and P' are given above.

The overall psuedo-first order decay constants used in the dispersion modeling for point sources were also used for area source modeling. The following equation was used to estimate the overall effective emissions rates:

$$Q_0 = (Q_M + Q_H + Q_N) \cdot \frac{\exp(-K_d \frac{A/2}{u})}{\exp(-K_n \frac{A/2}{u})}$$

where

Q_M, Q_H, and Q_N are defined above,

K_d = average daytime psuedo-first order decay constant, and

K_n = average negative psuedo-first order decay constant.

DRAFT Report

**HUMAN EXPOSURE TO ATMOSPHERIC
CONCENTRATIONS OF SELECTED CHEMICALS**

EPA Contract No. 68-02-3055

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5 March 1980

PREPARED BY

SYSTEMS APPLICATIONS, INC.

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4. "Priority Review Level 1: Formaldehyde." Draft Report. U.S. EPA Office of Toxic Substances, Washington, D.C. 20460. February 1981.

Example Categorization of Formaldehyde Exposure

Because of the large and diverse number of potentially exposed subpopulations and the potential diversity of information needed for further assessment of risks and reduction of those risks, AD has attempted to establish categories and assign priorities for further action. Although many different criteria could be used to establish categories, the attached table presents an example of a somewhat subjective categorization based on: size of the potentially exposed subpopulation; confidence in data on exposure levels; and significance of the risk. In this table, first priority is given to those situations where confidence in the exposure data is fair or good and either the total potentially exposed subpopulation is large (i.e. the number of potentially affected persons is large) or the estimated individual risk is high¹. Second priority is given where a moderate number of individuals are potentially exposed, confidence in the exposure data is fair, and the estimated individual risk is moderate. Third priority is given where the number of potentially exposed individuals is either small or unknown, confidence in the exposure level is poor, and/or the estimated risks may be considered low. Obviously, these priorities are subject to change as additional information becomes available.

February 19, 1981

DRAFT

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¹Because the risk estimates derived in this assessment are upper 95% confidence limits for lifetime risks, and are likely over-estimates in many cases, the lowest risk estimated for a given subpopulation was used to recommend priorities for further action.

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EXECUTIVE SUMMARY

Formaldehyde (CH_2O), the simplest member of the aldehyde chemical category, exists in many different forms. Pure monomeric formaldehyde (100% formaldehyde) is a colorless, pungent gas that spontaneously polymerizes in the temperature range of -90°C to 100°C . Aqueous formaldehyde (formalin) is a clear, colorless, pungent solution of about 37% by weight of formaldehyde gas in water, usually with 10-15% methanol added to prevent polymerization. Formaldehyde also exists in polymeric forms, the best known of which are paraformaldehyde and trioxane or trioxymethylene.

Formaldehyde is manufactured commercially by 15 companies at 52 sites by the catalytic oxidation of methanol. A second source of formaldehyde is its indirect production by natural processes and human activity such as the photochemical oxidation of airborne hydrocarbons and the incomplete combustion of hydrocarbons in fossil fuels and refuse. Approximately 1,580,000 kkg of formaldehyde were generated in the U.S. in 1978; 1,070,000 kkg from commercial production and 510,000 kkg from indirect production.

Almost all of the commercially produced formaldehyde is consumed domestically; less than 1% was exported in 1978. The uses of formaldehyde can be broken into three major categories: non-consumptive uses; pseudo-consumptive uses; and consumptive uses. In 1978, non-consumptive uses, wherein the chemical identity is not changed, most likely consumed less than 5% of the commercially produced formaldehyde. These uses generally employ formaldehyde as a preservative and disinfectant (e.g., in cosmetics and toiletries), as a preservative (e.g., for biological specimens and in embalming), or as a fungicide (e.g., in the manufacture of antibiotics and disinfection of sick rooms). Approximately 37% of the commercially produced formaldehyde was used in pseudo-consumptive uses (chemical identity not irreversibly altered), primarily in the manufacture of three

products: urea-formaldehyde resins; urea-formaldehyde concentrates; and hexamethylenetetramine. These products regenerate some or all of the original formaldehyde in the course of their intended use or incidental decomposition. The consumptive uses of formaldehyde, accounting for about 57% of the total production volume, include the synthesis of products such as melamine and phenol-formaldehyde resins, pentaerythritol, 1,4-butanediol, acetal resins, and trimethylolpropane.

