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Office Of Air Quality
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Research Triangle Park, NC 27711

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Air

RESIDUAL RISK
Report to Congress

EPA-453/R-99-001

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REPORT TO CONGRESS

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Air and Radiation
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Contents

List of Exhibits

Acronym List

ADI	Acceptable daily intake
AEGL	Acute exposure guidance level
AEL	Adverse effects level
AIHA	American Industrial Hygiene Association
AIRS	Aerometric Information Retrieval System
ARE	Acute reference exposure
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
BMC	Benchmark concentration
BMD	Benchmark dose
CAA	Clean Air Act
CAS	Chemical Abstracts Service
CRARM	Commission on Risk Assessment and Risk Management
CWA	Clean Water Act of 1972
DDT	Dichlorodiphenyltrichloroethane
DNA	Deoxyribonucleic acid
DOE	Department of Energy
DWEL	Drinking water equivalent level
ED_{10}	Effective dose at 10 percent response
EFH	Exposure Factors Handbook
EHS	Extremely hazardous substance
EMAP	Environmental Monitoring and Assessment Program
EOM	Extractable organic matter
EPA	Environmental Protection Agency
ERPG	Emergency Response Planning Guidelines
FACA	Federal Advisory Committee Act
FEL	Frank effects level
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
GACT	Generally Available Control Technology
GIS	Geographic information system
GLWQI	Great Lakes Water Quality Initiative
HAP	Hazardous air pollutant
HEM	Human Exposure Model
HEAST	Health Effects Assessment Summary Tables
HEC	Human Equivalent Concentration
HI	Hazard index
HQ	Hazard quotient
IDLH	Immediately dangerous to life and health

IEM	Indirect Exposure Model
IRIS	Integrated Risk Information System
ISCST3	Industrial Source Complex Short-Term 3
K_{oc}	Organic carbon-water partition coefficient
K_{OW}	Octanol-water partition coefficient
LEC_{10}	Lower 95% confidence limit on effective concentration at 10% response
LED_{10}	Lower 95% confidence limit on effective dose at 10% response
LOAEL	Lowest-observed-adverse-effect level
LOC	Level of concern
LOEL	Lowest-observed-effect level
MACT	Maximum achievable control technology
MCLG	Maximum contaminant level goal
MEI	Maximum exposed individual
MIR	Maximum individual risk
MOE	Margin of exposure
MRL	Minimum risk level
NAAQS	National Ambient Air Quality Standard
NAS	National Academy of Sciences
NCLAN	National Crop Loss Assessment Network
NESHAP	National Emission Standard for Hazardous Air Pollutants
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
NRC	National Research Council
NRDC	Natural Resources Defense Council
NTI	National Toxics Inventory
OAQPS	EPA Office of Air Quality Planning and Standards
OERR	EPA Office of Emergency and Remedial Response
ORD	EPA Office of Research and Development
ORNL	Oak Ridge National Laboratories
OSW	EPA Office of Solid Waste
PAH	Polycyclic aromatic hydrocarbon
PAMS	Photochemical Assessment Monitoring Station
PCB	Polychlorinated biphenyl
PIC	Product of incomplete combustion
POM	Polycyclic organic matter
P2	Pollution prevention
QSAR	Quantitative SAR
RAC	Risk Assessment Council
RfC	Reference concentration
RfD	Reference dose
RSC	Relative source contribution
SAB	Science Advisory Board
SAR	Structure-activity relationship

SPEGL	Short-term public emergency guidance level
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
TEF	Toxic equivalency factor
TEQ	Toxicity equivalent
TRI	Toxics Release Inventory
TRIM	Total Risk Integrated Methodology
TRV	Toxicity reference value
TSCA	Toxic Substances Control Act
UATMP	Urban Air Toxics Monitoring Program
UF	Uncertainty factor
URE	Unit risk estimate
VOC	Volatile organic compound

Abbreviated Glossary of Technical Terms

acceptable daily intake (ADI): An estimate of the daily exposure that is likely to be without deleterious effect even if continued exposure occurs over a lifetime.

acute exposure: One dose (or exposure) or multiple doses (or exposures) occurring within a short time relative to the life of a person or other organism (e.g., approximately 24 hours or less for humans).

adverse environmental effect: Defined in CAA section 112(a)(7) as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

assessment endpoint: An explicit expression of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together "salmon reproduction and age class structure" form an assessment endpoint.

benchmark dose (BMD), benchmark concentration (BMC): An exposure level that corresponds to a predetermined level of response, such as 10 percent of test animals affected.

bioaccumulation: The net accumulation of a substance by an organism as a result of uptake from all routes of exposure (e.g., ingestion of food, intake of drinking water, direct contact, or inhalation).

bioaccumulation factor (BAF): The concentration of a substance in tissue of an organism divided by its concentration in an environmental medium in situations where the organism and its food are exposed (i.e., accounting for food chain exposure as well as direct chemical uptake).

bioconcentration: The net accumulation of a substance by an organism as a result of uptake directly from an environmental medium (e.g., net accumulation by an aquatic organism as a result of uptake directly from ambient water, through gill membranes or other external body surfaces).

bioconcentration factor (BCF): The concentration of a substance in tissue of an organism divided by the concentration in an environmental medium, typically in situations where exposure is by contact or uptake directly from that medium (e.g., the concentration of a substance in an aquatic organism divided by the concentration in the ambient water, in situations where the organism is exposed through the water only).

bootstrap analysis: A method of statistical analysis in which the user empirically constructs sampling distributions when data are limited.

chronic exposure: Multiple exposures occurring over an extended period of time or a significant fraction of the animal's or the individual's lifetime.

confounder: A condition or variable that may be a factor in producing the same response as the agent under study. The effects of such factors may be discerned through careful design and analysis.

default assumption: Defined by the National Research Council as "essentially policy judgments of how to accommodate uncertainties. They include various assumptions that are needed for assessing exposure and risk, such as scaling factors to be used for converting test responses in rodents to estimated responses in humans."

dose-response assessment: The quantitative characterization of the relationship between the amount of an agent (either administered, absorbed, or believed to be effective) and changes in certain aspects of the biological system (e.g., critical adverse effects) apparently in response to that agent.

drinking water equivalent level (DWEL): A lifetime exposure concentration protective of adverse, non-cancer health effects that assumes all of the exposure to a contaminant is from a drinking water source.

ecological receptor: A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. An ecological entity is one component of an assessment endpoint.

ED_{10} or EC_{10}: Dose or concentration associated with a 10 percent level of response.

extrapolation: An estimation of a numerical value of an empirical (measured) function at a point outside the range of data that were used to calibrate the function. The quantitative risk estimates for carcinogens are generally low dose extrapolations based on observations made at higher doses.

hazard index (HI): The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways.

hazard quotient (HQ): The ratio of a level of exposure for a single substance over a specified time period to a reference level (e.g., RfC) for that substance derived from a similar exposure period.

hazardous air pollutant (HAP): Defined by the CAA as any air pollutant listed under CAA section 112(b) (in this document, synonymous with air toxics).

human equivalent concentration (HEC): Exposure concentration for humans that has been adjusted for dosimetric differences between experimental animal species and humans to be equivalent to the exposure concentration associated with observed effects in the experimental animal species. If occupational human exposures are used for extrapolation, then human equivalent concentration represents the equivalent human exposure concentration adjusted to a continuous basis.

LED_{10}, LEC_{10}: The 95 percent lower confidence limit on the ED_{10} or EC_{10} (dose or concentration associated with a 10 percent level of response).

lowest-observed-adverse-effect level (LOAEL): The lowest exposure level at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group.

margin of exposure (MOE): The ratio of the level or dose derived from a toxicity or epidemiologic study (e.g., the NOAEL, the dose associated with a 10 percent response rate, etc.) to the estimated exposure level or dose.

Monte Carlo method: A repeated random sampling from the distribution of values for each of the parameters in a generic equation to derive an estimate of the distribution of outputs of the equation**.**

no-observed-adverse-effect level (NOAEL): An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control. In an experiment with several NOAELs, the regulatory focus is primarily on the highest one, leading to the common usage of the term NOAEL as the highest exposure without adverse effect.

octanol-water partition coefficient (K_{ow}): The ratio of a chemical's solubility in n-octanol to its solubility in water at equilibrium. The logarithm of this value is often used as an indication of a chemical's ability to bioconcentrate in organisms.

pharmacokinetics: The study of the absorption, distribution, metabolism, and excretion of chemicals in living organisms and the genetic, nutritional, behavioral, and environmental factors that modify these parameters.

primary effect: An effect where the stressor (e.g., chemical) acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect).

reference concentration (RfC) or reference dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure or a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime.

relative risk: The ratio of incidence or risk among exposed individuals to incidence or risk among non-exposed individuals.

safety factor: see uncertainty factor.

secondary effect: An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects).

stressor: Any physical, chemical, or biological entity that can induce an adverse response (synonymous with agent).

uncertainty factor (UF): One of several, generally 10-fold factors, used in operationally deriving the RfD or RfC from experimental data. UFs are intended to account for: (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using LOAEL data rather than NOAEL data.

unit risk estimate (URE): The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent (e.g., chemical) at a concentration of 1 microgram per cubic meter in air or 1 microgram per liter in water.

Executive Summary

Purpose of Report

Section 112(f) of the Clean Air Act (CAA), as amended, directs EPA to prepare the Residual Risk Report to Congress on the methods to be used to assess the risk remaining (i.e., the **residual risk**) after control technology standards applicable to emission sources of hazardous air pollutants (HAPs)[1] have been promulgated and applied. CAA section 112(f)(1) contains several specific requirements for the Report, which are summarized in **Exhibit ES-1** along with a reference to where each is addressed in the Report. Though not specifically required to be included in the Report to Congress, EPA also presents a discussion of its residual risk assessment framework for addressing the requirements under section 112(f)(2) to promulgate standards, if required, to "provide an ample margin of safety to protect public health" or to set more stringent standards, if necessary, "to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect." EPA ecological risk assessment methods are also described in the Report.

EXHIBIT ES-1
CROSSWALK BETWEEN SECTION 112(f)(1) REQUIREMENTS AND REPORT

Section 112(f)(1) Provision	Discussed in Report
112(f)(1)(A) – Methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under section 112 after application of standards	Chapters 3 and 5
112(f)(1)(B) – The public health significance of such estimated remaining risk	Section 4.1.1
112(f)(1)(B) – The technologically and commercially available methods and costs of reducing such risks	Section 4.1.2
112(f)(1)(C) – The actual health effects with respect to persons living in the vicinity of sources	Section 4.2.1
112(f)(1)(C) – Any available epidemiological or other health studies	Section 4.2.1
112(f)(1)(C) – Risks presented by background concentrations of HAPs	Section 4.2.2
112(f)(1)(C) – Uncertainties in risk assessment methodology or other health assessment technique	Section 4.2.3
112(f)(1)(C) – Any negative health or environmental consequences to the community of efforts to reduce such risks	Section 4.2.4
112(f)(1)(D) – Recommendations as to legislation regarding such remaining risk	Section 4.3

[1] The CAA defines HAP as any air pollutant listed under section 112(b), and provides procedures for adding and deleting pollutants from the list. The terms "**hazardous air pollutants**," "**HAPs**," and "**air toxics**" are used throughout this Report synonymously to refer to the pollutants listed under section 112(b).

Background

The 1970 CAA mandated a health-based program that required EPA to identify and list HAPs based on human health criteria. EPA was to then promulgate standards (national emission standards for hazardous air pollutants, or NESHAPs) for each pollutant at a level that would ensure the protection of public health with "an ample margin of safety." In the 20 years following enactment of the 1970 legislation, EPA identified eight pollutants as HAPs and regulated sources of seven of them.

In the 1990 CAA Amendments, Congress shifted the focus from individual pollutants to industrial and commercial source categories, and a phased approach to controlling air toxics emissions was developed. In the first regulatory phase, EPA must promulgate national, technology-based emission standards for source categories emitting any of the 188 currently listed HAPs in amounts exceeding specific emission thresholds. The fundamental approach is the use of available control technologies or work practice changes to achieve emission reductions in a timely manner for as many of the listed HAPs as possible, without explicit consideration of a HAP's inherent toxicity and potential risk. This technology-based standards program is commonly referred to as the maximum achievable control technology (MACT) program. Regulation of air toxics emissions through the MACT program is expected to achieve significant reductions in emissions of HAPs. As of October 1998, 53 source categories have been subjected to MACT standards, resulting in estimated emission reductions of more than one million tons of HAPs per year as well as significant reductions in emissions of criteria pollutants through co-control.

In the second regulatory phase, the 1990 Amendments provide for a human health risk- and adverse environmental effects-based "needs test." In this phase, referred to as residual risk standard setting, EPA will consider the need for additional standards following regulation under section 112(d) to protect public health and the environment. Section 112(f) of the CAA specifies that such residual risk standards "provide an ample margin of safety to protect public health." Section 112(f) also requires EPA to determine whether residual risk standards are necessary to prevent "an adverse environmental effect," taking into consideration "costs, energy, safety, and other relevant factors" in deciding what level is protective.

Also included in the 1990 CAA Amendments are provisions that EPA study several specific topics. In accordance with this mandate, EPA has published a number of reports to Congress, including the Mercury, Great Waters, and Utilities Reports to Congress, and continues to study these and other special topics. Additionally, EPA currently is refining its strategy for reducing risks in urban areas resulting from the emission of HAPs. The draft *Urban Air Toxics Strategy* released in August 1998 proposes to address the problems of cumulative exposures to air toxics in urban areas through an integrated approach that considers stationary and mobile sources of urban air toxics. These programs, in combination with the residual risk program, will provide a coordinated federal approach to address air toxics.

In the absence of a strong federal air toxics program prior to passage of the CAA Amendments of 1990, many State and some local agencies began to respond to the air toxics problem by developing their own programs. Many States in the country currently have an air toxics control program in place addressing, at a minimum, new sources of toxic air pollutants. Some have their own regulations that allow them to actively control air toxics emissions to a level protective of human health; others rely on comprehensive policies or authority provided to implement the federal program. Some State and local programs are risk-based, while others are technology-based.

The State and local programs have made progress in protecting the health of their people and their environment from exposure to air toxics. A successful comprehensive air toxics program will be one that integrates the residual risk and other federal programs with State and local programs and strengthens those existing programs. Program integration will involve interactive sharing of expertise, data, analyses, and methodologies. Additionally, State and local authorities may complement the federal program by addressing local risk issues that may not be effectively addressed nationally.

EPA is fully committed to environmental protection that is founded on sound and credible science. Objective, independent peer review of the scientific and technical bases of the Agency's actions is critical to accomplishing the Agency's mission. Although most of the major references that form the foundation of this Report have undergone (or are currently undergoing) external peer review, EPA requested and obtained from its Science Advisory Board an independent evaluation of the presentation of risk assessment methods and supporting data. This final Report was developed in consideration of both the SAB review comments and the comments received during the public comment period.

Risk Assessment Methods and Their Development

Three external reports have greatly influenced the development of human health risk assessment methods for air toxics at EPA: (1) the National Research Council's (NRC) 1983 report on risk assessment; (2) the NRC's 1994 risk assessment report; and (3) the Presidential/Congressional Commission on Risk Assessment and Risk Management's (CRARM) 1997 report. The 1983 NRC report, entitled *Risk Assessment in the Federal Government: Managing the Process*, describes the four-step paradigm for risk assessment that continues to serve as EPA's model for human health risk assessments. In a follow-up report entitled *Science and Judgment in Risk Assessment* mandated by the 1990 CAA Amendments, the NRC observed that several themes were common to all elements of the risk assessment process and noted that these themes were usually the focal points for criticisms of specific risk assessments. The NRC's discussion of these points and their recommendations in the different areas were viewed as a way to increase the effectiveness and accuracy of the risk assessment process. This Report describes EPA methods and strategies, which have incorporated many of their suggestions. The third document, the 1997 CRARM report, builds on the methods presented in these NRC reports. Section 303 of the CAA Amendments of 1990 mandated formation of the CRARM in response

to unresolved questions about the approach EPA should take in determining whether significant risks to human health remain after the implementation of technology-based HAP emission controls under CAA section 112. The CRARM's framework fosters an integrated approach to addressing complex, real-world issues that affect more than one environmental medium and involve exposures to mixtures of chemicals.

Ecological risk assessment at EPA began in the 1970s primarily in two program areas, water quality and pesticide registration. In 1986, the Agency published standardized guidelines for deriving water quality criteria and separate standard evaluation procedures for estimating pesticides' effects. By the late 1980s, EPA recognized a need for consistency in evaluating ecological risks across program offices and a need to make its ecological research efforts more responsive to its risk assessment needs Agency-wide. In 1992, the Agency's Risk Assessment Forum published the *Framework for Ecological Risk Assessment,* which could accommodate all the diverse kinds of ecological risk assessments. Various Agency-wide efforts to improve ecological risk assessment have followed. In 1998, EPA issued *Guidelines for Ecological Risk Assessment*, which are the basis of the residual risk approach to ecological risk assessment.

The following text box summarizes the components of EPA's current risk assessment methodology. The 1998 ecological risk assessment guidelines present a general three-phase framework (problem formulation, analysis, and risk characterization) that is consistent with and also appropriate for human health risk assessment. The traditional human health risk assessment paradigm (described by NRC in 1983) includes components of the analysis and characterization phases of risk assessment. Because the problem formulation phase is appropriate for both ecological and human health risk assessment, the Agency will use the three-phase framework (inclusive of the NRC paradigm components) in both human health and ecological risk assessments performed for residual risk analysis of air toxics. Consistent with the CRARM and NRC reports and with risk assessment practices throughout the Agency, the risk assessment process for residual risk analyses includes the use of screening-level analyses, as appropriate, and additional analysis, when warranted, using more refined data and/or tools.

In addition to the improvements and refinements in risk assessment methods and guidance since the 1983 NRC report, there have been significant enhancements in the available data and tools for conducting risk assessments on air toxics. As knowledge has improved regarding the toxicology of environmental pollutants, EPA has responded by modifying assessment methods (e.g., the proposed revisions to EPA's carcinogen risk assessment guidelines). The development and revision of EPA human health risk assessment guidelines are shown in the text box below.

The number of hazardous air pollutants for which EPA has developed quantitative dose-response assessments for use in risk assessment has also substantially increased. However, as EPA's coverage does not yet include all 188 HAPs, residual risk assessment activities will

FRAMEWORKS FOR RISK ASSESSMENT

The NRC risk assessment paradigm, first described in 1983, consists of four steps.

- **Hazard Identification.** The first step in a risk assessment is to determine whether the pollutants of concern can be causally linked to the health effects in question (cancer and/or non-cancer). Factors such as the route of exposure, the type and quality of the effects, the biological plausibility of findings, the consistency of findings across studies, and the potential for bioaccumulation all contribute to the strength of the hazard identification statement.

- **Dose-response Assessment.** This step is the quantitative characterization of the relationship between the concentration, exposure, or dose of a pollutant and the resultant health effects. When adequate data exist, the typical end product of the dose-response assessment for non-cancer effects is the identification of a sub-threshold dose or exposure level that humans could experience daily for a lifetime without appreciable probability of ill effect. Sub-threshold short-term exposure levels are also under development. For cancer, the typical goal of this step is estimation of a full dose-response curve for low exposures.

- **Exposure Assessment.** EPA's current *Guidelines for Exposure Assessment*, published in 1992, provide the framework for this step. An exposure assessment for air toxics has four major components: (1) emissions characterization; (2) environmental fate and transport analysis; (3) characterization of the study population; and (4) exposure characterization for both inhalation and non-inhalation pathways.

- **Risk Characterization.** This step is where all the information from the previous steps is integrated to describe the outcome of the analysis, and where the uncertainty and variability in the results are described. EPA's 1995 *Guidance for Risk Characterization* is the foundation for this step of the process.

EPA's Ecological Risk Assessment Framework, presented in the 1998 Guidelines, describes three phases.

- **Problem Formulation.** In this phase, the problem is defined, the purpose of the risk assessment is articulated, and a plan for characterizing the risks is developed. Important steps include identifying assessment endpoints, developing the conceptual model, and preparing an analysis plan.

- **Analysis.** This phase involves evaluating how exposure to stressors might occur (characterization of exposure) and the relationship between stressor levels and ecological effects (characterization of effects).

- **Risk Characterization.** In this phase, the risk is estimated and described through integration of the exposure and ecological effects profiles generated in the analysis phase.

consider other sources of such information. Regardless of the endpoint of interest (acute or chronic non- cancer, cancer, or ecological effects), consensus toxicity values are preferred for conducting risk assessments. Regardless of the endpoint of interest (acute or chronic non-cancer, cancer, or ecological effects), consensus toxicity values are preferred for conducting risk assessments. For human health risk assessments, the preferred source of such information is the Agency's Integrated Risk Information System. Other Agency and outside sources will be consulted as needed. As assessments for some HAPs may be less current than others, the Agency will evaluate the appropriateness of these assessments in light of more recent credible and relevant information. For ecological risk assessments, a hierarchy of preferred data sources is more difficult to identify and may depend on the type of assessment (e.g., screening versus refined assessment, type of ecosystem at risk). EPA plans to establish data source hierarchies for each type of toxicity information to be used in residual risk assessments, and to continue to improve our ability to assess risks posed by all 188 HAPs.

The Agency's risk assessment tools (e.g., tools for dispersion modeling, exposure modeling, and uncertainty analyses) have also improved. The tools currently available have varying input data requirements and applications. In residual risk assessments, EPA will target the use of these tools such that resources are used most effectively and appropriately. Screening-level analyses will use simpler, less resource intensive tools, enabling the Agency to target use of more refined tools with greater resource needs where most appropriate. As the Agency gains experience and knowledge in air toxics risk assessment, it continues to improve and develop the tools for this area.

EPA HUMAN HEALTH RISK ASSESSMENT GUIDELINES

EPA has published final risk assessment guidelines that address the following areas:

- Mutagenicity (1986)
- Carcinogenicity (1986)
- Chemical mixtures (1986)
- Developmental toxicity (1991)
- Exposure assessment (1992)
- Risk characterization (1995)
- Reproductive toxicity (1996)
- Probabilistic analysis (1997)
- Neurotoxicity (1998)

Draft revisions have been issued for carcinogenicity (1996) and are under development for mixtures.

Other Items in CAA Section 112(f)(1)

Section 112(f)(1), parts (B) through (D), of the CAA lists several other items that this Report should contain in addition to a description of the residual risk assessment methods. These specific items, and EPA's approach to reporting on them, include the following.

Public health significance of risks remaining after application of a MACT standard (section 112(f)(1)(B)): Given the CAA schedule for MACT promulgation and for residual risk determinations, residual risk assessments for source categories have not yet been completed as of the date of this Report, and EPA is not able to report on the actual public health significance of any residual risks at this time. As the Agency completes residual risk assessments for individual source categories, public health significance will be evaluated, and public health information, as available, will be presented. The Agency considers the ample margin of safety concept as introduced in the 1970 CAA Amendments and as applied in the 1989 benzene NESHAP a reasonable approach to evaluate public health significance and to manage residual risks under CAA section 112.

The available methods for and costs of reducing residual risks (section 112(f)(1)(B)): Current controls on major sources, which include State actions and federal requirements in addition to requiring MACT on major sources, do not necessarily guarantee that HAP emissions will be reduced sufficiently to protect public health. EPA believes that methods to reduce emissions beyond MACT exist. However, it is not possible to determine specific methods or to estimate the costs to reduce residual risks because of the timing of this Report in relation to MACT standard implementation and residual risk analyses. The discussion provided in the Report focuses on several key factors that will influence available methods for and costs of reducing residual risk.

The current state of knowledge regarding actual health effects of HAPs on humans (section 112(f)(1)(C)): Very few well-conducted health effects studies have focused on air toxics exposures to populations near sources of HAPs, largely because of methodological and statistical limitations to such studies. For this reason, information on health effects of air toxics is primarily based on laboratory animal and occupational studies. Animal studies are available for many HAPs and provide information on the potential for adverse human effects, but usually evaluate chemicals at higher exposures than normally expected for human populations. In addition, physiology and metabolic pathways that affect responses may differ between animals and humans. Occupational human data provide evidence of human effects, but are often limited by a lack of clarity about actual exposure conditions and the fact that occupational exposures are typically higher than those resulting from the ambient air. Therefore, extrapolation from higher doses to lower environmental concentrations creates uncertainty. This Report presents a summary discussion of epidemiological data, laboratory data, and other study data. It also briefly describes how EPA intends to use these data and any actual source category-specific health effects data that may become available when residual risk assessments are conducted.

EPA's strategy for collecting and assessing epidemiological and actual health effects data (section 112(f)(1)(C)): EPA recognizes the difficulties that exist in obtaining actual health effects data and conducting valid epidemiological studies involving populations near HAP sources. However, EPA believes that it is useful to incorporate any available health effects/epidemiology data in the residual risk assessments and intends to use such data wherever possible in decision-making. In the data gathering stage, EPA will search the scientific literature for published epidemiological studies related to the specific source categories, HAPs, and/or locations studied. Where published epidemiological studies are unavailable, EPA will consider examining other human health data for evaluation of correlations between exposure and adverse human health effects. However, EPA expects that such data will rarely be available.

Assessing risks of background concentrations (section 112(f)(1)(C)): Background concentrations are defined generally as the levels of contaminants that would be present in the absence of source-related contaminant releases. Background concentrations come from either contaminants that may occur naturally in the environment or contaminants that are emitted by other (i.e., not the sources being assessed) anthropogenic sources. Narrowly defined for HAPs and the residual risk program, background concentrations are the levels of HAPs in environmental media that are attributable to natural and anthropogenic sources other than the source(s) under evaluation. At this date, EPA does not have comprehensive Agency-wide guidance or policies on incorporating background concentrations into risk assessments and risk management decisions. Furthermore, analyses of background concentrations and risks can be extremely data- and resource-intensive. EPA's general approach in previous risk assessments and risk management decisions has been to assess the incremental risk of a particular source or activity and compare that risk to an acceptable risk criterion. The residual risk program will continue to use this approach, although background concentrations may be considered in the more refined analyses for some source categories.

Uncertainty and variability in the estimation of residual risks (section 112(f)(1)(C)): The Agency recognizes and supports recommendations of NRC regarding evaluation of uncertainty and variability in risk assessment. As feasible and appropriate, EPA will follow these recommendations. The Agency has published several guidance documents addressing this issue, which will be used to guide our analysis. While the exact approach to be taken has not been finalized and may differ from source category to source category, a number of general approaches will be considered for addressing uncertainty and variability in residual risk assessments, including: (1) qualitative assessment; (2) multi-scenario approaches and limited sensitivity analysis; (3) systematic sensitivity analysis; and (4) Monte Carlo simulation and related probabilistic methods.

Negative health or environmental consequences to the community of efforts to reduce residual risks (section 112(f)(1)(C)): EPA recognizes the possibility of creating or transferring risks as an unintended by-product of actions that may be taken to reduce residual risks of HAPs. EPA intends, as part of the section 112(f) standard-setting process, to the extent feasible, to identify potential negative health and environmental consequences and consider the risk-risk tradeoffs associated with any standards established under the residual risk program. Where deemed necessary, EPA will conduct analyses of these tradeoffs at an appropriate level of detail.

Recommendations to Congress for legislative changes (section 112(f)(1)(D)): At this time, EPA believes that the legislative strategy embodied in the 1990 CAA Amendments provides EPA with adequate authority to address residual risks to public health and the environment and provides a comprehensive and flexible strategy for addressing a variety of air toxics risk concerns. Therefore, the Agency is not recommending any legislative changes.

Framework for Risk Assessment Under the Residual Risk Program

EPA has developed a residual risk assessment framework to implement the requirements of CAA sections 112(f)(2) through (6). Those sections require EPA to promulgate standards beyond MACT when necessary to provide "an ample margin of safety to protect public health" and to "prevent, considering costs, energy, safety, and other relevant factors, an adverse environmental effect." The objectives for residual risk activities under section 112(f)(2) are two-fold:

(1) Assess any risks remaining after MACT standard compliance; and

(2) Set standards for the identified source categories, if additional HAP emission reductions are necessary to provide an ample margin of safety to protect public health or, taking into account cost, energy, safety, and other relevant factors, to prevent an adverse environmental effect.

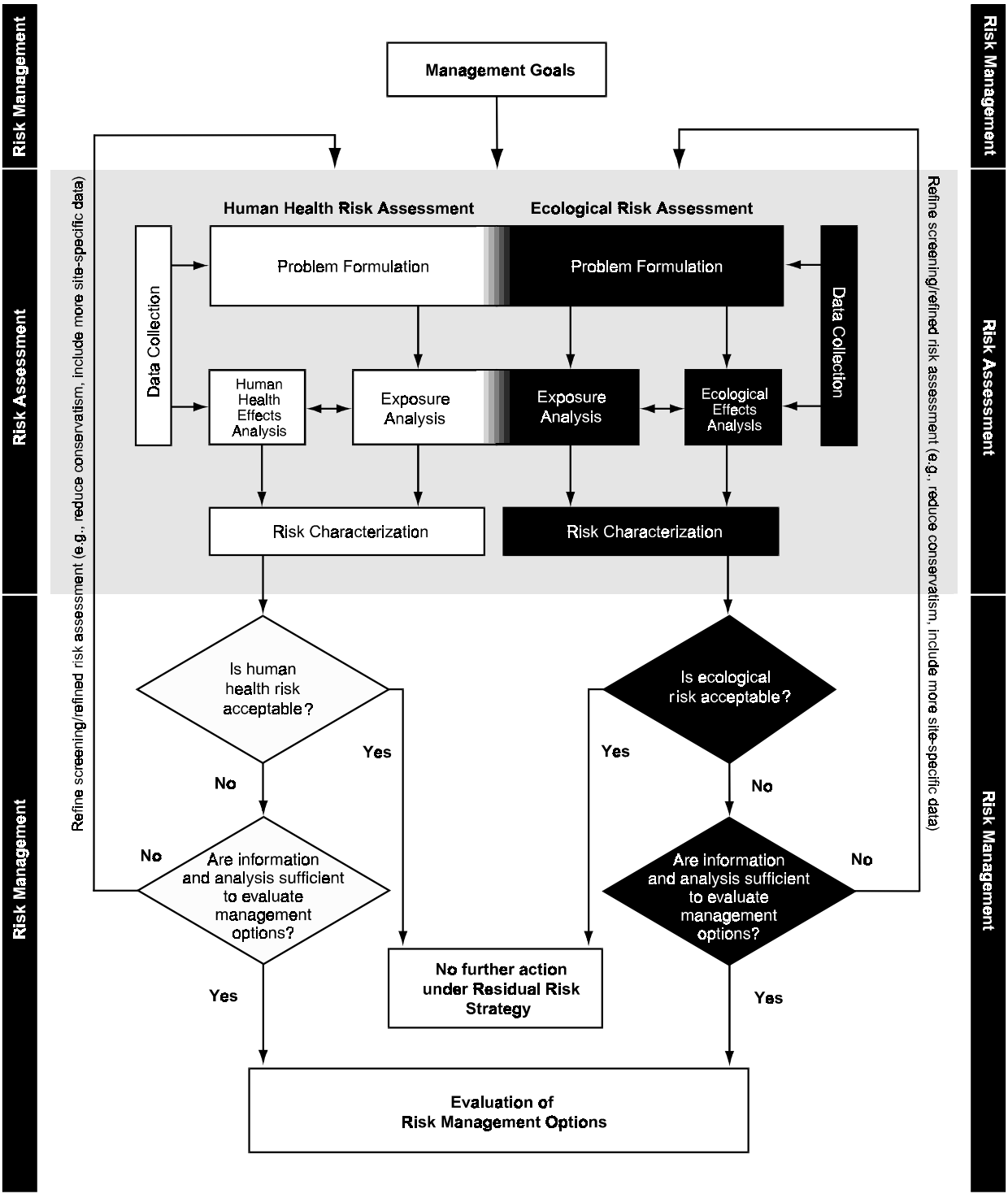
EPA's intent is to implement a residual risk assessment framework that will allow the Agency to be flexible in its decisions while ensuring that public health and the environment are protected. EPA's objectives also include integration of all portions of the federal air toxics program, continuing the partnership with State/local programs in the sharing of data and expertise, and including groups who may be affected by residual risk decisions (e.g., industry, public interest groups) as part of the process.

Using knowledge gained from past risk assessments, information from other regulatory agencies, and guidance from Reports such as the NRC and CRARM reports, the Agency has developed a general framework for assessing residual risks. **Exhibit ES-2** is a flowchart representation of the general residual risk strategy. This strategy calls for an iterative, tiered assessment of the risks to humans and ecological receptors through inhalation and, where appropriate, non-inhalation exposures to HAPs. The first component of the residual risk strategy is a statement of management goals. Those management goals help direct the problem formulation phase of both the human health and ecological risk assessments.

As shown in Exhibit ES-2, each human health and ecological risk assessment is organized into three phases: (1) the problem formulation phase, in which the context and scope of the assessments are specified; (2) the analysis phase, in which the HAPs' toxicity and exposure to humans or ecological receptors are evaluated; and (3) the risk characterization phase, in which the toxicity and exposure analyses are integrated to determine the level of risk that may exist. As illustrated in Exhibit ES-2, the problem formulation and analysis phases of the human health and ecological risk assessments will partially "overlap" in that some pathways of concern for humans (e.g., consumption of contaminated fish) may also be pathways of concern for ecological receptors (e.g., fish-eating wildlife). Consequently, exposure analyses for some HAPs may be designed to provide exposure assessments for both ecological and human health assessments.

In both human health and ecological risk assessments, there is essentially a continuum of possible levels of analysis from the most basic screening approach to the most refined, detailed assessment. The screening level or tier of analysis is designed, through the use of conservative inputs, to identify for no further action or analysis, situations or HAPs for which risks are unlikely to be of concern. Screening tier analyses are designed to be relatively simple, inexpensive, and quick, using existing data, defined decision criteria, and models with simplifying conservative assumptions as inputs. More refined levels of analysis include the refinement of aspects of the analysis that are thought to influence risk most or may contain the greatest uncertainty. At the refined tier, each analysis requires more effort, but produces results that are less uncertain and less conservative (i.e., less likely to overestimate risk). Under residual risk, an assessment will start at the level considered most appropriate upon examination of the available information during the scoping or problem formulation phase; iterations of the assessment, with refinements, will occur when warranted.

EXHIBIT ES-2
OVERVIEW OF RESIDUAL RISK FRAMEWORK
ITERATIVE APPROACH



Risk Management Decision Points

There will be many opportunities throughout the residual risk process for risk managers to make decisions that will determine the direction and scope of these assessments. Initially, EPA plans to set priorities for analyzing the more than 170 source categories based on a number of considerations, including the MACT promulgation dates for source categories (from which the statutory time period for residual risk determinations is measured) and any available information bearing on the relative level of residual risks attributable to various source categories. Following this, the problem formulation phase will determine how each risk assessment will be framed. For example, decisions regarding which HAPs, what exposure pathways, and what level of analysis (early screen or more refined) will be made. Much of the data that will feed these decisions will come from existing data that are easily accessible and determined to be adequate for this step.

The purpose of a screening analysis is to identify those situations or HAPS for which no further action is needed and those for which further analysis is needed. When a subsequent analysis is performed, those aspects of the analysis that are thought to influence risk most or contain the greatest uncertainty are refined. Although the screening analysis can serve as a basis for a decision to eliminate low-risk source categories from further consideration under section 112(f), it is not adequate to serve as a basis for establishing additional emission reduction requirements. The results of a more refined assessment can support either a conclusion of "no further action" or "additional emissions reductions may be needed," and will be used by EPA to make decisions on whether additional emission reductions are needed for individual source categories.

For public health risk management decision-making in the residual risk program, EPA considers the two-step process culminating with an "ample margin of safety" determination, as established in the 1989 benzene NESHAP and endorsed by Congress in the 1990 CAA Amendments as a reasonable approach. In the first step, a "safe" or "acceptable risk" level is established considering all health information including risk estimation uncertainty. As stated in the preamble to the rule for benzene, which is a linear carcinogen (i.e., a carcinogen for which cancer risk is believed or assumed to vary linearly with exposure), "an MIR (maximum individual risk) of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability." In the second step, an emission standard is set that provides an "ample margin of safety" to protect public health, considering all health information including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors including costs, economic impacts, technological feasibility, and any other relevant factors. In notifying the public of the 1989 benzene NESHAP, the Agency stated that it "strives to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million and (2) limiting to no higher than approximately 1 in 10 thousand the estimated risk that a person living near a plant would have."

Thus, the benzene NESHAP established specific risk management policy for the protection of public health with an "ample margin of safety," and provided a specific application for public health risks posed by a linear carcinogen, including some numerical criteria, that will be used in addressing residual risks. Under this risk management policy, EPA is developing risk management framework applications to specifically address non-cancer public health risks and public health risks posed by carcinogens with non-linear risk assumptions. Further, the Agency is also developing a risk management framework to address adverse environmental effects in the residual risk program. None of these framework applications are presented in this Report.

Summary

This Report responds to section 112(f)(1) of the Clean Air Act and contains EPA's general framework for assessing risks to public health or the environment remaining after implementation of emissions standards under 112(d). EPA's risk assessment methods and the corresponding data and tools have developed substantially since the adoption of the 1990 Amendments containing this section. The Agency will apply these improved assessment methods, data, and tools, augmented as appropriate with current information or findings, in assessing the need for standards under section 112(f)(2). The residual risk assessment framework is intended to provide EPA with appropriate flexibility in its analyses and decisions while ensuring that public health and the environment are protected from air toxics as envisioned by Congress in the CAA.

1. Introduction

In 1990, Congress amended section 112 of the Clean Air Act (CAA) and mandated a new approach to the regulation of hazardous air pollutants (HAPs).[1] Under the original CAA (1970), air toxics were addressed through a risk-based program, and emission standards were set for individual pollutants. The new approach first requires the development of technology-based emission standards under section 112(d) for major and, in some cases, area sources of the currently listed 188 HAPs. The statute directs that these standards are to be developed over a 10-year time frame and based on the maximum achievable control technology (MACT). The Environmental Protection Agency (EPA) is currently in the process of developing MACT standards for more than 170 categories of HAP sources. As of October 1998, MACT standards had been promulgated for 53 source categories. When fully implemented, these standards are expected to result in estimated HAP reductions of approximately a million tons per year, plus more than two million tons per year of particulate matter and precursors to ground level ozone.

SECTION 112(f)(1) REPORT REQUIREMENTS

". . . the Administrator shall investigate and report, after consultation with the Surgeon General and after opportunity for public comment, to Congress on:

- Methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under this section after the application of standards under subsection (d) of this section;
- The public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks;
- The actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies, risks presented by background concentrations of hazardous air pollutants, any uncertainties in risk assessment methodology or other health assessment technique, and any negative health or environmental consequences to the community of efforts to reduce such risks; and
- Recommendations as to legislation regarding such remaining risk."

Section 112(f) of the CAA, in addition to requiring this Report to Congress (Report), calls for an evaluation of the health and environmental risks remaining after technology-based standards have been promulgated (i.e., the **residual risks**) and requires more stringent regulation if certain criteria are not met. Specifically, its focus is to achieve a level of protection that protects the public health with an "ample margin of safety" (see Section 2.1 for a discussion of this term) while also ensuring that "taking into consideration costs, energy, safety, and other

[1] The Clean Air Act defines hazardous air pollutant as any air pollutant listed under section 112(b), and also provides procedures for adding and deleting pollutants from the list. The terms "**hazardous air pollutants**," "**HAPs**," and "**air toxics**" are used throughout this Report synonymously to refer to the pollutants listed in the CAA under section 112(b).

relevant factors," residual emissions do not result in "an adverse environmental effect."[2] The accompanying text box outlines the requirements in section 112(f)(1) that this Report addresses.

1.1 Scope of Report

This Report responds to the statutory directives in section 112(f) of the CAA and also provides the general framework of EPA's strategy for assessing residual risk remaining from the HAPs being emitted from source categories subject to MACT standards. This chapter provides a brief introduction and describes the scope and organization of the Report. It presents the specific requirements for the Report listed in CAA section 112(f)(1) and briefly discusses each. Chapter 1 concludes with a discussion of peer review in the context of this Report. Chapter 2 provides a brief legislative and regulatory background on the CAA air toxics program in order to provide context for what follows. The Report then addresses, in Chapters 3 and 4, the required statutory elements of the Report, as shown in the text box on page 1. Chapter 3 provides information on the methods for conducting human and ecological risk assessments for emissions of air toxics, describes the data required, and discusses limitations in the available methods and data. As discussed in Section 3.1, the development of the Agency's risk-based program for air toxics has incorporated input from the National Research Council (NRC), the Commission on Risk Assessment and Risk Management (CRARM), State and local air toxics programs, and a variety of risk assessment policies and guidelines developed (and in some cases under development) by the Agency. Chapter 4 addresses the remaining statutory elements listed in CAA sections 112(f)(1)(B), (C), and (D) in the order listed in the CAA. In Chapter 5, the Report describes the Agency's strategy to conduct residual risk analyses as well as discusses other provisions in sections 112(f)(2) through (6) of the CAA. Appendix A provides the full text of CAA section 112(f), Appendix B provides relevant text from the preamble to the 1989 national emission standard for benzene, Appendix C presents the schedule for promulgation of MACT standards for industry source categories, and Appendix D provides a summary of EPA's responses to the major review comments of its Science Advisory Board (SAB).

The intent of this Report is to address the legislative requirements of section 112(f)(1) and to provide the reader with a basic understanding of the methods and process the Agency plans to follow in conducting risk analyses for air toxics. In response to section 112(f)(1)(A), the Report describes methods for human health and ecological risk assessment of air toxics. For these methods, the current availability and completeness of data or methodology are described along with how analyses will progress given the existing limitations (e.g., assessments will necessarily be limited to those HAPs for which toxicity information is adequate) and data and tool development activities. Methodology is presented in a descriptive manner rather than in

[2] The Clean Air Act at section 112(a)(7) defines adverse environmental effect as any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.

guidance form, with sufficient detail to inform the reader of the Agency's intentions and directions in performing "residual risk" and other air toxics analyses. Indicative of the Agency's desire to conduct analyses consistent with current, scientifically appropriate data and methodology, flexibility and the ability to incorporate changes in methodology and new data are essential to the process.

It is important to note that this Report does not contain the results of any residual risk analyses or a description of potential EPA actions after conducting such analyses (e.g., additional emission reductions for a given source category). The Agency is collecting existing data on source categories for which MACT standards have been promulgated and is beginning to analyze these data consistent with the framework described here.

In addition to risk assessment methods for residual risk, section 112(f)(1) specifies that EPA report on elements related to estimates of residual risk. The following section outlines the presentation of these additional elements within this Report.

Section 112(f)(1)(B)

Public Health Significance. Without having any actual residual risk analyses completed at this time, the Agency cannot draw conclusions about the public health significance of residual risks. However, the Agency considers the "ample margin of safety" concept, discussed in Section 2.1 of this Report, an appropriate basis for determining the significance of and for managing any residual risks for individual source categories. As residual risk assessments are completed for individual source categories, public health information, as available, will be identified along with risk estimates and attendant uncertainties and limitations as part of the risk characterization and decision-making process.

In making regulatory decisions for air toxics thus far, EPA has emphasized consideration of cancer risk to humans. However, air toxics can cause health effects other than cancer. EPA plans to consider non-cancer effects under the residual risk program. Although not available for discussion in this Report, the Agency currently is developing a policy framework for this management issue.

Technologically and Commercially Available Methods and Costs. This Report describes a range of control options for consideration if it is determined that additional control is needed. The Report provides an overview of these options, with an emphasis on pollution prevention (P2) approaches.

Section 112(f)(1)(C)

Acute Health Effects/Epidemiological and Other Health Information. The information available on actual health effects resulting from exposure to air toxics is limited. This Report presents a summary discussion of epidemiological data, laboratory data, and other exposure study data. It also briefly describes how the Agency intends to use these data and any actual source category-specific health effects data that may become available when residual risk assessments are conducted.

Risks Presented by Background Concentrations. This Report discusses general information on assessing risks posed by background levels of HAPs and presents a definition of background concentrations for air toxics and residual risk purposes. It describes approaches used by several EPA programs and includes examples of rules and guidance that consider the issue of background concentrations. It also presents a discussion of the difficulties in addressing background concentrations in residual risk analyses and identifies data needs to assess background. The discussion concludes by describing the Agency's options to analyze and consider background concentrations in residual risk analyses.

Uncertainties. This Report provides a general description of uncertainty in residual risk assessments and how uncertainty affects the level of confidence that can be placed in the estimates of risk. It also briefly presents approaches to addressing uncertainty and variability in the estimation of residual risks.

Negative Health or Environmental Consequences to Communities. In specifying that EPA report on negative health or environmental consequences to communities from efforts to reduce residual risks, section 112(f) indicates the importance of considering such potential consequences of risk management or risk reduction options. Pollution control technologies targeted at a single pollutant (e.g., a specific HAP) and single medium (e.g., air), especially conventional end-of-the-pipe treatment technologies, can inadvertently transfer pollutants and risks to different media, different locations, and different receptors, and can unintentionally create new and different risks in the process of controlling the targeted risk. Thus, as the Agency conducts residual risk analyses and before it takes subsequent standard-setting actions, efforts will be made, as feasible, to identify potential negative health and environmental consequences and to consider the risk-risk tradeoffs associated with any standards established under the residual risk program.

Section 112(f)(1)(D)

Legislative Recommendations. Section 112(f)(1)(D) requires EPA to investigate and report to Congress on "recommendations as to legislation regarding such remaining risk." Thus, if an unacceptable residual risk were identified, and no current authority within the CAA were determined to be adequate to reduce that risk, then the EPA would recommend an approach that

would assure that risk reductions would occur. However, the Agency believes that the regulatory approach embodied in the CAA is adequate for maintaining the goal of protecting the public health and environment, and, therefore, is not recommending any legislative changes.

1.2 Peer Review

The Agency is fully committed to environmental protection that is founded on sound and credible science. Objective, independent peer review of the scientific and technical bases of the Agency's actions is critical to accomplishing the Agency's mission. The Agency's commitment to credible, effective peer review is stated in its Peer Review Policy of June 7, 1994. Full implementation of this policy remains an Agency priority.

Although most of the major references that form the foundation of this Report have undergone (or are currently undergoing) external peer review, EPA requested that the SAB provide an independent evaluation of questions such as whether the Report identified the most relevant and useful methods of assessing risks from stationary sources and whether it properly characterized the types of data on which these methods rely. The Residual Risk Subcommittee of the SAB convened its review panel on August 3, 1998 to review the draft Report. Appendix D includes a summary of the Agency's responses to SAB's major comments. This final Report was developed in consideration of both the SAB review comments and the comments received during the public comment period.

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2. Background: Air Toxics Program

In order to understand the mandate of CAA section 112(f) and the purpose behind its charge to EPA, it is helpful to understand the legislative approach used to regulate HAPs in the 1970 CAA Amendments, the subsequent regulatory history in the 1970s and 1980s, and the legislative strategy behind the approach taken by the 1990 CAA Amendments. It is also useful as background to consider State and local air toxics programs and their role in EPA's air toxics program.