Although indirect production is believed to be the larger contributor to environmental release of formaldehyde, commercially produced formaldehyde appears to be responsible for the most significant human exposures to this substance. Indirect production accounts for about 97% (510,000 kkg) of the annual formaldehyde emissions to the atmosphere. Since the major mechanisms for atmospheric degradation depend on sunlight, the persistence of airborne formaldehyde is expected to be greater in indoor air than in outdoor air. For outdoor air, the levels in urban areas are expected to be higher than the levels in rural ^{areas} ~~air~~ because of the larger number of indirect sources (e.g., vehicular exhausts and incinerators) in urban areas. With indoor environments, however, the absence of the relatively fast, sunlight-induced degradation is expected to allow airborne releases to build up in concentration. Physical processes such as ventilation will be the major factor affecting the formaldehyde concentrations in these situations.

No waterborne releases of formaldehyde were identified or quantified in this report; any such releases are expected to be short lived. Formaldehyde, per se, is not persistent in water because it rapidly hydrates to glycols which are biodegradable. Very low concentrations of formaldehyde, thus, are projected for ambient waters, except in extreme cases such as spills of concentrated solutions.

Monitoring data indicate that the highest potential exposures to formaldehyde are the result of its direct production and the commercial and consumer uses of formaldehyde and formalde-

hyde-containing products. Although the available monitoring data are limited in their statistical representativeness of the populations studied, it appears that situations having a particularly high potential for exposure to formaldehyde include: workplace environments in industries as diverse as formaldehyde manufacturing, resin-manufacturing, textile and garment manufacturing, plywood and particleboard production and those involved in the production and application of urea-formaldehyde foam; residences containing particleboard manufactured with urea-formaldehyde resins; residences containing urea-formaldehyde foam insulation; biology laboratories; and autopsy rooms. Two other situations, mushroom farming and particleboard veneering, also show a high potential for formaldehyde exposure based on monitoring data, but these data may not be representative of general levels for these occupations. The entire U.S. population also is exposed to formaldehyde in the ambient air at the low part per billion level, and potentially through the use of products containing formaldehyde as a preservative/disinfectant.

The potential for exposure to high concentration of formaldehyde is of concern because of the preliminary results of a recent bioassay conducted by the Chemical Industry Institute of Toxicology (CIIT). The CIIT bioassay results provide evidence that formaldehyde causes cancer in rats receiving long-term exposures via inhalation (the major route of human exposure). In the CIIT bioassay, rats (120/sex/dose) were exposed via inhalation to 2, 6, and 15 ppm formaldehyde (actual measured concentrations were 2.1, 5.6, and 14.1) for 6 hours per day, 5 days per week for 24 months.¹ Examination of rats serially sacrificed at months 6, 12, 18, and 24 showed distinct hyperplasia and metaplasia of the nasal epithelium. In addition, 95 tumors (92 osteolytic squamous cell carcinomas of the nasal

turbinates and 3 respiratory epithelial tumors) were detected in rats (all unscheduled deaths and scheduled sacrifices through the 24-month sacrifice) exposed to 14.1 ppm formaldehyde. Three tumors also were detected at 24 months in rats exposed to 5.6 ppm formaldehyde.

The CIIT bioassay protocol was reviewed by a panel of experts convened by the Consumer Product Safety Commission (CPSC), under the aegis of the National Toxicology Program (NTP), and found to be consistent with accepted standards for conducting inhalation exposure bioassays. The NTP panel, using bioassay data available through the 18-month sacrifice (i.e., 36 squamous cell carcinomas of the nasal turbinates) concluded that "formaldehyde poses a cancer risk to humans".

Using a linearized multistage carcinogenesis model, in conjunction with the available results from the CIIT bioassay and estimated levels of formaldehyde exposures for various subpopulations in the U.S., the upper 95% confidence limits on lifetime human carcinogenic risks were calculated. The calculated risk estimates suggest that a high level of risk may be associated with a number of situations involving exposures to formaldehyde. For most of the identified subpopulations, the estimated risks are equal to or greater than 10^{-5} , however, in some instances the risks are in the range of 10^{-1} (e.g., U-F foam producers/distributors exposed to 5.4 ppm, pathologists exposed to 7.9 ppm), 10^{-2} (e.g., workers in U-F foam insulated buildings exposed to 3.1 ppm U-F foam installers/dealers exposed to 2.4 ppm), and 10^{-3} (e.g., direct producers of formaldehyde). The reader, however, should note that these risk estimates are upper 95% confidence limits; i.e., risks generally will not exceed these estimates, but may, in fact, be considerably less.

¹The same type of bioassay also was conducted using mice. Results from the mouse bioassay were not used in this report because of problems in interpreting the available data.

5. "An Exposure and Risk Assessment for Zinc." U.S. EPA Office of Water Regulations and Standards, Washington D.C. 20460. August 1980.