2.1 History of the Air Toxics Program: 1970-1990

Congress first required regulations limiting emissions of HAPs in 1970 by including an air toxics provision in the 1970 CAA Amendments. This provision described a health-based program that required EPA to identify and list HAPs based on human health criteria described in the Amendments. The EPA was to then promulgate standards for each pollutant, on a source category-by-source category basis, at a level that would ensure the protection of public health with "an ample margin of safety." After EPA listed a pollutant, regulation was required within a short time.

The EPA produced few air toxics regulations under the program established by the 1970 CAA Amendments. In the 20 years following the enactment of this legislation, EPA identified eight pollutants as HAPs and regulated seven of these. Impediments to regulation included the amount and type of data needed to establish a chemical as a HAP, emissions standards based on what the Agency interpreted to be solely human health effects considerations, extremely short statutory deadlines, and disagreements over how health effects should be assessed. A common theme running through many of these impediments to regulatory action was the lack of a consistent risk management framework with which to make regulatory decisions.

The most significant example of EPA's attempts to regulate HAPs under the 1970 CAA Amendments resulted in a DC Circuit Court decision that would guide the development of EPA's risk management approach for air toxics (Natural Resources Defense Council v. EPA 1987). Natural Resources Defense Council (NRDC) sued EPA on the Agency's attempt to establish a national emission standard for hazardous air pollutants (NESHAP) for vinyl chloride, stating that the Agency improperly used cost in regulating this HAP. The U.S. Court of Appeals for the DC Circuit Court agreed with NRDC, and in its decision presented a two-step framework by which to apply the "ample margin of safety" language: (1) first determine a "safe" or "acceptable risk" level, considering only public health factors, and (2) then set an emission standard that provides an "ample margin of safety" to protect the public health, considering relevant factors in addition to health, such as costs, economic impacts, technical feasibility, uncertainties, and other factors.

The 1989 NESHAP for benzene (EPA 1989a) presented the following risk management framework for cancer risk, which reflects the two-step approach suggested by the court. The benzene rule preamble states that in determining acceptable risk:

> The Administrator believes that an MIR [maximum individual risk] of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in light of the other health risk factors (EPA 1989a).
>
> The EPA believes that the level of the MIR, the distribution of risks in the exposed population, incidence, the science policy assumptions and uncertainties associated with risk measures, and the weight of evidence that a pollutant is harmful to health are all important factors to be considered in the acceptability judgment (EPA 1989a).

The preamble also states that in the second step, where the standard is set with an ample margin of safety:

> EPA strives to provide protection to the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million. In the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors (EPA 1989a).

In the benzene NESHAP, EPA established risk management policy for the protection of public health with an ample margin of safety and provided a specific application for cancer risks such as those posed by benzene. Appendix B provides excerpts of the preamble text from the 1989 benzene NESHAP.

The HAP provisions of the 1970 CAA Amendments were written specifically in terms of public health effects, with no mention of ecological or environmental effects anywhere in section 112. In its original form, CAA section 112(b) directed that NESHAPs be set to provide ". . . an ample margin of safety to protect the public health . . ." In fact, HAPs were defined specifically in terms of human health; section 112(a) of the 1970 CAA defined a HAP as an air pollutant that ". . . may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." Thus, there was no legislative directive to consider environmental effects in regulating HAPs in the pre-1990 air toxics program.

2.2 Strategy For Air Toxics: Post-1990

Recognizing that the "health test" (i.e., the requirement for the protection of public health with an "ample margin of safety") was the most contentious part of section 112 under the 1970 CAA Amendments, Congress shifted the focus from individual pollutants to industrial source categories and developed a phased approach to controlling air toxics emissions in the 1990 CAA Amendments. Congress initially listed 189 HAPs in section 112(b), one of which has since been delisted by EPA (EPA 1996a). As part of the first phase of the new air toxics program, EPA must promulgate national, technology-based emission standards for sources in 174 source categories emitting any of the 188 listed HAPs above specific emission thresholds. The overall approach is to use available control technologies or work practice changes to get emission reductions in a timely manner for as many of the listed HAPs as possible, regardless of a HAP's inherent toxicity and potential risk. This technology-based standards program is commonly referred to as the MACT program.[3] Although there is no health test in this phase, it is intended that effective MACT standards will reduce a majority of the HAP emissions and much of the significant risk. It is expected that this program will reduce adverse environmental effects as well.

The revised air toxics legislative strategy embodied in the 1990 CAA Amendments maintains the goal of protecting the public health and preventing an adverse environmental effect and provides a more complete approach for dealing with a variety of adverse effects. The strategy recognizes that not all problems are national in scope or have a single solution. National emission standards must be promulgated to decrease the emissions of as many HAPs as possible from stationary major sources[4,5] and some area sources,[6] but authority is also provided to look at multiple source exposures in the urban environment and the deposition of HAPs to certain water bodies in order to address those specific concerns. In addition, there are mechanisms for increasing partnerships among EPA, States, and local programs in order to address problems specific to these regional and local environments.

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[3] MACT is defined as the emission standard specified in CAA section 112(d) as requiring the "maximum degree of reduction in emissions of the hazardous air pollutants subject to this section . . . that the Administrator, taking into consideration the cost of achieving such emission reduction, . . . determines is achievable." The MACT for existing sources in a category or subcategory (with at least 30 sources) must not be less than the average emission level achieved by the best performing 12 percent of existing sources.

[4] A stationary source is defined in CAA section 112(a)(3) as any building, structure, facility, or installation that emits or may emit any air pollutant.

[5] A major source is defined in CAA section 112(a)(1) as a stationary source (or group of stationary sources located within a contiguous area and under common control) that emits, or has the potential to emit, greater than 10 tons per year of any single HAP or 25 tons per year of any combination of HAPs (see footnote 4) .

[6] An area source is defined in CAA section 112(a)(2) as any stationary source of HAPs that is not a major source (see footnote 5). In the context of CAA sections other than 112, this definition may differ.

The air toxics program developed by the Agency in response to this strategy is multi-faceted. In addition to the implementation of technology-based national emission standards on stationary sources of HAPs (see next section), the program contains several risk-based components. The component that is the subject of this Report (and outlined in a subsection below) involves the assessment of post-MACT residual risks under section 112(f) and the promulgation of emission standards, if necessary "to protect public health, . . . or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect." Another component that emphasizes reduction of air toxics associated public health risks is the integrated Urban Air Toxics Strategy. This strategy, currently in draft form (EPA 1998a), emphasizes the need to address risks from the cumulative emissions of HAPs from multiple sources and source types, particularly area and mobile sources. The urban strategy seeks to combine the complementary authorities of sections 112(k) and 202(l), and other CAA authorities including 112(f), with State and local authorities to provide a sound basis for the protection of public health from risks posed by area, major, or mobile sources in individual urban areas.

In summary, the 1990 CAA Amendments developed a comprehensive strategy that, when taken as a whole, provides EPA with the flexibility to address a wide range of air toxics problems. The provisions of this strategy describe the approaches for identifying the nature and scope of the problem and provide a diversity of authorities for protecting public health and the environment while managing the identified risk in a cost-effective way.

Emissions Control Under MACT – CAA Section 112(d)

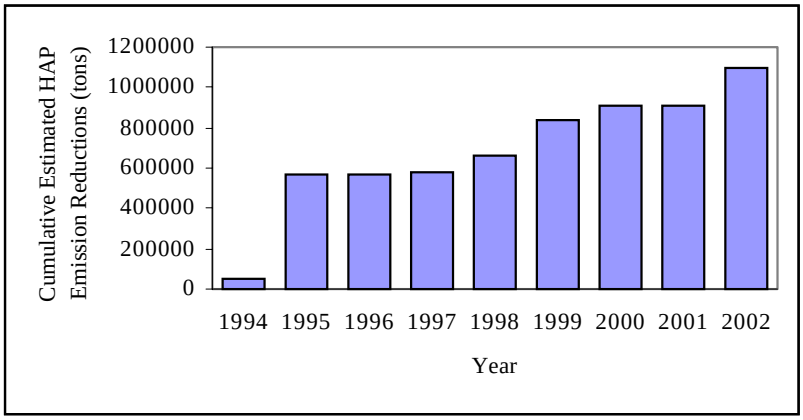
The 1990 CAA Amendments greatly expanded the number of industries that will be affected by national air toxics emission controls; the emission reductions from these controls are just beginning to be realized. Major sources of HAPs, which include large industrial complexes such as chemical plants, oil refineries, marine tank vessel loading operations, aerospace manufacturers, steel mills, and a number of surface coating operations, are some of the sources being controlled for toxic air pollution. Where warranted, smaller sources (area sources) of air toxics such as dry cleaning operations, solvent cleaning activities, commercial sterilizers, secondary lead smelters, and chromium electroplating facilities are also controlled. Within the next six years, EPA estimates that emission standards set under section 112(d) will reduce emissions of toxic air pollutants by well over 1.5 million tons per year.

Regulation of air toxics emissions through the section 112(d) process is beginning to achieve substantial emission reductions of HAPs. The MACT regulations are also resulting in substantial co-control of criteria air pollutants.[7] Appendix C shows a complete list of the section 112 source categories, along with the status of the MACT standard and compliance dates. As of October 1998, 53 source categories have been subjected to standards under section 112. With

[7] Criteria air pollutants are defined as air pollutants for which national ambient air quality standards (NAAQS) have been established under the CAA; at present, the six criteria air pollutants are particulate matter, ozone, carbon monoxide, nitrogen oxides (NO_x), sulfur dioxide, and lead.

some exceptions, sources must comply with the MACT regulations within three years of the effective date of the regulation. **Exhibit 1** shows that the estimate of cumulative reductions expected to be achieved by 2002 with the standards for these 53 source categories is approximately 1,100,000 tons of HAPs per year.[8] Additionally, these regulations will result in estimated emission reductions of approximately 2,500,000 tons per year of particulate matter (a criteria pollutant) and volatile organic compounds (VOCs), a class of ozone precursor.

EXHIBIT 1
PROJECTED ANNUAL CUMULATIVE HAP EMISSION REDUCTIONS



Special Areas of Evaluation

As part of the second phase of the program outlined in the 1990 CAA Amendments, EPA is to conduct specific studies to assess the potential for adverse effects and, if necessary, take action to reduce the potential for these effects. These studies include (but are not limited to) the *Mercury Study Report to Congress* (EPA 1997a), the Great Waters Studies (EPA 1994a, EPA 1997b), and the Utilities Study (EPA 1998b).

In response to CAA section 112(n)(1)(B), the Mercury Study provides an assessment of the magnitude of U.S. mercury emissions by source, the health and environmental implications of these emissions, and the availability and cost of control technologies. Given the continuously and rapidly evolving state-of-the-science for mercury, this Study is considered a "snapshot" of EPA's understanding at the time and identifies research needed to reduce the scientific uncertainty in a number of important areas.

In the Great Waters component of the air toxics program (CAA section 112(m)), the Agency provides Reports to Congress, at biennial intervals, on the atmospheric deposition of

[8] Based on emission reductions as reported in promulgated NESHAPs; see Appendix C: Schedule for Source Category MACT Standards for *Federal Register* citations.

pollutants to the Great Lakes, Chesapeake Bay, Lake Champlain, and certain coastal waters (the "Great Waters"). In cooperation with the National Oceanic and Atmospheric Administration, EPA conducts a program to evaluate the extent of atmospheric deposition of HAPs (and a few other air pollutants) to these waters, investigate sources and deposition rates, and evaluate any adverse effects to public health or the environment caused by such deposition. Research and monitoring are a large part of this program, and the results are summarized in the biennial Reports. In addition, the Reports describe any changes to federal law that have been identified as necessary to protect human health and the environment.

In CAA section 112(n)(1)(A), the Agency was directed to perform a study of "hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units" of HAPs after imposition of CAA-required controls. In the Utilities Study, HAP emissions test data from a range of utility units (i.e., boilers) along with facility-specific information was used to estimate HAP emissions for all 684 utility plants in the U.S. The risks of priority HAPs and potential control strategies were analyzed and reported. On the basis of this Study and other information, EPA will determine the need to regulate HAP emissions from the electric utility industry under section 112.

Urban Air Toxics Strategy

In recognition that emissions of HAPs from area sources (sources emitting lesser amounts of HAPs than major sources) may "individually, or in the aggregate, present significant risks to public health in urban areas," section 112(k) directs EPA to develop a strategy aimed at reducing such emissions and associated public health risks. The strategy, published in draft form in September 1998 (EPA 1998a), will build on the substantial emission reductions EPA, State, and local governments have already achieved. EPA's MACT-required emission reductions are described in a previous subsection. The Agency also has substantially reduced air toxics emissions through mandated controls on municipal waste combustors, as well as fuel and emission standards for cars and trucks.

The CAA, under section 112(k), requires EPA to develop a strategy for reducing urban air toxics with a focus on stationary sources, including a specific emphasis on area sources. Additionally, under CAA section 202(l), EPA is directed to study the need for and feasibility of controlling emissions of toxics from motor vehicles, focusing on emissions that pose the greatest risk to human health, and, based on this study, to promulgate fuel or vehicle standards. Recognizing the overlapping problems these programs are intended to address, the Agency is evaluting an integrated approach.

Consistent with the requirements of section 112(k), the final strategy will identify a list of at least 30 HAPs that EPA believes pose the greatest threat to public health in urban areas. It will also identify area source categories that are or will be listed under section 112(c) and potentially subject to regulation under section 112(d). Additionally, the strategy will contain a schedule of specific actions to reduce public health risks posed by hazardous air pollutants. These activities will rely on the appropriate regulatory tools implemented by EPA under the CAA or other

federal environmental statutes or by the States. Following consideration of public comment on the draft, the final *Urban Air Toxics Strategy* is scheduled to be published in June 1999.

Residual Risk

To ensure protection of public health and the environment, the 1990 CAA Amendments include section 112(f), which requires a human health risk- and adverse environmental effects-based "needs test" in the second regulatory phase of the air toxics program (see Appendix A for full text of section 112(f)). In this phase, referred to as residual risk standard setting, EPA will consider the need for additional national standards on stationary emission sources following regulation under section 112(d) to protect public health and the environment. Congress directed that such residual risk standards should "provide an ample margin of safety to protect public health."

Section 112(f) also requires EPA to determine whether residual risk standards are necessary to prevent adverse environmental effects, taking into consideration "costs, energy, safety, and other relevant factors" in deciding what level is protective. Adverse environmental effect is defined in section 112(a)(7) as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

In summary, Congress developed a comprehensive strategy that, when taken as a whole, provides EPA with the flexibility to address a wide range of air toxics problems. The provisions of this strategy describe the approaches for identifying the nature and scope of the problem and the mechanisms for involving all concerned parties in discussions. Congress' strategy provides a diversity of authorities for managing the identified risk in a cost-effective way while protecting human and environmental health in the process.

2.3 State and Local Air Toxics Programs

An additional component of risk assessment development has been the emergence of State and local air toxics programs and the interactions that EPA has had with these programs. Prior to passage of the 1990 CAA Amendments, the federal air toxics program progressed slowly. In the absence of a strong federal program, many State and some local agencies began to respond to the air toxics problem by developing their own programs. As a result, many States in the country currently have air toxics control programs in place addressing, at a minimum, new sources of toxic pollutants. Some have their own regulations that allow them to actively control air toxic emissions to a level protective of human health; others rely on comprehensive policies or authority provided to implement the federal program. Some programs are risk-based, while others are technology-based (STAPPA/ALAPCO 1989). State programs may also achieve HAP reductions through regulations developed under CAA section 110 or part D of Title I that control emissions of air pollutants to meet national ambient air quality standards (NAAQS). Various State and local government programs have now been in place for many years and, for some of

the source categories regulated by federal emissions standards under section 112 of the Act, the State or local government programs have likely reduced air toxics emissions and may have succeeded in reducing such emissions to levels at or below those required by the federal MACT standards promulgated under section 112(d).

The State and local programs have focused on three methods for addressing air toxic emissions: (1) ambient air levels; (2) control technology standards; and (3) risk assessment. Over time, many have begun to use combination approaches, such as residual risk assessment, which combines control technology and risk assessment. The main difference between the State/local residual risk assessment approach and the strategy set forth in sections 112(d) and 112(f) of the CAA is one of timing. While the CAA envisions control of HAPs from major sources as a two-step process (MACT followed by residual risk), with the two steps separated in time by as much as nine years, many State and local agencies consider these simultaneously. Both steps are generally completed within the context of a single permit application.

The State and local air toxics programs were invaluable prior to the CAA, and they remain invaluable. The EPA has drawn upon the expertise and experience of State and local agencies to assist in the development of the federal risk program for HAPs. Over the years, more and more State and local air toxics programs have begun to use risk assessment, especially residual risk assessment. In a survey of State and local agencies, conducted in August of 1995, 60 percent of the respondents indicated that their air toxics program was risk-based, and 50 percent of those had residual risk programs addressing both new and existing sources.

Most State and local agencies that are currently using residual risk assessments plan to continue to use them for permitting purposes, so these may be available to EPA as residual risk assessments are prepared on a national basis. The EPA will identify the programs that are currently producing residual risk assessments, the situations in which they are produced, and the type of information contained in the permit applications or accompanying documents in order to add this information to the national residual risk assessment program.

The State and local programs have made progress in addressing the air toxics problem and protecting the health of their people and their environment. A successful residual risk program will be one that integrates the federal program with the State and local programs and strengthens or complements those existing programs. The federal program will need to integrate these existing programs through the interactive sharing of expertise, data, analyses, and methodologies in order to ensure that human health and the environment are protected. Additionally, the State and local authorities may complement the federal program by addressing local risk issues that may not be effectively addressed nationally.

3. Section 112 (f)(1)(A): Methods for Assessing Risks — EPA's General Risk Assessment Approach for Air Toxics

The information presented thus far provides a summary of the legislative and programmatic basis for EPA's air toxics risk assessment process as it exists today. The EPA has refined the process over time using guidance from the reports discussed in Section 3.1, information from and discussions with State, local, and regional air toxics risk assessors, and information and experience gathered from the practical application of risk assessments throughout the Agency. In this chapter, we describe the risk assessment process for air toxics that has developed at EPA. EPA's air toxics program, including residual risk, necessarily will be based on these risk assessment methods, and others that will be developed. The application of these methods to the residual risk assessment process is discussed in Chapter 5. Section 3.1 summarizes the development of human health and ecological risk assessment methods in the federal government and at EPA, Section 3.2 discusses the basic frameworks for risk assessment, Section 3.3 describes how we estimate and characterize exposure, Section 3.4 describes the assessment of human health and environmental effects, and Section 3.5 describes risk characterization.

3.1 Background — Development of Human Health and Ecological Risk Assessment Methods

This section describes some of the history and key events in the development of EPA's air toxics risk assessment methodology, and the general residual risk assessment framework described in this Report. Identifying the nature and scope of the various air toxics problems through data collection, analysis, and mandated studies is an essential step in implementing the post-1990 air toxics strategy. Risk assessment is the primary method to be used in determining the magnitude of potential impacts resulting from continued HAP exposures. In the CAA, Congress included mechanisms that would assist in the development of the residual risk assessment process, including the reports discussed in the next two sections. In developing the air toxics risk assessment methodology, EPA has built on its existing (and continuously evolving) risk assessment policies and guidance, and also has taken into account State and local air toxics risk programs.

3.1.1 National Academy of Sciences Reports of 1983 and 1994

The National Academy of Sciences (NAS) has on several occasions been requested by Congress to evaluate and discuss the processes of risk assessment and risk management. Two of their studies, published in 1983 and 1994, are especially relevant as a foundation for this Report. The emerging practice of risk assessment at EPA and other federal agencies spurred Congress to commission a report from the National Research Council (NRC) of the NAS in the early 1980s. The result was the landmark 1983 study entitled *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983). This report was written at a time when there was an

increasing concern about the risk of cancer resulting from exposure to chemicals in the environment – the fear was that policy might not keep up with the state-of-the-science, which was changing very rapidly in this area.

PURPOSE OF THE 1983 NRC REPORT

The 1983 NRC report was intended to:

- "Explore the intricate relations between science and policy" in the field of risk assessment; and
- "Search for the institutional mechanism that best fosters a constructive partnership between science and government."

The 1983 NRC report recognized the importance of the relationships that exist between science and risk assessment, and between risk assessment and risk management, and undertook the task of clearly defining these relationships. The NRC acknowledged that risk assessment must take full advantage of the available science while maintaining the need to accommodate the various regulatory requirements, and that risk assessment was only one component of the risk management decision process. To define this more clearly, the NRC made a series of recommendations. In general, the NRC recommended the development of specific guidelines for performing risk assessments (at that time, cancer was the main endpoint of concern), that risk assessments developed using the guidelines be reviewed and distributed to the public, and that these risk assessments clearly distinguish the science and policy components from the political, economic, and technical considerations that influence the risk management decisions. This report also provided a description of the health risk assessment paradigm that continues to serve as EPA's model. Partly in response to this report, EPA began a process that continues today of publishing Agency-wide guidelines addressing important areas of risk assessment (see Sections 3.1.3 and 3.1.4).

STEPS INTEGRAL TO RISK ASSESSMENT

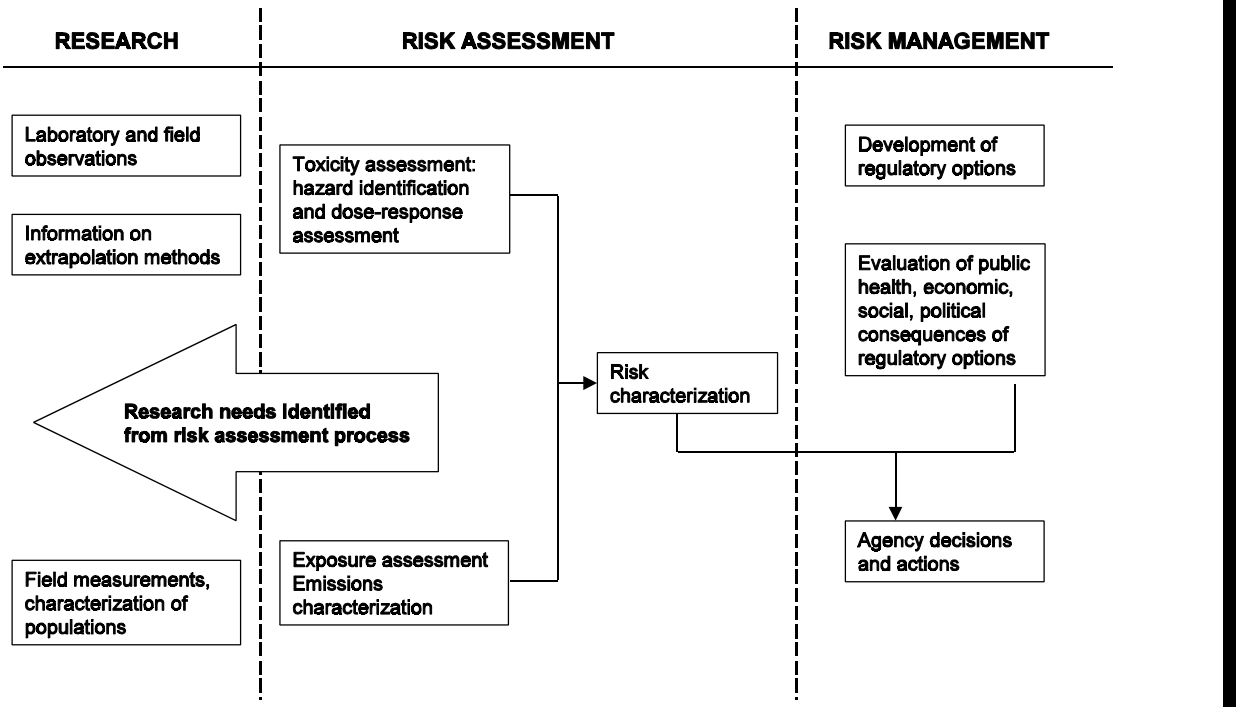
The NRC risk assessment paradigm includes four steps that are integral to any risk assessment (NRC 1983, NRC 1994):

- Hazard identification
- Dose-response assessment
- Exposure assessment
- Risk characterization

The NRC's follow-up report, *Science and Judgment in Risk Assessment* (NRC 1994), mandated by Congress under section 112(o) of the CAA, took a closer look at current risk assessment methods, with a statutorily directed focus on carcinogenic risk. The intent (and mandate) of the report was not to look at EPA's regulatory decisions but the methods used to support those decisions. The NRC committee observed that several themes were common to all elements of the risk assessment process and noted that these themes were usually the focal points for criticisms of specific risk assessments. The themes discussed included the use of default assumptions; the available data; uncertainty and variability; assessment of multiple chemical exposures, multiple routes of exposure, and the potential for multiple adverse effects; and steps taken to validate the methodologies used throughout the risk assessment process. NRC's concerns, discussions, and recommendations were viewed as a way to increase the effectiveness and accuracy of the risk process defined in their 1983 report.

Exhibit 2 shows the risk assessment/risk management paradigm as presented in the 1994 NRC report.

EXHIBIT 2
NRC RISK ASSESSMENT/RISK MANAGEMENT PARADIGM



Source: NRC 1994

The NRC discussed the use of default options in risk assessment, which it defines to be "essentially policy judgments of how to accommodate uncertainties. They include various assumptions that are needed for assessing exposure and risk, such as scaling factors to be used for converting test responses in rodents to estimated responses in humans." Another example of a default option in EPA's cancer risk assessment guidelines is the assumption that cancer risk declines linearly with exposure below the range for which data are available, such that any level of exposure poses some risk. Under current and proposed revisions to these guidelines this assumption is recommended when data are unavailable to support an alternate theory. The NRC concluded that "because of limitations on time, resources, scientific knowledge, and available data, EPA should generally retain its conservative, default-based approach to risk assessment for screening analysis in standard-setting; however, several corrective actions are needed to make the approach more effective." The NRC went on to say:

- EPA should continue to regard the use of default options as a reasonable way to deal with uncertainty about underlying mechanisms in selecting methods and models for use in risk assessment;
- EPA should explicitly identify each use of a default option in risk assessment;
- EPA should clearly state the scientific and policy basis for each default option; and
- The Agency should attempt to give greater formality to its criteria for a departure from default options, in order to give greater guidance to the public and to lessen the possibility of *ad hoc*, undocumented departures from default options that would undercut the scientific credibility of the Agency's risk assessment process. At the same time, the Agency should be aware of the undesirability of having its guidelines evolve into inflexible rules.

The committee recommended that EPA develop and use an iterative approach to health risk assessments to delist source categories and eliminate residual risk. The NRC also proposed a possible iterative approach that will allow for improvements in the default-based approach by improving both models and the data used in each successive iteration of analysis. Furthermore, the committee suggested that EPA present not only point estimates of risk, but also the sources and magnitudes of uncertainty associated with these estimates.

The NRC also discussed how the risk assessment recommendations in its report could be implemented in the context of section 112. Section 112 calls for EPA to regulate HAPs in two stages. In the first, sources would be required to do what is feasible to reduce emissions based on currently available technology. In the second, EPA would set residual risk standards to protect public health with an ample margin of safety if the Agency concluded that implementation of the first stage of standards did not provide such a margin of safety.

The committee indicated that neither the resources nor the scientific data exist to perform a full-scale risk assessment on all the chemicals listed as HAPs and their sources. Therefore, the committee supported an iterative approach to risk assessment of HAPs. This approach would start with relatively inexpensive screening techniques and move to a more resource-intensive level of data-gathering, model construction, and model application as the particular situation warranted. The result would be a process that supports the risk management decisions required by the CAA and that provides incentives for further research, without the need for costly case-by-case evaluations of individual chemicals at every facility in every source category. It also recommended a priority-setting scheme based on initial assessments of each chemical's possible impact on human health and welfare. EPA has been moving, and continues to move, in the directions recommended by this report as it transitions into the risk-based phase of the CAA legislative strategy for HAPs.

3.1.2 CRARM

Section 303 of the 1990 CAA Amendments mandated formation of the CRARM in response to unresolved questions about the approach EPA should take to assessing risks to public

health remaining after implementation of the CAA Amendments' technology-based emission controls. On June 13, 1996, the CRARM released a draft of its report, *Risk Assessment and Risk Management in Regulatory Decision-Making* (CRARM 1996). At the completion of the public comment period, the CRARM announced that it planned to release its final report in two parts. Volume I, released in January 1997, focuses on the framework for environmental health risk management (CRARM 1997a). Volume II, released in March 1997, addresses a variety of technical issues related to risk assessment and risk management, including margin of exposure (MOE), management of residual risks from air toxics, comparative risk, decision criteria, uncertainty analysis, and recommendations to specific agencies (CRARM 1997b).

The CRARM's framework fosters an integrated approach to addressing complex, real-world issues that affect more than one environmental medium and involve exposures to mixtures of chemicals. The CRARM anticipates that its framework will assist Congressional committees and subcommittees, and government agencies (e.g., EPA, DOE), in developing integrated approaches to environmental risk management.

The Commission's Mandate

The Commission's mandate was to investigate "the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various federal laws to prevent cancer and other chronic health effects which may result from exposure to hazardous substances" (CRARM 1996, 1997a, and 1997b). The CRARM's final report indicated that the Commission's mandate included:

- Assessing uses and limitations of risk assessment and economic analysis in regulatory decision-making (e.g., setting emission, ambient, and exposure standards for hazardous substances);
- Considering the most appropriate methods for measuring and describing cancer risks and non-cancer chronic health risks from exposures to hazardous substances;
- Evaluating exposure scenarios for risk characterization (e.g., use of site-specific exposure data in setting emissions standards);
- Determining how to describe and explain uncertainties (e.g., associated with measurement, extrapolation from animal data to humans);
- Discussing approaches to determining the existence of synergistic or antagonistic effects of hazardous substances;
- Enhancing strategies for risk-based management decisions;
- Considering the desirability of developing a consistent standard of acceptable risk across various federal programs;
- Suggesting ways to improve risk management and risk communication;
- Commenting on the conclusions in the NRC report *Science and Judgment in Risk Assessment*; and
- Making recommendations about peer review.

Although the Commission's mandate was limited to "cancer and other chronic human health effects," the group did discuss ecological risk assessment for the following reasons:

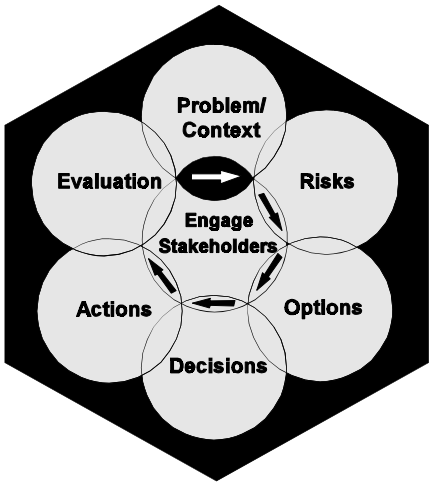
- Human health is related to the health of the environment;
- Principles of health risk assessment are relevant to ecological risk assessment; and
- Economic analyses should not be limited to human health benefits.

The Commission's Report

The final report of the Commission addresses a number of topics, several of which are highlighted below to provide additional context for the residual risk information in this report.

Risk Management Framework. The Commission's framework for environmental health risk management is presented graphically in **Exhibit 3**. The emphasis on stakeholders in this framework is consistent with risk assessment paradigms presented in other recent studies (e.g., NRC 1996). The framework calls for some level of stakeholder involvement during each of the six stages of risk management. In fact, stakeholder collaboration is the central element in the framework. In addition, the framework is designed to be iterative. If appropriate, the risk problem can be redefined and reassessed as new data and new views are found.

EXHIBIT 3
CRARM'S FRAMEWORK FOR RISK MANAGEMENT



Source: CRARM 1997a

Another key principle of the framework is that risk management should explicitly consider the comprehensive real-world context of a risk problem, rather than limit the problem's context to one that considers only one type of risk associated with a single chemical in a single environmental medium. The Commission identified several risk management contexts:

- Multisource context (e.g., the population may be exposed to the same pollutant from sources other than the one in question);
- Multimedia context (e.g., exposure to the pollutant may be occurring from other environmental media);
- Multichemical context (e.g., other pollutants from the same source may pose additional risks); and

- Multirisk context (e.g., the magnitude of risk from one problem may be insignificant compared to similar risks that a population faces from other stressors).

According to the Commission's framework, the relevant contexts for a risk problem are first identified and characterized in the problem/context phase of risk management. These risk contexts are then refined in the risk analysis phase and are addressed in all of the remaining phases of the risk management process.

Comparative Risk Assessment. The CRARM report recommends that federal agencies try a comparative risk analysis approach on an experimental or demonstration basis to seek consensus on priorities for managing environmental risks. The results of such efforts should influence agency resource allocation. The Commission noted that there is wide disagreement on the efficacy of this approach for setting priorities, and that experience shows there is no guarantee that this process will result in consensus among stakeholders, agencies, and funding authorities. However, the Commission also noted that experience shows that the process itself can help to build coalitions that favor priority shifting and shifting resources to identified priorities.

Harmonization of Cancer and Non-cancer Methodologies. The Commission recommended that the assessment techniques for carcinogens and non-carcinogens be harmonized, and discussed the margin-of-exposure and margin-of-protection approaches as ways to do this that would aid in risk communication, risk management decisions and comparative risk assessment. The **margin-of-exposure** approach for expressing risks for carcinogens was recommended as a method which may be more useful for risk managers and stakeholders than the expression of cancer risk in terms of predicted incidence or numbers of deaths per unit population, which can imply an "unwarranted" degree of precision. In EPA's 1996 proposed revisions to the cancer risk assessment guidelines (EPA 1996b), the MOE is defined as the ratio of a specified dose derived from a tumor bioassay, epidemiologic study, or biologic marker study, such as the dose associated with a 10 percent response rate, to an actual or projected human exposure. Lower margins of exposure indicate greater concern. This approach is comparable to the **margin-of-protection** methodology that EPA has used in its "hazard quotient" (HQ) approach for non-cancer risk assessment, which compares an estimated exposure to the estimated acceptable daily intake (ADI), reference dose (RfD), or reference concentration (RfC) value.

Realistic Exposure Scenarios. The report states that risk management decisions should be based on realistic exposure scenarios, rather than on the hypothetical maximum exposed individual (MEI), and supports agencies' recent progress toward this end. It recommends that distributions of population's varied exposures be evaluated with explicit attention to segments of the population with unusually high exposures. The Commission believes that, where possible, exposure assessments should include information about specific groups: infants, children, pregnant women, low-income groups, and minority group communities with exposures influenced by social or cultural practices.

Cost-benefit Analysis. The Commission supports the use of economic analysis as a consideration in risk management decisions, but not as the overriding factor in a decision. The report calls for explicit descriptions of assumptions, data sources, sources of uncertainty, and costs across society to be presented in parallel with descriptions associated with risk assessments.

Interagency Consistency. In conducting risk assessments, agencies should coordinate their risk assessment methods and assumptions unless there is a specific statutory requirement for different choices. Scientific disagreements should be explained.

Residual Risk Recommendations of the Commission

The Commission recommended a tiered approach, which is summarized in **Exhibit 4**, to manage residual risks of section 112 CAA HAPs after implementation of the CAA's technology-based (MACT) standards. Specifically, CRARM proposed that EPA develop their approach in accordance with the five recommendations:

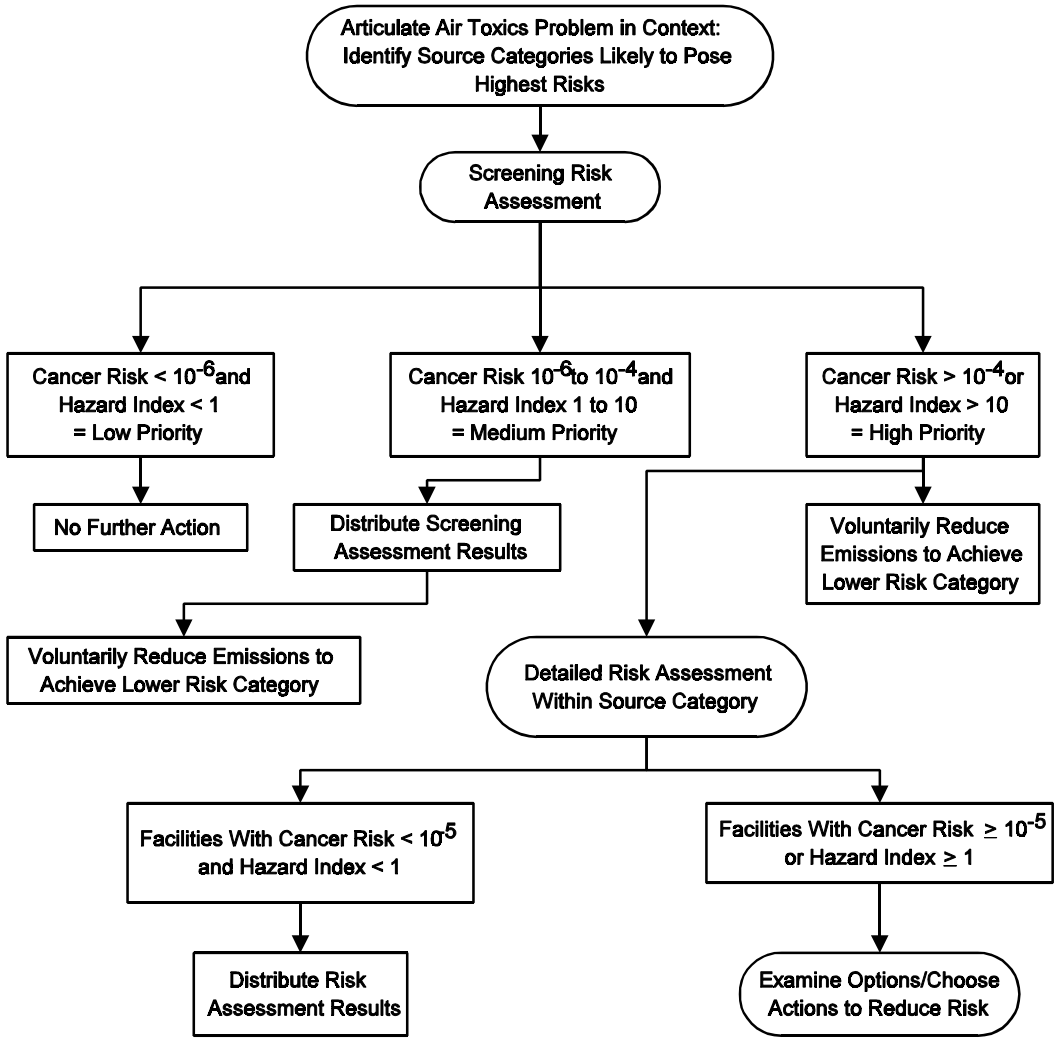
(1) Characterize and articulate the scope of the national, regional, and local air toxics problems and their public health and environmental contexts;
(2) Use available data and default assumptions to perform screening-level risk assessments to identify sources with the highest apparent risks;
(3) Conduct more detailed assessments of sources and facilities with the highest risks, providing guidance and incentives to regulated parties to either conduct these risk assessments or reduce emissions to below screening thresholds;
(4) At facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or that have exposure concentrations greater than reference standards, examine and choose risk reduction options in light of total facility risks and public health context; and
(5) Consider reduction of residual risks from source categories of lesser priority.

A specific comparison of EPA's residual risk framework with the Commission's recommendations is presented in Section 5.3.7.

3.1.3 Development of Human Health Risk Assessment at EPA

While the first NRC document on risk assessment in the federal government was published in 1983, EPA has used risk assessment techniques since its inception in 1970. Some quantitative analysis of cancer and other risk was performed prior to 1970 by the Food and Drug Administration and the Federal Radiation Council. The EPA built on this knowledge soon after its inception by confronting potential hazards associated with pesticide use. After considering available human and non-human toxicity data, EPA restricted domestic use of DDT and other pesticides, in part due to their cancer risks. It was acknowledged by EPA that regulations such as these needed appropriate scientific basis, and thus information on the cancer risks associated with these pesticides was collected through administrative hearings and testimony. Summary

EXHIBIT 4
CRARM's RESIDUAL RISK RECOMMENDATIONS FOR AIR TOXICS



Source: CRARM 1997b

documents from these hearings were collectively referred to as the "Cancer Principles." Criticisms of these documents, which were inadvertently perceived as a formal Agency cancer risk assessment policy, led to the development of interim guidelines published by EPA in 1976. Three years later, the Interagency Regulatory Liaison Group (a conglomeration of several federal agencies, including EPA) published additional cancer risk assessment guidelines. At about the same time, cancer risk assessment techniques were used by EPA in the regulation of toxic chemicals under the 1976 Toxic Substances Control Act, and by the end of EPA's first decade,

risk assessment techniques were being used to develop water quality criteria for protection of human health. Throughout the 1980s, the use of risk assessment in EPA grew significantly and increasingly covered non-cancer risks in addition to cancer risks. During the 1980s, cancer risk assessment techniques were used in the development of national emission standards for air toxics such as vinyl chloride and benzene.

As the use of risk assessment increased in the 1980s, there was a growing awareness of both the lack of standard guidance for and the inconsistencies in the use of risk assessment at EPA. To address this need, the Agency undertook some administrative reforms and published several key guidelines and other policy documents, particularly during the second half of the decade. In response to the 1983 NRC report discussed in Section 3.1.1, the Agency published *Risk Assessment and Management: Framework for Decision Making* (EPA 1984), designed to address NRC recommendations and help EPA make better and more rapid decisions about environmental toxic chemical problems. Beginning in 1986, EPA has published an influential series of Agency-wide guidelines in the *Federal Register* identifying the recommended methods for assessing human health risks from environmental pollution. These guidelines (see text box), which cover both cancer and non-cancer risks, are not meant to be static but may be revised as new information and methods become available. EPA's use and development of human health risk assessment has continued to grow through the 1980s and 1990s with establishment of the Integrated Risk Information System (IRIS) toxicity data base, the repository of Agency consensus non-cancer RfDs and RfCs and cancer assessments.

EPA HUMAN HEALTH RISK ASSESSMENT GUIDELINES

EPA has published final risk assessment guidelines that address the following areas:

- Mutagenicity (EPA 1986a)
- Carcinogenicity (EPA 1986b)
- Chemical mixtures (EPA 1986c)
- Developmental toxicity (EPA 1991)
- Exposure assessment (EPA 1992a)
- Risk characterization (EPA 1995a)
- Reproductive toxicity (EPA 1996c)
- Probabilistic analysis (EPA 1997c)
- Neurotoxicity (EPA 1998c)

Draft revisions have been issued for carcinogenicity (EPA 1996b) and are under development for mixtures (EPA 1997d).

Since 1996, EPA has published draft revisions to its carcinogenicity guidelines (EPA 1996b) and is developing revisions to its mixtures guidelines (EPA 1997d). Revisions made to these guidance documents as a result of increased knowledge are designed to accommodate and reflect recent changes in the state-of-the-science for risk assessment. Some revised guidelines explicitly accommodate the replacement of default assumptions when supported by scientifically sound information (e.g., the 1996 proposed revisions to the cancer risk assessment guidelines). Human health risk assessment techniques embodied in these Agency-wide guidance documents are the foundation of the estimation of residual risks from air toxics under the CAA.

3.1.4 Development of Ecological Risk Assessment at EPA

The development of ecological risk assessment at EPA began in the 1970s primarily in two program areas, water quality and pesticide registration. The 1972 Clean Water Act (CWA) set objectives for eliminating surface water pollution based on receiving water uses of "fishable, swimmable waters." The 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) required that pesticides be evaluated for "any unreasonable adverse effects on the environment." Subsequent legislation for environmental protection resulted in the development of other lines of ecological assessment practices in the late 1970s and in the 1980s, each tailored to the mandates of particular statutes (e.g., the Toxic Substances Control Act).

To meet its statutory mandates and promote consistency among assessments within program areas, EPA began developing program-specific guidelines for ecological assessments in the 1980s. Some of EPA's earliest ecological risk assessments were performed to meet the Agency's CWA mandate. NAS initiated the effort by publishing *Water Quality Criteria 1972* (the "Blue Book") (NAS 1973). In 1976, EPA published *Quality Criteria for Water* (the "Red Book") (EPA 1976). Then, in 1980, EPA published 64 individual ambient water quality criteria (AWQC) documents for pollutants listed as toxic in CWA section 307(a)(1) (EPA 1980). The process for deriving AWQC was formalized in 1986 when EPA published standardized guidelines on this subject (EPA 1986d). The guidelines specified that the criteria provide a "reasonable amount of protection of most species in an balanced healthy aquatic community" (EPA 1986d). For pesticide registration evaluations, EPA developed a framework for evaluating the effects of pesticides on nontarget organisms such as wildlife or aquatic communities and published these standard evaluation procedures in 1986 (EPA 1986e). Efforts to develop and document ecological assessment practices in other EPA program offices followed in the late 1980s (e.g., the *Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual* (EPA 1989b)).

By the mid and late 1980s, EPA recognized a need for consistency in evaluating ecological risks across program offices and a need to make its ecological research efforts more responsive to ecological risk assessment needs Agency-wide. In response, the Office of Research and Development (ORD) began an evaluation of program-specific ecological risk assessment practices and initiated development of guidelines to establish a consistent and scientific basis for assessing ecological risks associated with toxic substances, for use Agency-wide. EPA's Risk Assessment Forum assumed responsibility for the Guidelines in 1990 and initiated three ecological risk guidance projects: (1) a "framework" to describe the basic principles for ecological risk assessment; (2) a set of case studies to illustrate the "state-of-the-practice" in ecological assessments; and (3) a long-range plan for developing specific ecological risk guidelines.

To accommodate the diverse kinds of ecological risk assessments conducted across program offices at EPA, the Agency found it necessary to modify the 1983 NRC paradigm for risk assessment. Most notably, EPA added a problem formulation phase to the beginning of the

ecological risk assessment process. In problem formulation, the scope, context, and ecological values of concern are identified. In 1992, EPA published its *Framework for Ecological Risk Assessment* (EPA 1992b). As the foreword of that document states, "use of the framework ... is not a requirement within EPA, nor is it a regulation of any kind. Rather, it is an interim product that is expected to evolve with use and discussion." As an interim method of providing more detailed guidance for its different program offices, EPA published two volumes of *A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective* (EPA 1993a; EPA 1994b). The case studies are wide-ranging in scope, representing a variety of ecosystems, ecological endpoints, chemical and non-chemical stressors, and programmatic requirements within EPA, and illustrate how the *Framework* could be applied in each case.

As mentioned in Section 3.1.2, the CRARM discussed ecological risk assessment issues specific to air toxics risks and considered EPA's 1990 Framework document in their 1997 report (CRARM 1997a,b). CRARM recommended that EPA guidance include explicit involvement of stakeholders, particularly in the problem formulation stage, as well as a description of how ecological risk assessment measures and models should be selected.

In April 1998, EPA published its *Guidelines for Ecological Risk Assessment* (EPA 1998d), as a counterpart to the existing EPA health risk guidelines. The Guidelines, which expand upon and replace the widely used *Framework for Ecological Risk Assessment* (EPA 1992b), were developed to improve the quality of and consistency among EPA's ecological risk assessments. The guidelines are intentionally broad in scope in order to cover the full range of ecological risk assessment problems and do not provide detailed guidance. In the future, EPA plans to prepare more detailed guidance on specific areas of ecological risk assessment. The content and focus of the guidelines include the following.

- Ecological risk assessment is defined as a process for organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects.

- Ecological risk assessments consist of three primary phases.

    - **Problem formulation** includes identifying goals and assessment endpoints, preparing a conceptual model, and developing an analysis plan. It is a formal process for generating and evaluating preliminary hypotheses about why ecological effects have occurred, or may occur, from human activities (EPA 1998d). It provides a foundation upon which the entire ecological risk assessment depends. However, because problem formulation is inherently interactive and iterative, rather than linear, substantial re-evaluation is expected to occur within and among all products of problem formulation.

    - **Analysis** is the technical stage in which exposure and effects are characterized. Analysis of exposure includes the collection of data on source emissions and their

fate and transport that results in exposure to human or environmental receptors. Effects characterization includes the evaluation of toxicity of these emissions and takes into account any criteria that have been established for these substances.

- **Risk characterization** is the phase in which risks are estimated by integrating the estimates of exposure and effects developed in the analysis phase (e.g., stressor-response profiles) and, of equal importance, are presented in the manner most informative to risk managers. This includes a discussion of the assessment's strengths, limitations, assumptions, and major uncertainties.

- The interaction between risk assessors and risk managers is highlighted. The guidelines emphasize the complementary roles of assessors and managers in determining the scope and boundaries of the assessment and selecting endpoints that will be the focus of the assessment. When the risk characterization is complete, the risk assessor must communicate the risks "in a manner that is clear, transparent, reasonable, and consistent" with Agency risk characterizations of similar scope. The interaction between risk assessors and risk managers is critical to ensure that the results of the assessment can be used to support a management decision.

EPA ECOLOGICAL RISK ASSESSMENT GUIDANCE DOCUMENTS

Since 1990, EPA has published several documents (listed below) intended to improve the quality and consistency of Agency ecological risk assessments.

- *Framework for Ecological Risk Assessment* (EPA 1992b)
- *A Review of Ecological Assessment Case Studies from a Risk Assessment Perspective* (EPA 1993a; EPA 1994b)
- *Guidelines for Ecological Risk Assessment* (EPA 1998d)

The ecological risk assessment framework presented in the Guidelines is shown in **Exhibit 5** and explained in more detail in later sections. In refining environmental risk assessment methods for the air toxics program in general, and residual risk analyses specifically, we will be referring to the framework and general approaches contained in the Guidelines, the companion case study document, and future supplements.

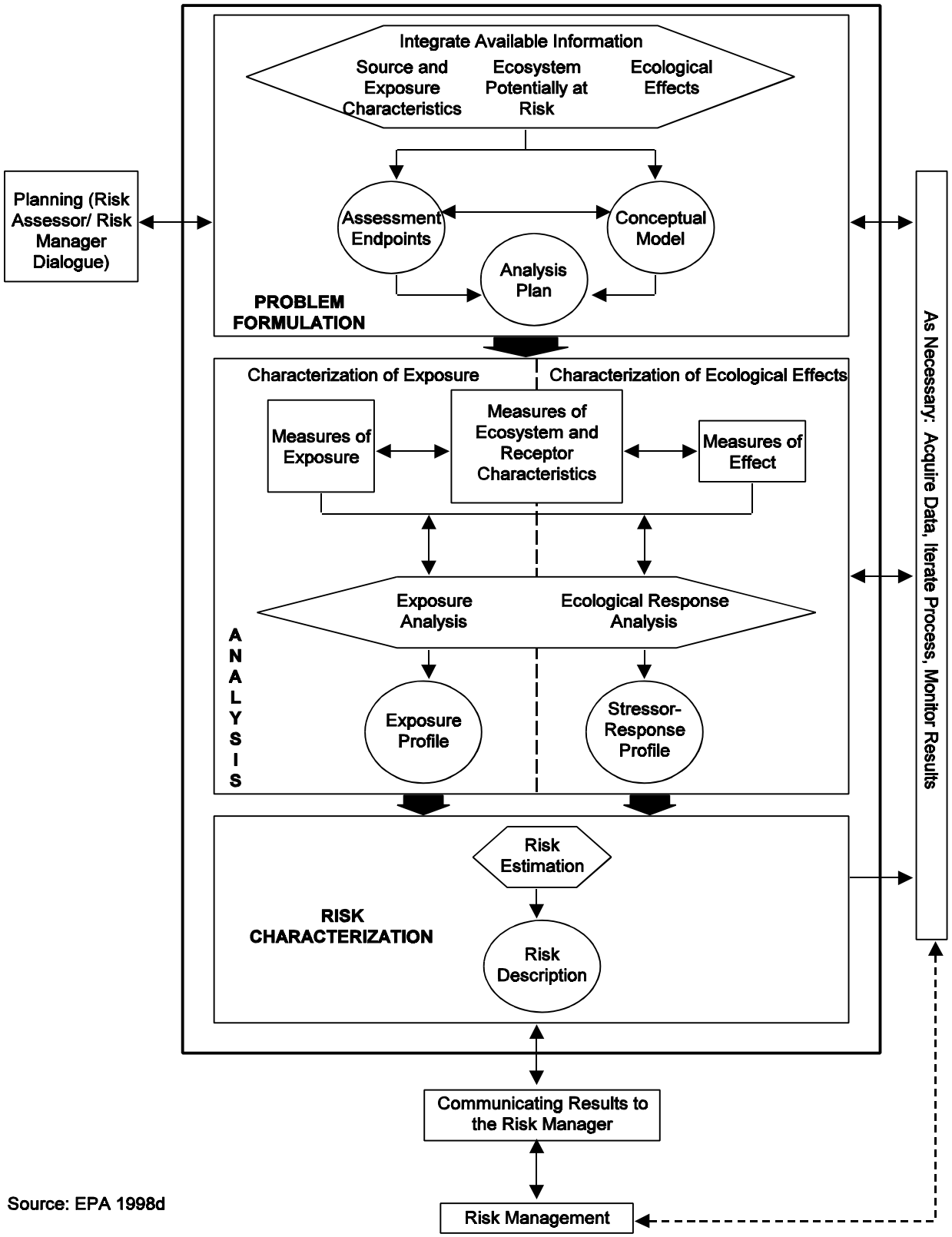
EXAMPLES OF ASSESSMENT ENDPOINTS

- Sustained aquatic community structure, including species composition and relative abundance and trophic structure.
- Sufficient rates of survival, growth, and reproduction to sustain populations of carnivores typical for the area.
- Sustained fishery diversity and abundance.

Source: EPA 1997e

The framework for ecological risk assessment is conceptually similar to the approach used for human health but is distinctive in its emphasis in three areas. First, ecological risk assessment should consider effects beyond those on individuals of a single species, examining effects at a population, community, or ecosystem level. Second, no single set of

EXHIBIT 5
ECOLOGICAL RISK ASSESSMENT FRAMEWORK



Source: EPA 1998d

ecological values to be protected can generally be applied. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. Given these complexities in the ecological risk assessment process, and its more recent history in EPA guidance, the reader is provided here with a description of some of the unique aspects of the problem formulation stage. The problem formulation stage of ecological risk assessment includes the determination of assessment endpoints, a conceptual model, and an analysis plan.

An assessment endpoint is an explicit expression of the "actual environmental value that is to be protected" or is of concern (EPA 1992b), and includes the identification of the ecological entity for the analysis (e.g., a species, ecological resource, habitat type, or community) and the attribute of that entity that is important to protect and that is potentially at risk (e.g., reproductive success, production per unit area, surface area coverage, or biodiversity) (EPA 1998d). A manageable subset of the most important assessment endpoints is selected for the risk assessment, and the measures by which these endpoints will be assessed are also identified. Additional issues important to the identification of assessment endpoints, which will be considered in ecological risk assessments for air toxics, are provided in the *Guidelines for Ecological Risk Assessment* (EPA 1998d).

Appropriate selection of relevant assessment endpoints is critical in order that the risk assessment provide valuable input to the associated risk management decisions. Assessment endpoints that can be measured directly are most effective, although assessment endpoints that cannot be measured directly, but can be represented by measures that are easily monitored or modeled may also be used. Additional uncertainty is introduced depending on the relationship between the measure and the assessment endpoint. Examples of assessment endpoints, measures of effect, and other elements of the problem formulation phase are presented in the text box for EPA's water quality criteria derivation process.

A second component of the problem formulation phase for ecological risk assessment is the development of a conceptual model to describe potential interactions between pollutant emission and the assessment endpoints. The model includes both the relevant risk hypotheses and a diagram which links pollutant emissions, exposure pathways, ecological receptors, and ecological effects. Risk hypotheses are statements that describe possible relationships between emissions of a pollutant, exposure, and assessment endpoint response. They include the information that sets the problem in perspective as well as an identification of the proposed relationships that need evaluation (EPA 1998d). Consequently, conceptual models developed early in the process are intended to be broad in scope and identify as many potential relationships as possible. As more information is incorporated, we assess the plausibility of specific hypotheses and identify the most appropriate risk hypotheses for subsequent evaluation in the analysis phase of the risk assessment. The following examples, one specific and one generic, illustrate risk hypotheses involving the contribution of air pollutants to aquatic ecosystem risks (EPA 1998d).

- Nutrient loadings from septic systems, air pollution, and lawn fertilizers cause eelgrass loss in Waquoit Bay by shading due to algal growth and direct toxicity from nitrogen.

- When a specific chemical (e.g., a HAP) is released to the environment at a specific rate, based on the chemical's K_{ow}, its mode of action, and the food web of the target ecosystem, it will bioaccumulate sufficiently in "X" years to cause developmental problems in receptors of concern (e.g., fish).

Conceptual model diagrams are used, along with the risk hypotheses, to select the pathways to be evaluated in the analysis phase of the ecological risk assessment, as well as to assist in communication with risk managers. There is no set configuration for conceptual model diagrams. **Exhibit 6** is a conceptual model diagram for exposure of piscivorous birds to HAPs.

In preparation for the analysis step, the data and measures to be used in evaluating the risk hypotheses are identified in an analysis plan (EPA 1996d). That is, we identify the ways we will quantify HAP exposure (e.g., incorporating information such as emission rates, dispersion, persistence and partitioning properties) and effects (e.g., survival, growth, reproduction, and community structure). In the analysis plan we also specify how risks will be characterized.

AN EXAMPLE OF ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION: EPA'S WATER QUALITY CRITERIA

A specific example of elements of the problem formulation phase in a national-level ecological risk assessment, as provided in *EPA's Guidelines for Ecological Risk Assessment* (EPA 1998d) can be found in the development of AWQC by EPA's Office of Water under the CWA. Water quality criteria have been developed for the protection of aquatic life from chemical stressors (EPA 1986d). This text box shows how the elements of a water quality criterion correspond to elements of problem formulation, which include management goals, management decisions, assessment endpoints, and measures. These elements of problem formulation support subsequent analyses in the risk assessment.

Regulatory Goal

- CWA, section 101: Protect the chemical, physical, and biological integrity of the Nation's water

Program Management Decisions

- Protect 99% of individuals in 95% of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor

Assessment Endpoints

- Survival of fish, aquatic invertebrate, and algal species under acute exposure
- Survival, growth, and reproduction of fish, aquatic invertebrate, and algal species under chronic exposure

Measures of Effect

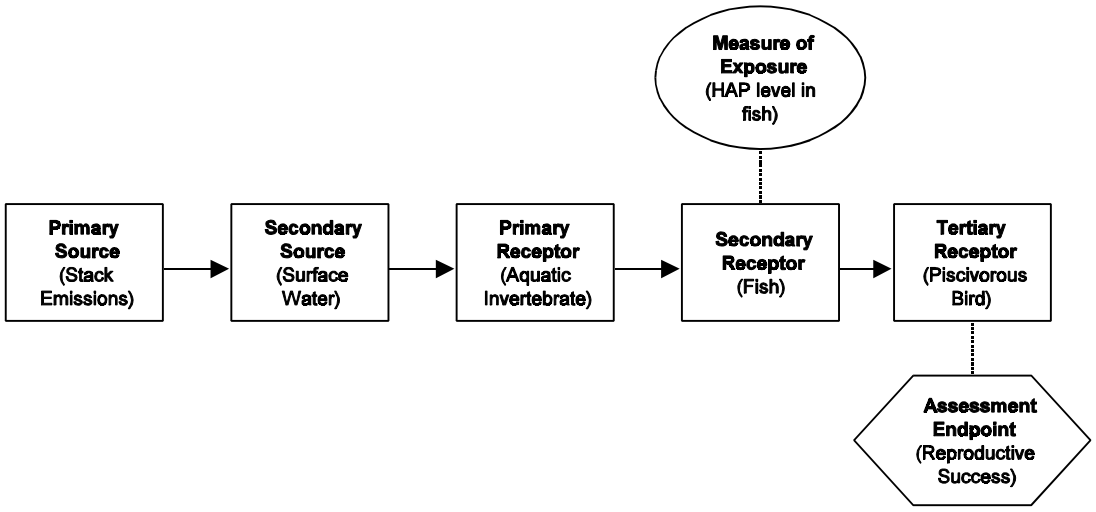
- Laboratory LC_{50}s for at least eight species meeting certain requirements
- Chronic no-observed-adverse-effect levels (NOAELs) for at least three species meeting certain requirements

Measures of Ecosystem and Receptor Characteristics

- Water hardness (for some metals)
- pH

The water quality criterion is a benchmark level derived from a distributional analysis of single-species toxicity data. It is assumed that the species tested adequately represent the composition and sensitivities of species in a natural community (EPA 1986d).

EXHIBIT 6
CONCEPTUAL MODEL DIAGRAM FOR EXPOSURE OF PISCIVOROUS BIRDS TO HAPs



3.2 Framework for Risk Assessment

Using knowledge gained from past risk assessments, information from other regulatory agencies, and guidance from Reports such as the NRC and CRARM reports, the Agency has developed a general framework for assessing residual risks. Consistent with the recently published *Guidelines for Ecological Risk Assessment* (EPA 1998d), and noted in Section 3.1.4, each human health and ecological risk assessment is organized into three phases.

- In the **problem formulation** phase, the content and scope of the assessments are specified. This phase includes identifying goals and assessment endpoints, preparing a conceptual model, and developing an analysis plan.

- The **analysis** phase involves evaluating exposure and effects and the relationship between them.

- **Risk characterization** requires estimating and interpreting risk through integration of the exposure and effects analyses. The risk results are presented in context with the uncertainties and limitations of the analysis and other relevant information.

Current thinking regarding both human health and ecological risk assessments recommends reliance on a tiered or iterative approach, beginning with a simple screening analysis and moving as warranted to a more detailed and resource intensive analyses (NRC 1994; CRARM 1997a,b; EPA 1998d). When the available information precludes the need for screening analysis, it may be omitted. Each assessment includes the three phases.

Three of the four components of the risk assessment paradigm introduced by NAS (as described in Section 3.1.1) – exposure assessment, hazard identification, and dose-response assessment – fall within the analysis phase of risk assessment. The fourth component of the NAS paradigm is the risk characterization. In the NAS paradigm, information from the three types of analysis is combined to yield a characterization of risk.

- The level of exposure being received by people from the pollutant source is estimated in the exposure assessment.

- The type and severity of adverse effects that can be caused by the pollutant are assessed in the hazard identification step of the effects assessment.

- The adverse effects of a pollutant observed at different levels of exposure and the relationship between exposure and effects are considered in the dose-response assessment step of the effects assessment.

The presentation in this chapter of both human health and ecological risk assessment methods is organized into three sections, which parallel the three components of the analysis phase: Exposure Assessment in Section 3.3, Effects Assessment (includes both hazard identification and dose-response assessment) in Section 3.4, and Risk Characterization in Section 3.5.

3.3 Exposure Assessment

The nature and complexity of the exposure assessment is often a function of the particular risk management question (or other purpose) to be addressed. Simple screening analyses, using conservative default assumptions, are appropriate to rule out the need for further analyses or action. On the other hand, a detailed exposure analysis may be needed to determine the necessity for or type of emission controls, particularly when those controls are associated with large economic consequences. In some cases, the critical policy question may be to estimate the risks to a small subset of the population at high exposure levels, whereas in another, the overall risks across the entire nation may be the driving policy question. Either human health or ecological risks may be the main focus of a given exposure assessment. Thus, there is no single "right" way to conduct an exposure assessment.

The initial EPA *Guidelines for Exposure Assessment* were issued on September 24, 1986 (EPA 1986f) and the *Proposed Guidelines for Exposure-related Measurements* on December 2,

1988 (EPA 1988a). In response to recommendations from the EPA Science Advisory Board and the public, the 1986 Guidelines were updated and combined with the 1988 Proposed Guidelines and reissued as the 1992 *Guidelines for Exposure Assessment*, which were published in final form on May 29, 1992 (EPA 1992a). Publication of the 1992 Guidelines made information on the principles, concepts, and methods used by the Agency available to all interested members of the public. The Guidelines establish a broad framework for Agency exposure assessments by describing the general concepts of exposure assessment, including definitions and associated measurement units, and by providing broad guidance on the planning and conduct of an exposure assessment. The Guidelines also provide information on presenting the results of the exposure assessment and characterizing uncertainty. Although the Guidelines focus on exposure of humans to chemical substances, much of the guidance also pertains to assessing ecological exposure to chemicals, or to human exposures to biological, radiological, or other agents.

In the Guidelines, EPA established a specific definition of exposure to minimize ambiguity in the use of terms and units for quantifying exposure (EPA 1992a). Human exposure is defined as contact with a chemical or agent at the visible external boundary of a person, including skin and openings into the body such as mouth and nostrils (but not necessarily contact with exchange boundaries where absorption may take place, such as skin, lung, and gastrointestinal tract). Therefore, an exposure assessment is the quantitative or qualitative evaluation of contact, and includes such characteristics as intensity, frequency, and duration of contact. Often, an assessment also will evaluate the rate and route at which a chemical crosses the external boundary (dose) and the amount absorbed (internal dose). The numerical output of an exposure assessment may be either exposure or dose, depending on the purpose of the evaluation.

Exposure characterization for ecological risk assessment describes potential or actual contact or co-occurrence of air toxics concentrations with ecological receptors. It is based on measures of exposure and ecosystem and receptor characteristics that are used to analyze HAP sources, their distribution in the environment, and the extent and pattern of contact or co-occurrence. The objective is to produce a summary exposure profile that identifies the exposed ecological entity, describes the course a stressor takes from the source to that entity (i.e., the exposure pathway), and describes the intensity and spatial and temporal extent of co-occurrence or contact. The profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur (EPA 1998d).

An exposure assessment has four major components: emissions characterization, environmental fate and transport characterization, characterization of the study population, and exposure characterization. These components are discussed individually in this section.

3.3.1 Emissions (Source) Characterization

In the first step of exposure assessment for air toxics, the specific HAPs emitted and the sources of their airborne emissions are determined. Data are collected on the emission rates of the pollutants and parameters of the source. Knowledge of the emission rate and release characteristics enables the pollutant fate and transport to be estimated.

Ideally, the emission estimates are from direct measurements of source emissions. Although direct measurement is likely to provide the most accurate data for an emission source, these data are typically not available, as such sampling is often time- and resource-intensive. When specific emission measurements are not feasible or available, other emission estimation methods, including material balances and emission factors, are sometimes used as an alternate method. Emission factors indicate the quantity of a pollutant typically released to the atmosphere for a particular source operation, and are usually considered to be representative of an industry or emission type as a whole. Actual emissions from a specific source may be higher or lower or may be comprised of a different set of individual HAPs than the emission factors indicate because of site-specific process design, control equipment, operation and maintenance practices, or other factors. Before using an emission factor, available documentation on how the emission factor was derived should be studied to determine whether it is appropriate for the source under consideration. Each approach to estimating emissions, including use of direct measurement data, has an inherent level of uncertainty, which adds to the overall uncertainty of a risk analysis.

HAPs THAT ARE GROUPS OF CHEMICALS

As described later in Exhibit 19, there are 17 HAPs that represent groups of chemicals rather than individual compounds, substantially complicating the exposure assessment process. In the case of the 12 elements listed (e.g., mercury compounds), obtaining emissions information may be complicated by speciation of the element as well as its combination with other chemicals. As another example, the HAP polycyclic organic matter (POM) is a complex mixture of thousands of polycyclic aromatic compounds. In order to obtain consistent emission estimates for such a complex chemical group, the Agency has identified three representative subgroups for which emissions inventories are usually compiled: (1) 7-PAH includes the seven polynuclear aromatic hydrocarbons that we have identified as probable human carcinogens; (2) 16-PAH includes the 7-PAH group plus nine other commonly measured PAHs; and (3) EOM (extractable organic matter) is the extractable subfraction of particulate matter that some research indicates may provide a better estimate of POM cancer risk than any of the individual PAHs or PAH subgroups.

Source parameters define how the pollutant is released to the environment, and they affect the initial dispersion of the pollutant in the atmosphere. For point sources of air toxics, source parameters can include the volume flow rate or exit velocity of the stack gas, stack gas exit temperature, stack height, inner stack diameter, knowledge of the proximity of structures to the release point, and other characteristics. For small sources within a larger facility (e.g., emissions from storage piles or ponds), the dimensions of the small source should be identified. While point source emission rates are expressed in terms of mass per unit time, non-point source emission rates are more typically modeled in terms of mass per unit time per unit area. Another important consideration in specifying the source emission rates is whether the rates should reflect short-term or annual operating conditions. Ideally, it is better to have hourly or daily emission

rates; however, these data are not typically available. Short-term emission rates provide the flexibility to model emissions over a range of release times, to assess risk over shorter intervals than annual, and to permit more accurate assessments through the incorporation of microenvironment and population activity pattern analyses.

Depending on the analysis, source and emissions data can be derived from broad-scale emission inventories, specific data collection efforts with particular industries, or information from regional, State, or local air toxics agencies. Other information, such as the geographic location of release points, the temporal pattern of emissions (e.g., periodic "puffs" vs. constant emission rates), and the release height may be necessary depending on the level of detail needed or types of exposure examined in the assessment.

Data and Tool Availability, Limitations, and Closing Gaps

In the analyses to be performed under the residual risk program, it is important that the data, regardless of the form in which they are obtained, represent post-MACT emissions (i.e., estimated or measured HAP emissions for a source that has already implemented MACT standards). In collecting the variety of information for each source category (e.g., emissions, source characteristics), there are several data sources we will be consulting:

- EPA's National Toxics Inventory (NTI) (see text box below);
- State or local air toxics agencies;
- Industry;
- EPA's Aerometric Information Retrieval System (AIRS);
- EPA's Toxic Release Inventory (TRI); and
- MACT development data.

While the 1996 and future generations of the NTI are intended to contain facility-specific data and to support site-specific modeling applications, the timing for completion of the 1996 version precludes its use for the initial residual risk analyses. For these analyses, data will be obtained from the same sources (see preceding list) that are being consulted in development of the 1996 NTI. The hierarchy of preference for source data for assessments will be consistent with that established to ensure the rigor of the NTI. For source categories for which the MACT compliance date has not yet occurred, however, a screening risk assessment may be performed based on information compiled by EPA during the MACT rule development process for that source category. Refined analyses will typically rely on the availability of post-MACT emissions data.

3.3.2 Environmental Fate and Transport Characterization

After the pollutants of interest and their sources and emission rates are defined, the exposure assessment process continues with estimation of pollutant fate and transport. This step describes how the pollutant is transported, dispersed, and transformed over the area of interest.

THE NATIONAL TOXICS INVENTORY

In 1995, EPA initiated development of the National Toxics Inventory (NTI), a central repository of air toxics emissions and inventory data for HAPs. Although its development was not explicitly required by the CAA, the NTI is useful in assisting stakeholders in conducting the analyses required by the Act. The NTI is updated every three years, on the same schedule as the criteria air pollutant inventories.

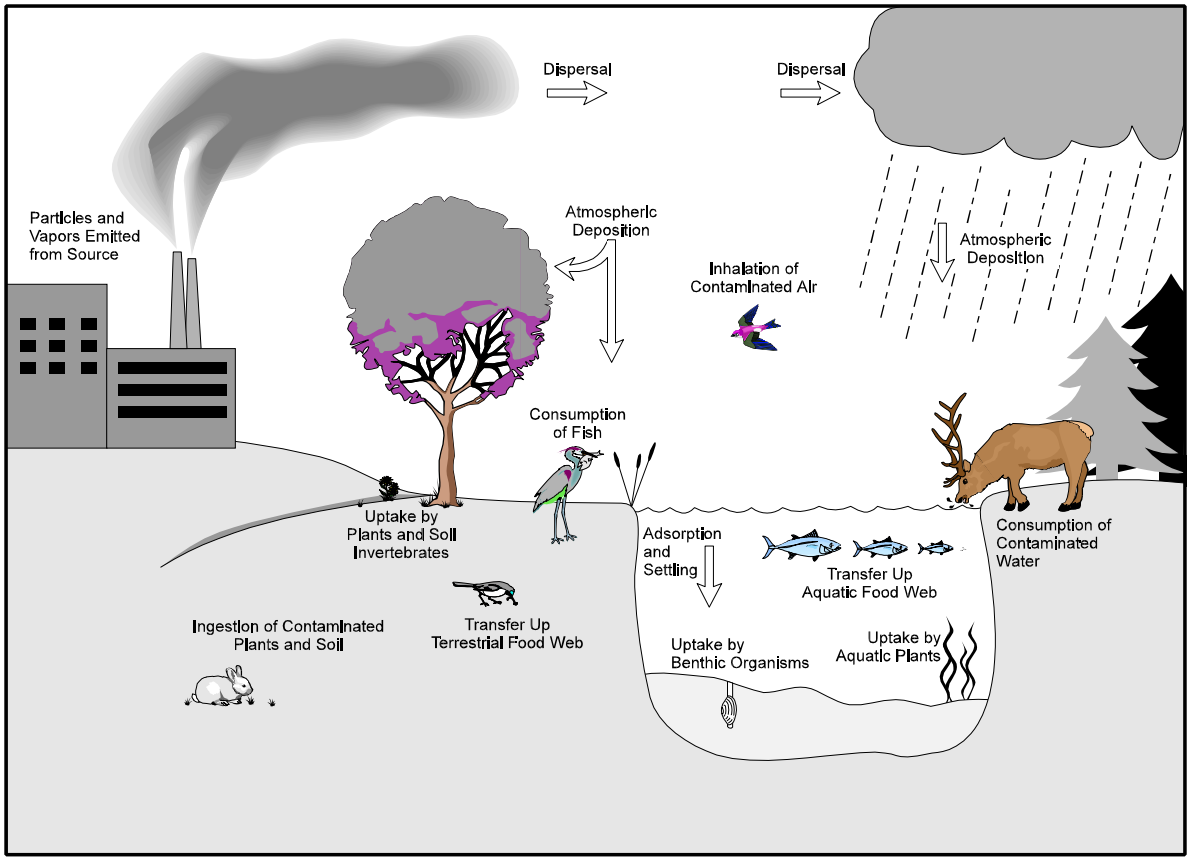
The goal of the NTI is to compile the best available emissions information about the 188 HAPs for many of approximately 960 source categories. The data are from multiple data sources, which we have prioritized to provide the most complete, consistent data repository. The hierarchy of data sources is: (1) data developed by State and local air agencies; (2) data we collected and developed as part of the MACT development process; (3) data from inventories developed to support requirements of section 112(c)(6) and 112(k); (4) emissions reported in the TRI; and (5) emissions generated by the Agency using widely recognized emission factors and activity factors. We have recently compiled the NTI for 1993 and are currently compiling the 1996 inventory, which following review by States is scheduled for completion in October 1999. (For more information on the NTI, see EPA's 1997 Trends Report (EPA 1999).)

Initially, the fate of the emitted pollutants is largely determined by the source release characteristics. After pollutants are released to the atmosphere, their transport, dispersion, and transformation are governed by meteorological principles, terrain characteristics, wet and dry deposition rates, and certain chemical properties of the HAP (such as aqueous solubility, vapor pressure, air-water partition coefficient (i.e., Henry's Law constant), molecular diffusivity, phase partition coefficient, melting point, and adsorptivity). For a limited subset of HAPs, it is important to consider deposition from air to soil, vegetation, or waterbodies. For others, such deposition is not important.

A variety of mathematical models, each with specific data needs, has been developed or is under development to describe the transport and fate of pollutants released to the atmosphere. The model chosen must be appropriate for the intended application, which may vary among estimates of short-term peak concentrations immediately adjacent to a facility, long-term concentrations over a city-wide area, or deposition over hundreds or even thousands of miles. The HAP's reactivity and persistence will influence its fate as well and can be important factors in estimating exposure for certain pollutants. Additionally, secondary transformation products of some HAPs may need to be identified for consideration in risk assessment. High quality, representative meteorological information is crucial to a valid exposure assessment for air toxics, as well as information on local topography. Any available HAP monitoring data can be used either to check the validity of modeled concentration estimates or as a primary or supplemental source of information for the exposure assessment itself.

Many studies indicate that a limited number of pollutants emitted into the atmosphere (e.g., mercury) are passed to humans or wildlife through non-inhalation pathways (EPA 1990). An example would be a HAP depositing from the air onto the soil, followed by ingestion of the soil by a child or by biota in an ecosystem. **Exhibit 7** is an example of the conceptual model diagram for an ecological risk scenario involving multipathway exposure to HAPs. For a limited subset of HAPs, greater human and ecological exposures to the HAP occur through non-

EXHIBIT 7
CONCEPTUAL MODEL DIAGRAM FOR MULTIPATHWAY EXPOSURE TO AIR TOXICS



inhalation exposures than through inhalation exposures. These HAPs typically are persistent in the environment, have a strong tendency to bioaccumulate, and exhibit moderate to high toxicity.

Data and Tool Availability, Limitations, and Closing Gaps

Modeling. The Agency relies on a variety of models for air dispersion modeling. Tier 1 from *A Tiered Modeling Approach for Assessing the Risks Due to Sources of Hazardous Air Pollutants* (EPA 1992c), SCREEN3 (EPA 1995b), and others (NRC 1994) are available for simpler types of applications and needs. As the applications and needs become more complex, the Industrial Source Complex Short-Term 3 model (ISCST3), a Gaussian plume model, can be used to estimate both short-term peak and long-term average air concentrations and deposition rates (EPA 1995c). In addition, the Agency is working with the scientific community to develop improved dispersion models such as AERMOD (EPA 1998e).

Regardless of the model used in the exposure assessment, it is important to ensure that the averaging time of exposure estimates derived from a modeling exercise are appropriate for the time frame of interest (e.g., short-term acute exposure or long-term chronic exposure). Dispersion models such as ISCST3 are designed to estimate ambient pollutant concentrations on the order of an hour or to run multiple hourly iterations to calculate longer-term averages such as seasonal or annual average concentrations. It should be noted, however, that ISCST3 is designed to calculate ambient pollutant concentrations resulting from an emission source that has an essentially constant release rate over an extended period of time (e.g., over a month or year). Therefore, ambient concentrations that result from intermittent emissions (such as those resulting from an industrial batch process) may not be predicted accurately by this model. Other EPA models can predict short-term concentrations from pulse or intermittent releases. It is also important to note that the type and quality of input data available to the model can affect the accuracy and usefulness of the modeling results (e.g., whether available meteorological data are representative of site conditions, whether emissions estimates are available on an annual or monthly basis, whether the site is in simple or complex terrain).

Various equations and scenarios are available for modeling exposures that occur through routes other than inhalation, and each equation requires the appropriate input data. The simplest multipathway exposure assessments require chemical-specific data (e.g., octanol-water partition coefficient (K_{ow})) to model the partitioning of the chemical in the environment and uptake rates (e.g., 3 liters water/day) to predict intakes. Combining this information yields general predictions of non-inhalation exposure.

The EPA's initial detailed guidance on multipathway exposure assessment methods was issued by ORD in 1990 (EPA 1990), updated a few years later (EPA 1993b), and recently consolidated and updated again (EPA 1997f) . These documents present the Indirect Exposure Model (IEM), which consists of equations and default input values to be used in calculating exposure levels for a set of multimedia, multipathway exposures. The associated equations for such an analysis typically start with atmospheric deposition rates and require additional chemical data and many other input parameters related to the environmental setting and population. For example, modeling pollutant fate and transport through a waterbody requires information such as waterbody location, size, and drainage area for each waterbody being evaluated. As another example, modeling exposure via vegetable consumption involves parameters such as soil type, soil depth, annual rainfall, and vegetable type (e.g., root, leafy). A critical input to these calculations for the location(s) being assessed is the HAP deposition rate (i.e., amount per unit time being deposited from the air to land and/or surface water), which can be estimated using air models such as EPA's ISCST3. The Total Risk Integrated Methodology (TRIM) model, a new multimedia, multipathway exposure model under development by EPA is discussed in a later section.

Monitoring Data. With the exception of monitoring for a limited number of volatile organic HAPs, there is no national ambient air quality monitoring network making routine measurements of air toxics levels. Therefore, ambient data for individual HAPs are limited (both

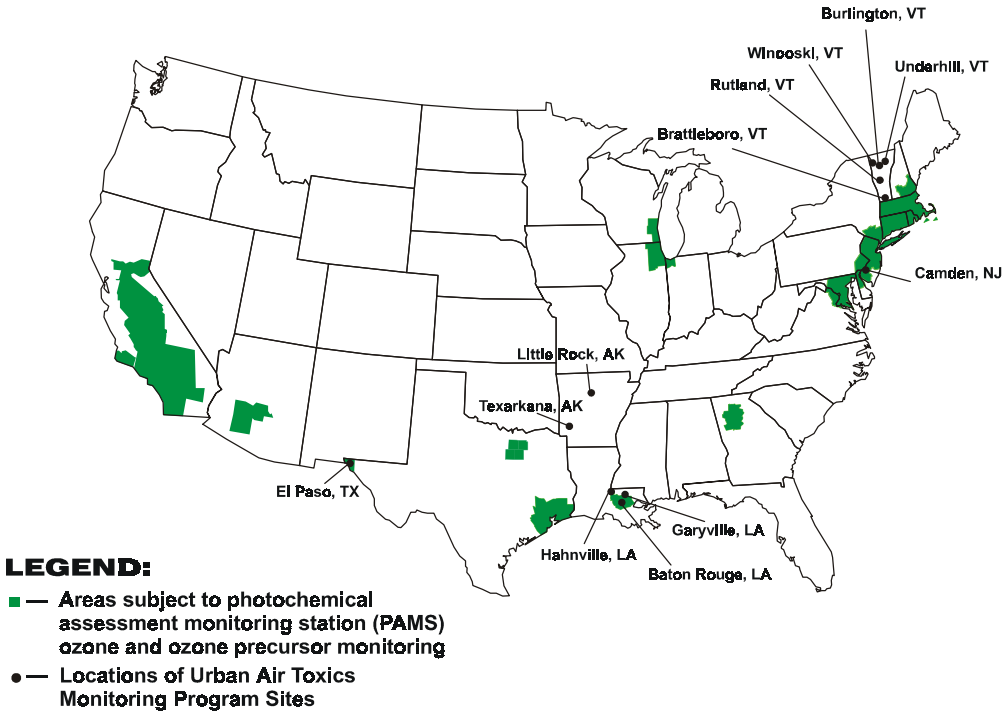
spatially and temporally) in comparison to the data available from the long-term, nationwide monitoring for the six criteria air pollutants. However, several State and local agencies operate independent toxics monitoring programs. For example, the California Air Resources Board has administered a 30-site Toxics Data Network since 1985, and the Texas Natural Resources Conservation Commission initiated a 22-site Community Air Toxics Monitoring Network in 1992. In addition, EPA sponsors the Urban Air Toxics Monitoring Program (UATMP), a "participatory" or voluntary program through which State and local agencies can take part in air toxics monitoring. The UATMP involves measurements of 38 volatile organic compounds and 16 carbonyl compounds; in 1997, the UATMP was comprised of 12 monitoring stations in five States (see **Exhibit 8**).

Although designed primarily as an effort to monitor and characterize ozone precursors, the Photochemical Assessment Monitoring Stations (PAMS) program also includes measurement of several HAPs: acetaldehyde, benzene, ethyl benzene, formaldehyde, hexane, styrene, toluene, 2,2,4-trimethylpentane, and xylenes (m,p,o-xylene). Initiated in February 1993, the PAMS program requires establishment of an enhanced monitoring network in all ozone nonattainment areas classified as serious, severe, or extreme. The 24 affected areas, shown in Exhibit 8, cover approximately 120 thousand square miles and have a total population of 84 million people (approximately 30 percent of the U.S. population). The PAMS program may play a significant role as a foundation for future ambient monitoring for air toxics. Additionally, ambient air quality data for some HAP constituents of particulate matter (e.g., some elements and semi-volatile organic compounds) may be obtained under the current plans for the national $PM_{2.5}$ (fine particulate matter) speciation network.

Without a national mandate for ambient monitoring for air toxics, there is also little incentive for the data from these various programs to be centrally archived. The Agency is attempting to remedy this problem through an ongoing effort to identify all sources of ambient air quality data for toxics. The newly identified data are being compiled into a data base, which is updated on a quarterly basis. Recognizing competing resource needs, EPA is encouraging State and local agencies to tailor their monitoring programs to address their most pressing air toxics issues and local needs. EPA is also requesting that the State and local agencies work with EPA to develop a monitoring network distribution that capitalizes on existing efforts and capabilities. EPA expects to add 17 new monitoring sites to this network in 1999. This will include one new site in the major metropolitan areas of each of the 10 EPA Regions and an additional site in each of the seven areas with existing PAMS networks. EPA expects to increase that number by up to 40 additional sites in 2000.

It should be noted, however, that for the purposes of risk assessments, specifically residual risk assessments, even comprehensive and high quality monitoring data would not be adequate and would need to be supplemented with modeling data. For example, the contributions of individual sources and source categories often cannot be determined based on monitoring data alone.

EXHIBIT 8
URBAN AIR TOXICS MONITORING PROGRAM SITES (1997)
AND PHOTOCHEMICAL ASSESSMENT MONITORING STATIONS OR PAMS (1998)



While not collected specifically for air toxics assessment purposes, monitoring data for non-air media (e.g., soil, sediments, surface water, biota) are collected under programs sponsored by EPA and other federal agencies and by the States. A number of these programs collect data on sets of pollutants that overlap with the 188 HAPs. For example, the Agency's Environmental Monitoring and Assessment Program (EMAP) monitors polycyclic aromatic hydrocarbon (PAH), polychlorinated biphenyl (PCB), DDT, other pesticide, and butyltin levels in sediments in three large estuarine areas (Mid-Atlantic, Gulf of Mexico, and Louisiana). Under the National Status and Trends programs implemented by the National Oceanic and Atmospheric Administration, chemical contaminant levels are monitored in fish and surficial sediments from 170 coastal and estuarine sites, and chemical contaminant trends in mollusks are tracked at 287 coastal and estuarine sites. Fish, shellfish, and sediment monitoring is also conducted by many States. In addition, air deposition of a small subset of HAPs is measured in selected regions of the country under the CAA Great Waters program. Any of these data sources may be consulted as appropriate for verification of multimedia modeling output or identification of background contaminant levels.

3.3.3 Characterization of the Study Population

After ambient concentrations have been derived, human and/or ecological exposures to these concentrations are determined. In this component, the study population is defined in terms of geographic distribution and other characteristics relevant to the exposure pathways of concern.

For the more frequently performed human inhalation exposure analyses, the locations of resources, homes, workplaces, schools, and other receptor points will partially determine the extent of actual exposure. Factors such as age, sex, and activity patterns affect the amount of pollutant actually inhaled by an individual, while mobility of the subject affects the concentration levels to which an individual is exposed over time. In screening analyses, potential exposure may be estimated using the maximum off-site concentration, which may be more easily calculated than an exposure estimate linked to population location and behavior. In a refined assessment, we will incorporate more specific information about actual receptor points and the population's movement throughout the area, including, if appropriate, the amount of time spent in specific microenvironments (e.g., indoors at home, outdoors, in motor vehicles). Depending on the focus of the analysis, output of the exposure assessment may vary. In some cases the most highly exposed 5 to 10 percent of the population may need to be well-characterized, while for others, the distribution of exposures across a wider area is needed. Information on specific sensitive populations, such as children or the elderly, is another layer of detail that may often be needed in refined analyses.

As with inhalation, assessing non-inhalation exposure to human populations involves combining pollutant concentration information with relevant information concerning the study population. The kinds of information needed depend on the relevant exposure pathways. EPA's Office of Solid Waste and Emergency Response has considered multipathway exposures in various risk assessment activities, including the assessment of hazardous waste combustion (EPA 1994c; EPA 1998f). Examples of recommended pathways include:

Air —(deposition)→ Soil —(ingestion)→ Human

Air —(deposition + uptake of vapor phase)→ Above-ground Vegetable —(ingestion)→ Human

Air —(see above)→ Soil + Above-ground Vegetable —(ingestion)→ Beef —(ingestion)→ Human

Air —(see above)→ Soil + Above-ground Vegetable —(ingestion)→ Milk —(ingestion)→ Human

Air —(deposition + runoff + erosion)→ Waterbody —(bioaccumulation)→ Fish —(ingestion)→ Human

Air —(deposition)→ Surface Water —(ingestion)→ Human

Air —(deposition)→ Soil —(overland flow)→ Surface Water —(ingestion)→ Human

After identification of the relevant exposure pathways, information such as soil, drinking water, and food ingestion rates (often including specific foods, such as fish, beef, pork, eggs, root vegetables, grains, fruit), generally for both adults and children, as well as contact frequencies with soil and surface water, may be needed. Some activities of particular interest for non-inhalation modeling are subsistence farming and subsistence fishing because of the unique dietary habits of these two groups (i.e., eating much more garden vegetables and fish,

respectively). Also, as with inhalation exposure, the extent to which these factors are included in the risk assessment depends on the purpose of the assessment, available resources, uncertainties in the assessment, and data quality and quantity. Not only are the data requirements often extensive, particularly when many different pathways are being assessed, but the computational demands also can be quite large in a multimedia, multipathway assessment.

To relate estimated ambient concentrations to exposures in ecological assessments, characteristics of the ecosystem and ecological population are identified. These include behavior, location, and important life history characteristics that may affect the exposure or response of assessment endpoints to the HAPs. Examples include the timing of the study population's reproductive cycles or migration patterns in relation to ambient concentrations, as well as features of ecosystem habitats which may affect exposures. A screening-level multipathway assessment may be used to identify potentially significant exposure pathways and to develop an exposure profile for ecological receptors of concern.

Data and Tool Availability, Limitations, and Closing Gaps

Human Population Assessment. Exposure and risk to human populations via the inhalation route involves combining pollutant concentration information with information on the geographical distribution of people in the study area, including consideration of data on the activities and characteristics of the exposed population. Human exposure and susceptibility and sensitivity to pollutant effects may vary with factors such as age, gender, intensity and amount of activity, time spent in microenvironments, diet, overall health, lifestyle, genetic factors, and the concentration of pollutant. The extent to which these factors are included in the risk assessment depends on the purpose of the assessment as defined in the problem formulation step, available resources, uncertainties in the assessment, and data quality and quantity.

In characterizing the exposed population, the U.S. Bureau of Census is a major source of population information (i.e., the 1990 Census). In air toxics exposure assessment, the Agency typically uses population and demographic data that are based on the census block level. There are approximately 6.9 million census blocks in the U.S. The number of people residing in each census block and the geographical center of each are specifically used in the assessments. The population included within a census block is highly variable (from less than 10 to a few thousand), but, on average, about 30 to 40 people reside in each block. These data provide a good estimate of how people are geographically distributed near emitting sources, and are also useful for defining the population cohorts for analysis. Cohorts may be defined on the basis of age, gender, race, income levels, length of time in primary residence, or other characteristics. Data on population characteristics relevant to exposure potential are obtained from documents and studies such as EPA's *Exposure Factors Handbook* (EFH) (EPA 1997g) and national population surveys of people's activity patterns, including where they spend each hour of a day (microenvironment) and each hour's activity level (EPA 1994d).

In estimating inhalation exposure from stationary sources of HAPs for residual risk analyses, we currently use modeling techniques such as the Human Exposure Model (HEM)

(EPA 1986g). In residual risk analyses, we will be relying on an approach that incorporates more sophisticated techniques using detailed and site-specific information when warranted. Some of these techniques are currently being developed by EPA, e.g., TRIM (described below). In the interim, HEM, which contains meteorological data, census data, an EPA air dispersion model, and to address population activities and the variability associated with exposure assessment, an add-on Monte Carlo simulation routine, will continue to be used in air toxics risk assessments.

Predictions of ambient concentrations and atmospheric deposition derived from atmospheric dispersion models have rarely been validated. Model validation is a difficult, resource intensive process that relies heavily on monitoring data, and often, models predict concentrations that are below the levels that can be detected using current analytic methods. Nevertheless, we continue to seek to improve our modeling techniques by enhancing their capacity to incorporate exposure assessment tools and exposure data bases. For example, over the past decade the Agency has significantly expanded available data bases on human activity patterns (e.g., recent development of the Combined Human Activity Database (CHAD)), breathing rates, residential occupancy periods, and microenvironmental exposures. The outputs of these improvements along with improvements in dispersion models can be used as inputs to HEM, along with more detailed and realistic exposure profiles, to generate better estimates of individual and population risk.

As discussed in Section 3.3.2, the primary tool currently used by the Agency for multipathway exposure modeling of the subset of HAPs for which this is appropriate is the IEM. This model includes a fate and transport component that estimates multimedia concentrations and a component that estimates multipathway exposures. The recently released draft guidance document on hazardous waste combustion risk assessment for human health risks (EPA 1998f) includes a full discussion of multimedia exposures and assessment of the resulting risks. This document will be considered in refining our human multipathway exposure assessment methodology.

Additionally, the Agency is currently developing the TRIM, which is a multimedia, multipathway modeling system being designed to address all quantitative dimensions of a complete residual risk evaluation, including the exposure assessment. The TRIM will provide a framework for assessing human health and ecological risks from exposure to hazardous and criteria air pollutants. It will allow for the evaluation of multipathway exposure to air pollutants, using a dynamic mass-balance approach to estimate the exposure and dose profiles received by selected receptors. Both uncertainty and variability will be explicitly treated within the model framework. The TRIM will consist of four modules: (1) the Environmental Fate, Transport, and Exposure module (TRIM.FaTE), (2) the TRIM exposure event module (TRIM.Expo), which will track population cohorts through time and space, (3) a dosimetry module to account for pollutant uptake, biokinetics, and dose-response in humans, and (4) a risk characterization module. The first module was reviewed initially by EPA's SAB in May 1998, and comments received are

being addressed through further development and testing efforts. The first, second, and fourth modules are scheduled to be reviewed by the SAB in 1999. These three modules should be available for EPA use in the year 2000.

Ecological Exposure Assessment. Emission sources, HAP distribution in the environment, and contact with ecological receptors are described in the ecological exposure characterization. Much of the information used in this characterization is similar to that used for the human exposure assessment. For example, monitoring data and emissions and multipathway modeling are major sources of information. As with human exposure assessment, non-inhalation pathways may be important for a limited subset of HAPs that are persistent and/or have the potential for bioconcentration and biomagnification in aquatic and terrestrial food webs. This potential is evaluated based on fate and transport data specific to the pollutant of concern, such as the K_{ow}, organic carbon-water partition coefficient (K_{oc}), and bioconcentration factor (BCF) or bioaccumulation factor (BAF) values.