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August 1980

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FOR ZINC**

FINAL DRAFT REPORT

by

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ABSTRACT

This report assesses the risk of exposure to zinc, as part of an ongoing program of the Monitoring and Data Support Division, Office of Water Regulations and Standards, U.S. Environmental Protection Agency. The goal of this program is to identify the sources of and evaluate exposure to the 129 priority pollutants.

A materials balance is developed for zinc that considers major sources of release from the cultural and natural environments to the first point of entry into air, soil, or water. The amount of material released from each source is estimated and, to the degree possible, the locations of releases are identified.

The distribution of zinc in the environment is assessed by consideration of available monitoring data and the physical, chemical, and biological processes that determine the environmental pathways and ultimate fate of pollutant releases.

For both humans and other biota, the significant routes of exposure are identified and the extent and magnitude of exposure estimated. All available data on deleterious effects are reviewed in order to identify the nature of the effects reported and potentially harmful levels of exposure.

Information concerning all of the above topics is combined in an attempt to assess the risks of exposure to zinc for various subpopulations.

1. EXECUTIVE SUMMARYMATERIALS BALANCE

Approximately 1.19 million metric tons (MT) of zinc were consumed in the U.S. in 1977, about half of which was imported. Zinc is used primarily in metallic form in galvanizing (41%), alloys and die casting (36%), brass (12%), and rolled zinc (3%) in construction, transportation, electrical, machinery and other industries. The remainder (8%) is used as zinc oxide and other zinc compounds, which are used in a wide variety of products, such as plastics, paper, paints and cosmetics.

Less than 10% of the zinc supply is recycled domestically. An unknown amount is accumulating within the economic system, and the remainder is released to the environment, primarily as solid wastes disposed of to land. Refuse comprised of spent products containing zinc, ore mine tailings, metals working wastes, coal ash, and municipal and industrial sludges constitute major sources of landfilled zinc. In addition, significant quantities of zinc are agriculturally landspread as fertilizer adjuvant.

The largest input of zinc to water results from erosion of soil particles containing natural traces of zinc (43,400 MT/yr). Culturally accelerated erosion accounts for 70% of this soil loss; geologic or natural erosion constitutes the other 30%. However, as this source is dilute and widely dispersed it is unlikely to result in significantly elevated aquatic concentrations. On the other hand, urban runoff (5250 MT/yr), inactive mine drainage (4060 MT/yr), and municipal and industrial effluents (17,000 MT/yr combined) are smaller but more concentrated sources, capable of affecting many local areas. Drainage from active mining areas is considerably less than from inactive areas due to the disposal methods currently employed.

POTW represent the largest total point source zinc discharges, receiving contributions from water supply and distribution system corrosion, combined sewer area runoff, industrial wastes, and human excrement. Industries with large discharges of zinc directly to water include iron and steel, zinc smelting (primarily from a single mill), and possibly plastics and electroplating.

The total quantity of zinc estimated to be emitted to air (7130 MT/yr) is a small portion of the total environmental release. Refuse incineration, coal combustion, and some metals working industries constitute the major sources. Along with releases of zinc through metal corrosion and tire abrasion, these sources contribute to urban runoff contaminat

DISTRIBUTION OF ZINC IN THE ENVIRONMENT

Zinc in ambient water is usually found at concentrations of less than 50 ug/l. However, in many locations concentrations of 100-1000 ug/l are found. The fact that higher concentrations are more common in New England, the Southeast, the Missouri River Basin, the Rio Grande River Basin and the Upper Colorado, appears to be correlated with mining activities in these areas. However, in all river basins there are some locations with zinc concentrations of 100-1000 ug/l.

Zinc has a tendency to absorb to sedimentary material. Consequently, anthropogenic discharges of zinc in excess of levels natural in equilibrium with aquatic sediments result in removal from the water column and enrichment of sediments. Severe zinc contamination thus tends to be confined to the region of the source. Zinc in the water column is primarily in the form of the free ion.

Zinc is generally found in soils at concentrations between 10 mg/kg and 300 mg/kg, with a mean of about 50 mg/kg. Soils near highways and smelters have been found to contain higher concentrations, due to deposition of zinc released in tire abrasion and stack emissions.

The mobility of zinc in soil depends on the solubility of the compound and, to some extent, on the soil properties. Zinc in a soluble form, such as zinc sulfate, is fairly mobile in most soils. However, as relatively little land disposed zinc is in soluble form, the slow rate of dissolution will limit mobility. Consequently, movement toward groundwater is expected to be slow unless zinc is applied to soil in soluble form (such as in agricultural applications) or accompanied by corrosive substances (such as in mine tailings). The transport of soil zinc may also result from surface runoff or entrainment of particles into the atmosphere.