Some of the information needed to characterize the contact of a pollutant such as a HAP with potential receptors, however, is specific to the ecological risk assessment methodology. For example, an understanding of the site characteristics, including such factors as site topography, soil and water types, and habitat types, is important. Furthermore, the "significance" of potential ecological effects depends on other site-related factors, including the type and significance of the ecological receptors affected and the areal extent of exposures at concentrations sufficient to cause adverse effects. Tools risk assessors can use to determine the locations and types of ecological receptors in areas surrounding the sources include information gathered using maps (e.g., U.S. Geological Survey, National Wetlands Inventory, and EPA's ESTAT Geographical Information System), aerial photographs, communication with scientists knowledgeable about the area (e.g., State agencies, U.S. Fish and Wildlife Service, National Oceanic and Atmospheric Administration), and site surveys.

In the absence of readily available site-specific information and prior to the recommendation of a site-specific ecological risk assessment, it may be appropriate to use approximate source location information to infer the existence of adjacent aquatic and terrestrial ecosystems, and a set of assessment endpoints can be selected that represent the most appropriate sensitive elements of those ecosystems for the contaminants in question. The Agency is considering these issues in developing an approach for use in residual risk ecological exposure assessment activities.

3.3.4 Exposure Characterization

In the exposure characterization component, the pollutant concentration and study population are spatially integrated to characterize exposure (EPA 1993c). For a human health inhalation risk assessment, predicted ambient air concentrations for a certain location – for example, the location of the individual most exposed (see text box) – are compared to the population at that point, taking into account factors that can affect the population's exposure as

MIR, MEI, AND INDIVIDUAL MOST EXPOSED

Maximum individual risk (MIR) is a concept included in the benzene NESHAP and is similar but not identical to the concept of maximum exposed individual (MEI) risk. An MIR represents the highest estimated risk to an exposed individual in areas that people are believed to occupy. The MEI risk represents the highest estimated risk to a hypothetical exposed individual, regardless of whether people are expected to occupy that area. Thus, MEI risk is greater than or equal to MIR.

Depending on the expected magnitude of risk and ready availability of appropriate data, we may use the maximum modeled off-site concentration in screening-level risk assessments. Where risks are expected to be elevated, in order to conserve resources, we may pass over this conservative assumption step and incorporate population data to derive the MIR for areas that people are believed to occupy.

We are proposing that the "individual most exposed," a phrase used in CAA section 112(f)(2), be considered equivalent to the MIR for areas that people are believed to occupy for the purposes of regulation under the residual risk program.

described above. If non-inhalation (multimedia) exposures are of concern, these pathways and the potentially affected populations are considered as well.

The exposure characterization of an ecological risk assessment describes the sources of HAPs, the distribution of HAPs in the environment, and the contact of HAPs with ecological receptors. The characterization is based on measures of exposure and of ecosystem and receptor characteristics developed initially in the problem formulation phase. Many aspects of the exposure characterization process, especially analyzing the sources and distribution of HAPs in the environment, are similar for the ecological and the human health exposure assessment. The primary difference is that the exposure points for ecological receptors can differ from those for humans. Moreover, for ecosystems, exposure "areas" may be more meaningful than exposure "points."

In recent years, there has been increasing interest in explicitly characterizing the extent of uncertainty and variability in risk assessment, and especially in the exposure assessment step. To do this, we may use various approaches, including a technique known as Monte Carlo simulation analysis. Using this technique, important variables in the exposure assessment (as well as in the other parts of the risk assessment) are specified as distributions (rather than as single values) according to what can be expressed about their underlying variability and/or uncertainty. Variables are sampled repeatedly from these distributions and combined in the analysis to provide a range of outcomes. While this technique can offer a useful summary of complex information, it must be noted that the analysis is only as good as the underlying data. It is important that the individual modeled variables are expressed in a way consistent with the best information available, or the results of the Monte Carlo analysis can do more to confuse than enlighten.

3.4 Effects Assessment

3.4.1 Human Health Effects

Hazard Identification

An initial step in the effects assessment is to determine whether the pollutants of concern are causally linked to adverse health effects. This is the hazard identification. Factors such as the route of exposure, the type and quality of the effects, the biological plausibility of findings, the consistency of findings across studies, and the potential for bioaccumulation all contribute to the strength of the hazard identification statement. There are many sources of information that can be brought to bear in the hazard identification. **Exhibit 9** summarizes important sources of information for hazard identification.

HAZARD IDENTIFICATION FOR MIXTURES

While some groups of pollutants, when part of a multiple chemical exposure, act independently in causing health effects, others may interact and elicit an effect that may be different or may occur at a different exposure level than would be expected if exposure were to the chemicals individually. Even when individual pollutant levels are so low that exposure to them one at a time would not be expected to pose harm, some mixtures of pollutants may work together such that their potential for harm adds up and exposure to the mixture poses risk. For some groups of pollutants that can interact chemically, the total risk they pose as a group is greater than what would be expected from adding up the individual risk posed by each. This is known as a synergistic relationship. Antagonistic relationships between chemicals are also possible. In this case, the pollutants interfere with one another and the potential for harm is lessened. This is a significant simplification, but the important point to note is that depending on the mixture of pollutants, the total effect may be different than what would be expected from separate exposures to the individual pollutants because of the potential for additive, synergistic, or antagonistic relationships among some chemicals.

The types of effects that are relevant to a particular chemical (e.g., cancer, non-cancer) are determined as part of the hazard identification. The current approaches for dose-response assessment and risk characterization can differ for various types of effect.

Non-cancer Effects – Chronic and Acute. In large part due to the wide variety of endpoints, hazard identification procedures for non-cancer effects are less formally described in EPA guidance than procedures for the identification of carcinogens. The EPA has published guidelines for assessing several specific types of non-cancer effects, including mutagenicity assessment (EPA 1986a), developmental toxicity assessment (EPA 1991), neurotoxicity assessment (EPA 1998c), and reproductive toxicity assessment (EPA 1996c). Rather than specifying risk assessment methodology, these non-cancer guidelines tend to focus on the proper conduct of testing and the appropriate toxicological interpretation of results of the commonly performed assays. The guidance for hazard identification decisions is fairly general.

For assessment of chronic toxic effects other than cancer, EPA's general approach to hazard identification is to review the health effects literature and characterize its strengths and weaknesses, using primarily a narrative approach rather than a formal classification scheme. Available data on different endpoints are arrayed and discussed, and the effects (and their

EXHIBIT 9
SOURCES OF INFORMATION FOR HAZARD IDENTIFICATION

- **Epidemiologic Data.** Epidemiologic studies of human populations exposed to HAPs in occupational settings or in the general environment can provide valuable information on the effects of HAPs. These studies have advantages over other sources of information in that they directly assess the effects of exposure to humans and, in the case of studies of the general population, address exposures that actually occur in the environment. In addition, recent work with biomarkers (chemicals in the body which allow for better quantification of exposure) promises to boost the utility of epidemiology in the future. Shortcomings include concerns about the relevance of high exposure levels often seen in occupational studies to environmental concentrations, concerns over the control of confounding variables (such as tobacco use) that may obscure true causal relationships (or imply false ones), difficulties in adequately characterizing exposure, and the difficulty most epidemiologic studies have in discerning subtle effects (see Section 4.2.1 for a more complete discussion of epidemiologic data in the context of section 112(f)).

- **Human Data from Case Reports or Controlled Exposure Studies.** Where available, human health effects data from case reports or controlled exposure studies can be extremely valuable, although such data generally have shortcomings. Case reports often involve one or a small number of people, limiting the ability to generalize from them, and they may involve exposures very different than typical environmental exposures. For most HAPs and effect types of interest, controlled human exposure studies are unlikely to be available.

- **Animal Toxicology Data.** High quality studies of human populations exposed to HAPs are rare, due to both expense and the inherent limitations of epidemiology. As a result, EPA and others commonly rely on animal studies to infer potential risk to humans. Animal toxicologic data are typically much easier to obtain than good epidemiologic data, and effects can be explicitly linked with exposure to the HAP(s) being tested with little fear of confounding. However, issues of high-to-low dose relevance are compounded by the need to extrapolate the effects seen in animals to those anticipated in humans. Although there have been considerable advances in understanding the relevance of specific results in animal studies to human biology, such extrapolations remain a considerable source of uncertainty. The EPA has operated under the conservative public health policy that assumes that adverse effects seen in animal studies indicate potential effects in humans.

- **Short-term *in Vitro* Assays.** *In vitro* tests can be carried out quickly and at relatively low cost, and they can provide valuable information on specific aspects of a pollutant's toxicity, such as a particular mechanism of mutagenicity that may be an initiating event for cancer. However, such tests typically provide only supporting information about a pollutant's effects, as few tests have been developed that are specific to a particular effect or disease.

- **Structure-activity Relationships (SARs).** By comparing the molecular structure of a pollutant with that of others of known toxicity, toxic effects can sometimes be inferred, particularly if there is knowledge about the mechanism of action. This approach is often useful when examining the hazards associated with individual compounds within a class of related compounds (e.g., dioxins) or when identifying compounds for future study. Although structure-activity analyses are rarely a substitute for existing experimental or epidemiologic data, and represent a relatively uncertain basis for hazard identification, they are useful when experimental data are absent.

attendant dose/exposure levels) are described. While there may be no formal hierarchy, particular attention is given to effects that occur at relatively low doses or that may have particular relevance to human populations. The narrative description of the data base discusses factors such as the methodological strengths and weaknesses of individual studies (as well as the overall data base), the time period over which the studies were conducted (e.g., chronic vs. subchronic), routes of exposure, and possible biological mechanisms. In the course of this narrative, there is discussion of effects, which may range from severe frank effects that can cause

incapacitation or death to subtle effects that may occur at the cellular level but are early indicators of toxic effects. Not all effects observed in laboratory studies are subsequently judged to be adverse effects. The distinction between adverse and non-adverse effects is not always clear-cut, and considerable professional judgment is required in applying criteria to identify adverse effects. All of these observations are integrated into a presentation that gives a concise profile of the toxicological properties of the pollutant.

In addition to toxicity related to long-term exposures, many HAPs also can cause toxic effects after short-term exposures lasting from minutes to several hours. Indeed, for some pollutants acute exposures are of greater concern than chronic exposures. The hazard identification step for acute effects is comparable to that for chronic effects, with the primary difference being the duration of exposure. As with chronic exposures, the severity of effects from acute exposures may vary widely. The selection of a severity level for acute effects assessment may vary with the purpose of the assessment. While various EPA offices have addressed acute exposures across a variety of regulatory programs, Agency-wide guidance on how to assess toxic effects from short-term exposures is only recently being developed. This guidance for acute reference exposure (ARE) levels is intended to assist Agency acute risk assessment activities (EPA 1998g). Additionally, a discretionary federal advisory committee supported by EPA currently is assessing hazard and developing quantitative values (referred to as acute exposure guidance levels (AEGLs) for acute toxicity of specific chemicals (EPA 1997h), following guidance published by NRC (NRC 1993).

Cancer. The EPA's 1986 *Guidelines for Carcinogen Risk Assessment* (EPA 1986b) provide guidance on hazard identification for carcinogens. The approach recognizes three broad categories of data: (1) human data (primarily epidemiological); (2) results of long-term experimental animal bioassays; and (3) a variety of data on short-term tests for genotoxicity and other relevant properties, pharmacokinetic and metabolic studies, physio-chemical properties, and structure-activity relationships (SAR). In hazard identification of carcinogens under the 1986 guidelines, the human data, animal data, and "other" evidence are combined to characterize the weight of evidence regarding the agent's potential as a human carcinogen into one of several hierarchic categories.

- **Group A – Carcinogenic to Humans**: Applies when there are adequate human data to demonstrate the causal association of the agent with human cancer (typically epidemiologic data).

- **Group B – Probably Carcinogenic to Humans**: Agents with sufficient evidence (i.e., indicative of a causal relationship) from animal bioassay data, but either limited (i.e., indicative of a possible causal relationship, but not exclusive of alternative explanations) human evidence (Group B1), or with little or no human data (Group B2).

- **Group C – Possibly Carcinogenic to Humans**: Agents with limited animal evidence and little or no human data.

- **Group D – Not Classifiable as to Human Carcinogenicity:** Agents without adequate data either to suggest or refute the suggestion of the human carcinogenicity.

- **Group E – Evidence of Noncarcinogenicity for Humans**: Agents that show no evidence for carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies (EPA 1986b).

In 1996, EPA proposed major revisions of the carcinogen hazard identification scheme. The proposed revision to the cancer risk assessment guidelines (EPA 1996b), which is expected to be finalized in 1999, focuses on narrative statements describing the main lines of evidence and their interpretation, in place of the current pre-defined hierarchical categories with alphabetic designations. Rather than the three-step process used under the 1986 guidelines of separately evaluating human evidence, evaluating animal evidence, and combining these judgments into an overall weight of evidence (while considering the short-term test data), the proposed guidelines suggest a single comprehensive evaluation process. This process stresses the explicit consideration of coherence of the various data elements into one scientific interpretation that evaluates, to the extent possible, how well the commonality of mode of carcinogenic action between human beings and the various test systems has been established. Emphasis is also placed on defining the qualitative conditions under which carcinogenic hazards might be expected. If warranted, limitations to the finding of carcinogenic hazard can be drawn based on route of exposure, necessity of some other factors for which tumorigenesis is necessary, and doses below which elevation of cancer risk is not expected. Key differences in the hazard identification step between the 1996 proposed revised cancer guidelines and the original 1986 guidelines are highlighted in **Exhibit 10**.

Dose-response Assessment

Dose-response assessment is the characterization of the relationship between the concentration, exposure, or dose of a pollutant and the resultant health or environmental effects. The nature of quantitative dose-response assessment varies among pollutants. Sufficient data often exist for criteria air pollutants, such as ozone or carbon monoxide, so that relatively complete dose-response relationships can be characterized. In such cases, there is no need for extrapolation to lower doses because adequate health effects data are available, often in humans, at environmental levels. Such is not the case for most air toxics. Most

DOSE-RESPONSE ASSESSMENT FOR MIXTURES

The EPA mixtures guidelines (EPA 1986c), which are currently in the process of being updated (EPA 1997d), indicate the following hierarchy for evaluating mixtures:

- Use toxicity data on the specific mixture of concern;
- If such data are not available, use toxicity information on a similar mixture; and
- If such data are not available, use toxicity information on the components of the mixture.

It is unlikely that mixtures of HAPs from sources under review for residual risk will have been studied as independent entities because of their variability. Thus, the default has been and will continue to be to evaluate data on the individual mixture components, in accordance with EPA's guidelines.

EXHIBIT 10
SUMMARY OF MAJOR DIFFERENCES IN THE HAZARD IDENTIFICATION STEP BETWEEN EPA'S 1986 GUIDELINES (EPA 1986b) AND 1996 PROPOSED GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (EPA 1996b)

1986 Guidelines	1996 Proposed Guidelines
Weighing Evidence of Hazard	
▸ Decisions are based almost exclusively on tumor findings in animals and/or humans.	▸ Decisions take into account all available evidence (e.g., structure-activity relationships, mode of action).
▸ Human and animal evidence are evaluated separately and combined into the overall weight of evidence.	▸ All data are evaluated in a single comprehensive evaluation process.
Classification Descriptors	
▸ Substance is assigned a weight of evidence classification (A through E) regarding its potential to cause cancer in humans.	▸ A narrative statement with descriptors (e.g., "known/likely" to be carcinogenic) is developed for a substance, and includes information on the lines of evidence, exposure pathways, conclusions, and limitations.

epidemiologic and toxicologic data on HAPs typically result from exposure levels that are high relative to environmental levels.

In summary, dose-response assessment methods for HAPs generally consist of two parts. First is the evaluation of data in the observable range, and second is the extrapolation from the observable range to low doses/risks. Recent terminology refers to the result of analysis in the observable range as the "point of departure," from which extrapolation begins. The approaches used for evaluation in the observable range are similar for all types of effects, while the Agency's current extrapolation methods differ considerably for cancer and non-cancer effects.

Non-cancer Effects – Chronic. The inhalation RfC and oral RfD are the primary Agency consensus quantitative toxicity values for use in non-cancer risk assessment. The RfC or RfD is defined as an estimate, with uncertainty spanning perhaps an order of magnitude, of an inhalation exposure/oral dose to the human population (including sensitive subgroups) that is likely to be without appreciable risks of deleterious effects during a lifetime. The RfC or RfD is derived after a thorough review of the health effects data base for an individual chemical and identification of the most sensitive and relevant endpoint and the principal study(ies) demonstrating that endpoint. As discussed above under hazard identification, not all effects that can be observed in studies are determined to be adverse effects; a non-adverse effect would not be selected as the critical effect on which to base an RfC or RfD. Inhalation RfCs are derived according to the Agency's *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (EPA 1994e). The RfC or RfD should represent a synthesis

of the entire data array. The evaluation of and choice of data on which to base the RfC or RfD derivation are critical aspects of the assessment and require scientific judgment.

Derivation of the RfC or RfD begins with identification of the critical adverse effect from the available valid human and animal study data, followed by identification of a lowest-observed-adverse-effect level (LOAEL) or, preferably, a no-observed-adverse-effect level (NOAEL). The LOAELs or NOAELs from animal studies are converted to human equivalent concentrations (HECs) using dosimetric methods (described in EPA 1994e). The NOAEL[HEC] or LOAEL[HEC] from one or a few studies that is representative of the threshold region of observable effects is the key value gleaned from evaluation of the dose-response data. Recently, the benchmark dose (BMD) or benchmark concentration (BMC) approach (described below) has sometimes been used to effectively derive the LOAEL or NOAEL used as the "departure point" for extrapolation to the human exposure of interest. The RfC or RfD is then derived by consistent application of uncertainty factors (UFs) to account for recognized uncertainties in the extrapolation from the experimental data and exposure conditions to an estimate (the RfC or RfD) appropriate to the assumed human lifetime exposure scenario (EPA 1994e).

The standard UFs are applied as appropriate for the following extrapolations or areas of uncertainty:

- Laboratory animal data to humans;
- Average healthy humans to sensitive humans;
- Subchronic to chronic exposure duration;
- LOAEL to NOAEL; and
- Incomplete data base.

Other chemical-specific uncertainty factors (sometimes called modifying factors) may also be applied for individual HAPs depending on the existing health effects data set. The UFs that are generally applied range from a factor of three to an order of magnitude. The composite UF will depend on the number of extrapolations required. RfCs have been derived using composite UFs that range from 10 to 3,000, with most RfCs using factors of 100 to 1,000. The UF for animal to human extrapolation in RfC development often is less than an order of magnitude due to the dosimetric adjustments employed. It is also common that chemical-specific information is used to reduce the UF in other extrapolations. For example, the subchronic to chronic UF for acrylic acid was reduced because a comparison of two-week and 90-day studies showed minimal difference in the incidence or severity of effect, suggesting that there was little difference at various exposure durations. Likewise, the LOAEL to NOAEL extrapolation UF has been reduced for several RfC derivations because the effect at the LOAEL was very mild. In general, studies (e.g., Baird et al. 1996) have shown that the default UF of 10 may be conservative in many cases, and the UF is therefore a key parameter for examination in uncertainty analyses. When reductions in the UF are used, a factor of three is used as a convention because it is a half-order of magnitude on a logarithmic scale (i.e., $10^{1/2}$), rounded to one significant figure. It is also common to reduce the composite UF when four areas of

uncertainty are present, in recognition of the lack of independence of these areas. The result of this procedure, subject to peer review, is an RfD for oral (ingestion) exposure to an agent or an RfC for inhalation exposure. In addition to a numeric RfD or RfC, EPA also develops a degree of confidence statement (of either high, medium, or low).

The use of order-of-magnitude uncertainty factors for RfCs and RfDs and the definition of the RfC or RfD as having "uncertainty, spanning perhaps an order of magnitude" are indications of the general lack of precision in the estimates. The uncertainty resulting from any single area of extrapolation is not well understood or precisely defined. Current efforts to develop more rigorous statistical descriptions of the uncertainty in extrapolating from, for example, animals to humans or subchronic to chronic exposures may lead to a probabilistic method for assigning UFs. The current state-of-the-art, however, relies on point estimates of uncertainty and therefore results in point estimates of the RfC or RfD. The individual UFs are generally considered to be somewhat conservative, when they have not been reduced in conjunction with the availability of data relevant to the various extrapolations. It follows that the greater the overall magnitude of the UF (i.e., the more individual UFs that were combined to get the total UF), the more conservatism is included. The precision of "an order of magnitude" should be considered to apply on the average. Less precision would be implied in the case of an RfC with a greater UF (e.g., $\geq$1,000), and more precision would be suggested for RfCs with lower overall UFs (e.g., $\leq$100). The relative precision and the magnitude of the composite UFs will be important considerations in decisions involving comparisons of HQ for different chemicals and in assessing the hazard index (HI) for a mixture of chemicals.

Recently, the BMC/BMD approach has been used to supplement the approaches based on LOAELs and NOAELs. The BMD approach is an alternative to the NOAEL approach as a way to identify a dose associated with a given level of response, or a dose without appreciable effect based on experimental data. The BMD approach fits a dose-response curve to the data in the observed experimental range. A lower bound on the dose causing some specified level of risk above background (e.g., 10 percent) is calculated, and this dose value is used as a point of departure for the application of UFs in place of the experimental NOAEL or LOAEL. That is, it is taken as a standardized measure of a dose level near that at which an experimental response would no longer be expected to be evident using standard study designs. The BMD considers the entire data set, including the steepness of the dose-response relationship, accounts for the sample size, and does not depend on a single data point as does the NOAEL. A primary problem with a NOAEL is the wide range of risk that may be present at the NOAEL, depending on experimental design; the benchmark approach minimizes this problem. The benchmark approach has been used by EPA in several recent RfC and RfD assessments.

It should be noted that exposures above an RfD or RfC do not necessarily imply unacceptable risk or that adverse health effects are expected. Because of the inherent conservatism of the RfC/RfD methodology, the significance of exceedances must be evaluated on a case-by-case basis, considering such factors as the confidence level of the assessment, the

size of UFs used, the slope of the dose-response curve, the magnitude of the exceedance, and the number or types of people exposed at various levels above the RfD or RfC.

Non-cancer Effects – Acute. Methods for dose-response assessment of acute exposures are substantially similar to the approach for chronic exposure. Risk assessment for acute inhalation exposure is complicated by the steep concentration-response curves that are often observed, and because small differences in exposure duration (in some cases, a few minutes) need to be taken into account. Because increased exposure duration increases the incidence and severity of response, acute toxicity criteria or exposure guideline values are developed for a specified duration (e.g., one hour). An acute toxicity study providing well-characterized exposure and effects data for the exposure route of interest is used as the basis. Many acute toxicity studies only report on the incidence of death. It is preferred, however, to base the development of acute toxicity criteria on studies that evaluate additional endpoints, including clinical signs, clinical chemistry, and histopathology. For an inhalation criterion, the exposure duration of the study should ideally be the same as the one of interest (e.g., one hour). If significant interpolation across exposure durations is required, multiple studies are preferred to improve the quality of the interpolation. Such approaches based on applying uncertainty factors to acute toxicity data points (e.g., LOAEL, lower 95 percent confidence limit on effective concentration at 10 percent response (LEC_{10}), NOAEL) have been developed and used by various groups (see further discussion under following section, "Data Availability, Limitations, and Closing Data Gaps"). We are currently developing a new Agency method for acute dose-response assessment, the resultant value of which is termed an acute reference exposure (ARE) (EPA 1998g).

In developing the new Agency method, in addition to the use of either a LOAEL or NOAEL, or a BMC/BMD, an approach referred to as categorical regression is being evaluated. This approach allows the combination of data from different studies in order to evaluate the role of both exposure concentration *and* duration in producing the effect (EPA 1998g). Data are combined by expressing various effects on a common scale of severity and performing a regression analysis of severity versus concentration and duration. The results of a categorical regression analysis are used in the same way as a BMC/BMD or a NOAEL, i.e., as the departure point for extrapolation to the human exposure of interest. In the case of the NOAEL or the BMC/BMD, the departure point is a point estimate. In categorical regression, the departure point can be a line on a concentration versus time plot, with the result that any duration of acute exposure can be interpolated along that line. The line is actually a composite of likelihood estimates calculated from the regression results. For example, a concentration-time line indicating the 10 percent likelihood of observing a specific category of effect, termed an ECT_{10} line, could be generated that is analogous to a BMD_{10} or BMC_{10} as a point of departure. The appropriate approach for dose-response analysis will depend on the amount and quality of the available data. In general, the NOAEL, BMC/BMD, and categorical regression techniques have increasing data requirements, so the most appropriate approach will be dictated by the available data with the expectation that use of the data intensive categorical regression method may be

somewhat limited. After the best estimate of a point of departure is determined, the derivation of the ARE proceeds with the consistent application of UFs.

Cancer. The EPA's cancer risk assessment guidelines of 1986 adopted a default assumption that chemical carcinogens would exhibit risks at low doses (EPA 1986b). Extrapolation of cancer risk using the linearized multistage model, which results in a linear extrapolation of risk in the low dose region, was proposed as a reasonable upper-bound on risk, and this approach has been used for most chemicals with adequate data since then. However, as stressed in the *Proposed Guidelines for Carcinogen Risk Assessment* (EPA 1996b), when there are adequate mechanistic data to suggest that other models would be more appropriate to estimate low exposure risk, they may be used on a case-by-case basis. In the absence of such data, the assumption of response linearity is maintained although the modeling scheme has been simplified.

In cancer dose-response assessments relying on oral animal studies for which chemical-specific data are not available to guide the scaling of results to human equivalents, a default scaling factor based on the body mass raised to the 3/4 power of the test animals relative to humans is generally used to calculate a human equivalent dose.[9] For inhalation exposure studies, dosimetric methods such as those used in developing RfCs are generally used to calculate a HEC from animal data. Dose-response models such as the multistage model have historically been used to calculate upper-bound unit risk estimates (UREs). Typically, EPA has relied on the URE as a quantitative measure of potential cancer hazard. A URE represents an estimate of the increased cancer risk from a lifetime (assumed 70-year) exposure to a concentration of one unit of exposure. The URE for inhalation exposures is typically expressed as risk per $\mu g/m^3$ for air contaminants. The URE is a plausible upper-bound estimate of the risk (i.e., the risk is not likely to be higher but may be lower and may be zero).

Since the publication of the EPA's original cancer guidelines (EPA 1986b), considerable new knowledge has been developed regarding the processes of chemical carcinogenesis and the evaluation of human cancer risk. Currently, a revision of the cancer guidelines is in process (EPA 1996b) that represents a considerable departure from the original guidelines (see **Exhibit 11** for key differences in the dose-response assessment step between the two sets of guidelines). As mentioned above, a fundamental and important advance in the proposed revision is the distinction between linear and nonlinear modes of action. The cancer data in the observable range are analyzed using a dose-response model similar to the models used in the BMC approach for non-cancer effects. The LED_{10} (the 95 percent lower confidence limit on dose associated with the estimated 10 percent increase in tumor or tumor-related response) is proposed as a

[9] As specified in the July 5, 1992, *Federal Register* (EPA 1992d), "in the absence of adequate information on pharmacokinetic and sensitivity differences among species, doses of carcinogens should be expressed in terms of daily amount administered per unit of body mass raised to the 3/4 power. Equal doses in these units (i.e., in $mg/kg^{3/4}$/day), when experienced daily for a full lifetime, are presumed to produce equal lifetime cancer risks across mammalian species." This scaling method is assumed to be intermediate between scaling by body mass and scaling by body surface area.

EXHIBIT 11
SUMMARY OF MAJOR DIFFERENCES RELATED TO DOSE-RESPONSE ASSESSMENT BETWEEN EPA'S 1986 GUIDELINES (EPA 1986b) AND 1996 PROPOSED GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (EPA 1996b)

1986 Guidelines	1996 Proposed Guidelines
▸ Default model used for linear dose-response relationships is the "linearized multistage" procedure.	▸ Biologically based dose-response models are used whenever data are sufficient. Recommended default approaches include the margin of exposure approach and linear extrapolation to zero dose, zero response.
▸ Dose-response evaluation is limited to carcinogenicity data.	▸ If appropriate, data on noncarcinogenic effects may be used to help characterize the carcinogenicity dose-response relationship.

possible point of departure for extrapolation, although other options are being considered. The method of extrapolation to lower doses from the point of departure differs depending on whether the assessment of the available data on the mode of action of the chemical indicates a linear or nonlinear mode of action. A linear extrapolation is generally appropriate when the evidence supports a mode of action of gene mutation due to direct DNA reactivity or another mode of action that is thought to be linear in the low dose region. For linear extrapolation, a straight line is drawn from the point of departure to the origin, and the risk at any concentration is determined by interpolation along that line. A linear mode of action also will serve as a default when available evidence is not sufficient to support a nonlinear extrapolation procedure, even if there is no evidence for DNA reactivity.

An assumption of nonlinearity is used when there is sufficient evidence to support a nonlinear mode of action. A nonlinear mode of action could involve a dose-response pattern in which the response falls much more quickly than linearly with dose, but still indicating risk at low doses. Alternatively, the mode of action may theoretically have a threshold if, for example, the cancer response is a secondary effect of toxicity or an induced physiological change which is a threshold phenomenon. In most cases, EPA will not try to distinguish between modes of action with a "true threshold" and those that are nonlinear through the origin, because data are rarely sufficient to make this determination. As a default science policy, nonlinear extrapolation to low doses will not be performed because there is no current basis to choose a model or determine the shape of the dose-response function. However, as more specific information on a HAP's mechanism of action becomes available and where the data are sufficient to support the use of alternative models, EPA will use them.

For carcinogens with nonlinear modes of action, the Agency has proposed a "margin-of-exposure" (MOE) approach to cancer risk assessment (EPA 1996b). The MOE approach has also be advocated as a method to harmonize cancer and non-cancer non-response assessment methodology (*Proposed Guidelines for Carcinogen Risk Assessment,* EPA 1996b; CRARM

report, CRARM 1997b). In the proposed MOE approach, the point of departure as described above is compared directly with the estimated exposure level (rather than having uncertainty factors applied), and the current understanding of the phenomena that may be occurring as exposure decreases below the observed data is considered. It is possible that the point of departure will be based on effects other than tumor data if, for example, the cancer response is determined to be secondary to a non-cancer effect.

In the proposal for this approach, the Agency recommends that additional dose-response information also be supplied to the risk manager. The information should include points such as the slope of the dose-response curve, the nature of the response, the human variability in sensitivity, persistence of the agent in the body, and relative sensitivity of humans and animals. The point of providing related information is to allow the risk manager to consider all aspects of the data to inform the decision about the appropriate MOE and the amount of reduction in risk associated with reduction in exposure below the point of departure. The endpoints relevant to the cancer assessment are determined based on a review of all relevant data.

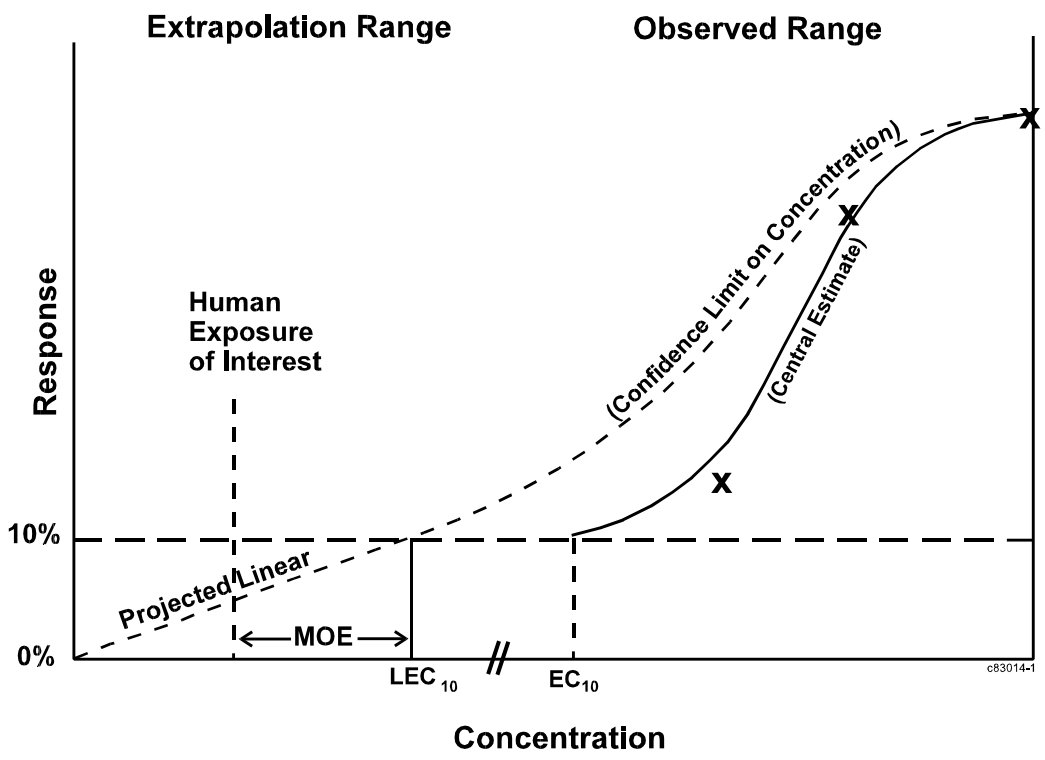
Linear Extrapolation. The dose-response approach for cancer-causing agents for which there is evidence of direct-acting genotoxicity is to model the data in the observable range to determine the point of departure (e.g., LEC_{10}). The only difference between the LEC_{10} approach and the BMC approach for non-cancer effects is that the cancer modeling may be done using a single default approach, rather than the evaluation of several models and statistical comparisons to determine the best-fitting model as currently proposed for non-cancer endpoints. Using the LEC_{10} as the point of departure, the low-concentration extrapolation is done by extending a straight line from the LEC_{10} to zero dose and zero risk (the origin). The risk at any exposure concentration is then determined using that line. **Exhibit 12** depicts the linear cancer dose-response curve being discussed. The linearity assumption implies, among other things, that some risk exists at low doses.

Nonlinear Extrapolation. The dose-response approach for nonlinear carcinogens is to model the data in the observable range in the same way as for linear carcinogens. Extrapolation from the point of departure (e.g., LEC_{10}) would involve an MOE analysis in which various other types of data would be considered to determine whether there is an adequate margin between the estimated exposures and the point of departure. This approach is qualitatively different than the linear extrapolation described above because the explicit consideration of exposure estimates moves it into the realm of risk characterization. Exhibit 12 also depicts the MOE approach being discussed.

Data Availability, Limitations, and Closing Data Gaps

Regardless of the endpoint of interest (acute, chronic non-cancer, or cancer effects), consensus toxicity criteria are preferred for conducting risk assessments. For chronic non-cancer and cancer criteria, the preferred source of data is EPA's IRIS. This data base provides toxicity criteria that have undergone internal peer review, and, for recent assessments, external peer

EXHIBIT 12
CANCER DOSE-RESPONSE CURVE



Source: Adapted from EPA 1996b

review, and have been approved Agency-wide. The toxicological basis for the criterion is provided, as well as other supporting data and information regarding the uncertainty in the assessment. Other chronic toxicity criteria that have undergone less rigorous internal Agency review are available in the Health Effects Assessment Summary Tables (HEAST), which may be consulted for residual risk assessments when data are unavailable in IRIS. For HAPs not having adequate toxicity information in IRIS, EPA will develop and follow a hierarchy of data sources, including various kinds of Agency health effects assessment documents, ATSDR toxicological profiles, and other sources. Consensus toxicity values for effects of acute exposures have been developed by several different organizations, and EPA is beginning to develop such values. The EPA also intends to develop and use a data source hierarchy for acute toxicity information. Consequently, we will not be relying exclusively on IRIS values, but will be considering all credible and readily available assessments. In more refined assessments, which may become the basis for a risk management regulatory decision, we will consider all credible and relevant toxicity information.

Significant progress is needed to improve the Agency's ability to comprehensively assess risks of the 188 HAPs. Assessments are currently available in IRIS for approximately two-thirds of the 188 HAPs, although these assessments may be incomplete. Inhalation assessment values (either cancer or non-cancer) are available for slightly less than half. Reliance on assessments from outside EPA, at least in initial screening-level assessments, provides inhalation assessment values (either cancer or non-cancer) for approximately 80 percent. The need to update assessments with newly available data as well as the need to round out the availability of assessments for all HAPs increases the importance of Agency activities to update IRIS (EPA 1998h). The Agency is in the final stages of a pilot program of improvements to IRIS, and is transitioning to full implementation of the improved system. Among the improvements, EPA has standardized the method for solicitation of scientific information from the public via a *Federal Register* notice and the use of rigorous external peer review procedures for both IRIS summaries and the new Toxicological Review documents. During fiscal year 1998, the Agency was able to update IRIS files for 10 substances and may increase that number during fiscal year 1999 and future years.

Chronic Non-cancer Effects Assessment. For chronic non-cancer risk assessment, the inhalation RfC and oral RfD are the primary quantitative consensus values used by EPA, the primary source for which is EPA's IRIS. The derivation of these values was discussed in detail in the dose-response section above. The RfC and RfD values in IRIS have undergone internal peer review, and, for recent assessments, external peer review, and have been approved Agency-wide. The toxicological basis for the values is provided, as well as other supporting data and information regarding the uncertainty in the assessment. As the IRIS assessments for some HAPs are less current than others, the Agency will evaluate the appropriateness of some assessments in light of more recent credible and relevant information.

To begin closing the gaps in human health effects toxicity data for HAPs, especially in IRIS, EPA has proposed a test rule for HAPs under section 4(a) of the Toxic Substances Control Act (TSCA) (EPA 1997i). Under the toxicity test rule, the Agency will require manufacturers and processors of certain HAPs to test these substances for specific health effects. The data collected under this test rule will be used in new or updated dose-response assessments for placement on IRIS. This regulatory mechanism will assist EPA in filling data gaps for other HAPs through future development of additional test rules. Improving the completeness of toxicity testing data sets used in HAP dose-response assessments assists in reducing the uncertainty in those assessments and any resultant risk assessments.

When chronic non-cancer toxicity criteria are not available from IRIS, several other sources may be consulted to obtain values for use in residual risk assessments. Some of these sources and criteria are summarized in **Exhibit 13**. These alternative sources use an approach similar to the approach used to derive RfC and RfD values for IRIS. If appropriate criteria are not available, the Agency may develop a provisional RfC or RfD using published EPA methodology.

EXHIBIT 13
EXAMPLES OF CHRONIC TOXICITY CRITERIA

Organization	Value	Definition and Basis
EPA/ORD	Integrated Risk Information System (IRIS) Reference Concentration (RfC)/Reference Dose (RfD) (EPA 1998i)	An RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime. Similarly, an RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime. The RfC/RfD values in IRIS have undergone rigorous review and received Agency-wide approval.
EPA/OSWER	Health Effects Assessment Summary Tables (HEAST) Reference Concentration (RfC)/Reference Dose (RfD) (EPA 1997j)	The RfC/RfD definitions are identical to those for the IRIS RfCs/RfDs. The HEAST is a comprehensive listing consisting almost entirely of provisional risk assessment information for oral and inhalation routes for chemicals of interest to Superfund, the Resource Conservation and Recovery Act (RCRA), and EPA in general. Although the values in HEAST have undergone review and have the concurrence of individual Agency program offices, they have not had enough review to be recognized as Agency-wide consensus information.
Agency for Toxic Substances and Disease Registry (ATSDR)	Chronic Minimal Risk Level (MRL) (ATSDR 1998)	An MRL is an estimate of the daily human exposure (inhalation or oral) to a hazardous substance that is likely to be without appreciable risk of non-cancer health effects over a specified duration of exposure. The intermediate exposure duration is 15-364 days, and the chronic exposure duration is 365 days and longer. MRLs are derived similarly to RfDs and RfCs; however, the ATSDR protocol uses different endpoints than EPA. MRLs are developed by ATSDR as substance-specific health guidance (i.e., screening) levels to identify contaminants of concern at hazardous waste sites. The data undergo a rigorous review process, including internal ATSDR reviews, peer reviews, and public comment periods.

NOTE: Criteria are available from other sources, including State agencies such as the California Environmental Protection Agency, and may be considered as needed.

Acute Non-cancer Effects Assessment. EPA efforts are underway to develop acute toxicity criteria with a consistent and sound scientific basis, including the AREs being developed by EPA's ORD (EPA 1998g). The methodology was reviewed by EPA's SAB in June 1998 and is being revised to address comments received. When they become available, AREs will be the preferred values to be used for residual risk assessments. AEGLs are being developed by the National Advisory Committee for AEGLs for Hazardous Substances (NAC/AEGL Committee), a discretionary federal advisory committee. The NAC/AEGL committee follows procedures consistent with NRC guidelines (NRC 1993). Proposed AEGL values for the first 12 chemicals have been published for public comment (EPA 1997h). Acute toxicity criteria known as emergency response planning guidelines (ERPGs) have been developed by the American Industrial Hygiene Association (AIHA) for various severities of effects (AIHA 1998). In the late

1980s, EPA developed LOCs (levels of concern) for extremely hazardous substances (EHSs) regulated under section 302 of the Emergency Planning and Community Right-to-Know Act (EPA et al. 1987). These and selected other acute toxicity criteria are summarized in **Exhibit 14**.

EXHIBIT 14
EXAMPLES OF ACUTE TOXICITY CRITERIA

Organization	Value	Definition and Basis
EPA/ORD	Acute Reference Exposure (ARE) (EPA 1998g)	Exposure (concentration and duration of 1-24 hours) that is not likely to cause adverse effects in the general population. Based on NOAEL/LOAEL or surrogate and UFs. Exposure levels at which increased mild (adverse effects level [AEL]-1), moderate/severe (AEL-2), or frank (FEL) effects occur also considered. Method under development.
Federal Interagency Group (includes EPA)	Acute Exposure Guidance Level (AEGL) (NRC 1993, EPA 1997h)	Under development by Federal Advisory Committee Act (FACA) committee. First 12 proposed AEGLs recently published (EPA 1997h). Concentrations for 1-8 hour exposure of the general population. Levels that are expected to protect from discomfort (AEGL-1), disability (AEGL-2), or life-threatening effects or death (AEGL-3). Based on NOAEL/LOAEL or surrogate and uncertainty factors (UFs).
American Industrial Hygiene Association (AIHA)	Emergency Response Protective Guideline (ERPG) (AIHA 1998)	Concentrations for exposure of the general population for durations up to 1 hour. Levels expected to protect individuals from other than mild, transient (ERPG-1), irreversible or serious (ERPG-2), or life-threatening (ERPG-3) effects. Based on weight of evidence and professional judgment.
Agency for Toxic Substances and Disease Registry (ATSDR)	Minimal Risk Level (MRL) (ATSDR 19xx)	For inhalation or oral exposure of the general population for up to 14 days, value at which adverse health effects not expected. Derived using NOAEL/LOAEL and UFs, similar to RfCs/RfDs.
National Research Council (NRC)	Short-term Public Emergency Guidance Level (SPEGL) (NRC 1986)	Ceiling concentration for an unpredicted single exposure (1-24 hours) designed to protect the general population. Based on professional judgment.
EPA/OPPT	Level of Concern (LOC) (EPA et al. 1987)	Concentration that may result in serious irreversible health effects or death in the general population after exposure for a relatively short (1-hour) period. Based on 0.1 x the IDLH (immediately dangerous to life and health) level or surrogates. (Note: The LOC is no longer preferred for emergency planning (EPA 1996e); AEGLs or ERPGs should be used if available.)

NOTE: Criteria are available from other sources, including State agencies such as the California Environmental Protection Agency, and may be considered as needed.

As for the chronic criteria, consensus values are preferred when available. If a suitable consensus value is not available, the Agency may derive a provisional value from acute toxicity data.

Cancer Assessment. As in the case of chronic non-cancer assessments, IRIS is the primary source of Agency consensus criteria. The derivation of these values was discussed in detail in the dose-response section above. The values in IRIS have undergone internal peer review, and, for recent assessments, external peer review, and have been approved Agency-wide. The toxicological basis for the values is provided, as well as other supporting data and information regarding the uncertainty in the assessment. As the IRIS assessments for some HAPs are less current than others, the Agency will evaluate the appropriateness of some assessments in light of more recent credible and relevant information. The EPA HEAST (described in Exhibit 13), as well as outside sources including State agencies, will also be consulted as needed.

The cancer criterion may be qualitative, in the form of a classification regarding the strength of the evidence concerning a chemical's carcinogenicity. Under the 1986 cancer guidelines, this classification might be "B2, probable human carcinogen based on sufficient evidence from animal studies." Under the proposed 1996 cancer guidelines, a chemical might be classified as “likely to be a human carcinogen by any route of exposure.” These classifications represent the hazard identification phase. A dose-response assessment is also needed for any quantitative risk assessment. For cancer, this is typically expressed as the cancer risk per unit dose, or slope factor. If a consensus cancer criterion is not available from the hierarchy of sources, a provisional value may be derived. In order to derive a cancer slope factor, data are needed from a well-conducted lifetime carcinogenicity study, in which an adequate number of tissues were evaluated histopathologically, and treatment-related cancer was observed. A sufficient number of animals should have been used (generally 50/sex/dose), and the incidence and type of tumor and other histopathologic lesions should have been reported. Using the cancer incidence data, a linear extrapolation to zero from a point of departure is then used to calculate the cancer risk per unit dose. Data on a chemical's pharmacokinetics, its genotoxicity, and other information on its possible mode of action can be used to refine the assessment.

As is described previously, cancer dose-response assessments are not currently available (within or outside EPA) for all HAPs. We have activities underway to increase the HAP coverage in IRIS and to collect the toxicity data for these assessments.

3.4.2 Ecological Effects

In ecological effects characterization, risk assessors evaluate the relationship between HAP exposure and adverse effects on the ecological assessment endpoints which might have been identified at the population, community, or ecosystem level. A variety of sources of ecological effects data can be used, such as field studies, laboratory studies, and SARs (see **Exhibit 15**). The ecological effects characterization identifies causal information linking exposure to the HAP with relevant observed ecological effects and determines the nature and intensity of the effects and, if appropriate, the time scale for recovery after exposure ceases. The effects estimates can be either point estimates of a specified effect level (e.g., a 20 percent response level) or probabilistic estimates describing the entire stressor-response curve.

EXHIBIT 15
SOURCES OF INFORMATION FOR ECOLOGICAL EFFECTS

Various types of original data are used for ecological effects characterization, some of which are common to the human health effects data base.

- **Human Health Data Base.** With the exception of epidemiological data and controlled human exposures, the toxicological data which are used in the hazard identification and dose-response steps of human health assessment are also relevant to ecological effects, specifically for mammalian wildlife (see Exhibit 9).

- **Laboratory Studies.** Due to the limitations and expense of field studies and microcosm studies, most risk assessors rely on laboratory ecotoxicology studies. These studies are typically easier to conduct, and effects can be directly linked to exposure to a single HAP. There is uncertainty, however, in extrapolating the results from standard laboratory species to the wide array of species in the environment. Additionally, in most cases, laboratory studies are not designed to assess effects on populations, communities, and ecosystems.

- **Field Studies.** Studies of wildlife, populations, communities, and ecosystems exposed to HAPs in natural settings can provide valuable information on the effects of HAPs. Field data can be valuable in demonstrating the presence or absence of a cause-effect relationship that can provide a basis for prioritization or for recognizing the efficacy of a risk reduction action. In many cases, however, wildlife are exposed to numerous types of stressors (chemical and non-chemical), and the effects of individual HAPs can be difficult to isolate. In addition, field studies are conducted infrequently due to the significant time and resources required.

- **Microcosm Studies.** Studies on the exposure of multi-species and multi-media enclosed experimental systems to HAPs can control some of the uncertainty associated with multiple stressor exposure in field studies. These studies can provide information about food web dynamics and the interactions of populations of organisms. As with field studies, microcosm studies are time and resource intensive and, therefore, are relatively uncommon.

- **SARs.** In the absence of adequate ecotoxicology studies, scientists may rely on SARs. By using SARs, the toxic effects of a HAP can be inferred based on the similarity of its chemical structure to a chemical whose ecotoxicity is better understood. Types of SARs include: quantitative SARs (QSARs), qualitative SARs, and best analog SARs.

In the case of air toxics, ecological impacts can result from exposure to airborne HAPs (e.g., via inhalation) or exposure to HAPs deposited or transferred to other environmental media (e.g., water, soils). The HAP emissions can be assessed for both primary and secondary effects. Primary effects (e.g., lethality, reduced growth, neurological/behavioral and impaired reproduction) result from exposure of aquatic and terrestrial organisms to HAPs. An extreme example of a primary effect might be deaths of waterfowl caused by an accidental release of an extremely toxic chemical. HAPs which accumulate in plant and animal tissue provide a well known example of a direct harmful effect on wildlife. During the 1950s and 1960s, DDT built up in the wild food chain such that it caused thinning of eggshells of top predators such as bald eagles and brown pelicans, which dramatically reduced the birds' hatching success. The populations of these birds plummeted, driving them to the brink of extinction.

Secondary effects are the result of HAP action on supporting components of the ecosystem (e.g., habitat destruction, loss of prey, and nutrient imbalances). These secondary effects occur through biological interaction of one or more species' populations with individuals or populations which have been primarily affected. For example, exposure to a toxic air

pollutant may adversely effect one or more species of microscopic algae, bacteria, or fungus, which can adversely affect an ecosystem's nutrient cycling and primary production. This can lead to an alteration in the abundance, distribution, and age structure of a species or population dependent on these microscopic organisms which can then lead to changes in competition and food web interactions in other species. These ecosystem effects can be propagated to still other populations, affecting their presence or representation within the ecosystem. A relatively simple example of secondary effects involves the aerial application of pesticides in Canada which dramatically reduced the population of an aquatic insect. This impact to the insect population indirectly affected wild ducklings in the ecosystem which depend on the insects as a food supply (Sheehan et al. 1987).

Both primary and secondary effects may occur within the same time frame of exposure, but secondary effects tend to be long lasting and can persist well after the direct effects have been eliminated because of the interrelationships among species in an ecosystem.

The HAP emissions also can be assessed for both local and regional impacts. Local impacts, which apply to most HAPs, may be short-term or long-term and affect receptors near the source. Regional impacts, which apply primarily to persistent and bioaccumulative HAPs, are most often long-term and generally affect organisms both near to and distant from the source.

In assessing the potential for estimated exposures to pose environmental risks, the available data relevant to the chosen assessment endpoints are reviewed and a measure of effect is determined. Criteria (e.g., point estimates of thresholds for ecological effects) may be calculated for site-specific ecological receptors depending on the importance of those receptors to the local ecosystem, or for an endpoint not previously evaluated. For example, while some criteria may be based on survival, growth, and reproductive success of a population, criteria protective of a threatened or endangered species, a valuable game species (e.g., trout), or an ecologically key species (e.g., wolf) might be based on an endpoint that is relevant to individual organism health (e.g., a neurological deficit) rather than to population maintenance. On the other hand, criteria based on higher effect levels (e.g., 20 to 50 percent or higher of the population is affected) might be appropriate for species for which great functional redundancy exists in the ecosystem (e.g., different herbaceous plants; see Lawton and Brown 1994). The "scaling up" approach to analysis, inherently assumes that data evaluated at the individual or population level are applicable to higher scales (e.g., community, ecosystem) or broader scales (e.g., landscape, watershed, or ecosystem). As we develop more fully our methods for ecological risk assessment, we will be carefully considering this issue.

Criteria may be developed for each combination of environmental medium and ecological community described by the generic assessment endpoints in the conceptual model. For a persistent HAP that might partition into all environmental media, criteria may be needed for all of the following media/receptor combinations:

- Air/terrestrial animals exposed via inhalation;
- Air/plants with their foliage exposed to the air;
- Water/aquatic biota exposed via direct contact with water;
- Sediments/benthic aquatic biota exposed via direct contact with sediments;
- Soil/soil macro- and micro-invertebrates; and
- Soil/plants.

For each medium/receptor combination identified above, the criteria are usually expressed as a concentration of the HAP in the environmental medium. EPA ambient water quality criteria (AWQC) for the protection of aquatic life are an example used by the Agency's Office of Water in implementing the water quality protection sections of the CWA.

For a persistent HAP that might also bioaccumulate in plants or animals, a RfD considered protective of wildlife that feed on those plants or animals would be needed along with information on food ingestion rates for sensitive and most exposed animal species and information on the degree of bioaccumulation in appropriate trophic components. Examples of that approach for aquatic systems can be found in the Great Lakes Water Quality Initiative (GLWQI) for mercury, DDT, PCBs, and 2,3,7,8-TCDD (EPA 1995d,e) and for terrestrial systems in the EPA methods of assessing exposures to combustor emissions (EPA 1993b).

Development of stressor-response curves, instead of point estimates of effect, can provide more information for and flexibility in evaluating risks. For example, stressor-response curves can allow a description of the areal extent of a community that might be affected to differing degrees (e.g., 40 percent mortality of soil invertebrates over 10 acres, 20 percent mortality over the surrounding 100 acres, and less than 10 percent mortality of soil invertebrates in areas beyond those 110 acres).

Data Availability, Limitations, and Closing Data Gaps

EPA's identification of appropriate criteria for use in the air toxics program and specifically in residual risk analyses is an ongoing effort. Currently available criteria are being evaluated to determine their applicability in residual risk analysis. The screening level of analysis may use conservative criteria derived from no-observed-adverse-effect levels (NOAELs) for a most sensitive species for the community in question. This reliance on a 'bottom up' approach, which is similar to that relied upon in derivation of EPA water quality criteria for the protection of aquatic life, is assumed to be more likely to overestimate rather than underestimate risk. Other options are available for more refined analyses. And analyses for risk management/risk reductions under residual risk would also take into account costs, safety, energy, and other relevant factors, as specified under the CAA.

If appropriate ecotoxicity criteria are not available for a specific HAP, criteria may be developed, if adequate toxicity data are available (types of data are described in Exhibit 15). The

most appropriate laboratory tests are those that measure effects on survival, growth, and reproduction.

Although some of the animal toxicity data used for human health assessment provide data for mammalian effects assessment, it should be stated that data are lacking for effects endpoints, especially for plants, birds, and wildlife. Data from field studies are also not widely available. Additionally, there is a paucity of established criteria for environmental effects. There are no data sets comparable to the IRIS or HEAST data bases for human health values. As part of our tool and methodology development, we intend to identify an appropriate methodology for development of ecological criteria. An example of ecological criteria the Agency has developed are the ambient water quality criteria for the protection of aquatic life derived under the Clean Water Act. Until we identify the appropriate criteria or criteria methodology for air toxics assessments, the available effects data (e.g., EPA's AQUIRE, TERRETOX, and PHYTOTOX data bases (EPA 1998j)) are considered appropriate for use in screening-level assessments, while more refined assessments may require completion of more refined tools and the collection or compilation of additional data.

3.5 Risk Characterization

The final step in the risk assessment process is the risk characterization, in which the information from the previous steps is integrated and an overall conclusion about risk is synthesized that is complete, informative, and useful for decision-makers. The nature of the risk characterization will depend on the information available, the regulatory application of the risk information, and the resources (including time) available. In all cases, however, major issues associated with determining the nature and extent of the risk should be identified and discussed. Further, EPA's March 1995 *Policy for Risk Characterization* (EPA 1995f) specifies that a risk characterization "be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency." EPA's 1995 *Guidance for Risk Characterization* (EPA 1995a) lists several guiding principles for defining risk characterization in the context of risk assessment. The three principles with respect to the information content and uncertainty aspects of risk characterization are as follows (EPA 1995a).

(1) **The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.** A good characterization should include different kinds of information from all portions of the foregoing assessment, carefully selected for reliability and relevance.

(2) **The risk characterization includes a discussion of uncertainty and variability.** The risk assessor must distinguish between variability (arising from true heterogeneity) and uncertainty (resulting from a lack of knowledge).

(3) **Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public.** "Truth in advertising" is an integral part of the characterization, discussing all noteworthy limitations while taking care not to become mired in analyzing factors that are not significant.

3.5.1 Human Health Effects

The 1995 *Guidance for Risk Characterization* (EPA 1995a) identifies several guiding principles, shown in **Exhibit 16**, with respect to descriptions of risk.

EXHIBIT 16
GUIDING PRINCIPLES WITH RESPECT TO RISK DESCRIPTORS

- **Information about the distribution of individual exposures is important to communicating the results of a risk assessment.** Both high-end and central tendency descriptors are used to convey the variability in risk levels experienced throughout the population.
- **Information about population exposure leads to another important way to describe risk.** Both a probabilistic number of cases (or environmental impacts) and an expected percentage of the exposed population (or ecological resource) with risk greater than a certain level are valuable ways to present information.
- **Information about the distribution of exposure and risk for different subgroups of the population are important components of a risk assessment.** Highly susceptible individuals or areas should be identified as well as those highly exposed, when possible.
- **Situation-specific information adds perspective on possible future events or regulatory options.** Consideration of alternative scenarios when conducting risk assessment can aid in risk management decisions.
- **An evaluation of the uncertainty in the risk descriptors is an important component of the uncertainty discussion in the assessment.** Both quantitative and qualitative evaluations of uncertainty can be useful to users of the assessment.

Integration of Exposure and Effects Analyses

Risk assessments are intended to address or provide descriptions of risk to: (1) individuals exposed at average levels and those in the high-end portions of the risk distribution; (2) the exposed population as a whole; and (3) important subgroups of the population such as highly susceptible groups or individuals (e.g., children), if known.

Individual Risk. Individual risk predictions are intended to estimate the risk borne by individuals within a specified population or subpopulation. These predictions are used to answer questions concerning the affected population, the risk levels of various groups within the population, and the average or maximum risk for individuals within the populations of interest.

- *Central Tendency Estimates of Risk* are intended to give a characterization of risk for the typical situation in which an individual is likely to be exposed. This may be either the arithmetic mean risk (average estimate) or the median risk (median estimate), either of which should be clearly labeled (EPA 1992a).

- *High-end Estimates of Risk* are intended to estimate the risk that is expected to occur in a small but definable segment of the population. The intent is to "convey an estimate of risk in the upper range of the distribution, but to avoid estimates which are beyond the true distribution. Conceptually, high-end risk means risk above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk" (EPA 1992a).

Population Risk. Population risk predictions are intended to estimate the extent of risk for the population as a whole. This typically represents the sum total of individual risks within the exposed population.

Sensitive or Susceptible Subpopulations. Risk predictions for sensitive subpopulations are a subset of population risks. Sensitive subpopulations consist of a specific set of individuals who are particularly susceptible to adverse health effects because of physiological (e.g., age, gender, pre-existing conditions), socioeconomic (e.g., nutrition), or demographic variables, or significantly greater levels of exposure (EPA 1992a). Subpopulations can be defined using age, race, gender, and other factors. If enough information is available, a quantitative risk estimate for a subpopulation can be developed. If not, then any qualitative information about subpopulations gathered during hazard identification should be summarized as part of the risk characterization.

Because cancer and non-cancer dose-response assessment methods are currently quite different, risk characterizations also differ and are discussed separately.

Non-cancer Effects. Unlike cancer risk characterization, non-cancer risks typically are not expressed as a probability of an individual suffering an adverse effect. Instead, the potential for non-cancer effects is evaluated by comparing an estimated exposure level over a specified period of time (e.g., lifetime) with a reference level such as an RfC (described in Section 3.4.1).

"Risk" for non-cancer effects typically is quantified by comparing the exposure to the reference level as a ratio. The resultant HQ can be expressed as an equation, where HQ = exposure/reference level. Exposures or doses below the reference level (HQ<1) are not likely to be

HAZARD QUOTIENTS AND HAZARD INDICES

The hazard quotient (HQ) is the ratio of the estimated exposure to the health criterion level for a given chemical. For example, for chronic inhalation exposure, the health criterion could be the RfC. If the HQ is less than 1, the RfC is not exceeded and health effects are unlikely. The hazard index (HI) is the sum of the HQs for each chemical considered to have a similar mechanism of action in a mixture. The HI (for a mixture of i compounds) may be calculated as: $HI = HQ_1 + HQ_2 + ...+ HQ_i$. If the HI is <1, health effects are unlikely.

associated with adverse health effects. With exposures increasingly greater than the reference level (i.e., HQs increasingly greater than 1), the potential for adverse effects increases. The HQ, however, should not be interpreted as a probability. Comparisons of HQs across substances may not be valid, and the level of concern (LOC) does not increase linearly as exposures approach or cross the reference level. This is because of the differences among reference levels in their derivation and the fact that the slope of the dose-response curve above the benchmark can vary widely depending on the substance and type of effect.

While some potential environmental hazards may involve significant exposure to only a single compound, exposure to a mixture of compounds that may produce similar or dissimilar non-cancer health effects is more common. In a few cases, reference levels may be available for a chemical mixture of concern or for a similar mixture. In such cases, risk characterization can be conducted on the mixture using the same procedures used for a single compound. However, non-cancer health effects data are usually available only for individual compounds within a mixture. In screening-level assessments for such cases, a conservative HI approach is sometimes used (see text box above). This approach is based on the assumption that even when individual pollutant levels are lower than the corresponding reference levels, some pollutants may work together such that their potential for harm is additive and the combined exposure to the group of chemicals poses greater likelihood of harm. Some groups of chemicals can also behave antagonistically, such that combined exposure poses less likelihood of harm, or synergistically, such that combined exposure poses harm in greater than additive manner. The assumption of dose additivity is most appropriate to compounds that induce the same effect by similar modes of action (EPA 1986c). As with the HQ, the HI should not be interpreted as a probability of risk, nor as strict delineation of "safe" and "unsafe" levels (EPA 1986c; EPA 1989c). Rather the HI is a rough measure of potential for risk and needs to be interpreted carefully. Although the HI approach encompassing all chemicals in a mixture may be appropriate for a screening-level study (EPA 1989c), it is important to note that application of the HI equation to compounds that may produce different effects, or that act by different mechanisms, could overestimate the potential for effects. Consequently, in a refined assessment, it is more appropriate to calculate a separate HI for each non-cancer endpoint of concern when mechanisms of action are known to be similar (EPA 1986c).

Cancer. Risks for cancer are generally expressed as either individual risks or population risks. The distribution of exposures and individual risks within a given population can also be presented, providing an estimate of the number of people exposed to various predicted levels of risk. The Agency's risk characterization guidelines recommend that risk assessments describe individual risk, population risk, and risk to important subgroups of the population such as highly exposed or highly susceptible groups (EPA 1995a). For air toxics emissions, individual or population cancer risks can be calculated by multiplying the corresponding exposure estimate by the unit risk estimate (URE). Cancer risk is defined as the upper-bound probability of contracting cancer following exposure to a pollutant at the estimated concentration over a 70-year period (assumed human lifespan). This predicted risk focuses on the additional risk of cancer predicted from the exposure being analyzed, beyond that due to any other factors.

Estimates of risk are usually expressed as a probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of 1 chance in 10,000 (or one additional person in 10,000) is written as $1x10^{-4}$. Because UREs are typically upper-bound estimates, actual risks may be lower than predicted.

Population risk is an estimate that applies to the entire population within the given area of analysis. Each estimated exposure level is multiplied by the number of people exposed to that level and by the URE. For the great majority of HAPs for which the unit risk estimate is an "upper confidence level" value, this provides an upper-bound prediction of cancer risk for that group after a 70-year exposure to that level. The risks for each exposure group are summed to provide the excess cancer cases predicted in the entire exposed population. This 70-year population risk estimate is sometimes divided by 70 to obtain an upper-bound prediction of the number of cancer cases per year.

When calculating individual or population risk, it is important to check the consistency and validity of key assumptions, such as the averaging period for exposure, the exposure route, absorption adjustments, and spatial consistency.

People are often exposed to multiple chemicals rather than a single chemicals. In those few cases where cancer potency values and UREs are available for the chemical mixture of concern or for a similar mixture, risk characterization can be conducted on the mixture using the same procedures used for a single compound. However, cancer dose-response assessments and UREs are usually available only for individual compounds within a mixture. Consequently, in screening-level assessments of carcinogens for which there is an assumption of a linear dose-response, the cancer risks predicted for individual chemicals may be added to estimate total risk. This approach is based on an assumption that the risks associated with individual chemicals in the mixture are additive. The assumption of additivity is generally considered conservative. In more refined assessments, the chemicals being assessed need to be evaluated for this concern. The following equation estimates the predicted incremental individual cancer risk, assuming additivity, for simultaneous exposures to several carcinogens:

$$Risk_T = Risk_1 + Risk_2 + ... + Risk_i$$

where:

R_T = the total cancer risk (expressed as an upper-bound risk of contracting cancer over a lifetime)

R_i = the risk estimate for the i^{th} substance.

A variation of the additivity approach is used for some mixtures of structurally similar carcinogens for which cancer slope factors (i.e., measures of potency) are not available for all mixture components. For carcinogenic dioxins and furans, for example, a toxic equivalency factor (TEF) approach is used as described in EPA's dioxin reassessment document (EPA

1994f). In this approach, which has an underlying assumption of additivity across mixture components, the cancer potency of certain dioxin and furan congeners is estimated relative to 2,3,7,8-TCDD based on other toxicity information that is available for all the congeners (e.g., LD_{50}). Then, TEFs based on these relative cancer potencies are used to adjust the exposure concentrations of mixture components, which are subsequently summed into a single exposure concentration for the mixture. That exposure concentration based on TEFs is then used, along with the 2,3,7,8-TCDD slope factor, to estimate cancer risks for the mixture.

For carcinogens being assessed based on the assumption of nonlinear dose-response, the MOE approach may be considered, consistent with the proposed revision of EPA's cancer guidelines (EPA 1996b). As described in Section 3.4.1, the MOE approach leaves the decision about the appropriate reduction in exposure compared to the point of departure (i.e., the observable toxicity data) up to the risk manager. An in-depth MOE analysis would be made in consideration of factors that could include the steepness of the dose-response curve, persistence of the compound in the body, known human variability in response, or demonstrated human sensitivity as compared with experimental animals. In a typical case, the point of departure derived from modeling the observable data would be a tumor incidence of 10 percent (e.g., risk of 1 in 10). If the chemical fits a linear mode of action, a reduction in the dose of 1,000 would result in an estimated risk of 1 in 10,000. For a nonlinear mode of action, a reduction of the same magnitude would lead to a much lower risk because of the nonlinearity in the dose-response slope. If the mode of action includes a threshold below which there is no risk of cancer, such a reduction could lead to a zero cancer risk.

Since neither thresholds nor risk are explicitly estimated, there is no analogous form of the simple dose addition approach that is amenable to assessment of mixtures of nonlinear carcinogens. Since the MOE analysis is done on a case-by-case basis, the determination of the appropriate "acceptable" MOE for each component would be required before a mixtures assessment could be performed. It is also not clear how the MOE approach should handle effects in different target organs or with different modes of action. A consideration of the mode of action that leads to the conclusion that the nonlinear dose-response evaluation is appropriate can also provide information relevant to whether nonlinear carcinogens should be considered additive. While the Agency's current mixtures guidelines (EPA 1986c) do not address nonlinear carcinogens, they generally recommend the assumption of additivity for carcinogens unless contrary information is available. Carcinogenic substances showing nonlinear modes of action through unrelated mechanisms or in different tissues would not generally be combined.

Interpretation and Presentation of Risks

In the risk characterization step of final assessments under residual risk, the estimates of health risk will be presented in the context of uncertainties and limitations in the data and methodology. Additionally, information relevant to public health context of the residual risk will be presented. This may include, as available, information on relevant health effects occurring in the study population. Available epidemiological studies or other human health data will be

discussed and presented along with a summary of the hazard identification and dose-response information for the HAPs being assessed. Uncertainties and limitations related to the hazard identification and dose-response assessment may also be discussed. Uncertainty analyses and the presentation of uncertainties is discussed in more detail in Section 4.2.3.

The degree to which all types of uncertainty need to be quantified and the amount of uncertainty that is acceptable varies. For a screening-level analysis, a high degree of uncertainty is often acceptable, provided that conservative assumptions are used to bias potential error toward protecting human health. Similarly, a region-wide or nationwide study will be more uncertain than a site-specific one. In general, the more detailed or accurate the risk characterization, the more carefully uncertainty needs to be considered.

On May 15, 1997, EPA issued a document entitled *Policy for Use of Probabilistic Analysis in Risk Assessment* (EPA 1997k). It also issued an accompanying document entitled *Guiding Principles for Monte Carlo Analysis* (EPA 1997c). The policy and guiding principles are designed to support the use of various quantitative techniques for characterizing variability and uncertainty, a critical part of a complete risk characterization. The policy establishes conditions that are to be satisfied by risk assessments that use probabilistic techniques. These conditions relate to the good scientific practices of clarity, consistency, transparency, reproducibility, and the use of sound methods. **Exhibit 17** provides the conditions for an acceptable risk assessment that uses probabilistic analyses techniques. EPA's position, as stated in these documents, is "that such probabilistic analysis techniques as Monte Carlo analysis, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments."

Data Availability, Limitations, and Closing Data Gaps

The NRC, in its recent review of EPA's risk assessment methodology for HAPs (NRC 1994), recommended that uncertainty and variability should be quantified and the distinction between uncertainty and variability maintained throughout the assessment. A model under development by EPA for air toxics risk assessments, TRIM, will do this explicitly. In the interim, a Monte Carlo assessment is sometimes conducted on the risk estimates produced by HEM or other methods. At present, such assessments primarily address variability, while uncertainty is largely described qualitatively. The variability assessment considers variation in such factors as the number of years residents occupy their primary residences, number of hours per day people are at home, breathing rates across the exposed population, the amount of ambient pollution that infiltrates to the indoor microenvironment, and certain meteorological variables. Thus, the results of the assessment may be expressed in probabilistic terms, potentially providing the risk manager and the affected public with more information than was previously provided. However, care must be taken in the interpretation of such analyses, as they are only as reliable as the underlying data and assumptions. Uncertainty in risk assessment is discussed further in Section 4.2.3.

EXHIBIT 17
CONDITIONS FOR AN ACCEPTABLE RISK ASSESSMENT THAT USES PROBABILISTIC ANALYSIS TECHNIQUES

- The purpose and scope of the assessment should be clearly articulated in a "problem formulation" section that includes a full discussion of any highly exposed or highly susceptible subpopulations evaluated (e.g., children, the elderly, etc.). The questions the assessment attempts to answer are to be discussed and the assessment endpoints are to be well defined.
- The methods used for the analysis (including all models used, all data upon which the assessment is based, and all assumptions that have a significant impact upon the results) are to be documented and easily located in the report. This documentation is to include a discussion of the degree to which the data used are representative of the population under study. Also, this documentation is to include the names of the models and software used to generate the analysis. Sufficient information is to be provided to allow the results of the analysis to be independently reproduced.
- The results of sensitivity analyses are to be presented and discussed in the report. Probabilistic techniques should be applied to the compounds, pathways, and factors of importance to the assessment, as determined by sensitivity analyses or other basic requirements of the assessment.
- The presence or absence of moderate to strong correlations or dependencies between the input variables is to be discussed and accounted for in the analysis, along with the effects these have on the output distribution.
- Information for each input and output distribution is to be provided in the report. This includes tabular and graphical representations of the distributions (e.g., probability density function and cumulative distribution function plots) that indicate the location of any point estimates of interest (e.g., mean, median, 95th percentile). The selection of distributions is to be explained and justified. For both the input and output distributions, variability and uncertainty are to be differentiated where possible.
- The numerical stability of the central tendency and the higher end (i.e., tail) of the output distributions are to be presented and discussed.
- Calculations of exposures and risks using deterministic (e.g., point estimate) methods are to be reported if possible. Providing these values will allow comparisons between the probabilistic analysis and past or screening-level risk assessments. Further, deterministic estimates may be used to answer scenario-specific questions and to facilitate risk communication. When comparisons are made, it is important to explain the similarities and differences in the underlying data, assumptions, and models.
- Because fixed exposure assumptions (e.g., exposure duration, body weight) are sometimes embedded in the toxicity metrics (e.g., reference doses, reference concentrations, unit cancer risk factors), the exposure estimates from the probabilistic output distribution are to be aligned with the toxicity metric.

Source: EPA 1997c

Information on health status of local study populations is not usually readily available. With regard to cancer prevalence and incidence, yearly estimates are available on a national basis from the National Cancer Institute's Surveillance Epidemiology and End Results Project (e.g., Ries et al. 1998). Additionally, many States now maintain cancer registries consistent with National Cancer Institute recommendations. In order to provide some public health context for predicted cancer risks, relevant information from these sources will be accessed. Less information is available on the prevalence or incidence of other health effects. Federal public health agencies such as the Centers for Disease Control will be consulted. Rates for diseases as causes of death are available from the National Center for Health Statistics. Many States have

surveillance requirements beyond those for CDC reporting (e.g., certain birth defect registries). Information on the proportion of cancer and other health effects that may be associated with environmental exposures would need to be identified to put overall incidence data in the appropriate perspective.

3.5.2 Ecological Effects

Integration of Exposure and Effects Analyses

Risk characterization is the final phase of an ecological risk assessment in which risks are described and estimated by integrating the estimates of exposure and effects developed in the analysis phase. As described in EPA's guidelines (EPA 1998d), and implied in the residual risk decision framework described in Section 5.3, this process requires comparison of the exposure and stressor-response profiles developed during the analysis. In this step exposure concentrations are compared to (1) published background concentrations in media and biota and (2) the levels estimated to cause adverse effects on the assessment endpoints. Generally, there are two ways to quantitatively estimate risks – point estimates and probabilistic estimates – and each has its advantages and disadvantages. One example of a quantitative ecological risk assessment is presented in **Exhibit 18**. Another example is the EPA Region 5 risk assessment for a hazardous waste incinerator in East Liverpool, Ohio (EPA 1997l). Additional case studies of quantitative ecological risk assessments are presented in Paustenbach (1989) and Maughan (1993).

The point estimate approach, which has been used in numerous EPA ecological risk assessments, uses single values (usually upper-bound estimates) to represent key variables in the assessment (Finley and Paustenbach 1994). The approach is relatively simple and straightforward; however, there are several major limitations. The repeated use of upper-bound point estimates can lead to unrealistically conservative risk estimates. In addition, point estimates provide a limited amount of information to the risk manager and the public. Therefore, the point estimate approach is most useful as a screening approach that approximates a plausible, worst case situation for some potentially exposed receptors.

In contrast, the probabilistic approach uses a distribution of data rather than a single point to represent key variables in the assessment (Finley and Paustenbach 1994). This method makes much greater use of the available exposure and toxicity data than the point estimate approach and provides more information to the risk manager. Instead of yielding a single point estimate of risk, the probabilistic approach provides a range of potential risks as well as their likelihood of occurrence. In addition, a probabilistic assessment is more conducive to sensitivity and quantitative uncertainty analysis. Major disadvantages of probabilistic assessments are that they require more time and resources and are more difficult to communicate or "sell" to some stakeholders. Another difficulty is that information on the distribution of input values is often lacking or uncertain.

EXHIBIT 18
AN ECOLOGICAL RISK ASSESSMENT CASE STUDY: OZONE RISKS TO AGROECOSYSTEMS

The case study summarized here provides an example of how EPA has assessed environmental risks from an air pollutant (ozone) under the National Ambient Air Quality Standards (NAAQS) program (EPA 1993a; EPA 1996f). In 1997, EPA set a new NAAQS for ozone (EPA 1997m). The new secondary standard was set at a level judged by the Administrator to "provide increased protection against adverse effects to public welfare ...," including "... against ozone-induced effects on vegetation, such as agricultural crop loss, damage to forests and ecosystems, and visible foliar injury to sensitive species." This example highlights ecological risk assessment concepts and methods.

- **Problem Formulation.** Under the CAA, EPA is required to set NAAQS for "any pollutant which, if present in the air, may reasonably be anticipated to endanger public health or welfare and whose presence in the air results from numerous or diverse mobile and/or stationary sources." EPA develops public health (primary) and welfare (secondary) NAAQS. According to section 302 of the CAA, the term welfare "includes ... effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values ...". A secondary standard, as defined in section 109(b)(2) of the CAA, must "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."

  This case study focuses on an assessment endpoint for agricultural crops (e.g., the prevention of an economically adverse reduction in crop yields). Yield loss is defined as an impairment of, or decrease in, the value of the intended use of the plant. This concept includes a decrease in the weight of the marketable plant organ, reduction in aesthetic values, changes in crop quality, and/or occurrence of foliar injury when foliage is the marketable part of the plant. These types of yield loss can be directly measured as changes in crop growth, foliar injury, or productivity, so they also serve as the measures of effect for the assessment.

- **Exposure Analysis.** The EPA used ambient ozone monitoring data across the U.S. and a Geographic Information System (GIS) model to project national cumulative, seasonal ozone for the maximum three month period during the summer ozone season. This allowed EPA to project ozone concentrations for some rural parts of the country where no monitoring data were available but where crops were grown, and to estimate the attainment of alternative NAAQS scenarios. The USDA's national crop inventory data were used to identify where ozone-sensitive crop species were being grown and in what quantities. This information allowed the Agency to estimate the extent of exposure of ozone-sensitive species under the different scenarios.

- **Ecological Effects Analysis.** Stressor-response profiles describing the relationship between ozone and growth and productivity for 15 crop species representative of major production crops in the U.S. (e.g., crops that are economically valuable to the U.S., of regional importance, and representative of a number of crop types) had already been developed from field studies conducted from 1980 to 1986 under the National Crop Loss Assessment Network (NCLAN) program. The NCLAN studies also included secondary stressors (e.g., low soil moisture and co-exposure with other pollutants like sulfur dioxide), which helped EPA interpret the environmental effects data for ozone.

- **Risk Characterization.** Under the different NAAQS scenarios, the Agency estimated the increased protection from ozone-related effects on vegetation associated with attainment of the different NAAQS scenarios. Monetized estimates of increased protection associated with several alternative standards for economically important crops were also developed. This analysis focused on ozone effects on vegetation since these public welfare effects are of most concern at ozone concentrations typically occurring in the U.S. By affecting commercial crops and natural vegetation, ozone may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife.

Mixtures. As with non-cancer assessments of human health risks, when ecological toxicity data for complex mixtures are unavailable, the HI approach may be used, as scientifically appropriate, to integrate the ecological risks of multiple chemical stressors (EPA 1996d). HQs for the individual constituents in a mixture are derived by dividing each

constituent's exposure level by a corresponding criterion for ecological effects. The resulting quotients would then be added together to generate an HI for the mixture for each media/receptor combination (e.g., air/terrestrial animals or water column/aquatic organisms). Use of the HI approach assumes that the toxicities of the mixture constituents are additive or close to additive. This assumption is likely to be true for mixtures of chemicals that have similar modes of action; however, it may be unrealistic to default to a molecular mechanism of toxicity for ecological risk analyses.

Screening-level risk assessment may use the HI approach to estimate the risks of mixtures of HAPs to ecological receptors, but the assumptions and associated limitations concerning HAP interactions should be clearly stated in the assessment's documentation. It may often be the case that a single chemical is responsible for the HI exceeding 1, and the assessment can then move forward with focus on that chemical. In more refined assessments, assumptions inherent in the use of the HI will need to be carefully evaluated with regard to scientific appropriateness.

A major limitation of the HI approach is that it provides a point estimate of the risk and is clearly a one dimensional model that relies on concentration (Suter 1993). Additionally, given the lack of fundamental knowledge of effects at the molecular level for most pollutants, it may be unrealistic to assume a molecular mechanism of toxicity as a means of addressing mixtures of all HAPs. In the future, we may need to consider how chemicals affect critical processes governing fitness of the ecosystem (e.g., photosynthesis in plants, reproduction) in our ecological risk assessments.

Interpretation and Presentation of Risks

The previous discussion on interpretation and presentation of risk in Section 3.5.1 is also applicable with regard to ecological risk characterization. As previously mentioned, the risk characterization phase should include a summary of the strengths, limitations, assumptions, and major uncertainties associated with the risk estimates. Uncertainty analysis in risk assessment is also discussed further in Section 3.5.1 and Section 4.2.3.

As with presentation of human health risks, assessments of environmental risk from air toxics should be presented in context of available information regarding other risks in addition to a summary of the exposure and effects characterizations and their integration. Depending on the problem formulation and analysis plan for the ecological risk assessment, social and economic concerns may need to be incorporated into the more refined assessments. In residual risk management decisions, various other factors must be considered along with the information presented in the characterization of risk of adverse environmental effect. These include "costs, energy, safety, and other relevant factors." These considerations will be documented with the risk management decision.

EXAMPLES OF CONSIDERATIONS FOR DETERMINING ECOLOGICAL SIGNIFICANCE

- How large is the area where ecological criteria have been exceeded?
- What proportion of the habitat is affected at local, county, State, and national levels?
- Are the exposure concentrations and ecological criteria above background levels for the area of interest?
- What types of ecological impacts have been associated with this pollutant or similar pollutants in the past?
- Is the criterion or stressor-response curve based on high quality data (i.e., is there a high degree of confidence in the criterion)?
- What are the costs, energy, safety, and other relevant considerations required for decision-making?

Without calibrated or validated population models, professional judgment is needed to estimate the ecological significance of contaminant concentrations that exceed levels associated with varying magnitudes of effect on different species or communities. Unless an endangered or threatened species is at issue, society is generally not concerned with the death of individual plants or animals. For other species, it is unlikely that a few percent additional mortality of individuals could result in population-level effects that might impair ecosystem structure and function. However, it is extremely difficult to estimate how much additional contaminant-induced mortality or reduced reproductive success a population can compensate for before population levels begin to decline, particularly if the population is subject to other stresses. These issues, which should be considered in the development of assessment endpoints in the problem formulation phase, should then be confirmed and described in the risk characterization.

Data Availability, Limitations, and Closing Data Gaps

Although our development of tools, data, and methods for ecological risk assessment of air toxics is in its early stages, the Agency has some experience in ecological risk assessment for air toxics (e.g., EPA 1997l) and other air pollutants (see Exhibit 18). A lack of certain types of criteria (e.g., for wildlife inhalation) and of criteria of any type for many of the HAPs may handicap our analyses, especially in the early stages. As part of data development for air toxics assessment, the Agency is in the process of identifying and assessing the available data and data bases for various ecological receptors.

As the Agency refines its tools, there are many issues we will try to address. For example, the issue of chemical residence times in the environment and the scale of ecological analysis is important (e.g., if a chemical has a residence time of a month or more, then the distribution of the chemical can approach hemispheric proportions). Longer residence times in the atmosphere will lead to global distributions and in order to more comprehensively address this issue, risk assessment methods may need the ability to scale appropriately.

4. Other Statutory Report Requirements of Section 112(f)(1)

The preceding chapter describes the methods and general process that will be used for performing human and ecological risk assessment under residual risk and other components of the air toxics program. The general analysis framework that the Agency is currently evaluating for use in the residual risk program is described in Chapter 5. The remaining elements required by statute to be covered in the section 112(f)(1) Report to Congress are addressed in this chapter. Additional aspects of some of these topics are also covered in other parts of this Report.

4.1 Section 112 (f)(1)(B)

Section 112(f)(1)(B) of the Clean Air Act directs EPA to investigate and report on "the public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks." These topics are presented in the following two sections.

4.1.1 Public Health Significance

This section addresses the directive in CAA section 112(f)(1)(B) that EPA investigate and report on "the public health significance of such estimated remaining risk." At present, the data are not available to conduct an analysis to determine the public health significance for residual risk from air toxics. Given the legislatively mandated schedules for MACT implementation and for performing residual risk assessments, analyses have not yet been completed on any source categories for the purposes of estimating potential residual risks. Without these analyses, it is not possible to determine at this time what the public health significance of any residual risks may be.

As residual risk assessments are completed for individual source categories, information relevant to public health context, as available, will be presented in the risk characterization step (see Section 3.5.1) of the final analysis. This information will include, for each source category or source, the estimated risks to public health remaining after MACT is in place, health effect information, and the attendant uncertainties. Additional available public health information relevant to the risks predicted may also be presented. For example, in the case of estimates of cancer risk, available relevant information on cancer incidence or prevalence may be presented with whatever specificity (e.g., cancer type relevant to HAP cancer hazard information, geographic unit relevant to the source or source category) is feasible. Estimates of non-cancer risk may be presented with a discussion of the health effects of concern and presentation of readily available information regarding prevalence of those health effects, as appropriate. The Agency recognizes, however, that availability of information on the health status of populations, especially on a local basis, is currently quite limited. While this is improving in some areas, such as in states that maintain cancer registries in accordance with National Cancer Institute

specifications, among the general population there are many other health effects for which HAPs pose potential risks that are not well tracked.

The available public health information will be considered along with estimated risks and uncertainties in the application of the ample margin of safety framework as part of the decision-making process of the risk management step (Section 5.3.6).

The Agency considers the ample margin of safety concept as introduced in the 1970 CAA Amendments, and as applied in the benzene standard (EPA 1989a), a reasonable approach to evaluate public health significance and to manage residual risks under CAA section 112. Such an approach is consistent with the Congressional language in section 112(f)(2) (see Appendix A). The 1989 benzene NESHAP presented a structure for applying ample margin of safety to setting standards for carcinogens. This two-step structure included an analytical first step to determine an "acceptable risk" after considering all health information, including risk estimation uncertainty. In the case of benzene, a linear carcinogen, this included a presumptive limit on maximum individual lifetime cancer risk of approximately 1 in 10 thousand. In the second step, the standard is set at a level that provides an ample margin of safety in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other factors such as costs and economic impacts, technological feasibility, and factors relevant to the particular decision.

4.1.2 Available Methods and Costs of Reducing Residual Risks

Section 112(f)(1)(B) of the CAA directs EPA to investigate and report on "the technologically and commercially available methods and costs of reducing [residual] risks" from HAPs. This section of the Report provides a broad characterization of post-MACT emissions, an overview of control strategies, and a discussion of key factors that will influence the available methods and costs.

Two general types of strategies can be used to reduce the human health and environmental risk associated with HAP exposure. One is to limit releases into the atmosphere. These "pre-release" strategies employ various control technologies and pollution prevention methods developed by industry to comply with regulations requiring them to reduce HAP emissions. A second approach, applicable primarily to protecting public health, is through the adoption of "post-release" strategies to keep people out of HAP exposure pathways – that is, to eliminate or minimize contact between people and HAP-contaminated media. Measures of this type can include institutional and regulatory approaches such as zoning controls and advisories, which limit public access to areas that contain unhealthful HAP concentrations, fishing restrictions and fish consumption advisories, and provision of alternate drinking water supplies. These strategies are used most often in cases where unregulated sources already have emitted large quantities of pollutants, or as emergency response measures to protect the public from pollution caused by accidents or spills.

Pre-release strategies have traditionally been the preferred method to protect the public from exposure to harmful pollutants because they minimize the impact on the environment and place the burden of managing wastes on the source itself. Pre-release methods are consistent with our environmental management philosophy of encouraging pollution prevention/recycling/treatment first, and pollution disposal/release only as a last resort. Hence, this section focuses on the technologically and commercially available pre-release strategies that can be used to reduce residual risk.

Given the site-specific and HAP-specific nature of control technology and cost determinations, combined with the fact that there are 188 HAPs and more than 170 source categories and that no post-MACT risk assessments for source categories have been completed, an in-depth discussion of the specific methods and costs of controlling post-MACT HAP emissions is beyond the scope of this Report. Instead, the remainder of this section presents a brief review of some of the emissions control strategies employed under the MACT requirements and discusses how these strategies will influence the available options for further reducing the risks of HAP emissions to the general public. A discussion of general MACT requirements is followed by an overview of currently available control strategies, with an emphasis on ways that industries can go beyond the requirements of MACT and other existing air regulations. Topics addressed include site-specific parameters needed to select appropriate controls for a specific facility and available options for reducing emissions, including add-on control equipment, process/work practice modifications, pollution prevention techniques, and voluntary/incentive based programs that encourage facilities to further reduce HAP emissions. Finally, a general discussion of the key factors that influence the costs of these various strategies is provided.

MACT Emission Standards

MACT emission standards typically require one or more of the following control requirements in order to reduce emissions: meeting a numerical or percent efficiency control target, or a design, equipment, work practice, or operational standard. For several MACT emission standards finalized as of October 1996, Tables I through IV of Appendix E summarize the control standard established for several types of emission sources (i.e., process vents, equipments leaks, coating operations, and solvent cleaning operations). The percent or level of control established in a MACT standard usually represents a certain type(s) of control technology. For example, the 98 percent control level shown in Table I for process vents usually translates to the use of thermal incineration as the control technology. However, the selection and exact specification of controls is a site-specific determination, as discussed further in the section below entitled “Available Control Strategies.”

The MACT determinations, like other broadly applicable emissions control standards, are based on decisions about the most effective, feasible, and reliable controls available. However, MACT standards in a particular source category do not necessarily represent the most stringent state-of-the-art controls available to that industry. Cost and other considerations may result in

the most stringent controls not being selected as the national MACT standard. This is because the CAA states that MACT standards for existing sources:

> ". . . shall require the maximum degree of reduction in emissions of the hazardous air pollutants... that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts...determines is achievable . . ."

Accordingly, controls capable of achieving greater HAP reductions may have been ruled out at the time of the MACT determination because of cost or other considerations. However, such costs may later be determined to be reasonable if analysis indicates significant residual risks. It is also possible that, over time, market conditions or technological improvements in certain control technologies could reduce the cost of currently expensive controls to less expensive levels, making their adoption more feasible.

Available Control Strategies

The most effective and feasible HAP control technology for a particular application must be determined on a case-by-case basis after careful consideration of many site-specific issues, such as the design of the facility, the overall manufacturing process, the chemicals being used, the emission stream characteristics, the desired control efficiency, and the cost-effectiveness of the various control options. Even within a particular industry, the methods used to control a specific type of HAP from a certain industrial process will vary from facility to facility. Because of this considerable variation in the types of controls used, a detailed discussion of specific strategies is beyond the scope of this Report. Instead, a review of the general types of methods available for control of post-MACT emissions is provided.

For the purpose of evaluating available control strategies, it is likely that emissions from source categories regulated by MACT emission standards will fall into two basic types:

(1) *Controlled* sources, which are emission sources where some degree of reduction has already taken place; or
(2) *Uncontrolled* sources, which are emission sources that emit directly to the atmosphere without constraints.

For both types of emission sources, a MACT determination was made to require either add-on controls or implementation of a work practice or an operational restriction, or not to require controls. Residual (post-MACT) emissions are emissions associated with both controlled and uncontrolled sources within the source category.

Residual emissions from controlled sources are generally streams of low HAP concentration because the original emission stream has already been subjected to a MACT level

of control. As a result, the range of available control strategies for further reductions from these low concentration streams is limited, especially for emission streams already controlled to 90 percent or higher.

Residual emissions from uncontrolled sources may range from low to high HAP concentration, but generally are of a lower magnitude of emissions than emissions from the sources subject to some level of control. Accordingly, controls capable of reducing HAP emissions from uncontrolled streams may exist, but at the time of the MACT determination there may have been no MACT floor, and controlling above the MACT floor may have been ruled out because of cost or other considerations. However, costs may later be determined to be reasonable if residual emissions are determined to present significant residual risks.

Potentially effective strategies for controlling HAP emissions – some of which will be applicable to further controlling sources already subject to MACT – include:

- Pollution prevention (P2) techniques, such as replacing hazardous substances with less harmful substitutes;
- Adding a technological control, either to a previously uncontrolled source or as a supplement to existing controls;
- Replacing existing controls with a more effective control technology; and
- Changing work practices.

Methods range from the complex and costly (e.g., redesigning the manufacturing process or retrofitting stacks with sophisticated technological controls) to less costly P2 approaches (e.g., substituting less toxic alternatives for hazardous substances or modifying work practices to reduce emissions). Facilities can be further encouraged to reduce HAP emissions through the use of voluntary/incentive based programs. This range of control options is discussed further below.

Add-on Controls. Different add-on control technologies are required for point and fugitive emission sources. Fugitive source emissions can be captured with hoods, enclosures, or closed vent systems and then transferred to a control device, such as those noted below. Improved equipment (e.g., pumps, valves, seals) may also be used to prevent fugitive HAP emissions. Different add-on technologies are used to control emissions of organic vapor, inorganic vapor, and particulate HAPs. Add-on devices used to control organic vapor emissions include combustion devices (i.e., thermal incinerators, catalytic incinerators, flares, boilers, and process heaters) and recovery devices (i.e., condensers and absorbers). The two most common methods available for controlling inorganic vapor emissions are absorption (scrubbing) and adsorption. A third technique, combustion, may be used for some inorganic HAPs (e.g., carbonyl sulfide). The three types of devices typically used to control particulate HAP emissions are fabric filters (baghouses), electrostatic precipitators, and venturi scrubbers. The applicability of each device depends on the physical and/or chemical/electrical properties of the HAP particle

under consideration in addition to the specific gas stream characteristics and parameters. Table V of Appendix E provides a summary of typical control devices currently used to reduce emissions from some source categories.

Process/Work Practice Modifications. Process modification refers to any strategy that seeks to reduce emissions by changing the operating practices of the facility or making internal equipment changes. Examples include the re-design of a system to recover and recycle the emissions stream. Some firms choose to make internal equipment changes by implementing cleaner processing technologies through equipment modifications and modernization. Many of these strategies overlap with the P2 tactics that are being used with increasing frequency by industry (discussed below). Operating practice changes include re-designing industrial processes to be more efficient, or instituting alternative work practices to reduce emissions. Work practice changes may include a wide variety of activities such as changing the ways that employees apply industrial solvents or reducing the amount of solvents used and allowed to evaporate. Also, where workers are directly involved in a manufacturing process there may be ways to change worker practices to reduce HAP emissions. Another example is increasing maintenance of process equipment. Implementing a leak monitoring program to detect and repair leaking components is an effective work practice to reduce fugitive emissions.