Annual average airborne zinc concentrations in urban areas of the United States are generally less than 1 ug/m^3 . Although data are sparse, higher airborne concentrations of zinc would be expected in the vicinity of iron and steel-producing plants and zinc smelters. Atmospheric emissions of zinc, consisting primarily of zinc sorbed to submicron particulate matter and the oxide of zinc, are expected to be short-lived in the atmosphere, with deposition upon soil and pavement occurring as fallout and washout.

EFFECTS OF ZINC

Zinc is an essential trace element in human and animal nutrition; the recommended dietary allowance for humans is 3-15 mg/day in humans. Zinc deficiency in humans has been associated with such effects as growth impairments, inhibition of sexual maturation, loss of appetite, inability to gain weight, skeletal abnormalities, perakeratotic esophageal and skin lesions, and hair loss.

Moderately high levels of zinc appear to have few adverse effects on humans or animals; the metal has not been shown to be either carcinogenic or mutagenic. Human survival has been reported after ingestion of up to 12,000 mg of metallic zinc, and most individuals appear capable of ingesting 150 mg zinc on a daily basis without adverse effect. Vomiting and diarrhea, acting to reduce further assimilation, are

generally the threshold effects. However, it is zinc's disagreeable metallic taste which constrains the drinking water criterion to 5 mg/l, well below any emetic threshold.

Inhalation of zinc oxide at concentrations of 15 mg/m^3 of zinc or a produces fever, malaise, headache, and occasional vomiting, thus necessitating the occupational exposure standards currently in effect.

The effects of zinc on aquatic organisms are of more concern. Severe fish kills in recent years have been attributed to zinc from runoff discharges from mining areas and smelters. However, the concentrations causing mortality were generally not well documented, and in many cases high levels of other metals were also present.

In the laboratory, avoidance reactions have been observed in rainbow trout at concentrations as low as 5.6 ug/l. Effects on growth, reproduction and survival are reported in various freshwater fish species after chronic exposure to concentrations of 106-1150 ug/l. There are not enough data to permit generalizations concerning invertebrates as a group. The proposed fresh water criterion ranges from approximately 15-80 ug/l depending on hardness.

Acute toxicity studies have been conducted for many species of freshwater fish. LC_{50} values range from 90-103,000 ug/l, with salmonids and striped bass reported as being the most sensitive. Invertebrates are, with some exceptions, sensitive to the same range of concentrations.

The limited information available suggests that marine invertebrates are less susceptible than freshwater species. Marine invertebrates such as oysters and crabs exhibit growth reductions at 50-125 ug/l.

A strong negative correlation between water hardness and zinc toxicity has been confirmed for freshwater organisms. The effects of temperature, pH, and other water quality parameters are not as well understood.

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EXPOSURE AND RISK

Humans are primarily exposed to zinc through ingestion; the dietary intake of an average teenage male has been estimated to be 18.6 mg zinc/day. Dietary supplements may provide up to an additional 75 mg zinc per tablet. The mean intake of zinc in drinking water is 0.4 mg/day (maximum of 26 mg/day). Negligible quantities are inhaled in ambient air. Since humans are able to tolerate 150 mg/day without adverse effects, little risk appears to be associated with these exposures.

Exposure of aquatic organisms to 100-1000 ug/l total zinc is common in the United States, especially in New England, the Western Gulf and the Southeast regions. Since calcium hardness appears to mitigate the toxicity of zinc, risk may be greater in New England and parts of the Southeast, which have soft water.

Salmonids and invertebrates are acutely sensitive to zinc concentration in the range of 100-1000 ug/l. Over 20% of the water samples taken nationwide have zinc concentrations exceeding 100 ppb. About 25% of all samples exceed the proposed chronic exposure water quality criterion. However, there is some uncertainty in estimating risk from laboratory toxicity data coupled with ambient monitoring data. Organisms in the environment may be somewhat less susceptible to toxicity than those in the laboratory due to differences in the make-up of the two systems. Compared to laboratory waters, where the toxic free ion of zinc can be expected to predominate, a portion of zinc in environmental waters may be adsorbed to solids or, under certain conditions, complexed with organic or inorganic material. In addition, acclimation may occur in environments receiving chronic exposures.

Consequently, estimation of the actual ecological risk due to zinc requires closer examination of areas having elevated aquatic zinc levels, employing both field and laboratory measures of stress. Also needed is a better understanding of the relationship between toxicity and chemical speciation of zinc.