Pollution Prevention. Pollution prevention is the term used to describe a set of control strategies designed to minimize waste generation through cleaner production. The Pollution Prevention Act of 1990 defines P2 as any source reduction practice that "reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal." The potential benefits of P2 strategies include improving plant efficiency, saving money, and enhancing the quality and quantity of natural resources for production. In addition, P2 can be more cost-effective than traditional add-on HAP controls. While there is much discussion and debate about what exactly constitutes P2, the following general characteristics are typical:

- Reduction of substance volumes;
- Substitution for toxic substances;
- Implementation of clean technology; and
- Installation of in-process recovery equipment (recycling).

Reducing the amount of toxic chemicals used in the production process generally results in cleaner production and the generation of less waste, including HAPs. Product substitution involves replacing hazardous substances used in the production process with alternatives that result in lower hazardous substance emissions. A common example is the replacement of VOC-laden solvents and lubricants with water based formulations. Many hazardous chemicals used in manufacturing have environmentally safe substitutes that can be used in their place. In some cases there may be effectiveness and cost trade-offs to using an alternative product, but for many

industrial substances cost-effective alternatives exist. Ultimately, each of these P2 programs reduces the amount of wastes that is generated in the production process. Because the combustion of industrial wastes is a major source of HAP emissions, designing facilities to produce less waste will result in direct air quality benefits.

Voluntary and Incentive Based Approaches. More industries than ever before are voluntarily controlling emissions. This is due in part to the many federal pollution prevention programs that have been established to encourage self-regulation by industry, as well as to liability considerations, community pressures, and the desire to be a "good citizen." For several years EPA has been experimenting with voluntary partnerships between government and industry as a means to more rapidly achieve environmental goals. The Agency's 33/50, Energy Star, Green Lights, and Green Chemistry programs have succeeded in gaining commitments from thousands of industrial sources to reduce air emissions, including HAPs. Industries have responded positively to these programs because of their voluntary nature and the positive public recognition they receive for participation. Their success in achieving environmental results demonstrates that voluntary programs can be an effective way to encourage companies to adopt control strategies for reducing HAP emissions and residual risks.

Incentive based policies may be another way to reduce the total HAP emissions released into the atmosphere beyond currently mandated MACT levels. These policies allow sources the flexibility not only to choose what technologies to use for their reductions, but how extensive their reductions will be.

Control Strategy Cost

Just as specific control technologies cannot be examined until the specific source category and HAP or HAPs have been identified, the specific cost to reduce any residual risk that may remain following MACT implementation cannot be determined at this time. Cost analyses are critically dependent on numerous and various conditions, including individual source stream characteristics, HAP characteristics, site conditions at a particular facility, level of control necessary, and the various control options that may be considered. After MACT has been promulgated and a source category and particular HAP (or HAPs) have been identified for residual risk reduction, a detailed cost analysis can be performed.

Factors that may be considered in assessing the cost-effectiveness of a particular control strategy include:

- Capital costs (e.g., the cost of the equipment, estimated costs for site preparation and installation, and cost of ancillary modifications and upgrades to monitoring and process control equipment);
- Cost of capital for the affected industry;
- Fuel costs;

- Chemical costs;
- Incremental labor costs to operate equipment;
- Production penalties associated with the equipment, and other opportunity costs;
- Control efficiency for various streams;
- Expected performance degradation over the life of the equipment;
- Expected equipment life;
- Lost producer surplus; and
- Lost consumer surplus.

With this information, capital costs can be annualized; operating costs can be disaggregated into fixed and variable costs; life cycle, annual emission estimates can be derived; and costs and emission reductions can be estimated for a variety of operating scenarios. These data are typically entered into an existing model, such as the EPA model HAP-PRO, to determine control cost-effectiveness in terms of cost per mass of pollutant reduced.

4.2 Section 112 (f)(1)(C)

4.2.1 Epidemiological and Other Health Studies

Section 112(f)(1)(C) requires EPA to assess and report on "the actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies . . ." Information on actual health effects on neighboring populations resulting from HAP emissions from source categories is limited. This section presents a summary discussion of epidemiological, laboratory, and other exposure studies, then briefly describes how EPA intends to use these data and actual source category-specific health effects data that may become available in the context of section 112(f) residual risk assessments.

Current State of Knowledge

The earliest efforts to investigate the relationship between air pollution and ill health were focused on characterizing the relationship between obvious and acute effects (respiratory irritation, exacerbation of asthma, other respiratory and cardiovascular disease and death) and short-duration incidents ("air pollution episodes") of high exposures to combustion products. In extreme cases (such as the episodes occurring in Donora, Pennsylvania in 1948 and London, England in 1952) noticeable increases in acute mortality have been seen. In less serious episodes, increased incidence of respiratory diseases often occurs. Beginning in the late 1980s, studies of adverse health effects near hazardous waste disposal sites began to appear, including U.S. studies such as those conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) (Dayal et al. 1995), as well as a number of foreign studies (Klemans et al. 1995). While it has been reported that individuals who live or work in the vicinity of sources of air toxics emissions were, in some cases, found to have higher exposures than the general population (EPA 1995g), most health effects studies, generally, do not focus on populations near sources of

HAPs. Therefore, information on potential health effects of air toxics is primarily based on laboratory animal and occupational studies. These types of studies are suggestive of potential adverse effects, but usually evaluate chemicals at higher exposures than normally expected for the general human population. Human epidemiological data can give evidence of potential effects, but are often limited by lack of actual exposure conditions, lack of statistical power, or confounding factors.

Besides laboratory and occupational studies to assess health effects, investigators have employed techniques such as follow-up studies of geographic patterns of disease (particularly cancer), emissions inventories, exposure and risk assessment studies, and biomarker studies of selected pollutants (see accompanying text box). These studies generally have focused on the following major types of health effects – cancer, respiratory irritation and other respiratory toxicity, neurobehavioral toxicity, hepatic effects, renal effects, and reproductive and developmental effects – attributed to air pollutants, and investigators have evaluated associations between exposures and health effects. For example, epidemiologic studies of air toxics have focused on the cancer endpoint because (1) there are established and easily accessible data bases of cancer mortality and, to a lesser extent, incidence at national and regional levels, and (2) many toxic air pollutants are suspect or confirmed human carcinogens. Some of these carcinogenic pollutants also are convenient subjects for environmental studies because they are persistent in air and soil-water systems, and exposures can thus can be more readily measured and estimated.

Focused studies of particular classes of toxic air pollutant sources to assess effects of adverse exposures have also been performed. Initially, attention was given to the well-studied and common metallic pollutants such as cadmium and lead, other criteria pollutants, or other general indicators of air quality. Some of the toxic metals represent special cases, each having its own unique pattern of non-cancer effects. The renal effects of cadmium exposures (ATSDR 1993a), neurodevelopmental impacts of lead (ATSDR 1993b), and reproductive toxicity of mercury exposures (ATSDR 1994) are the most well-studied examples. In addition, a few studies use total mortality, or cause specific mortality, as endpoints. Individually, these various studies have provided data that contribute to an understanding of the relationship between air pollution exposure and adverse effects, on both the qualitative and quantitative level.

The Agency has recently surveyed the published literature on the actual human health effects of outdoor air toxics exposures at ambient levels (EPA 1995g), and some information from this study is summarized in this section and provides examples of the difficulties inherent in making causal connections between exposure and effects. One of the most extensively investigated connections between exposure to air pollutants and health effects is that between lung cancer and exposure of populations near smelters to arsenic. Several studies have addressed this relationship (Brown et al. 1984; Frost et al. 1987; Pershagen 1985). These studies tend to show increased risk associated with exposure (or exposure surrogates, such as distance from the smelter), although the apparent increase was not statistically significant in all cases. For example, Frost et al. (1987) found that lung cancer patients were more likely to live close to an

SOME APPROACHES TO ESTABLISH RELATIONSHIP BETWEEN AIR TOXICS EXPOSURE AND HEALTH EFFECTS

- **Laboratory Studies.** Adverse health effects of exposures to specific pollutants are often evaluated in studies with laboratory animals or human volunteers. In these studies, the pollutant concentrations are likely to be higher than the exposures to the general population, and with animal studies, extrapolation of the observed effects to humans must be considered.
- **Studies of Geographic Patterns of Disease Incidence or Mortality.** Studies of vital statistics, disease incidence, or mortality may disclose geographic patterns of adverse health effects that are suggestive of a relationship to specific pollutants or pollutant sources. If such studies are not supplemented by exposure data, and are not controlled for confounding factors other than pollutant exposures, it is not possible to support inferences of causation associated with pollutant exposures.
- **Studies of General Population Exposures, Exposure Indices, and Biomarkers.** These types of studies have been used to estimate human exposures to pollutants and draw inferences about potential adverse effects. The collected information is often used, in conjunction with toxicity data, to conduct risk assessments. In some instances, measurable indices of exposures (biomarkers of exposures), such as body burdens or tissue concentrations of pollutants, can be used to document exposures and evaluate the potential for adverse effects.
- **Occupational Exposure/Epidemiology Studies.** Health effects of specific pollutants are often first discovered through observations of adverse effects in workers exposed to high levels of the pollutants. These studies, however, do not directly address the potential for adverse effects occurring in the general population at lower exposure levels.
- **Formal Environmental Epidemiology Investigations.** A "formal" environmental epidemiology study involves systematic investigation of the relationship between an observed pattern of adverse health effects and exposures to one or more agents. The analysis of actual (as opposed to estimated) health outcome information is what distinguishes an epidemiological study from a risk assessment or a biomarkers study. Systematic efforts to control for confounding factors (factors other than exposures to the toxic substances of interest which may be responsible for the observed effects) are what distinguish a formal ("analytical") epidemiologic study from a simple "descriptive" summary of geographic patterns of disease incidence. Often, formal epidemiologic studies are not a powerful enough tool to discern relatively small increases in disease.
- **Risk Assessments.** In a risk assessment, information about exposures (which may reflect actual measured exposures or exposures estimated using emissions and environmental models) is combined with toxicity information (from occupational or laboratory studies) to develop predictive estimates of the frequency or severity of occurrence of adverse effects in human populations. There is a high degree of uncertainty due to imprecision in exposure estimates and uncertainties in dose-response information, especially at low doses.

arsenic-emitting smelter (borderline statistical significance) in a case control study that was conducted with women to reduce confounding from occupational exposure. However, there was no control for smoking and no effect was seen in the cross-sectional phase of their study. Pershagen (1985) analyzed lung cancer data near an arsenic-emitting smelter, with the data stratified by smoking status and occupational exposure. In the group that was not occupationally exposed, there was an increased relative risk with proximity to the smelter for both nonsmokers and smokers, but the increase reached statistical significance only among the smokers. Hughes et al. (1988) reviewed more than 10 studies investigating health effects (primarily lung cancer) in communities near arsenic-emitting industries. They noted that about half of the studies reported significant increases in adverse effects while about half of them reported no effect or decreased

risk in the exposed populations. However, these authors noted that many of the studies (particularly those that observed no statistically significant effect) lacked sufficient statistical power to detect the small increases in risk that would be expected, and suggested that some small increase in risk is likely.

With respect to other effects, Nordstrom et al. (1978) found decreased birth weight in babies born to mothers who lived close to an arsenic-emitting smelter. However, it is unclear if the magnitude of the decrease was clinically significant (Hughes et al. 1988).

Several studies have attempted to show an association between vinyl chloride emissions and central nervous system birth defects (Edmonds et al. 1978; Rosenman et al. 1989; Theriault et al. 1983). While all of these studies reported some association between potential exposure and disease, each was limited by uncertainties in the exposure estimates, implausible results, or potential confounding factors such as smoking or drinking. Overall, these studies provide insufficient data to conclude that there is a causal relationship between ambient air exposure to vinyl chloride and central nervous system birth defects.

An overall view of the epidemiologic literature on exposure to air toxics in the environment is consistent with the notion that concern is warranted. However, understanding of the risks to individuals living near sources and exposed daily to these air toxics is limited or confounded by other factors. Except for a few well-known cases (the sudden release of a large volume of methyl isocyanate in Bhopal, India, for example) where extremely high exposures to accidental releases of industrial chemicals resulted in severe acute health effects, the adverse effects of exposures to airborne hazardous chemicals are generally very difficult to detect.

Because of the difficulties in the extent and usability of epidemiology data, EPA has looked into other types of data that may help bridge the gap between cause and effect. In this context, the state-of-the-art in exposure monitoring and the use of biomarkers has become an expanding field of research. For example, the existing literature on neurobehavioral effects of toxic air pollutants is dominated by discussions of the adverse effects of lead on intellectual and behavioral indices in children. These studies generally describe decrements in performance as a function of biomarkers of lead exposure, such as blood lead concentrations or heme metabolite levels. There is, however, little information available from these studies on the sources of lead exposures, and lead from deteriorating paint and in pipes and solders used for drinking water distribution can contribute significantly to total exposures.

In a study by Binkova et al. (1995), PAH DNA adducts were measured in a group of women in the Czech Republic who worked outdoors for about eight hours per day. Personal exposure monitoring was used, allowing both indoor and outdoor exposure to PAHs to be evaluated; exposure to respirable particles (<2.5 μm) and PAHs was measured. Levels of DNA adducts in white blood cells were increased immediately after days of high PAH exposure. This study demonstrated that DNA adducts can be used as biomarkers of exposure, reflecting short-term exposure levels. In addition, DNA adducts can be used as biomarkers of effect, because, if unrepaired, they can lead to gene mutations, which in some cases can ultimately lead to cancer.

However, due to the multiple steps from gene mutation to cancerous cell, DNA adducts and gene mutations are best viewed as indicating carcinogenic potential rather than indicating actual risk of cancer.

Blood or tissue concentrations of metals such as cadmium are also occasionally used as indicators of exposure and potential adverse effects for airborne toxics. Among the studies that use biomarkers of exposure are evaluations of tissue, hair, and urine cadmium levels in a population near heavily industrialized cities in Russia (Busteva et al. 1994). Urinary cadmium is a reliable indicator of recent cadmium exposure, as shown by several occupational studies. The presence of the protein β-2-microglobulin in urine (termed proteinuria) is also considered a reliable indicator of cadmium exposure. Busteva et al. (1994) reported that the percentage of factory workers having elevated levels of this protein in their urine (>250 ug/l) was highly correlated with the air content of cadmium. Although no significant effect was seen in the general population, this may have been due to the small sample size and resulting low statistical power. Collecting biological samples and conducting laboratory testing, as in this study, is more labor-intensive than doing epidemiological investigations using disease registries. However, because proteinuria is a well-characterized effect of cadmium exposure, and both exposure and effect biomarkers can be monitored by urinalysis, this technique has applicability where high exposure to cadmium is expected.

Another potential source of information may be nationally standardized and comprehensive disease registries or data bases for adverse effects of toxics exposures, such as birth defects and reproductive outcomes (Shy 1993), but again, there are limitations in its use. Currently, studies that use these sources require investigators to obtain access to local or State health status information, whose availability is highly variable from State to State, or to obtain information from hospital or other medical records where confidentiality may become an issue. This difficulty is less of a concern for case control studies, but can severely limit the ability to do large-population cohort analyses or cross-sectional studies.

Acute effects such as seen in occupational settings are less likely to be seen in studies of the general population exposed to toxic air pollutants at ambient levels, with the possible exception of chemicals that have specific irritant properties. In addition, the effects of usually low chronic exposures to toxic air pollutants may be subtle, and may develop slowly over time in response to cumulative exposures (chronic effects), or may not develop until long after exposures occur (latent effects). Information on exposure levels to toxic air pollutants near sources, as well as to "background" pollutants that may be confounding the results of air pollutant epidemiology studies, is also generally limited. Thus, it is not easy to directly estimate the risks associated with general population exposures to toxic air pollutants under conditions of chronic low-level exposures. Nonetheless, it is currently assumed for prudent public health reasons that such effects may be occurring because, for example, many toxic air pollutants are suspected or known human carcinogens and even low levels of exposure could theoretically cause increased cancer risks. In a smaller number of cases, animal or controlled human studies indicate that noncarcinogenic effects might be expected to occur at exposures near ambient levels. In some instances, allergic sensitization may result in adverse effects in a small, especially sensitive

subset of the exposed population. There is presently no national monitoring system for air toxics that can provide even general information on the urban and rural concentration patterns of these pollutants in ambient air.

Other issues to consider in trying to assess the actual health effects of air toxics include (1) the lack of indoor exposure data and (2) the often observed coincidence between exposures to toxic air pollutants and exposures to criteria air pollutants. Information on indoor exposure data is useful since the majority of individuals spend most of their time (usually 80 percent or more) indoors. Because concentrations of some air toxics in indoor air tend to be quite different from (and often higher than) those outdoors, studies which do not take indoor air quality into account will have difficulty in elucidating the true relationship between these air toxics exposures and effects. Both toxic air pollutants and criteria pollutants are associated with areas of high population density and industrial development, and many epidemiologic studies simply use measures of one or a few criteria pollutants as the sole measure of exposure, and use it as a proxy for all "air pollution." For example, in many studies that assess the relationship between particulate exposures and acute and chronic health effects (usually where there is no clearly identified dominant source of particulate air pollutants), it is not known which chemical or physical constituents of particulates contribute to the observed increases in risk, and it is therefore not possible to attribute any given fraction of these effects to toxic air pollutants.

Strategy for Considering Epidemiology/Other Health Information in Residual Risk Analyses

Early in the data gathering stage of a residual risk analysis, the Agency will search the scientific literature for published epidemiological studies related to the specific source categories, HAPs, and/or locations studied. These reports will be evaluated for quality, with preference given to those covering emissions from the source categories of concern at environmentally relevant concentrations over long periods. Where published epidemiological studies are unavailable, the Agency may also consider, as part of its refined analysis, examining other types of available human health data for possible correlations between exposure and adverse effects. Potential sources of health effects information include State or national disease registries (e.g., the Centers for Disease Control's Birth Defects Monitoring data base), hospital and other medical records, death certificates, and questionnaires. The EPA intends to coordinate the identification, collection, and review of such data with the Public Health Service and other federal, State, and local public health officials. Examples of widely reported outcomes include cancer incidence or mortality, birth defects, and respiratory symptoms. Information on pollutant specific biomarkers – biological measurements associated with exposure to certain pollutants – may also be available. Exposure to HAPs may be estimated in several ways, including ambient monitors, mathematical modeling, or personal air monitors. The Agency recognizes the difficulties that exist in obtaining actual health effects data. However, EPA believes that it may be useful to incorporate some kinds of health effects/epidemiology data in the residual risk assessments for selected air pollutants and source categories and intend to use existing data wherever scientifically appropriate. The Agency will consider any such available public health information in the risk characterization step, and will present and discuss the risk estimates in the

context of such information. Clearly, any actual health effects data can generally only be used to help establish current or past conditions, and cannot be used directly in the prediction of post-MACT risks that may occur in the future (i.e., residual risks).

4.2.2 Risks Posed by Background Concentrations

Section 112(f)(1)(C) also requires EPA to assess and report on "risks presented by background concentrations of hazardous air pollutants . . ." This section of the Report discusses general information on background levels and presents a definition of background concentrations for residual risk purposes. It describes approaches used by other EPA programs and includes examples of rules and guidance that consider the issue of background. It also presents a discussion of the difficulties in addressing background concentrations in residual risk analyses and identifies data needs to assess background. The section concludes by describing options to analyze and consider background concentrations in residual risk analyses. It describes how EPA will assess available monitoring data for individual source categories under study, and how background concentrations will be evaluated in residual risk assessments and treated in decision-making.

Background concentrations may be considered to be the levels of contaminants that would be present in the absence of contaminant releases from the source(s) under evaluation. Background concentrations come from contaminants that either may occur naturally in the environment or originate from anthropogenic sources. Background contamination can be localized or ubiquitous. An example of localized contamination is the presence of high concentrations of trace metals in dust from geologic formations naturally high in trace metals. An example of ubiquitous contamination is the widespread presence of low concentrations of polyaromatic hydrocarbons in soil and dust in areas near forest fires.

The EPA's Science Policy Council is developing a cumulative risk policy with the goal of developing a framework for conducting cumulative risk assessments. While Part 1 of the *Guidance on Cumulative Risk Assessment* released in August 1997 (EPA 1997n) does not provide an explicit definition of cumulative risk or background, in general cumulative risk is considered to include risks from multiple sources, pathways, and pollutants. The cumulative risk guidance identifies elements that must be considered in a cumulative risk assessment such as the cumulative effects of mixtures on different and the same target organs from multiple sources by direct and multipathway exposures. Cumulative risk is therefore broader than the "incremental

risk" (or "excess risk") attributable to a given source/pathway/pollutant combination under evaluation.

The general approach in risk assessments and risk management decisions has been to assess incremental risk of a particular source or activity and compare that risk to an "acceptable risk" criterion (or set of criteria). Various EPA programs, however, have taken specific approaches to considering background risks, some of which are summarized below.

EPA Programs and Rules that Consider Background Concentrations and Risks

Site risk assessments under Superfund and the RCRA corrective action program require the collection of background samples at or near hazardous waste sites in areas not influenced by site contamination, but that have the same basic characteristics as the medium of concern. Generally, comparison of background and source-related contamination is used to identify areas affected by the source and contaminants attributable to the source. Incremental risks are then assessed for contaminants in media demonstrated by comparison with background concentrations to have originated from the source. The level of risk reduction is generally set by cleanup levels based on achieving an acceptable risk or reducing contaminants to background concentrations, whichever is least stringent. However, in some cases where anthropogenic background levels exceed cleanup goals, EPA may determine that a response action under Superfund is necessary and feasible, and a comprehensive plan may be developed to address area-wide contaminated media not originating from the site source. In such cases, reduction of anthropogenic background risks becomes an additional goal of the remediation program.

In 1993, EPA's Office of Wastewater Management developed a comprehensive risk-based rule, known as the "Part 503" rule, to protect public health and the environment from the anticipated adverse effects of pollutants that may be present in sewage sludge that is applied to land. Using the results of the rule's multipathway risk assessment that considered soil background metal concentrations in the calculations of risk-based pollutant concentration limits, EPA set pollutant concentration limits above which sludge could not be applied. The limits were derived by calculating the increment of pollutant from sewage sludge that could be added to the total background receptor intake or plant uptake without exceeding a threshold dose. For human receptors, the threshold dose was set for noncarcinogens at the chronic effects RfD, and for carcinogens, at an incremental individual lifetime cancer risk of 10^{-4}. For non-human and plant receptors, background soil concentrations were subtracted from reference adverse effect concentrations to calculate the increment of a pollutant from sewage sludge that could be applied to soil without adverse impact. In short, soil-related background concentrations and risks were directly and quantitatively considered in this risk management decision.

The Office of Water has developed methods to set maximum contaminant level goals (MCLG) at concentrations at which no known or anticipated adverse health effects occur. Drinking water equivalent levels (DWEL) are calculated from RfDs by assuming a specific

receptor body weight and consumption rate. The MCLG is set by multiplying the DWEL by the percentage of the total daily exposure expected to be contributed by drinking water (i.e., the "non-background" portion), called the relative source contribution (RSC). Generally, the Agency assumes that the RSC from drinking water is 20 percent of the total exposure, unless specific exposure data for a chemical is available, and that 80 percent of exposure comes from other sources. The RSC may be as high as 80 percent. The Agency also is using this approach of reserving a portion of risk to background in setting pollutant limits covered by the Food Quality Protection Act (FQPA) and in the Office of Pesticide Program's re-registration decisions.

EPA has not addressed in detail the issue of background risks or cumulative risks in RCRA hazardous waste listing determinations. In a recent hazardous waste listing determination for petroleum refining process wastes, analyses were conducted that considered multiple wastes disposed in land units (wastes with similar constituents from other sources) and multiple units at a facility, thus accounting for the impact of certain other background sources.

Difficulties in Addressing Background Risk

The Agency's lack of a generalized approach to considering background risk in its risk assessments and risk management decisions is demonstrated by the absence of discussion of background risks in many of its major rules and the simplified approaches used in rules that consider background concentrations. This may be due to mandates of environmental laws and the fact that accounting for all possible sources and routes of exposure to pollutants with similar toxic mechanisms is a complex and expensive task with many variables requiring much input data. Methods used to assess risk are evolving and new, more sophisticated models and strategies to assess multiple pathways of exposure are being developed. These models require many variables to accurately account for all sources of background risk, at least some of which are not likely to be available. Lack of data and funds required to collect the extensive data needed to assess multiple direct and indirect pathways has often resulted in the use of simplified assumptions and models such as limiting assessments to direct exposure pathways and regulatory decisions that set background contributions to conservative default values. What is considered background risk is also affected by the approach taken to define a "source" (e.g., whether the assessment of risk is performed on a source category basis or a point source basis).

Background concentrations are not static. The half-lives of contaminants are wide ranging and must be considered when assessing risks over a period of time. Persistent and bioaccumulating contaminants moving along the foodchain alter background concentrations over time. The exchange of contaminants between media (e.g., particulate deposition in surface water) also introduces a time-related background change. In addition, regulatory changes that reduce releases of contaminants from sources will, over time, alter background concentrations of those contaminants. For example, if drinking water standards (or other standards affecting exposure) are lowered for certain pollutants, exposures and any resultant risks from those pollutants are also lowered. Similarly, residual risk reductions in the incremental risk of some HAPs will ultimately reduce any associated background risk and consequently, overall risk of those pollutants. However, given the considerable uncertainties in risk assessment generally, it is

not clear that a thorough consideration of background, even if possible, would greatly improve the overall conclusions of the assessment. An additional issue raised by the long residence time of certain HAPs is the relationship between the amount of emission reductions and the amount of risk reduction.

Defining Background for Residual Risk Analyses

Given the complexities associated with assessing cumulative risk from all chemicals and sources, background concentrations and risks for residual risk analyses will be assessed whenever possible on a chemical-by-chemical basis for the particular HAPs under evaluation. Although other chemicals may contribute to the cumulative background risk because of interactions or effects on the same target organ, the data needed to evaluate cumulative risks from multiple chemicals is quite extensive and difficult to collect. Thus, background concentration of a particular HAP for either an affected source or source category under evaluation is defined as the concentration of that particular HAP in environmental media attributable to natural and anthropogenic sources – both on-site and off-site – other than the source being evaluated. As described above, background concentrations may change over time, and analysis of background risks would be more accurate if these changes in background concentrations were accounted for. However, because of analytical complexity (e.g., data needs, modeling difficulty, high uncertainty), background concentrations generally will be based on a given point in time when taken into account for residual risk analyses.

Therefore, for the residual risk program, background concentrations will be considered from two perspectives: the contribution of HAPs from natural sources, and the contribution of HAPs from all anthropogenic sources other than the source under evaluation. For a particular point source at a facility, for example, the contaminants present in air in the absence of the source under evaluation may originate from natural sources as well as from other on-site and off-site emissions sources. It follows that the background risk is the cumulative risk from all possible natural and anthropogenic sources of a HAP other than the particular source or source category under evaluation. Residual risk may be assessed in the context of both kinds of background when the sources can be identified and their contributions measured and compared.

Strategy for Considering Background in Residual Risk Analyses

Residual risk analyses will assess incremental risk above background risk, and then assess the significance of these risk estimates using acceptable risk criteria developed and used historically for judging incremental risk. As described in this Report, residual risk will be addressed in a two-tiered approach. In the relatively simple screening tier of analysis, the residual risk analysis generally is performed without considering background at all. At most, local or regional scale estimates of background concentrations based on statistical analyses of monitoring data or screening-level modeling analyses (such as air concentration estimates developed in our cumulative exposure project) may be considered. This screening analysis is typically conducted using conservative methods and assumptions and results are compared to acceptable risk criteria. Where residual risk estimates exceed the criteria, a more refined analysis

is conducted. In general, an in-depth modeling analysis of background concentrations will be beyond the scope of the refined analysis, although available background concentration data or other relevant information would be considered. As discussed above, a detailed analysis of background concentrations typically would require extensive data gathering and modeling beyond that required for the incremental risk analysis. For example, numerous nearby (and possibly distant) HAP sources of varying types would need to be characterized in sufficient detail to support release and exposure modeling. In some cases, background risks from HAPs potentially could be considered to play a critical role in evaluation of the need for further reduction of the incremental risk. Thus, for some source categories, or some individual sources, it may be determined that detailed analysis of background concentrations is warranted.

In such cases, the relative contribution of background to the total risk from HAPs would be considered in decisions for more stringent regulation and may influence the level of reductions required to obtain an "ample margin of safety." If the relative contribution of background risk is high compared to the incremental residual risk, additional source risk reduction may provide relatively negligible benefit. Alternatively, a high relative contribution to total risk by the incremental risk might strengthen the rationale for requiring more stringent regulation. As described above, EPA has reserved part of the "risk burden" for background risk in other regulatory programs (e.g., drinking water and pesticide programs), and this kind of approach will be considered in residual risk decision-making for HAPs. In the risk characterization step, EPA will consider and present the risk estimates in the context of the available information on background.

The data needs for assessment of background concentrations may differ depending on whether a source category or a specific source is under evaluation. For a specific source, identifying the background concentrations from other natural and anthropogenic emissions sources within a specified radius of the source will usually be considered sufficient to demonstrate the relative contribution of background to overall risk and the impact of the single source relative to other sources surrounding it.

4.2.3 Uncertainties in Risk Assessment Methods

This section responds to the CAA section 112(f)(1) requirement to address “any uncertainties in risk assessment methodology or other health assessment technique,” with a focus on uncertainty in residual risk assessments. Uncertainty, when applied to the process of risk assessment, is defined as “a lack of knowledge about specific factors, parameters, or models” (EPA 1997c). When applied to the results of risk assessment, the term “uncertainty” refers to the lack of precision in the risk estimate due to uncertainties in the input assumptions, models,

and parameter values. Examples of uncertainty relevant to the estimation of residual risks include a lack of knowledge about the nature of a dose-response relationship for a given HAP or a lack of data about pollutant emissions over time. Such uncertainties affect the precision and reliability of any risk estimates that were developed for individuals exposed to the substances (EPA 1988b). Even using the most accurate data with the most sophisticated models, uncertainty is inherent in risk assessment. Uncertainty is usually present in all stages of risk assessment. Although other taxonomies are sometimes used, sources of uncertainty in risk assessment are often described by the following categories (Finkel 1990):

- Uncertainty related to the conditions and circumstances of exposure (scenario uncertainty);
- Uncertainty in the structure of models used to estimate risks (model uncertainty);
- Uncertainty in the input values used in risk assessment models (parameter uncertainty); and
- Inherent heterogeneity (variability).

Uncertainty can be introduced into a health risk assessment at every step in the process. It occurs because risk assessment is a complex process, requiring integration of the:

- Fate and transport of pollutants in a variable environment by processes that are often poorly understood or too complex to quantify accurately;
- Potential for adverse health effects in humans as extrapolated from animal toxicity tests; and
- Probability of adverse effects in a human population that is highly variable genetically, in age, in activity level, and in life styles.

The presence of uncertainty in risk assessment does not necessarily imply that the results of the risk assessment are biased, only that the risks cannot be estimated beyond a certain degree of precision. One of the key purposes of uncertainty analysis is to estimate the degree of precision in risk estimates derived from uncertain scenarios, models, and parameters. In addition, uncertainty importance analysis can be used to identify the factors that contribute the most to the overall uncertainty in risk estimates. Efforts to refine scenarios and models or to gather more data can then be prioritized to provide the greatest reduction in risk uncertainty at the lowest cost.

Evaluating these different kinds of uncertainty in risk assessment may require different methods, as discussed in more detail later in this section. An important general property of uncertainty is that it can be reduced by gathering information. Where directly relevant data are not available, appropriately selected surrogate data may serve to reduce uncertainty.

The other important part of the general problem of "uncertainty analysis" is the need to characterize the potential *variability* of scenarios, models, and parameters and how such

variability affects risk estimates. In contrast to uncertainty, variability has nothing to do with data quality or a lack of knowledge of fundamental relationships, but instead "refers to observed differences attributable to true heterogeneity" in the variables (EPA 1997c). Examples might include variations in hourly wind velocity or in the body weights among an exposed population. Because variability is an intrinsic property of the quantities being evaluated, it cannot be reduced by data gathering or refinements in models. Analyses of variability are still important, however, to assure that inputs to risk models are specified appropriately. For example, it may be found that certain HAP emission sources or exposed populations are heterogeneous, and more reliable estimates of risk can be developed by stratifying them and estimating risks separately for each group.

In the context of residual risks, uncertainty analysis has important implications both for risk assessment methods and for risk management. The following are among the key methodological issues that arise in the context of residual risk.

- Have all the important sources of uncertainty and variability in the scenarios, models, and input variables to the risk assessment been identified?

- What are the appropriate methods to evaluate uncertainty and variability, given the needs of the decision-making process, the capabilities of available models, and the data and resources that are available?

- What additional data or model refinements can be used to reduce uncertainty in the risk estimates?

- How can information about uncertainty be summarized and presented to decision-makers?

From the risk management perspective, important issues associated with uncertainty analysis may include the following:

- What are the most useful measures of uncertainty in risk estimates (from a risk management standpoint)?

- What is a reasonable range over which the risk estimate might vary?

- What is the level of certainty that the residual risk estimate is actually greater than zero or less than a defined LOC?

- How reliably can the relative risks be compared? How well can risks be ranked?

- What is the overall reliability of a specific risk estimate applied to a given decision?

Clearly, risk assessment and risk management issues overlap. In the discussions that follow, the importance of adequate communication between the risk assessors and EPA risk managers is stressed.

Approaches to Addressing Uncertainty and Variability in the Estimation of Residual Risks

Systematic uncertainty and variability analyses have been used in support of risk assessment in a number of fields, most notably nuclear engineering, for over three decades. The use of uncertainty analysis in health risk assessment for exposure to chemical agents did not become widespread until the 1980s (Bogen and Spear 1987). Since then, a wide range of techniques for quantitative uncertainty analysis have been developed and applied to risk-related policy analysis (e.g., Morgan and Henrion 1990; Frey 1992; Hoffman and Hammonds 1994; McKone 1994; Hattis and Barlow 1996). In its 1994 report, *Science and Judgment in Risk Assessment*, NRC recommended that, when possible, uncertainty and variability should be quantified and the distinction between them maintained throughout risk assessment (NRC 1994). As discussed below, a number of techniques are available that allow the separate analysis of the impacts of uncertainty and variability on the overall dispersion in risk estimates.

The EPA has long recognized the need to consider uncertainty and variability in risk assessment. Agency guidance on these issues has gradually evolved over more than a decade, with major documents including:

- Initial set of risk assessment guidance documents (e.g., EPA 1986f,b);
- Risk Assessment Council (RAC) guidance ("the Habicht Memorandum," EPA 1992e);
- *Guidelines for Exposure Assessment* (EPA 1992a);
- Policy and guidance for risk characterization ("the Browner Memorandum," EPA 1995a,f);
- *Summary Report of the Workshop on Monte Carlo Analysis* (EPA 1996g); and
- *Policy for Use of Probabilistic Analysis in Risk Assessment* (EPA 1997k) and *Guiding Principles for Monte Carlo Analysis* (EPA 1997c).

Among these documents, the 1992 exposure assessment guidance, the 1997 *Policy for Use of Probabilistic Analysis in Risk Assessment*, and 1997 *Guiding Principles for Monte Carlo Analysis* provide the most detailed recommendations for uncertainty and variability analysis. The former document primarily provides technical guidance on uncertainty evaluation in the context of exposure assessment, while the latter two provide refined technical guidance, as well as recommendations on presentation of uncertainty information to decision-makers. The 1997 Policy also documents EPA's judgment that probabilistic methods should be used wherever the circumstances justify these approaches. Thus, the Agency is committed to carefully considering use of quantitative methods for evaluating uncertainty and variability in its residual risk assessments. The Agency has also recently released a revised version of the *Exposure Factors*

Handbook (EFH) that supports probabilistic approaches to the treatment of a number of commonly employed risk assessment input variables (EPA 1997g). In April 1998, the EPA Risk Assessment Forum convened a workshop on uncertainty analysis in which the problems associated with defining probability distributions for uncertainty and variability analyses were discussed.

As techniques for uncertainty analysis have matured, the Agency has come to endorse a tiered approach to such analyses. In residual risk and other air toxics analyses, EPA plans on addressing uncertainty in a tiered approach. In this way, EPA can efficiently utilize resources, mirroring the level of uncertainty analysis to the overall level of analysis. In the *Policy for the Use of Probabilistic Risk Analysis in Risk Assessment* (EPA 1997k), four general steps (tiers) in the recommended approach to quantitative uncertainty analysis are identified:

- Single-value estimates of high-end and mid-range risk;
- Qualitative evaluation of model and scenario sensitivity;
- Quantitative sensitivity analysis of high-end or mid-point estimates; and
- Fully quantitative characterization of uncertainty and uncertainty importance.

This approach starts with simple assessments of potential risks using both representative and more conservative scenarios, models, and input values, using point estimates of the major parameters. This approach may provide sufficient information for the policy question being addressed in some cases. For example, if risks for a suitably defined high-end receptor are far below levels of concern, then no additional uncertainty analysis (or risk analysis) may be needed to support a risk management decision. Such screening analyses will probably be appropriate as the first step in the analysis of residual risk uncertainty for all of the source categories.

Where the single-value high-end and mid-range estimates do not provide sufficient information about residual risk, additional analyses can be conducted to determine the likely range of uncertainty in these estimates, and the major factors that contribute to the uncertainty of the estimates. The sensitivity of the high-end and mid-point estimates to the specification of scenarios and models can usually be evaluated by conducting a manageable number of case studies using different model specifications and observing the resulting changes in risks. If scenario or model specification turns out to strongly affect risk estimates, a more refined analysis (see below) may be necessary.

In addition to the evaluation of scenario and model uncertainty, it may be desirable to evaluate the sensitivity of the point estimates of risks to variability and uncertainty in model input parameters. This may be done through sensitivity analysis or through the use of more detailed probabilistic methods. If sensitivity analyses are used, care must be taken to insure that the combinations of parameter values that have the greatest impact on risks are identified. For example, the greatest contributions to uncertainty may arise where two or more variables take

values that are only moderately different from their mean values, rather than where either one of them takes an extreme value.

For some source categories, systematic sensitivity analyses would provide sufficient information regarding residual risks, and the uncertainties associated with these risks. If they do not, the next step is explicit probability modeling, most likely Monte Carlo or related simulation methods. Using such approaches, uncertainty and variability distributions can be defined for the major parameter values used in the derivation of the mid-range and high-end risk estimates. These distributions would then be used to develop Monte Carlo estimates of risk and risk uncertainty. There are many precedents for the application of such methods (Frey and Rhodes 1996) in the evaluation of potential risks from HAP sources.

Whether sensitivity analysis or simulation modeling is used, it is important to consider both uncertainty and variability at this stage of the analysis. Very often, key parameters in the residual risk assessment will be highly uncertain. Experience to date indicates that the emission-related parameters with a particularly high degree of uncertainty include measurements of emission rates, emissions inventories, ambient levels, and facility operating patterns that affect HAP releases. On the risk side, uncertainties in dose-response models, dose-response parameters, populations exposed, and behavior patterns associated with exposures seem to contribute significantly to the overall uncertainties in population risk estimates.

Where data are lacking or limited, it may be necessary to extrapolate beyond the range of available information, or use surrogate data where direct observations are not available, in order to develop estimates of parameter variability and uncertainty. The Agency is currently exploring a number of promising techniques in this area. Where relatively few data are available, statistical techniques such as bootstrap analysis may be used to develop variability and uncertainty distributions. Where important data are lacking, techniques for eliciting expert opinion (Morgan and Henrion 1990) may be useful in developing estimates of the uncertainty and variability of key parameters.

While these techniques can be very helpful in characterizing uncertainty, it is important that all assumptions and methods be fully documented, and that the available data sources be fully exploited before extrapolation or surrogate data are used. Decisions regarding the appropriate methods to be used in developing uncertainty distributions must be made on a case-by-case basis, carefully considering the specific needs of the analysis.

The final step in the analysis is a fully quantitative analysis of uncertainty and uncertainty importance. This approach is basically a more comprehensive extension of the previously described methods. In this case, however, rather than starting from pre-defined central-tendency and high-end risk estimates, all scenarios and models (to the extent possible) and all parameters are included in the modeling process as uncertainty and variability representations. Using standard two-dimensional Monte Carlo simulation methods, the effects of variability and

uncertainty on the overall dispersion in risk estimates can be separated and quantified. In addition, the relative importance of individual sources of uncertainty can be evaluated through partial correlation coefficients, regression methods, contributions to variance, or related methods. However, the data requirements of such an analysis often limit its ability to be truly comprehensive.

Within the residual risk program, this option will be appropriate for sources or source categories where potential risks may indicate the need for a risk management action. The importance analysis could be used to guide data gathering to parameters where uncertainty is the greatest, or to define conditions (e.g., average emissions or operating conditions) for which risk estimates would not exceed levels of concern with a high degree of confidence.

Uncertainty and the Management of Residual Risks

It is important to recall that the underlying purpose of the evaluation of uncertainty is to improve the quality of the decisions that are made regarding the management of risks. In the context of residual risks, the primary purpose of the assessment is to support decisions about whether additional controls are needed, over and above initial MACT standards, to reduce risks to acceptable levels. Thus, at a minimum, the uncertainty analysis needs to supply risk managers with a defensible technical basis for decisions. The important questions to be addressed include: What is the risk? How reliable is the risk estimate? What is the expected reasonable range of outcomes if a specific decision is acted upon? To these might be added two other key "threshold" question, namely: Is there enough information to support a decision and, if not, what kinds of data are needed to reduce uncertainty to acceptable levels?

A well-conducted uncertainty analysis can provide defensible and well-qualified answers to all of these questions. If it is to do so, however, a substantial degree of interaction between risk assessors and risk managers is required. Preferably, this interaction begins early in the risk assessment process, when risk managers clearly articulate their information needs to the assessors, and assessors present options for meeting those needs. The interaction continues throughout the assessment process and into the risk communication phase, when the results of the analysis are formally presented to risk managers. The Agency has made efforts to explore the nature of the interaction that needs to occur and the nature of the informational needs of risk managers (Bloom 1993), and will continue to do so to assure that uncertainty analysis makes a constructive contribution to risk management decisions.

A second key purpose of the uncertainty analysis is to provide information useful to stakeholders involved in the decision process. As the federal government pursues its goals of expanded stakeholder involvement in risk management decisions (CRARM 1997a,b), a premium is being placed, as it should be, on providing information that is useful and intelligible to non-technical audiences. If support is to be secured for decisions, the decision rationale must be"transparent" and understandable to affected parties.

The complexity of uncertainty evaluation, and particularly of probabilistic methods, may pose a significant barrier to understanding (and thus to the utility of the analysis). In the past, regulatory decisions have been evaluated primarily in terms of point estimates of risk and simple dichotomous decision rules. (If the point estimate of risk is above a certain level, take a certain action. If not, take another action.) In contrast, it may not be intuitively obvious, even to relatively sophisticated audiences, how to relate the outputs of quantitative uncertainty evaluation to a particular decision. For example, important aspects of the regulatory decision may rest on relatively subtle statistical distinctions (e.g., between a 95th percentile risk estimate and an upper 95th percentile confidence limit on a risk estimate), and the challenges in presenting such information can be formidable. In its recent guidance, the Agency has begun to define concrete approaches to the presentation of risk and uncertainty information to decision-makers and stakeholders. A promising approach involves relying heavily on narrative descriptions of uncertainty and simple diagrammatic presentations of risk information. These efforts will need to be continued and elaborated in the course of the Agency's residual risk assessments.

The question of how to present the results of uncertainty analyses overlaps with the more general problem of risk communication. As noted in Section 4.1.1, the Agency is required to report on the "public health significance" of residual risks. This level clearly has a probabilistic component; e.g., how certain does the Agency need to be that a risk is or is not "significant"? Is there some intermediate combination of risk and uncertainty that indicates the need for more data gathering, rather than immediate management? How can uncertain risks be compared and prioritized? The answers to these questions depend not only on the magnitude of the risks being evaluated and the magnitude of uncertainty associated with the risk estimate, but also on the specific control options available and their economic impacts. It will be important for the Agency to develop consistent approaches to defining the need for uncertainty evaluation for residual risk management and the larger air toxics program.

4.2.4 Negative Health or Environmental Consequences

This section addresses the CAA section 112(f)(1)(C) requirement to investigate and report on ". . . any negative health or environmental consequences to the community of efforts to reduce such [residual] risks." Pollution control technologies targeted at a single pollutant (e.g., a specific HAP) and single medium (e.g., air), especially conventional end-of-the-pipe treatment technologies, can inadvertently transfer pollutants and risks to different media, different locations, and different receptors, and can unintentionally create new and different risks in the process of controlling the targeted risk. Few control technologies, when viewed from a holistic, multimedia, life cycle perspective, are without health and environmental risks of their own. In the context of HAP residual risk, for example, a technology that removes a HAP from an air emission stream can produce contaminated water and/or solid waste, can require additional energy (which consumes resources and produces other pollutants), and in some cases may create new safety risks, especially for workers. Health or environmental consequences can be

secondary to other consequences, such as the example of increased energy usage that may have environmental consequences.

EPA recognizes the possibility of creating or transferring risks as an unintended byproduct of actions that may be taken to reduce residual risks of HAPs. Thus, as part of the section 112(f) standard-setting process, the Agency will consider significant negative health and environmental consequences and the risk-risk tradeoffs associated with any future standards. One of the Agency's primary goals is to ensure that measures taken to reduce risk under section 112(f) authorities do not create other risk problems.

A key step in the residual risk process for HAP source categories determined to need additional risk reduction beyond the MACT standards in place will be the development and analysis of a range of risk management options. Ultimately, a risk management approach will be selected for the source category and a standard developed under section 112(f) to reduce risks to acceptable levels. As part of the analysis of risk management options – which will include evaluation of the effectiveness, reliability, emission and risk reduction, and cost of each option – EPA will consider the broad range of positive and negative impacts of each risk management option under consideration, rather than focusing simply on one criterion, such as control efficiency or cost. Information describing and, where practicable, quantifying potential negative consequences will be presented along with the other critical information to decision-makers responsible for selecting the risk management strategy. The Agency also plans to assess and consider, to the extent practicable, the uncertainty associated with its estimates of negative health and environmental effects, and also the uncertainty associated with its evaluation of effectiveness, reliability, and cost of risk management options.

In contrast to conventional air pollutant removal and treatment technologies, many pollution prevention approaches to reducing residual risks have fewer negative health and environmental consequences. This is primarily because pollution prevention approaches eliminate pollutants (and thus emissions) at the front end of a process rather than attempting to treat and dispose of them at some downstream step of the process. Thus, the Agency intends to identify pollution prevention approaches as risk management options and considers them in the standard-setting process. There will be a strong preference for selecting feasible and cost-effective pollution prevention approaches to reduce the residual risks of HAPs, in large part because they generally have fewer negative health and environmental consequences than other options.

4.3 Section 112 (f)(1)(D): Legislative Recommendations

Section 112(f)(1)(D) gives EPA the opportunity to make "recommendations as to legislation regarding such remaining risk" that may be identified during the analysis for residual risk.

The Agency is not proposing any legislative recommendations to Congress in this Report. At this time, EPA believes the legislative strategy embodied in the 1990 CAA Amendments

provides the Agency with adequate authority to address residual risks and provides a complete strategy for dealing with a variety of risk problems. The strategy recognizes that not all problems are national problems or have a single solution. National emission standards will be promulgated to decrease the emissions of HAPs from stationary sources. The authority is also provided to look at smaller scale problems such as the urban environment or the deposition of HAPs to water bodies in order to address specific concerns, to focus or prioritize efforts to meet specific needs such as a concern for a class of toxic and persistent HAPs, and to allow for partnerships among EPA, States, and local programs in order to address problems specific to these regional and local environments. Congress developed a strategy that, when taken as a whole, provides EPA with the flexibility to identify and deal with a wide range of air toxics problems. As the EPA gathers data, performs risk assessments, and develops standards, EPA may reevaluate the adequacy of the CAA strategy.

Residual risk will play a major role as EPA moves into the risk-based phase of the CAA strategy. Using information gathered from a variety of sources, including Congressionally mandated studies, the residual risk program will provide part of the "safety net" that will insure that the public and the environment will be protected. The following chapter describes this program's strategy in more detail.

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5. The Residual Risk Analysis Framework

The remainder of section 112(f) – sections 112(f)(2) through (6) – describes the authority and schedule for setting residual risk standards. Section 112(f)(2) requires EPA to promulgate residual risk standards where necessary to provide an "ample margin of safety" to protect the public health and to prevent, taking into consideration costs, energy, safety, and other relevant factors, an "adverse environmental effect." This chapter describes EPA's overall goals and framework for conducting residual risk analyses in response to sections 112(f)(2) through (6).

5.1 Legislative Context

5.1.1 The Context for the Analyses

Section 112(f) defines the context for residual risk standards to be the list of source categories or their subcategories that have been subjected to emission standards under section 112(d) of the CAA. On December 3, 1993, EPA established the promulgation schedule for technology-based (MACT) emission standards for 174 listed source categories (EPA 1993d). The source categories were divided into four groups, or bins, based on their expected promulgation date: 1992, 1994, 1997, and 2000 (also referred to as 2-year, 4-year, 7-year, and 10-year bins). MACT regulations are intended to identify and control air emissions from those major sources that emit HAPs listed pursuant to section 112(b) of the CAA. For existing sources in most source categories or subcategories, the minimum level of emissions reduction to be achieved is determined by establishing the current level of control of the best controlled 12 percent of the sources of emissions and establishing a "floor level" of emissions that is the average emissions limitation achieved by the sources in that 12 percent group. MACT emission reductions are based on source and technology analyses and do not consider risks presented by potential HAP exposures.

Congress intended risks to be considered eventually, however, as evidenced by the fact that most of the CAA-mandated air toxics programs other than MACT involve risk analyses and strategies to reduce risk to the public and environment. Congress stated in section 112(f)(2) that if a 112(d) standard does not reduce estimated lifetime excess cancer risk to the "individual most exposed" to less than one in a million, then the Administrator shall promulgate residual risk standards for the source category to protect the public health. EPA does not consider the one in a million individual additional cancer risk level as a "brightline" mandated level of protection for establishing residual risk standards, but rather as a trigger point to evaluate whether additional reductions are necessary to provide an ample margin of safety to protect public health. This interpretation is supported by the guidance provided in the September 14, 1989 *Federal Register* notice promulgating national emissions standards for benzene (i.e., the benzene NESHAP), which was cited by Congress in section 112(f) (see Section 2.1 for more discussion of the benzene NESHAP, and Appendix B for excerpts from the preamble to the final regulation). EPA

plans to continue to use this guidance for making final risk management decisions under section 112(f) for carcinogens rather than adopting any single "brightline."

Residual risk is one of the air toxics programs that begins to shift the emphasis from control technologies toward the receptors being exposed (i.e., the human populations or the particular environments). While the source category defines the range or scope of the data that will be required for performing residual risk analyses, the receptor defines the context for the characterization of the risk. The HAPs emitted, the routes of exposure, and the nature of the populations or environments being exposed become very important to the risk assessment outcome.

5.1.2 Compliance Schedule and Effective Date

According to section 112(f)(2), residual risk standards must be promulgated within eight years of the promulgation date of the MACT standard for that category unless the source category MACT was scheduled for promulgation within the first two years after the date of enactment of the 1990 CAA Amendments. In the latter case, residual risk standards must be promulgated within nine years. Therefore, for purposes of any residual risk standards, the eight-year limit applies to all source categories listed in the 4-, 7-, and 10-year bins, and the nine-year limit applies to categories listed in the 2-year bin, regardless of the actual promulgation date. This means that the 2-year bin standards promulgated under the residual risk program are due to be finalized in the year 2002 (earliest MACT promulgation for a category in the 2-year bin was 1993). Appendix C contains tables of the source category MACT standards, organized according to their promulgation schedule, and the actual promulgation dates of those that have been issued.

Section 112(f)(3) establishes that residual risk standards will become effective upon promulgation, although section 112(f)(4) provides existing sources subject to residual risk standards a 90-day time period after promulgation to comply, unless the Administrator grants a compliance waiver of up to two years. Actions must be taken during the waiver period to assure that "the health of persons will be protected from imminent endangerment."

5.1.3 Area Sources (CAA Section 112(f)(5))

Area sources are defined as sources that have the potential to emit less than 10 tons/year of a single HAP or 25 tons/year of HAPs in aggregate. Section 112(f)(5) provides that the Administrator shall not be required to conduct a residual risk review of any category or subcategories of listed area sources for which an emission standard, referred to as Generally Available Control Technology (GACT), is promulgated under section 112(d)(5). The EPA interprets this statutory language to mean that any area source for which the emission standard is based on MACT will be included in the residual risk analyses according to its specific schedule of promulgation, but an area source for which GACT was the basis of the standard will be reviewed under the residual risk program only if deemed necessary by EPA. Area sources to which MACT has been applied are identified in Appendix C.

In an effort to utilize our resources wisely and maximize the information gained from the residual risk analysis process, source category analyses may include area sources not subject to MACT or GACT. The results of those analyses, with regard to such area sources, would then be considered under the relevant components of our overall air toxics program, such as the Urban Air Toxics Strategy.

5.1.4 Unique Chemical Substances (CAA Section 112(f)(6))

There are 17 HAPs listed under section 112(b) that are not specific individual compounds and for which no CAS numbers are given (see **Exhibit 19**). Eleven of these are classes of metal compound HAPs, and the rest cover a variety of other HAP classes. Congress has directed in section 112(f)(6) that in setting residual risk standards applicable to sources that emit any of these HAPs, the Administrator should consider information on the HAP that is actually emitted. Each of these HAP classes may contain hundreds of individual compounds for which there may be very limited or no toxicity, emissions, or other risk-related data.

In the screening tier of analysis, we may default to relying on data from unspeciated HAPs in this category of "non-CAS number HAPs" as the basis for evaluating risks, or use data for one member of a class as a surrogate for other members of the class that have data gaps. In the absence of toxicity, emissions, and other risk-related information about the specific "non-CAS number HAPs" that may be emitted by a source under study, we will continue to use information that is available on any of the constituents, including the elemental compounds, as scientifically appropriate. Where substance-specific data are available, we will use those data. In analyses that may form the basis for risk reduction/risk management decisions, assumptions about a group or members of a group will be carefully evaluated for scientific appropriateness.

An additional requirement of section 112(f)(6) is that any direct transformation byproducts resulting from the emissions of any of these classes of HAPs should be the basis for setting standards.

5.2 Objectives

The objectives for residual risk activities under section 112(f)(2) are two-fold.

(1) Assess any risks remaining after MACT standard compliance; and

(2) Set standards for the identified source categories, if additional HAP emission reductions are necessary to provide an ample margin of safety to protect public health or, taking into account cost, energy, safety, and other relevant factors, to prevent an adverse environmental effect.

EXHIBIT 19
17 HAP CLASSES LISTED UNDER CAA SECTION 112(b)

Antimony Compounds	Lead Compounds
Arsenic Compounds (inorganic including arsine)	Manganese Compounds
Beryllium Compounds	Mercury Compounds
Cadmium Compounds	Fine Mineral Fibers[c]
Chromium Compounds	Nickel Compounds
Cobalt Compounds	Polycyclic Organic Matter[d]
Coke Oven Emissions	Radionuclides (including radon)[e]
Cyanide Compounds[a]	Selenium Compounds
Glycol Ethers[b]	

a X'CN where X = H' or any other group where a formal dissociation may occur. For example, KCN or $Ca(CN)_2$.

b Includes mono-and di-ethers of ethylene glycol, diethylene glycol, and triethylene glycol $R-(OCH2CH)_n-OR'$ where:
n = 1, 2, or 3
R = alkyl or aryl groups
R' = R, H, or groups which, when removed, yield glycol ethers with the structure:
$R-(OCH2CH)_n-OH$.
Polymers are excluded from the glycol category.

c Includes mineral fiber emissions from facilities manufacturing or processing glass, rock, or slag fibers (or other mineral derived fibers) of average diameter 1 micrometer or less.

d Includes organic compounds with more than one benzene ring, and which have a boiling point greater than or equal to 100°C.

e A type of atom which spontaneously undergoes radioactive decay.

We will evaluate source categories for which MACT standards are promulgated under section 112(d) using the direction provided in section 112(f) and the risk assessment methods described in Chapter 3. The general framework for the risk analysis process is described in Section 5.3.

The MACT program is achieving substantial emissions reductions across many HAPs and industries. In doing so, it is reducing risks and also leveling the emissions playing field within industry types. The residual risk framework is intended to provide the Agency flexibility in its decisions while ensuring that public health and the environment are protected. Our objectives also include continuing the partnership with State and local programs in the sharing of data and expertise, and including groups who may be affected by residual risk decisions as part of the process, when it appears feasible and appropriate to do so.

5.3 Residual Risk Assessment Strategy Design

Using the context provided by Congress in section 112(f) and the methodologies, data, and assessment process for air toxics described in more detail in previous sections of this Report, EPA has developed a residual risk framework. The framework for residual risk analysis may be described in several steps: identifying management goals that reflect the legal requirements, problem formulation, data collection, exposure and toxicity assessment, risk characterization, and risk management/risk reduction. **Exhibit 20** presents a flowchart of the general residual risk analysis process. In short, the framework calls for an iterative, tiered assessment of the risks to humans and ecological receptors through both direct and multipathway exposures to HAPs, leading ultimately to a decision on whether additional emission reductions are needed for individual source categories. This type of iterative or tiered approach is consistent with the NRC (NRC 1994) and Risk Commission (CRARM 1997a,b) reports written pursuant to the 1990 CAA Amendments.

The first component of the residual risk framework is that EPA state its risk management goals, which are identified at a broad level in the CAA legislation:

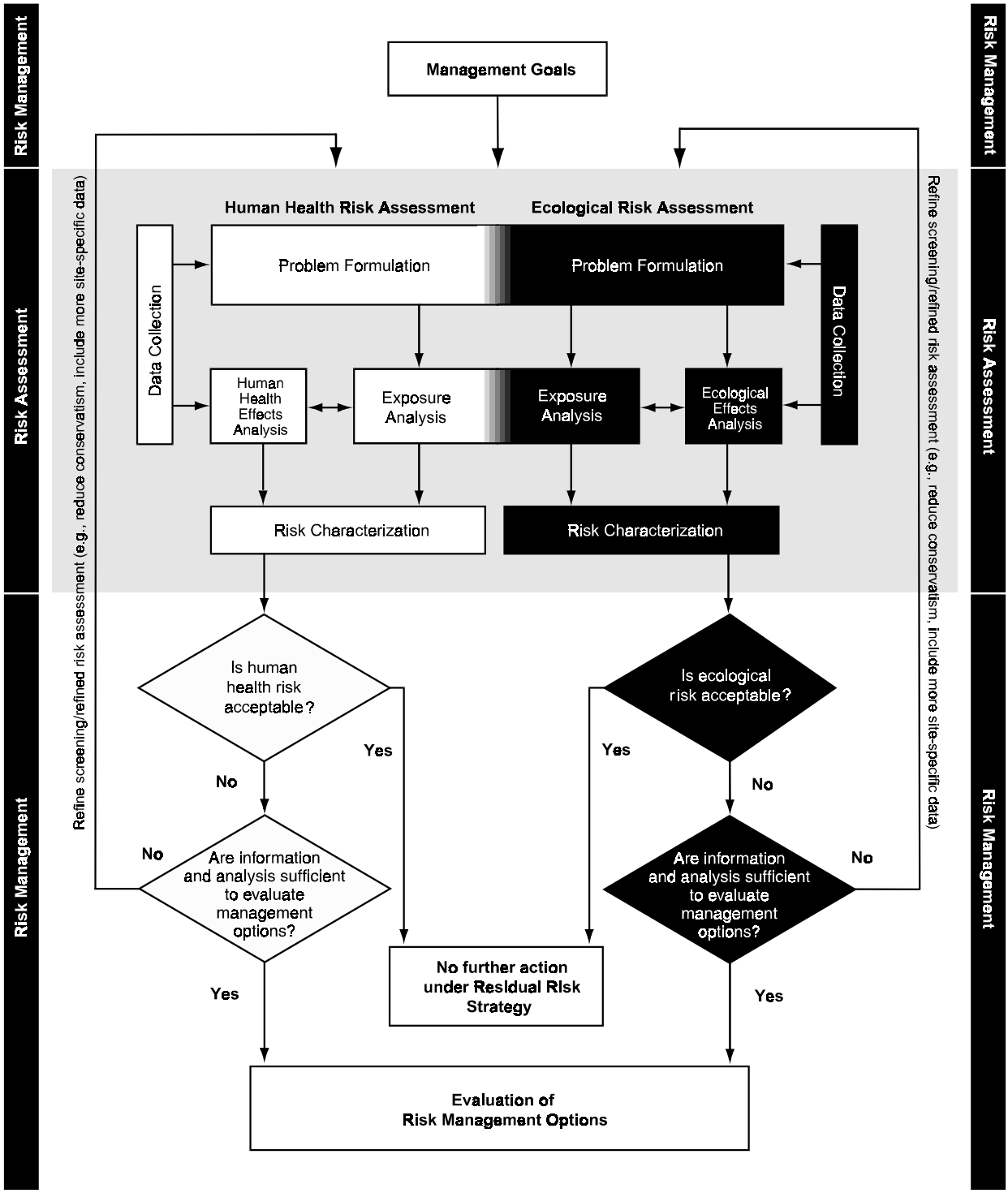
- to achieve a level of emissions that ensures that the public health is protected with an ample margin of safety; and
- to ensure, taking into account cost, energy, safety, and other relevant factors, that the above level of emissions do not result in an adverse environmental effect.

EPA may decide to translate those legislative objectives into more specific management goals. Those management goals help direct the problem formulation phase of both the human health and ecological risk assessments.

For both the human health and ecological risk assessments, the basic premise of the tiered approach is that the early analysis is generally screening in nature. This analysis is designed to be relatively simple, inexpensive, and quick, use existing data and defined decision criteria, and rely on models with simplifying, conservative assumptions as inputs. These simple default assumptions are conservative in nature to ensure that a lack of data does not result in overlooking a source category that may pose significant risk. A more refined analysis requires more resources and data, but the results are more certain and less likely to overestimate risk. While the strategy is represented generally as having two tiers (screening and refined), additional analyses might be performed within one or both tiers. The key point is that the additional analyses of increasing complexity (and resource requirements) will be performed in a manner EPA determines is cost-effective for a given source category. Where the available information indicates the potential for substantial risks, a more refined analysis might be implemented at the start.

In using this approach, EPA will follow the recommendation of the NRC (1994) which stated “EPA should use bounding estimates for screening assessments to determine whether

EXHIBIT 20
OVERVIEW OF RESIDUAL RISK FRAMEWORK
ITERATIVE APPROACH



further levels of analysis are necessary. For further analysis, the committee supports EPA's development of distributions of exposures based on actual measurements, results from modeling, or both." The EPA believes that the analysis being evaluated for use in screening-level assessments does, in most cases, produce bounding estimates. However, if this iteration is so conservative that source categories will not be screened out for further consideration under the residual risk program, an additional iteration that uses less conservative assumptions will be evaluated and used. In the refined analysis, the exposure assessment will provide distributions of exposures and a probabilistic distribution of risk will be estimated.

As shown in Exhibit 20, the human health and ecological risk assessments for a source category are organized into three phases: (1) the problem formulation phase, in which the context and scope of the assessments are specified; (2) the analysis phase, in which the HAPs' toxicity and exposure to humans or ecological receptors are evaluated; and (3) the risk characterization phase, in which the toxicity and exposure analyses are integrated to assess the nature, magnitude, and uncertainty of any risks. Also as illustrated in Exhibit 20, the problem formulation and analysis phases of the human health and ecological risk assessments will partially "overlap" in that certain pathways of concern for humans (e.g., inhalation of outdoor air, consumption of contaminated fish) will in some cases also be pathways of concern for some ecological receptors (e.g., terrestrial wildlife, fish-eating wildlife). The development and conduct of risk assessments by this three-phased approach are described more fully in the Agency's ecological risk assessment framework (EPA 1992b) and guidelines (EPA 1998d). Although described in those documents in the context of ecological risk assessment, the basic phased approach is also appropriate for human health risk assessment.

Following the risk characterization phase of each assessment, a decision step occurs. How much the risk estimates can be improved by refining the analysis is an important consideration at this step. If no unacceptable risks have been identified for human health or environmental effects and the analyses are adequate to support those conclusions (i.e., risks are acceptable), then no further action is required under this process, and the results of the risk assessment should be documented. If human health or environmental risks appear unacceptable, and if sufficient information is available to evaluate management options considering risks, costs, economic impacts, feasibility, energy, safety, and other relevant factors, the risk assessment is complete (i.e., no additional iterations are needed), and the process moves to risk management decision-making. If the information from the risk characterization is insufficient to fully evaluate risk management options, the residual risk assessment should proceed to a still more refined analysis.

5.3.1 Stakeholder Involvement

As the federal government pursues its goals of expanded stakeholder involvement in risk management decisions, consistent with recent recommendations of the Risk Commission (CRARM 1997a,b) and the NRC (NRC 1996), EPA is committed to involving stakeholders, as appropriate, at various stages throughout the residual risk analysis process. The NRC's

Understanding Risk presents a risk assessment/risk management model that also emphasizes extensive interaction and involvement of stakeholders. Thus, an important component of this process will be the establishment of interactive discussions with the parties involved. In the residual risk analysis process, EPA expects the level of stakeholder involvement to vary for the different source categories, depending on the complexity of the analysis and the potential risks involved. For source categories with the potential for higher risks and more complex analyses, stakeholder involvement is likely to occur more frequently throughout the process.

The stakeholders in this case are State and local public health and air toxics agencies, Tribal groups, the affected industries, and public interest groups. The purpose of these interactions may be to identify available data, to discuss the results of the risk assessments, to determine the nature and the scope of the potential risks, to hear concerns and perceptions about the level of risk, to discuss the next steps in the process (e.g., need for refinements to the analysis), and to discuss the options available to reduce risk if necessary. Stakeholder involvement adds another dimension by allowing affected parties to have input and to be given the opportunity to understand the views of other participants. Feedback from stakeholders, including those whose concerns may extend beyond the technical capabilities of modeling to better discern the complete problem, may assist in our evaluation of results. For example, while the scope of the residual risk analyses will be national, it is possible that local, State, or regional level problems would only be brought to light by groups at that level. As noted above, stakeholder involvement may not be the same for all analyses. The level of stakeholder involvement may be driven by the complexity of the analyses and the expected impacts of decisions that will result from the analyses. With regard to ecological risk assessments, stakeholder input can also be valuable in characterizing the societal importance of the ecosystems at risk.

At important points in the process, the Agency will make information available to State and local public health and air toxics agencies, Tribal groups, affected industries, and concerned public interest groups, and may take other steps to facilitate meaningful stakeholder participation. Those with concerns, specific interests, or information about the specific source category are encouraged to provide input and assist in the process by pointing out source categories or HAPs of concern, or by identifying issues to consider. In addition, the Agency expects that stakeholders will bring valuable new data on HAP toxicity, emissions, or exposure to its attention. In the problem formulation phase and more extensive data collection step of refined risk assessments, involvement of stakeholders, specifically affected industries and State and local agencies, is especially important. As the process for a source category moves closer to risk reduction/risk management decisions, stakeholder involvement is considered more critical. The opening of a stakeholder dialogue, consistent with legal limitations such as the Federal Advisory Committee Act, provides the opportunity for all groups to be involved early in the risk management process and for the implementation of a rational risk reduction strategy that proceeds from mutual understanding rather than a one-sided argument.

5.3.2 Priority Setting

Priority setting among the large number of source categories to be reviewed – that is, determining the order in which residual risk assessments for specific source categories will be conducted – also is a critical part of the overall strategy. EPA intends to set priorities based on a number of considerations, including the actual MACT promulgation dates for source categories (which determines the statutory time period for residual risk determinations) and any available information bearing on the level of residual risks attributable to various source categories. While meeting statutory deadlines, EPA will, to the extent possible and based on the available data, set priorities aimed at achieving the largest, most cost-effective risk reductions first. Priority setting also will be iterative; priorities are likely to be revised during the course of the residual risk program as new information becomes available and initial analyses are performed on various source categories.

Prioritization may occur at many stages of the process. For example, information collected in the initial problem formulation step will help in setting priorities for a screening-level analysis. Results of the screening analyses will aid in determining the need for and setting priorities for a refined analysis. It is also noted that results of screening and refined analyses are expected to contribute to our priority setting with regard to new research, data collection, and tool development.

As discussed in Section 5.1.2, the MACT promulgation dates, which determine the statutory time period for residual risk determinations, fall into four "bins" (2-year, 4-year, 7-year, and 10-year). Section 112(f)(2) requires standard-setting to address residual risks within eight or nine years of the promulgation of MACT standards. As a practical matter, this establishes a tight timeframe in which to develop the information necessary for conducting and refining screening analyses and in using this information for priority setting. The later two bins, the 7-year and 10-year, contain many more source categories than the earlier ones. Given the greater number of source categories in these later bins, priority may be largely driven by the residual risk statutory deadlines. The Agency's intention is to consider other factors as described above. The extent to which this is feasible may vary for the later bins and will be determined as we initiate the process for those source categories.

5.3.3 Problem Formulation and Data Collection

Residual risk analysis for a given source category will begin by describing the context and scope of the problem to be evaluated. As much data as are readily available will be used at this stage of the assessment, and stakeholders with interest in this category may be encouraged to provide input. Information from State, local, or Tribal entities may help the planning process by pointing out source categories or HAPs of concern, or by identifying issues to consider. It would be at this stage that key decisions about the HAPs of concern would be made and reassessed in any subsequent iteration of analysis. For example, do the HAPs being emitted trigger the need for human health or ecological assessments of pathways other than inhalation? What are the

endpoints of concern, and what populations may be most affected by the HAPs being emitted? These evaluations may be largely at a qualitative level, but they will inform the design of the analysis to follow, in either a screening or refined level.

As discussed in the previous section, the timing of the MACT promulgation schedule, as well as the need for efficient utilization of resources, will require some prioritization of work. A number of source categories may be scheduled for analyses during the same time period. The problem formulation phase will help to prioritize which source categories need earlier attention. It also will help to determine what data are needed to support certain decisions and whether those data are available.

Designing the risk assessments during problem formulation involves the following main activities:

- Characterize key sources of HAP release;
- Characterize environmental behavior of HAPs and determine for which, if any, multipathway analyses might be required;
- Identify need for ecological assessment;
- Identify receptors that are potentially at risk;
- Select assessment endpoints; and
- Identify exposure pathways of concern.

Many types of data from a wide variety of data sources are needed to assess the residual risks of source categories. Data collection is expected to occur throughout the residual risk assessment process. Some data collection is needed even before any screening analyses are begun on individual source categories, to serve as a basis for setting priorities and ordering the source categories for residual risk assessment. Because the screening assessment is intended to be based on readily available data, data collection for this step generally will involve gathering and organizing the existing data (e.g., health and environmental effects of HAPs, post-MACT source emission rates for HAPs, previously performed risk assessments of source emissions), generally from EPA sources (e.g., MACT rulemaking docket, MACT data base) and State and local air toxics agencies.

The data available will, in part, determine whether an analysis is done on specific facilities in a source category or on model plants of the type developed during MACT rule development. EPA anticipates that the amount of information available about facilities within a source category may be more extensive after the Agency promulgates a MACT standard versus what was known during MACT rule development. Some of the additional information anticipated is increased knowledge of the HAPs being emitted, the regulatory level or estimated emission reductions for these HAPs, the locations of the facilities subject to a MACT rule, and whether a specific facility is in compliance with the rule. This type of information could narrow the scope of the analysis to those facilities that appear most likely to be a residual risk concern.

Problem formulation, including establishment of the conceptual model, sets the context and scope of human health and ecological risk assessments. For the initial assessment, it also includes an evaluation of the potential for specific HAPs to accumulate in the environment, which influences the need for multimedia analyses.

Information on the potential for HAPs to accumulate in the environment can be used to narrow a comprehensive set of assessment endpoints in the ecological risk screen. Given that HAPs are initially released to the air, the most important question for the initial problem formulation is the degree to which the HAPs might persist and partition into other environmental media. If a HAP is unlikely to accumulate in the environment, then only those ecological communities that come into direct contact with HAPs in the air need be considered. The question of whether a multipathway analysis is needed is also asked during problem formulation in the human health risk assessment.

To identify HAPs that are likely to accumulate in the environment, and thus potentially pose risks (ecological and/or human health) via food chains and other environmental media, the most important HAP characteristics are environmental persistence and bioaccumulation potential.

environmental persistence If field data, chemical property data, or inference from chemical structure suggest that the HAP will persist in the environment for several weeks to several years (or longer), then a multimedia analysis might be necessary. For persistent and non-volatile HAPs, it is likely that the HAP will be deposited and accumulate over time in aquatic and terrestrial systems downwind of the source.

bioaccumulation If field data, laboratory data, models (e.g., food web), and/or the log K_{ow} suggest that the HAP might accumulate in plant or animal tissues, then a food chain analysis might also be needed. Various cutoff values for screening bioaccumulation potential have been used. For example, the *Final Water Quality Guidance for the Great Lakes System* (EPA 1995e) used a bioaccumulation factor (BAF) in fish of 1,000 to identify bioaccumulative chemicals, and log K_{ow} values from 3.0 to 5.0 have been used to identify constituents likely to bioaccumulate in aquatic and terrestrial ecosystems (e.g., Connell 1988; Garten and Trabalka 1983; Suter 1993).

Where possible in the screening assessment, environmental characteristics that influence the behavior of a HAP in different media (e.g., persistence in water versus air) and thus their potential exposure to different ecosystems will be identified. For example, if a HAP is readily degraded by hydrolysis in surface water, aquatic life might not be at risk even if the HAP is toxic and persistent in air and deposits to surface waters, into which it readily partitions. In a refined

ecological risk assessment, a literature search and review of studies that describe ecological impacts that have been clearly attributed to the HAP, or field measurement studies that indicate environmental "sinks" for the pollutant (i.e., in what environmental compartment(s) the pollutant is likely to accumulate), can be useful.

For ecological risk assessment, the screening step may also include selection of HAPs for analysis based on their relative toxicity. For some source categories, several HAPs might be released. It is possible that the environmental behavior of several HAPs is such that they are expected to partition into the same environmental medium. If information is available to indicate that one or a few of those HAPs are much more toxic to ecological communities in contact with that medium than the remaining HAPs, then it might be possible to focus the ecological screening assessment on the most toxic of those HAPs. If, in the screening analysis, the most toxic of those HAPs indicate no risks, then the less toxic HAPs may not need to be evaluated further.

Developing the Conceptual Model

The conceptual model for a residual risk assessment includes a description of the sources of HAP releases, information on emission rates, and a description of exposure pathways, assessment endpoints, and the measures that will be used to evaluate the assessment endpoints. Multimedia analyses are likely to be needed for many of the persistent HAPs, whereas only the air pathway may need to be considered for some short-lived HAPs. For those HAPs that are not expected to accumulate in the environment, either locally or regionally, the conceptual model is relatively simple, and can be assumed to involve inhalation of air by humans and terrestrial animals and direct exposure of plant foliage to the air. For those HAPs that might accumulate in other environmental media (e.g., in water, sediments, soil, or plants), a multimedia exposure model with the appropriate receptor communities will be needed.

In ecological risk assessments, the various environmental communities need to be carefully considered. For HAPs that are likely to partition into sediments and soils, receptors of concern include the benthic aquatic community, the soil macro- and microinvertebrate community, and plants. For HAPs that are likely to partition into water, the benthic and free-swimming aquatic communities should be included. For HAPs that might bioconcentrate or bioaccumulate in aquatic organisms, the animals that feed on those organisms should be considered (e.g., piscivorous wildlife). For HAPs that might bioaccumulate in terrestrial plants, herbivorous animals should be included in the conceptual model.

5.3.4 Screening Analyses

Screening-level analyses will often be applied as a first step in the assessment of both human health and ecological risks, and may include other pathways in addition to inhalation as appropriate (see discussion in Section 5.3.3). When a screening assessment is complete, EPA will assemble the information it has collected, as well as the results of the screening analysis, to

prepare a characterization of the source category that would describe any potential public health or environmental concerns. This information may include both quantitative and qualitative data and results; at this level, any quantitative exposure and risk estimates will generally be point estimates (not probabilistic estimates). The screening assessment results will typically be used to eliminate low-risk source categories from further consideration, to prioritize the remaining source categories as to the need for a refined assessment, and also to focus any refined assessment so that it is done more efficiently.

While the screening analysis can serve as a basis for a decision to pursue additional analyses or to eliminate low-risk source categories from further consideration under section 112(f), it may not be adequate to serve as a basis for establishing additional emission reduction requirements under section 112(f). These analyses are typically conservative in nature and specifically designed to more likely overestimate than underestimate risks (yielding a certain level of false positives). Their results should not be misinterpreted to provide a realistic prediction of risk. That is, the purpose of a screening analysis is to identify those situations or HAPs for which no further action is needed and those for which further analysis is needed. When a subsequent analysis is performed, those aspects of the analysis that are thought to influence risk most or contain the greatest uncertainty are refined.

The screening analysis will rely largely on readily available data, use simple approaches to estimate emissions, use simple fate and transport models, use simple multimedia models (with simple conservative bioaccumulation factors and models of transfer of HAPs from air and soils to plants, or from air and water to biota), and incorporate readily available toxicity values. The approximate physical locations of the HAP emission sources are determined from available information such as emissions profiles derived from the development of MACT source categories, the Background Information Documents for proposed MACT standards, and MACT model plants data.

Human Health

Screening analyses will rely largely on readily available data and incorporate readily available toxicity values. The general methods to be followed are described in Chapter 3.

Depending on the expected magnitude of risk and ready availability of appropriate data, the maximum off-site modeled concentration may be used to estimate the most exposed individual in screening-level risk assessments. Where risks are expected to be elevated, in order to conserve resources, we may pass over this conservative assumption step and move to a refined assessment that incorporates population data in order to derive the MIR (maximum individual risk) for areas that people are believed to occupy. Because screening-level risk assessments will be used for the purpose of determining whether or not further analysis and concern are warranted, the MEI estimate may be used for risk management decisions that result in the judgment not to regulate a given source category, but will not be used for risk management decisions that call for additional controls or regulatory actions.

When a screening assessment has been conducted for a source category, the risk characterization will typically be used by EPA managers to decide if a more refined risk assessment should be conducted or if nothing more needs to be done under the residual risk program. As described in Section 5.3.1, stakeholder involvement at this point may be valuable.

Criteria for Evaluating Screening Analysis Results. Exhibit 21 summarizes human health risk assessment assumptions and criteria for the screening level of analysis and for the more refined analysis. EPA will consider a wide range of available toxicity values in determining if the continued emission of HAPs poses a risk to the public or the environment. When EPA-verified toxicity values are not available, other sources of toxicity values may be used (see Section 3.4.1).

Cancer. In the assessment of cancer risks, dose-response assessments developed in a manner consistent with the direction of the 1996 proposed cancer guidelines (EPA 1996b), which utilize information on the mechanism of action more than the previous guidelines (EPA 1986b), are preferred. For early screening analyses, a linear mechanism will be assumed (unless an EPA assessment is complete which assumes otherwise). Screening analyses may assume additivity of individual HAP associated cancer risks. Where the screening risk results are below a 10^{-6} level of risk, excess cancer risks will usually be considered acceptable and no further action will be necessary under this process.

Non-cancer effects. Acute and chronic exposures will be assessed separately. For chronic exposures, long-term exposure estimates (e.g., annual average) will be used. For acute risks, a similar analysis will occur except that short-term exposure estimates (e.g., one-hour averages) will be used. In early iterations of the screening analysis, the health criterion for all non-cancer assessments (acute and chronic) may be based on the hazard index (HI) calculated by assuming additivity of HAPs in a mixture, where plausible. For each HAP emitted from a source category's facilities, the toxicity value will be compared with the upper-end HAP exposure level, as determined in the exposure screen, resulting in a hazard quotient (upper-end HAP exposure level ÷ toxicity value (such as the RfC)). In a screening analysis, the hazard quotients for each HAP in the mixture may be added regardless of endpoints, resulting in an HI value. This will result in a more conservative outcome than looking at HAPs individually, or than looking at different endpoints separately. In a more refined analysis, the assumption of additivity may be reviewed and limited to HAPs for which the assumption has a plausible basis or for which no data are available to support its rejection. A more refined risk assessment will likely be conducted when the HI exceeds 1 in the screening analysis (i.e., when exposure estimates exceed toxicity reference levels).

Ecological

Not all HAPs will automatically be considered in ecological risk analyses. Consistent with EPA guidelines (EPA 1998d), priority will be given to certain HAPs based on their environmental behavior and toxicity. As discussed in section 5.3.3, HAPs with the potential for

EXHIBIT 21
SUMMARY OF ASSUMPTIONS AND CRITERIA FOR EVALUATING PUBLIC HEALTH RISKS

Component of the Risk Assessment	Screening Level[a]	Refined[b]
Problem Formulation	‣ From readily available information, identify HAPs for analysis ‣ Identify HAPs that require multipathway analysis ‣ Use generic multimedia conceptual model simplified based on HAP characteristics and likely exposure pathways,	‣ Screening analysis results or other information used to identify HAPs and exposure scenarios for assessment ‣ Screening analysis results or other information used to identify multipathway HAPs of concern ‣ More site-specific multimedia model
Analysis Phase	‣ Simple conservative assumptions and screening-level exposure models are used ‣ In early iterations, assume additivity for all HAPs; refine this assumption as scientifically appropriate in later iterations ‣ Variety of sources relied upon for toxicity values ‣ Conservative individual exposure estimate (may use theoretical MEI in early iterations) ‣ Size and nature of potentially exposed population not necessarily considered ‣ Simple analysis of uncertainty	‣ Where scientifically appropriate, assume additivity for HAPs ‣ More careful consideration of toxicity value basis and source ‣ Evaluate population distributions of exposure and risk ‣ More refined uncertainty analyses
Criteria	‣ Upper-end individual cancer risk $<10^{-6}$ generally considered acceptable ‣ Upper-end individual cancer risk $\geq 10^{-6}$ may lead to refined analysis ‣ HI < 1 generally considered acceptable ‣ HI $\geq$ 1 leads to reexamination of additivity assumptions and if HI still greater than 1, may lead to refined analysis	‣ Upper-end individual cancer risk $<10^{-6}$ generally considered acceptable ‣ Upper-end individual cancer risk of roughly 1 in 10,000 is ordinarily considered the upper end of the range of acceptability ‣ Decisions on unacceptable risk will be made on a case specific basis, considering information including confidence in the risk estimate, population size, distribution of risk within the population, presence of sensitive subpopulations at various risk levels, the effects of concern, uncertainties in the effects information, and other factors

[a]Screening assessment may be based on upper-end estimated HAP exposure at the location of either the hypothetical MEI or the MIR in locations people are believed to occupy. Available toxicity values will be considered.

[b]Refined assessment based on more detailed and site-specific, and less conservative, estimated HAP exposures at the MIR location and throughout the spatial area of impact. EPA consensus toxicity values, or equivalent, reviewed in light of any additional credible and relevant information, are typically used.

adverse environmental effects due to a particular ability to persist, bioaccumulate, or exhibit acute toxicity will be considered high priority in analyses for environmental risks. It is likely that this will result in the identification of only a small minority of HAPs that will entail quantitative risk analyses.

For both screening and refined assessments, the analysis phase of the ecological risk assessment involves two main steps: estimating HAP concentrations in the environment (including biota, where appropriate) and evaluating exposure-response profiles. In the initial screening assessment, point estimates for both the HAP concentrations in the environment and for ecological effects will generally be used.

A main purpose of the screening-level ecological risk assessment is to screen out those HAPs and sources of HAPs that are unlikely to pose threats to ecological receptors based on readily available information. Because information on the habitats and ecosystems surrounding individual facilities of a source category generally is not readily available, for purposes of the screen, EPA generally assumes the presence of generic ecological systems and receptors. The simple multipathway analysis is employed to estimate if, and to what extent, generic ecological receptors may be exposed to HAPs. Using the approximate source locations, a generic ecosystem model including representative environmental and ecological receptors for the sites at risk is developed. The exposure and potential impact are then modeled and predicted concentrations in the various environmental media are compared to available ecotoxicity criteria (i.e., point estimates of thresholds for ecological effects). Ecotoxicity criteria are described in Section 3.4.2.

EPA assumes, for purposes of screening, that if the most sensitive species known to occur within an ecological community is protected from adverse effects caused by a HAP, the structure, and therefore the function, of the community also will be protected. Protection of the ecosystem as a whole is inferred from the protection of its component communities. These assumptions are consistent with those made by the Office of Water in developing ambient water quality criteria for the protection of aquatic life and with those made by the Office of Solid Waste in developing a variety of screening ecotoxicity criteria. These assumptions will need to be carefully evaluated as the ecological risk assessment methodology for residual risk is developed.

Criteria for Evaluating Screening Analysis Results. The results of the screening exposure and ecological effects assessments are integrated to characterize risk. In the screening-level ecological risk characterization, the maximum HAP concentrations estimated for the various environmental media are compared to the appropriate screening-level ecotoxicity criteria for each ecological community specified in the conceptual model. The ratio of the estimated environmental concentration to the ecotoxicity criteria is called the hazard quotient. When the hazard quotient exceeds 1, a more refined assessment may be needed. **Exhibit 22** summarizes the assumptions and criteria used to evaluate environmental risks for the screening analysis and for the more refined analyses.

EXHIBIT 22
SUMMARY OF ASSUMPTIONS AND CRITERIA FOR EVALUATING ENVIRONMENTAL RISKS

Component of the Risk Assessment	Screening Level	Refined[a]
Problem Formulation	‣ Based on generic aquatic and terrestrial ecosystems assumed to be near source category facilities ‣ HAPs screened for those that might require multipathway analyses ‣ Generic multimedia conceptual model simplified based on HAP characteristics and likely exposure pathways ‣ Generic assessment endpoints of maintaining ecological community structure and function are used for the communities that might be exposed	‣ Based on more site-specific information on ecosystems, habitats, and species near the facilities of concern ‣ Results of screening analysis or other information used to identify HAPs and exposure pathways of concern ‣ More site-specific conceptual model developed based on results of screening analysis or other information and site-specific data ‣ Correspondingly more refined assessment endpoints are developed
Analysis Phase	‣ Simple conservative assumptions and screening-level exposure models are used ‣ Conservative values from the literature are assumed for factors such as bioavailability and bioaccumulation ‣ Locations with maximum estimated HAP concentration are used to estimate exposure ‣ Screening-level ecotoxicity benchmarks are identified or developed as point estimates of no-observed-effect levels for the most sensitive species in the generic communities	‣ More refined assumptions, site-specific data, and refined exposure models are used ‣ More representative values from the literature or actual measurements from the field are used for factors such as bioavailability and bioaccumulation ‣ Spatial and temporal extent and magnitude of contamination are estimated ‣ Refined ecotoxicity benchmarks are identified or developed as point estimates of low-observed-effect levels for the assessment endpoints identified under problem formulation ‣ As data permit, full stressor-response curves might be developed ‣ Actual field evaluation of ecological condition near some facilities might be performed
Criteria	‣ HI <1 acceptable; $\geq$1 leads to a reexamination of conservative assumptions and, if the HI continues to exceed 1, to a more refined analysis ‣ Consideration of potential environmental significance of effects limited to benchmark selection and prioritization	‣ HI <1 acceptable; $\geq$1 may be acceptable depending on ecological significance ‣ Potential environmental significance of effects is evaluated based on a number of factors, including areal extent and magnitude of estimated effects on assessment endpoints and local, State, Tribal, regional, or national significance of the assessment endpoints

[a]Refined assessment based on more detailed and site-specific, and less conservative, estimated HAP exposures at the MIR location and throughout the spatial area of impact. EPA consensus toxicity values, or equivalent, reviewed in light of any additional credible and relevant information, are typically used.

At the end of the screening-level risk characterization, if none of the estimated environmental concentrations are greater than the corresponding criteria, the conservative risk screen indicates that the source category does not pose a risk of "an adverse environmental effect." The results of the screening analysis should be documented, and the ecological risk assessment process would stop. On the other hand, there might be one or more HAPs and combinations of exposure media and ecological communities for which the exposure concentration is greater than the screening ecotoxicity criteria (i.e., the hazard quotient is greater than 1) or for which the sum of the hazard quotients that apply to the same communities exceeds 1. If any sources or HAPs result in exposures in excess of the appropriate ecotoxicity screening criteria, further analysis may be warranted.

If estimated levels are only slightly greater than screening-level ecotoxicity criteria (e.g., less than an order of magnitude), it is worth reexamining all of the conservative assumptions used in the screening analyses to see if a more realistic combination of fate and transport parameters or more realistic values for other key parameters would change the result. Common conservative assumptions that should be reexamined at this point include, among others, use of conservative bioaccumulation factors from the literature, assuming that bioavailability is 100 percent, or assuming that 100 percent of a metal is present in its most toxic form (e.g., methyl mercury instead of elemental mercury). The basis for the criteria may also be reexamined at this point with regard to underlying uncertainties.

If estimated environmental concentrations are substantially greater than screening-level ecotoxicity criteria (e.g., more than an order of magnitude) and remain so after selected less conservative assumptions are used, then a more refined risk assessment may be indicated. If only one or a few of the facilities within a source category are likely to be causing the result, then a more refined assessment for those individual facilities using site-specific information might be appropriate. If several facilities are likely to be at issue, a more refined analysis for the source category might be needed.

5.3.5 Refined Analyses

For source categories that proceed from screening to refined risk assessments, additional data collection will be required, with a greater emphasis on site-specific data for affected facilities. As mentioned previously, some assessments may begin at the refined level. In some cases, this data collection effort may be relatively extensive, although it should be able to be focused based on the results of the screening assessment, when done, on the HAPs, types of effects (i.e., endpoints), sources, locations, exposure pathways, and receptors of most concern. Data collection to support the refined assessment may involve more detail about data elements used in the screening assessment (e.g., HAP emission rates, source characteristics) as well as information about additional data elements (e.g., exposed populations and subpopulations, epidemiology and disease registry information, actual ecosystems and endangered and threatened species that might be exposed). This data collection step is also more likely to include collection

of data from industry sources and possibly other stakeholders, in addition to more extensive data collection from State and local agencies.

The sources of this additional information for the refined assessment will vary. It is assumed that State, local, and EPA Regional offices should have information that is more site-specific, especially about which facilities are subject to a particular MACT rule, which have applied for operating permits, and which are in compliance at a particular time. Other facility-specific information that is needed to conduct the more detailed exposure and risk analysis may have to be obtained from the information request mechanisms that were used to gather data for the MACT process. Other information needed may come from existing data bases, such as U.S. Census data, geographic information systems (GIS), or other types of data bases that may provide needed inputs for modeling. EPA may also work together with industry to obtain needed data.

Considerable professional judgment is required to carry out and interpret a more refined residual risk assessment, and the steps taken and approaches used may vary from one source to the next, even within the same source category. As noted earlier, refinement might be necessary for some or all components of the analysis. Evaluating the sensitivity of the risk results to different components of the risk analysis can help identify which components are most important and allow us to preferentially refine the more sensitive components or assumptions.

Human Health

The refined analyses will be based on the methods and approaches described in Chapter 3 and will incorporate more site-specific data, fewer simple default assumptions, and more comprehensive and complex models (e.g., ISCST3 for atmospheric dispersion and deposition). In general, these analyses will be probabilistic and will produce estimates of risk distributions (in addition to point estimates). The theoretical MEI risk estimate will not be used in refined assessments; instead, the MIR estimate for areas that people are believed to occupy will be used to provide input for risk management decisions that may call for additional controls or regulatory actions.

Criteria for Evaluating Refined Analysis Results. The refined analysis, like the screening analysis, may be iterative with increasing complexity at each iteration. General assumptions and criteria are summarized in Exhibit 21. In refined risk assessment, the level of confidence is increased through the use of EPA or comparable consensus toxicity values that reflect currently available information. This ensures that toxicity criteria of consistently high quality and derived by a consistent methodology are used in the assessment. At this level of analysis, additional available credible and relevant data for all toxicity values used will be considered by the Agency. In the exposure assessment, more site-specific data and more refined models are used to estimate exposure concentrations and intakes. In addition, the refined analysis considers the number of people exposed at different levels.

Carcinogens subject to benzene NESHAP. In assessing cancer risk in the refined analysis, multiple HAP exposures are treated as additive where scientifically appropriate or in the absence of information to the contrary (consistent with EPA policy), and the numbers of people exposed in various subpopulation groups may be considered. This is to allow the characterization of risks to specific populations that may need a greater degree of protection. The Agency will evaluate results consistent with the benzene NESHAP, which states that "an MIR of approximately [10^{-4}] should ordinarily be the upper end of the range of acceptability." In addition, EPA would attempt to provide protection to the greatest number of people possible at an excess individual lifetime risk of cancer no higher than one in a million (10^{-6}), taking into account additional factors relating to the appropriate level of control (e.g., costs, economic impacts, feasibility).

Carcinogens for which a margin of exposure analysis is appropriate. For HAPs that EPA has identified as carcinogens with a nonlinear mode of action, consistent with the guidance in EPA's proposed revised cancer guidelines (EPA 1996b) or subsequent final revised guidelines, when available, an MOE analysis may be undertaken.[10] The MOE analysis may take into consideration the number of people exposed, especially sensitive subpopulations, at the various exposure levels. Individual chemical assessments of the "appropriate" MOE may be made, considering factors specific to the individual assessment, which could include any or all of the following: the steepness of the dose-response curve, persistence of the compound in the body, known human variability in response, and demonstrated human sensitivity as compared with experimental animals. In addition, the chemical-specific MOE evaluation should provide information on the appropriate combination or segregation of the chemicals in the mixture. The use of additivity will be maintained, where scientifically appropriate. The methodology for combining chemical-specific MOE values across mixture components has not yet been developed by the Agency. One way this might be done is by first calculating the ratios of individual HAP exposure levels to the corresponding departure point divided by the chemical-specific "appropriate" MOE.[11] These ratios could be summed for multiple chemicals, and a sum of ratios (i.e., total ratio) greater than 1 might be considered indicative of a potential hazard. This is roughly analogous to treating the MOE as a UF and calculating a hazard index.

Non-cancer effects. An RfC that reflects currently available credible and relevant information is preferred for the calculation of an HQ, at this level of analysis. For chemicals

[10] EPA recognizes that the use of an HI approach for non-cancer health effects and a MOE approach for nonlinear carcinogens presents challenges to the economist in performing economics benefits analysis. This concern was raised in the CRARM report, which also discussed a general approach to address the issue (CRARM 1997b). In the coming years, the scientific community will need to work with economists to devise defensible methodologies for economic analyses of these types of effects.

[11] For example, if the departure point for a given chemical is 5 $\mu g/m^3$, the chemical-specific "acceptable" MOE is determined to be 1,000, and the exposure level is 0.0005 $\mu g/m^3$, the ratio for that chemical would 0.0005 ÷ (5/1,000) = 0.1.

with no RfC or if the RfC is not verifiable, a scientifically appropriate alternate value with comparable basis may be used.

For mixtures of HAPs, the HI is calculated based on target organ effects, where adequate data exist to allow such calculations (EPA 1986c; EPA 1997d). For each chemical in the mixture, a thorough review of the toxicity literature may be required to determine which organ systems are affected (e.g., liver, respiratory, central nervous system). It is expected that an HI less than 1 that is derived using target organ specific hazard quotients would ordinarily be considered acceptable. If the HI is greater than 1, then the amount by which the HI is greater than 1, the uncertainty in the HI, the slope of the dose-response curve, and a consideration of the number of people exposed would be considered in determining whether the risk is acceptable.

Evaluation of the acceptable value for an HQ or an HI of 1 also would consider the values of UFs and the confidence in the RfCs that are used in the calculation of the HI. In general, it is considered that each UF is somewhat conservative; because all factors are not likely to simultaneously be at their most extreme (highest) value, a combination of several factors can lead to substantial conservatism in the final value. Larger composite UFs lead to more conservative RfCs. Conversely, lower composite UFs are less conservative and usually indicate a higher level of confidence in the RfC. Intermediate UF values or a mixture of high and low UFs would require an examination of the relative contribution of various chemicals to the HI. Thus, an HI or HQ greater than 1 may be considered acceptable based on consideration of other factors.

The non-cancer acute HQ should be calculated based on estimates of exposure for the appropriate short duration. The ARE, when available, should be used as the chemical-specific health criterion in the calculation of an acute HQ. For chemicals with no ARE, a provisional ARE may be developed from other acute toxicity criteria (see Exhibit 14) or from the available health effects data. For HAP mixtures, the non-cancer acute HI should be calculated, as appropriate, based on estimates of related effects (e.g., in the same target system). On a case-by-case basis, HQs or HIs greater than 1 may be considered acceptable based on consideration of the factors described above for chronic HQs and HIs.

Ecological

For the more refined ecological assessments, spatial and temporal patterns of HAP contamination of the environment and more complete exposure-response profiles will likely be considered. Also, more sophisticated models can be used to simulate the fate and transport of contaminants in the ecosystem of concern, or concentrations in environmental media might actually be measured in the field and mapped to depict the contamination pattern at the specific site.

Natural populations and communities usually can compensate for some degree of loss in survivorship or reproduction. The ability for populations to compensate for some loss depends on species' characteristics (e.g., longevity, growth rate, reproductive rate) and characteristics of

the ecosystem and communities in which the species exists (e.g., food abundance, presence of competitors, natural stress levels). Plants tend to be very resilient and able to tolerate or compensate for a wide range of natural (e.g., drought) and anthropogenic stressors. All "natural" populations and communities undergo changes on at least a seasonal basis, and ecosystems can exist in many different states, all of which might be "healthy" and likely to persist over time. These issues will be important to consider in the development of residual risk methodology for identifying "adverse environmental effects."

Evaluating the sensitivity of the risk results to different components of the risk analysis can help identify which components are most important and allow the assessors to refine the more sensitive analyses or assumptions sequentially. If it appears that some site-specific information will need to be collected in the field (e.g., identify and evaluate the ecosystems surrounding a facility and the pattern of contamination around the facility), the problem formulation step and conceptual model will need to be refined as thoroughly as possible, and an analysis plan should be developed for the field data collection and assessment. During this problem formulation, assessment endpoints may need to be defined on a site-specific basis. It might be possible to identify species that require a higher level of protection (e.g., game fish) than species for which greater functional redundancy exists (e.g., forage fish, for which many species can play a similar functional role in the ecosystem). Moreover, on a site-specific basis, endpoints other than direct toxicological effects might be considered, such as a change in algal species composition in response to a chemical stressor that results in a decline in water quality.

If a refined analysis is needed, more realistic (i.e., less generic) approaches can be used to characterize risks. General assumptions and criteria are summarized in Exhibit 22. For example, in early iterations of the refined analysis, an ecotoxicity criterion may be compared to an average instead of maximum estimated HAP concentration, using an ecologically relevant area over which to average the concentrations. A refined assessment may involve comparing a series of isopleths (i.e., lines of constant concentration) of estimated HAP concentrations in the environment to stressor-response curves. For a refined analysis of a specific site, mapping the overlap of isopleths of estimated or measured HAP concentrations with the location of ecological receptors can be helpful in evaluating the significance of the risks. For example, population-level models might be adapted for an ecological risk assessment application to delineate the impact of a chemical stressor on population dynamics over space and time. Such tools have already been used successfully in ecological risk assessments, particularly for fish populations (see Suter 1993). Information to be included in such refined risk characterizations would also include the local, State, Tribal, regional, and/or national ecological value or significance of the ecological entities at risk.

5.3.6 Risk Management/Risk Reduction Decisions

Prior to a decision on the need for a standard and specifically what that standard needs to accomplish, there are risk management decision points within the residual risk assessment strategy after the risk characterization step in each of the risk assessments (see Exhibit 20). To

consider a source category to be of no further concern under the residual risk program, the health criteria ("ample margin of safety") and, considering costs and other factors, the environmental criteria (no "adverse environmental effect") would need to be satisfied. Where the available information is too limited to make a "no further action" determination, those components of the source category responsible for the uncertainty would be subject to more data collection and more refined analysis. If the decision is made not to continue the analysis of a source category (i.e. that source category is eliminated from further consideration under section 112(f) in this process), then the information supporting that decision would be made available to stakeholders.

While the screening analyses can serve as a basis for a decision to pursue additional analyses or to eliminate low-risk source categories from further consideration under section 112(f), early iterations at the screening tier of analysis are not adequate to serve as a basis for establishing additional emission reduction requirements under section 112(f).

In addition to the results of the risk analysis/characterization based on human health and environmental data, EPA is also required by CAA section 112(f) to consider other factors before the establishment of additional risk standards. In determining whether further regulation is warranted in order to protect public health with an ample margin of safety and/or to prevent an adverse environmental effect, the risk manager will evaluate the level of risk and the risk reduction achievable against costs, feasibility, and other factors and, in the case of environmental risks, against costs, energy, safety, and other relevant factors. The Agency recognizes that because of location (or other factors) there may be cases where, after application of MACT standards, only a subset of facilities within a source category poses risks of concern. In determining the need for additional standards, EPA would look at all federal, State, and local regulations for that particular category. The proposed integrated air toxics budget initiative for fiscal year 2000 is intended to be a significant tool that could be used to achieve additional air toxics reduction beyond MACT control through available authority and approaches prior to residual risk determination. EPA will then evaluate the remaining risk and consider ample margin of safety as discussed below. In those cases where it is determined to be necessary, EPA will use CAA section 112(f)(2) residual risk authority to set national standards but focus the applicability of standards only on those portions of the source category.

The EPA will apply the ample margin of safety framework to public health risks in the context of the tiered risk assessment and management approach for air toxics' residual risks. For carcinogens, EPA will apply a two-step ample margin of safety approach, as described here and in Section 2.1. EPA developed the benzene risk management framework, which forms the basis for human health risk management in the residual risk program, in response to a 1987 DC Circuit Court decision on the Vinyl Chloride national emission standard, also taking into consideration public comment on several alternative risk management approaches it had proposed for benzene (see Section 2.1 for more historical background on the benzene national emission standard). According to the benzene framework, EPA would develop national emission standards for HAPs in two steps: (1) first determine a "safe" or "acceptable risk" level, considering only public health factors, and (2) then set an emission standard that provides an "ample margin of safety"

considering relevant factors in addition to health such as costs, economic impacts, and feasibility. In establishing the acceptable risk level, EPA would consider the extent of the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime, i.e., maximum individual risk (MIR). Although an MIR for cancer of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability under this approach, EPA would consider other health and risk factors (e.g., projected overall incidence of cancer or other serious health effects within the exposed population, the number of people exposed within each individual lifetime risk range, the science policy assumptions and estimation uncertainties associated with the risk measures). In the second step, EPA would attempt to provide protection to the greatest number of people possible at an excess individual lifetime risk of cancer no higher than 1 in 1 million (10^{-6}), taking into account additional factors relating to the appropriate level of control (e.g., costs, economic impacts, feasibility). The acceptable risk established in the first step would not be exceeded by the standards EPA adopts based on the second step. This approach is consistent with risk management approaches taken by other EPA programs intended to broadly protect public health. For example, other EPA programs use a risk management range of 10^{-6} to 10^{-4} under their reasonable maximum exposure scenario to guide their decision-making for carcinogens.

The EPA has not yet implemented the ample margin of safety approach as interpreted by the Vinyl Chloride decision with respect to non-cancer effects or carcinogens for which the MOE analysis is appropriate, though EPA believes that the 1989 benzene NESHAP could provide important guidance for residual risk decisions in these areas. The Agency does not yet have applications of the benzene NESHAP two-step approach to specifically address non-cancer public health risks and public health risks posed by carcinogens with non-linear risk assumptions, but such risk management framework applications are being developed. In applying the benzene NESHAP approach, the EPA would first determine an "acceptable" level of such risk, again without taking into consideration the cost of achieving such protection or other, non-health factors. As a second step, EPA would set standards sufficient to provide an "ample margin of safety," and these other factors would be weighed in such standard-setting. Under this approach, the Agency would have the discretion under Vinyl Chloride to identify both the "acceptable risk" level and methods of arraying factors for consideration in the "ample margin of safety" step.

Section 112(f) also gives EPA the authority to promulgate more stringent controls as necessary to protect against an adverse environmental effect. In promulgating such controls, EPA must, according to the statute, take into consideration costs, energy, safety, and other relevant factors. The EPA is currently developing a policy for how it will implement this authority and make residual risk management decisions regarding prevention of adverse environmental effects.

5.3.7 Comparison to CRARM Recommendations

In formulating its strategy for assessing residual risks under the CAA, EPA has conformed to many of the specific recommendations articulated by CRARM in their 1997 final report (CRARM 1997a,b). EPA's overall consistency with the tiered approach advocated by the

Commission (see Exhibit 4) is evident throughout this Report in the methods and strategies described (see, for example, Exhibit 20). In addition, five specific recommendations of the Commission (see Section 3.1.2) are listed here along with a short explanation of how EPA is fulfilling each.

- *Characterize and articulate the scope of the national, regional, and local air toxics problems and their public health and environmental contexts.*

  We are in the process of defining an Air Toxics Strategy that will assess what we know about these problems and will identify how the provisions in section 112 can best address them. As part of the air toxics program directed by Congress in the CAA, we have and continue to characterize specific issues such as mercury emissions (EPA 1997a), emissions from utilities (EPA 1998b), and deposition of air pollutants to the Great Waters (EPA 1997b). The integrated Urban Air Toxics Strategy (EPA 1998a), which is focused on risks posed by cumulative emissions in urban areas, and the residual risk program (described in this Report), through which post-MACT risks from industrial source categories are assessed, are two major elements of EPA's characterization of the air toxics problem as part of the air toxics program.

- *Use available data and default assumptions to perform screening-level risk assessments to identify sources with the highest apparent risks.*

  This is the underlying strategy of EPA's residual risk approach described throughout this Report and illustrated in the flow chart in Exhibit 20. The flow chart is an adaptation of the approach proposed by the Commission in their 1997 final report.

- *Conduct more detailed assessments of sources and facilities with the highest risks, providing guidance and incentives to regulated parties to either conduct these risk assessments or reduce emissions to below screening thresholds.*

  EPA is currently evaluating the potential for both EPA and regulated parties to carry out detailed risk assessments, when appropriate based on screening assessment results, using the methods described in detail in Chapter 3 of this Report. EPA will develop guidance for such assessments as necessary.

  EPA will consider incentives to industry to reduce residual risks, as described in Section 4.1.2.

- *At facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or that have exposure concentrations greater than reference standards, examine and choose risk reduction options in light of total facility risks and public health context.*

In accordance with CAA section 112(f)(2), EPA will consider the estimated cancer risks for facilities and implement management options that ensure an "ample margin of safety" as defined in the 1989 benzene NESHAP. The two-step benzene approach, described in detail in Section 2.1, is generally consistent with the Commission's recommendation, although it does not incorporate a "flexible bright line" of 10^{-5} (CRARM 1997b). As discussed in Section 5.3.6, the Agency is developing risk management frameworks for non-cancer effects and carcinogens analyzed by an MOE approach.

EPA may consider total facility risks and public health context in risk management decisions when doing so will ensure that the concept of ample margin of safety is maintained.

- *Consider reduction of residual risks from source categories of lesser priority.*

EPA interprets this statement to say that the Agency should address highest risk source categories first, and then consider additional risk reductions from the lower priority (i.e., lower risk) source categories. The Agency will prioritize source categories for evaluation under the residual risk program to the extent possible, given data limitations and legislative time constraints. The goal of prioritizing will be to address source categories with higher risk first. EPA will use information from the Agency's overall air toxics program and data gathered in the problem formulation part of the risk assessments to help prioritize source categories.

An alternative interpretation of this statement is that lesser priority risk sources should not be ignored in the implementation of risk reduction actions. While these sources may not be identified for additional risk reduction requirements under residual risk, they will receive attention, as appropriate, under our broader programs aimed at pollution prevention and waste minimization nationwide.

5.4 Summary

Following the CAA section 112(f), EPA has developed a framework to identify, assess, and manage the residual risks associated with air toxics emissions following the application of MACT standards to source categories. We will be relying on the general methodology and process illustrated by the framework described in this document in our risk assessment activities throughout the air toxics program. The framework is guided by sections 112(f)(2) through (6) and influenced by the recent recommendations made by the NRC (NRC 1994) and the Risk Commission (CRARM 1997a,b), and it incorporates EPA's current risk assessment and risk management policies, published guidelines, and methods. In short, the residual risk analysis framework consists of a tiered, iterative assessment of the human health and environmental risks resulting from both inhalation and non-inhalation exposures to HAPs following MACT implementation, leading ultimately to decisions on whether additional emission reductions are needed. Key steps in the process include problem formulation, data collection, risk analysis, and

risk management/risk reduction decision-making. The human health risk management decision criteria are based on the "ample margin of safety" principles, first laid out in EPA's 1989 national emission standard for benzene and affirmed in the 1990 CAA Amendments, and the environmental decision criteria are based on the "prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect" language in the statute. This framework is intended to provide EPA appropriate flexibility in its decisions while ensuring that public health and the environment are protected from air toxics as envisioned by Congress in the CAA.

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Appendix A

Full Text of Clean Air Act Section 112(f)

Appendix A
Full Text of Clean Air Act Section 112(f)

(f) Standard to Protect Health and the Environment. — (1) Report. — Not later than 6 years after the date of enactment of the Clean Air Act Amendments of 1990 the Administrator shall investigate and report, after consultation with the Surgeon General and after opportunity for public comment, to Congress on —

(A) methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under this section after the application of standards under subsection (d);

(B) the public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks;

(C) the actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies, risks presented by background concentrations of hazardous air pollutants, any uncertainties in risk assessment methodology or other health assessment technique, and any negative health or environmental consequences to the community of efforts to reduce such risks; and

(D) recommendations as to legislation regarding such remaining risk.

(2) Emission Standards. — (A) If Congress does not act on any recommendation submitted under paragraph (1), the Administrator shall, within 8 years after promulgation of standards for each category or subcategory of sources pursuant to subsection (d), promulgate standards for such category or subcategory if promulgation of such standards is required in order to provide an ample margin of safety to protect public health in accordance with this section (as in effect before the date of enactment of the Clean Air Act Amendments of 1990) or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. Emission standards promulgated under this subsection shall provide an ample margin of safety to protect public health in accordance with this section (as in effect before the date of enactment of the Clean Air Act Amendments of 1990), unless the Administrator determines that a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. If standards promulgated pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million, the Administrator shall promulgate standards under this subsection for such source category.

(B) Nothing in subparagraph (A) or in any other provision of this section shall be construed as affecting, or applying to the Administrator's interpretation of this section, as in effect before the date of enactment of the Clean Air Act Amendments of 1990 and set forth in the Federal Register of September 14, 1989 (54 Federal Register 38044).

(C) The Administrator shall determine whether or not to promulgate such standards and, if the Administrator decides to promulgate such standards, shall promulgate the standards 8 years after promulgation of the standards under subsection (d) for each source category or subcategory concerned. In the case of categories or subcategories for which standards under subsection (d) are required to be promulgated within 2 years after the date of enactment of the Clean Air Act Amendments of 1990, the Administrator shall have 9 years after promulgation of the standards under subsection (d) to make the determination under the preceding sentence and, if required, to promulgate the standards under this paragraph.

(3) Effective date. — Any emission standard established pursuant to this subsection shall become effective upon promulgation.

(4) Prohibition. — No air pollutant to which a standard under this subsection applies may be emitted from any stationary source in violation of such standard, except that in the case of an existing source —

(A) such standard shall not apply until 90 days after its effective date, and

(B) the Administrator may grant a waiver permitting such source a period of up to 2 years after the effective date of a standard to comply with the standard if the Administrator finds that such period is necessary for the installation of controls and that steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent endangerment.

(5) Area sources. — The Administrator shall not be required to conduct any review under this subsection or promulgate emission limitations under this subsection for any category or subcategory of area sources that is listed pursuant to subsection (c)(3) and for which an emission standard is promulgated pursuant to subsection (d)(5).

(6) Unique Chemical Substances. — In establishing standards for the control of unique chemical substances of listed pollutants without CAS numbers under this subsection, the Administrator shall establish such standards with respect to the health and environmental effects of the substances actually emitted by sources and direct transformation byproducts of such emissions in the categories and subcategories.

Appendix B

Preamble Excerpts from 1989 Benzene NESHAP

Appendix B
Preamble Excerpts from 1989 Benzene NESHAP

[Full Text of Preamble Sections 1, 2, and 3 Only]

ENVIRONMENTAL PROTECTION AGENCY (EPA)

40 CFR Part 61
National Emission Standards for Hazardous Air Pollutants;
Benzene Emissions from Maleic Anhydride Plants,
Ethylbenzene/Styrene Plants, Benzene Storage Vessels,
Benzene Equipment Leaks, and Coke By-product Recovery Plants

[AD-FRL-3620-4]
RIN 2060-AC41

54 FR 38044

September 14, 1989

ACTION: Final rule

I. Summary of Decisions

Overview

This section provides a description of the EPA's approach for the protection of public health under section 112. In protecting public health with an ample margin of safety under section 112, EPA strives to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million and (2) limiting to no higher than approximately 1 in 10 thousand the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years. Implementation of these goals is by means of a two-step standard-setting approach, with an analytical first step to determine an "acceptable risk" that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime risk (MIR) of approximately 1 in 10 thousand. A second step follows in which the actual standard is set at a level that provides "an ample margin of safety" in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors including costs and economic impacts, technological

feasibility, and other factors relevant to each particular decision. Applying this approach to the five benzene source categories in today's notice results in controls that protect over 99 percent of the persons within 50 kilometers (km) of these sources at risk levels no higher than approximately 1 in 1 million.

A principle that accompanies these numerical goals is that while the Agency can establish them as fixed numbers, the state of the art of risk assessment does not enable numerical risk estimates to be made with comparable confidence. Therefore, judgment must be used in deciding how numerical risk estimates are considered with respect to these goals. As discussed below, uncertainties arising from such factors as the lack of knowledge about the biology of cancer causation and gaps in data must be weighed along with other public health considerations. Many of the factors are not the same for different pollutants, or for different source categories.

Background

On July 28, 1988, EPA proposed decisions on standards under Section 112 for five source categories of benzene. A principal aspect of the proposal, and the basis for the proposed decisions on the source categories, were four proposed approaches for decisions under Section 112 as mandated by the DC Circuit's decision in NRDC v. EPA, 824 F.2d at 1146 (1987) (the "Vinyl Chloride" decision). The Vinyl Chloride decision required the Administrator to exercise his judgment under Section 112 in two steps: first, a determination of a "safe" or "acceptable" level of risk considering only health factors, followed by a second step to set a standard that provides an "ample margin of safety," in which costs, feasibility, and other relevant factors in addition to health may be considered.

The four proposed approaches were designed to provide for consideration of a variety of health risk measures and information in the first step analysis under the Vinyl Chloride decision – the determination of "acceptable risk." Included in the alternative approaches were three that consider only a single health risk measure in the first step: (1) Approach B, which considers only total cancer incidence with 1 case per year (case/year) as the limit for acceptability; (2) Approach C, which considers only the maximum individual risk ("MIR") with a limit of 1 in 10 thousand for acceptability; and (3) Approach D, which considers only the maximum individual risk with 1 in 1 million as the limit. The fourth approach, Approach A, was a case-by-case approach that considers all health risk measures, the uncertainties associated with them, and other health information.

In the second step, setting an "ample margin of safety," each of the four approaches would consider all health risk and other information, uncertainties associated with the health estimates, as well as costs, feasibility, and other factors which may be relevant in particular cases. The proposal solicited comment on each of the approaches as well as other approaches for implementing the Vinyl Chloride decision (53 FR 28511-28532). The Agency received many public comments on the approaches from citizen's groups, companies and industry trade groups,

State and local governments, and individuals. Most of the comments supported either Approach A or D, with little comment in support of Approach B or C.

Selection of Approach

Based on the comments and the record developed in the rulemaking, EPA has selected an approach, based on Approaches A and C but also incorporating consideration of incidence from Approach B and consideration of health protection for the general population on the order of 1 in 1 million from Approach D. Thus, in the first step of the Vinyl Chloride inquiry, EPA will consider the extent of the estimated risk were an individual exposed to the maximum level of a pollutant for a lifetime ("MIR"). The EPA will generally presume that if the risk to that individual is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability. The presumptive level provides a benchmark for judging the acceptability of maximum individual risk ("MIR"), but does not constitute a rigid line for making that determination.

The Agency recognizes that consideration of maximum individual risk ("MIR") – the estimated risk of contracting cancer following a lifetime exposure at the maximum, modeled long-term ambient concentration of a pollutant – must take into account the strengths and weaknesses of this measure of risk. It is an estimate of the upperbound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years. As such, it does not necessarily reflect the true risk, but displays a conservative risk level which is an upperbound that is unlikely to be exceeded. The Administrator believes that an MIR of approximately 1 in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.

In establishing a presumption for MIR, rather than a rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors. These include the overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50 km exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, other quantified or unquantified health effects, effects due to co-location of facilities, and co-emission of pollutants.

The EPA also considers incidence (the numbers of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risk to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other

serious health effects in the exposed population. The EPA believes that even if the MIR is low, the overall risk may be unacceptable if significant numbers of persons are exposed to a hazardous air pollutant, resulting in a significant estimated incidence. Consideration of this factor would not be reduced to a specific limit or range, such as the 1 case/year limit included in proposed Approach B, but estimated incidence would be weighed along with other health risk information in judging acceptability.

The limitations of MIR and incidence are put into perspective by considering how these risks are distributed within the exposed population. This information includes both individual risk, including the number of persons exposed within each risk range, as well as the incidence associated with the persons exposed within each risk range. In this manner, the distribution provides an array of information on individual risk and incidence for the exposed population.

Particular attention will also be accorded to the weight of evidence presented in the risk assessment of potential human carcinogenicity or other health effects of a pollutant. While the same numerical risk may be estimated for an exposure to a pollutant judged to be a known human carcinogen, and to a pollutant considered a possible human carcinogen based on limited animal test data, the same weight cannot be accorded to both estimates. In considering the potential public health effects of the two pollutants, the Agency's judgment on acceptability, including the MIR, will be influenced by the greater weight of evidence for the known human carcinogen.

In the Vinyl Chloride decision, the Administrator is directed to determine a "safe" or "acceptable" risk level, based on a judgment of "what risks are acceptable in the world in which we live." 824 F.2d at 1165. To aid in this inquiry, the Agency compiled and presented a "Survey of Societal Risk" in its July 1988 proposal (53 FR 28512-28513). As described there, the survey developed information to place risk estimates in perspective, and to provide background and context for the Administrator's judgment on the acceptability of risks "in the world in which we live." Individual risk levels in the survey ranged from 10^{-1} to 10^{-7} (that is, the lifetime risk of premature death ranged from 1 in 10 to 1 in 10 million), and incidence levels ranged from less than 1 case/year to estimates as high as 5,000 to 20,000 cases/year. The EPA concluded from the survey that no specific factor in isolation could be identified as defining acceptability under all circumstances, and that the acceptability of a risk depends on consideration of a variety of factors and conditions. However, the presumptive level established for MIR of approximately 1 in 10 thousand is within the range for individual risk in the survey, and provides health protection at a level lower than many other risks common "in the world in which we live." And, this presumptive level also comports with many previous health risk decisions by EPA premised on controlling maximum individual risks to approximately 1 in 10 thousand and below.

In today's decision, EPA has selected an approach based on the judgment that the first step judgment on acceptability cannot be reduced to any single factor. The EPA believes that the level of the MIR, the distribution of risks in the exposed population, incidence, the science policy assumptions and uncertainties associated with the risk measures, and the weight of evidence that a pollutant is harmful to health are all important factors to be considered in the acceptability

judgment. The EPA concludes that the approach selected best incorporates all of this vital health information, and enables it to weigh them appropriately in making a judgment. In contrast, the single measure Approaches B, C, and D, while providing simple decision making criteria, provide an incomplete set of health information for decisions under section 112. The Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information. As applied in practice, the EPA's approach is more protective of public health than any single factor approach. In the case of the benzene sources regulated here, more than 99 percent of the population living within 50 km would be exposed to risks no greater than approximately 1 in 1 million; and, the total number of cases of death or disease estimated to result would be kept low.

Under the two-step process specified in the Vinyl Chloride decision, the second step determines an "ample margin of safety," the level at which the standard is set. This is the important step of the standard-setting process at which the actual level of public health protection is established. The first step consideration of acceptability is only a starting point for the analysis, in which a floor for the ultimate standard is set. The standard set at the second step is the legally enforceable limit that must be met by a regulated facility.

Even though the risks judged "acceptable" by EPA in the first step of the Vinyl Chloride inquiry are already low, the second step of the inquiry, determining an "ample margin of safety," again includes consideration of all of the health factors, and whether to reduce the risks even further. In the second step, EPA strives to provide protection to the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million. In the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors. Considering all of these factors, the Agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by section 112. Application of this approach to the five source categories under consideration in this rulemaking is summarized in the following discussions.

Maleic Anhydride Process Vents

Summary of Decision: Benzene is no longer used in the manufacture of maleic anhydride because all plants in the industry have converted their process equipment to the more economical n-butane feed process. Thus, all benzene exposure from this industry has been eliminated, and no Federal regulation is needed. Maleic anhydride plants are, therefore, not discussed in the remaining sections of this notice.

Ethylbenzene/Styrene Process Vents

Summary of Decision: The existing level of control is judged to provide an ample margin of safety. Under existing State requirements, overall current emissions have been reduced

98 percent or more from uncontrolled levels. The present level of emissions are estimated to present an MIR of 2 in 100 thousand and a total nationwide incidence of about 1 case every 300 years (0.003 case/year). Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the exposures comparable to the MIR.

Most people exposed to benzene from these sources are exposed to very low risk levels. Specifically, the risk estimates show: (1) About 600 people are exposed to risk levels of about 1 in 100 thousand reflecting 1 cancer case every 5,000 years (0.0002 case/year) and (2) at least 90 percent of the population modeled to 20 km (about 400,000 people) is exposed to risk levels of less than 1 in 1 million, reflecting about 1 cancer case every 300 years (0.003 case/year). It is anticipated that if modeling were conducted to a 50 km radius, the percentage of the exposed population at risks of less than 1 in 1 million would be at least 99. Further reductions would provide only negligible additional risk and emission reductions (less than 1 percent additional control) and would cost approximately $0.2 million per year (1982 dollars), which would be about the same in 1988 dollars.

Benzene Storage Vessels

Summary of Decision: In providing an ample margin of safety for this source category, the final standards require effective controls on storage vessels not already controlled. The final standards would reduce nationwide benzene emissions by an estimated additional 20 to 60 percent beyond the baseline level, which already includes emission reductions for most storage vessels. The MIR after application of the standards is estimated to be 3 in 100 thousand. This reflects a reduction from an MIR range of between 4 in 100 thousand and 4 in 10 thousand without the standards. The estimated cancer incidence would be reduced from the range without the standards of 1 case every 10 to 20 years (0.1 to 0.05 case/year) to 1 case every 25 years (0.04 case/ year). Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the exposure level after an ample margin of safety is provided by EPA.

Most people exposed to benzene from this source category would be exposed to very low levels. The standards are estimated to result in an emission level where: (1) No people are exposed to a risk level greater than 1 in 10 thousand, (2) about 100,000 people would be exposed to a risk level between 3 in 100 thousand and 1 in 1 million, and (3) a majority of the modeled population (70 million people, or greater than 99 percent) is exposed to a risk level of less than 1 in 1 million. While EPA was unable to estimate the cancer incidences associated with various risk levels for this source category, the cancer incidences for the higher risk levels would occur very infrequently and for the lower risk levels would occur about once every 25 years (0.04 case/year). To reduce these exposures further, the next most effective level of control would cost an additional estimated $1.2 million per year (1982 dollars) or roughly $1.3 million in 1988 dollars, but it was not chosen because it would not reduce the MIR and would reduce the cancer incidence by only 1 case every 100 years (0.01 case/year).

Summary of the Standards: The final standards require control of all new and existing vessels with capacities greater than or equal to 38 cubic meters (m^3) (10,000 gallons) used to store benzene. The standards do not apply to storage vessels used for storing benzene at coke by-product recovery facilities because they are considered under the coke by-product recovery plant standards. The standards require use of certain kinds of equipment and work practices for each type of benzene storage vessel. The standards require the use of internal floating roofs (IFR's) with continuous primary seals on fixed roof vessels, and improvements to fittings (e.g., gaskets). For external floating roof (EFR) vessels, secondary seals are required. The standards also require periodic inspections of the vessel roofs, seals, and fittings. Detailed summaries of the regulation and changes since proposal are contained in sections IV and V of this notice.

Coke By-product Recovery Plants

Summary of Decision: In providing an ample margin of safety for this source category, the final standards reduce benzene emissions by about 97 percent for affected facilities nationwide. The MIR after application of the standards is estimated to be 2 in 10 thousand and the cancer incidence is about 1 cancer incidence every 20 years (0.05 case/year). This reflects significant risk reduction from the MIR of 7 in 1 thousand and the cancer incidence of 1 cancer incidence every 6 months (about 2 case/year) that are estimated to occur without the standards. Given estimating uncertainties in this case, the MIR level after the standards is comparable to the EPA's benchmark of approximately 1 in 10 thousand. As discussed in Section III of this preamble, EPA views this level as an overstatement of the actual MIR because the emission estimates associated with this level are likely to be overstated. Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the exposure level expected after an ample margin of safety is provided by EPA.

Most people exposed to benzene from this source category would be exposed to very low levels. The standards reduce emissions to a level where: (1) Approximately 100 people would be exposed to a risk level between the estimated MIR and about 1 in 10 thousand reflecting about 1 cancer incidence every 5,000 years (0.0002 case/year), (2) about 300,000 people would be exposed to a risk level between 1 in 10 thousand and 1 in 1 million reflecting about 1 cancer incidence every 100 years (0.01 case/year), and (3) a majority of the modeled population (70 million people, or greater than 99 percent) would be exposed to a risk level of less than 1 in 1 million, reflecting about 1 cancer incidence every 25 years (0.04 case/year). To reduce these exposures to the level associated with the next most effective level of control would cost an additional estimated $6 million per year (1984 dollars), which would be roughly $6.6 million in 1988 dollars. Furthermore, it would involve the use of a control technology that may not be technically feasible, and would only provide a small overall risk reduction of about 1 percent, reflecting an estimated cancer incidence of 1 in every 33 years (0.03 case/year). Additionally, there would be no change in the MIR of about 2 in 10 thousand.

Summary of Standards: The final standards require that process vessels and tar storage tanks in furnace and foundry coke by-product recovery plants be enclosed and the emissions ducted to an enclosed point in the by-product recovery process where they will be recovered or

destroyed. This requirement is based on the use of a gas blanketing system. The same requirements also apply to storage tanks for benzene, benzene-toluene-xylene (BTX) mixtures, and light oil in furnace coke by-product recovery plants. To ensure proper operation and maintenance of the system, the standards require semiannual visual inspections and monitoring to detect and repair leaks as well as annual maintenance inspections. The final standards also require that light-oil sumps be completely enclosed; this requirement is based on the use of a permanent or removable cover equipped with a gasket. Semiannual visual inspections and monitoring for leak detection and repair are also required for this source.

The final standards establish a zero emissions limit applicable to naphthalene processing, final coolers, and the associated final-cooler cooling towers at both furnace and foundry plants. The limit is based on the use of a wash-oil final cooler, although other types of systems that achieve the emissions limit can also be used.

The final standards also contain provisions for the control of equipment in benzene service, including pumps, valves, exhausters, pressure-relief devices, sampling connections, and open-ended lines. The leak detection and repair requirements are the same as the requirements in 40 CFR 61 subpart V, and additionally include quarterly leak detection and repair requirements for exhausters. A detailed summary of the regulation can be found in section V of this notice.

Benzene Equipment Leaks

Summary of Decision: The existing standards for this source category (Subpart J of part 61) are judged to provide an ample margin of safety, especially considering the overstatement of emissions. When these standards were issued in 1984, EPA estimated it would reduce emissions by about 70 percent from the level that would occur without the standards. Using these emission estimates (which overstate emissions as discussed in the next paragraph), the MIR was estimated to be 6 in 10 thousand and the incidence was estimated to be 1 case every 5 years (0.2 case/year).

Based on information received in the past year, EPA considers the present level of emissions associated with the existing standards to be substantially lower than previously estimated. Thus the available risk estimates are substantially overstated. The EPA has reached this conclusion after reviewing information demonstrating compliance with the existing standards and new information about emissions from equipment leaks. However, because the changes in the control of equipment leaks, especially leaks of air toxics, and the changes in the analytical tools needed for determining emissions from these sources have occurred very recently, EPA has not been able to develop better estimates of benzene emissions from equipment leaks. If EPA were to roughly estimate emissions based on this information, the resulting MIR would be comparable to the benchmark of approximately 1 in 10,000. (This is discussed further in sections III and IV of this preamble). Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above current levels of exposure.

Most people exposed to benzene emissions from this source category are exposed to very low risk levels. Even at the estimated emission levels, the existing standards result in: (1)

About 1 million people at a level between 1 in 10,000 and 1 in 1 million with an incidence of 1 case every 25 years (0.04 case/year) and (2) the vast majority of the modeled population (200 million people or greater than 99 percent) is exposed at risks of less than 1 in 1 million with an incidence of 1 case every 5 years (0.2 case/year). If the actual emission rates were known, the exposures would be lower than these estimates. To reduce these exposures further to the next most effective level of emission control would require the use of control technologies that may not be technically feasible at an estimated cost of $52.4 million per year (1979 dollars), which would be roughly $75 million in 1988 dollars.

II. Background

Regulatory Background

In 1977, the Administrator announced his decision to list benzene as a hazardous air pollutant under section 112 of the CAA (42 FR 29332, June 8, 1977). Benzene was determined to be a hazardous air pollutant because of its carcinogenic properties, evidenced by elevated leukemia incidence in populations occupationally exposed. Detailed information about the hazard identification, dose/response assessment, exposure assessment and risk characterization for benzene were presented in the preamble to the policy approaches and standards proposed in July 1988 (53 FR 28496), and will not be repeated in today's notice.

The listing of benzene as a hazardous air pollutant was followed by proposal of standards for benzene emissions from maleic anhydride process vents, EB/S process vents, benzene storage vessels, and benzene equipment leaks in 1980 and 1981 (45 FR 26660, April 18, 1980; 45 FR 83448, December 18, 1980; 45 FR 83952, December 19, 1980; and 46 FR 1165, January 5, 1981). On June 6, 1984, after receipt of comments from industry and members of the public, EPA published a final rule setting emission standards for benzene equipment leaks (49 FR 23498) and published proposed standards for benzene emissions from coke by-product recovery plants (49 FR 23522). On that date, EPA also withdrew its proposed standards for maleic anhydride process vents, EB/S process vents, and benzene storage vessels (49 FR 23558). The withdrawal was based on the conclusion that both the benzene health risks to the public from these three source categories, and the potential reductions in health risks achievable with available control techniques were too small to warrant Federal regulatory action under section 112 of the CAA.

On August 3, 1984, the Natural Resources Defense Council (NRDC) filed a petition for review in the United States Court of Appeals for the District of Columbia Circuit, seeking review of the EPA's three withdrawals of proposed benzene emission standards, and the EPA's final standards for benzene equipment leaks (Natural Resources Defense Council, Inc. v. Thomas, No. 84-1387). On October 17, 1984, NRDC petitioned EPA under section 307(d)(7)(B) of the CAA to reconsider its decisions to withdraw standards for maleic anhydride process vents, EB/S process vents, and benzene storage vessels, and to reconsider the promulgated standards for benzene equipment leaks. The EPA denied this petition on August 23, 1985 (50 FR 34144).

On July 28, 1987, the court handed down an en banc decision in a case concerning the national emission standards under Section 112 for vinyl chloride (Docket No. OAQPS 79-3, Part I, Item X-I-4). The court concluded in Vinyl Chloride that EPA had acted improperly in withdrawing a proposed revision to the standards for vinyl chloride by considering costs and technological feasibility without first determining a "safe" or "acceptable" emission level. In light of the Vinyl Chloride opinion, EPA requested a voluntary remand to reconsider its June 6, 1984, benzene decisions. In an order dated December 8, 1987, the court granted the EPA's motion and established a schedule under which EPA was to propose its action on reconsideration within 180 days of the order and take final action within 360 days of the order. This order was subsequently modified to extend the time for proposal by 45 days and then to establish August 31, 1989, as the deadline for final action. The EPA also decided to reconsider the proposed standards for benzene emissions from coke by-product recovery plants in light of the Vinyl Chloride decision and to publish a supplemental proposal. All of these actions were proposed on July 28, 1988 (53 FR 28496).

Public Participation

A public hearing was held in Washington, DC, on September 1, 1988, and was attended by about 90 people. Oral testimony was presented by 12 organizations and individuals. The public comment period closed on October 3, 1988, with over 200 comments received among the four dockets. The public comment period was reopened from December 15, 1988, to January 30, 1989, based on the EPA's review of the comments and the number of requests for an extension of the comment period. Additional comments were received, raising the combined number of comments to more than 275.

Legal Framework Under Vinyl Chloride

The EPA considers the Vinyl Chloride decision to further define the legal framework for setting NESHAP under Section 112 of the CAA. The court set out a two-step process for EPA to follow in making these judgments: first, determine a "safe" or "acceptable risk" level, and then set standards at the level -- which may be equal to or lower, but not higher than, the "safe" or "acceptable" level -- that protects public health with an ample margin of safety. It should be noted that the Vinyl Chloride court acknowledged that EPA could employ a single step analysis under certain circumstances provided cost and feasibility were excluded from consideration. Vinyl Chloride, 824 F.2d at 1165, n.11.

In Vinyl Chloride, the court acknowledged that judgments by EPA concerning scientific uncertainty are a relevant part of the process for establishing NESHAP. As the court noted, Congress, in directing EPA to set NESHAP, recognized that uncertainties over the health effects of the pollutants complicate the task. Vinyl Chloride, 824 F.2d at 1152. These same uncertainties, according to the court, mean that the Administrator's "decision in this area 'will depend to a greater extent upon policy judgments' to which we must accord considerable deference." Id., 824 F.2d at 1162 (citations omitted).

"Safe" or "Acceptable" Level: The first step is for the Administrator to determine what level of risk to health caused by emissions of a hazardous air pollutant is "safe" or "acceptable." (The court used these terms interchangeably.) The court in Vinyl Chloride explicitly declined to determine what risk level is "acceptable" or to set out the method for determining the "acceptable risk" level. Instead, the court stated that these determinations are within the Administrator's discretion.

The court did, however, provide some guidance on the "safe" or "acceptable risk" determination. To make this judgment, "the Administrator must determine what inferences should be drawn from available scientific data and decide what risks are acceptable in the world in which we live." Id., at 1165. However, the court emphasized that "safe" does not require elimination of all risk. To support these propositions, the court cited Industrial Union Dept., AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 642 (1980) and its statement that "[t]here are many activities that we engage in every day – such as driving a car or even breathing city air – that entail some risk of accident or material health impairment; nevertheless, few people would consider those activities 'unsafe'." Vinyl Chloride, 824 F.2d at 1165. As a final matter, the court said that the Administrator cannot consider costs or technological feasibility in this step.

Ample Margin of Safety: Once an "acceptable risk" level is determined, the second step under Vinyl Chloride is to determine whether the emission levels accompanying that determination should be reduced further in providing an "ample margin of safety." Noting that the purpose of the ample margin of safety requirement is to protect against incompletely understood dangers, uncertainties, and variabilities, the court stated that EPA "may * * * decide to set the level below that previously determined to be safe." The court reiterated that because the assessment of risk is uncertain, "the Administrator must use his discretion to meet the statutory mandate." The court added that it is at this stage of the standards-setting process that EPA may consider costs and technological feasibility and other relevant factors: "Because consideration of these factors at this stage is clearly intended to 'protect the public health,' it is fully consistent with the Administrator's mandate under section 112." Vinyl Chloride, 824 F.2d at 1165.

Uniqueness of Decision: The effect of the Vinyl Chloride decision is to require a decision making process for public health protection decisions unique to section 112, and unlike any other regulatory decision faced by EPA. This is the result of the court's prescription of two separate steps for decision making, the first in which only health factors can be considered in setting an acceptable risk level, and the second in which additional factors including cost, technological feasibility, and other relevant factors may be considered in providing an ample margin of safety. This scheme is unlike any other under the CAA itself, or any of the other statutes administered by EPA because the acceptable risk that EPA adopts in the first step cannot be exceeded by the standards EPA adopts in the second step. Thus, the EPA's approach to regulating hazardous air pollutants under section 112 is not applicable to regulatory decisions under other statutes or other sections of the CAA. Regulatory decisions under other statutes or other sections of the CAA will continue to be made using individual deliberative processes pursuant to those distinct statutory mandates.

In contrast to section 112, other EPA statutes have very different structures and legal requirements for decision making on public health standards. For example, while the Safe Drinking Water Act provides for two separate decisions, the first is a purely health-based goal toward which to work, but not necessarily meet; the second is an enforceable standard that is based on cost and feasibility considerations. Under both the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the balancing of health concerns and benefits of continued chemical use, and control costs are explicitly provided for in decision making. The Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act both require statutory decision making very different from the bifurcated process mandated by the court for Section 112.

Prior to issuance of Vinyl Chloride decision by the DC Circuit Court, the EPA's recent judgments under section 112 were made in integrated approaches that considered a range of health and risk factors, as well as cost and feasibility in certain cases. However, the Vinyl Chloride decision has required a change in the EPA's approach to section 112, since the previously employed integrated approaches did not partition consideration of health factors into a first step separate from consideration of the other relevant factors. Thus, the Vinyl Chloride decision requires EPA to consider whether a risk is acceptable without at the same time considering benefits of the activity causing risk, feasibility of control, or other factors that EPA (or anyone) would normally consider in determining whether a risk was "acceptable."

III. Application of Policy to Benzene Source Categories

Introduction

This section of the preamble explains the application of the EPA's policy for the regulation of the benzene source categories discussed in the July 28, 1988, proposal (53 FR 28496). For each source category, the following are provided: (1) Background information particularly noting any changes to the EPA's risk assessment since the July 1988 proposal, (2) the decision on the acceptable risk noting the health-related factors and uncertainties associated with the EPA's decision, and (3) the decision on the ample margin of safety noting health-related impacts, technological feasibility, and cost information associated with this decision. For those sources for which EPA made decisions that result in additional regulatory requirements, the requirements are explained in Section V of this notice.

Ethylbenzene/Styrene Process Vents

Background: This source category covers process vents of plants manufacturing ethylbenzene, styrene, or both. (Benzene emissions from equipment leaks and storage vessels at EB/S plants have been considered separately and are not included in this source category). As of 1985, there were 13 plants in this source category. Information received during the public

comment period indicates that emissions have declined since 1985 and emissions are now estimated to be 135 megagrams per year (Mg/yr) or less.

Decision on Acceptable Risk: The baseline MIR of 2×10^{-5} is below the presumptive benchmark of approximately 1×10^{-4} (which is 1 in 10 thousand expressed in scientific notation). In estimating these risk levels, EPA has not found that co-location of EB/S plants significantly influences the magnitude of the MIR or other risk levels. The nationwide incidence of cancer from exposure to emissions from these facilities is estimated to be about 1 case every 330 years (0.003 case/year) or lower. The majority (more than 90 percent) of the population within 20 km of these sources is exposed to risk levels lower than 1×10^{-6} . For exposures to risk levels greater than 1×10^{-6}, the incidence is estimated to be 1 case every 10,000 years (0.0001 case/year). Benzene concentrations reported to produce noncancer health effects are at least three orders of magnitude above the exposures predicted from these sources. After considering all these factors, EPA judged the emission level associated with an MIR of 2×10^{-5} is acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a control level more stringent than the level associated with the acceptable risks. This option would require control of the few remaining uncontrolled intermittent emission sources using 98-percent efficient combustion devices (e.g., boilers and flares). In comparing this control option and the existing level of control, EPA found that they provide essentially the same level of safety. Both control levels reflect a significant reduction in risks and emissions from the uncontrolled level. Control of these sources would further reduce benzene emissions by approximately 70 to 90 Mg/yr at most and would reduce the estimated MIR from 2×10^{-5} to 1×10^{-5}. The annual incidence would be reduced by about 1 case every 500 years (0.002 case/year).

The number of people exposed at risks greater than 1×10^{-6} is essentially the same between these two control levels. For the total population exposed to these sources, the incidence would change from 1 case every 330 years (0.003 case/year) to 1 case every 1,000 years (0.001 case/year). Essentially all (95 percent) of this additional reduction in incidence occurs in the population exposed to risks lower than 1×10^{-6}. The proportion of the population at risk levels below 1×10^{-6} is not changed by this emission reduction. In addition, benzene concentrations reported to produce noncancer health effects are at least three orders of magnitude above the exposures predicted for these sources.

As noted above, this control option will reduce benzene emissions by 70 to 90 Mg/yr, which represents less than an additional 1 percent reduction over the uncontrolled level. The cost of this additional emission reduction (and consequent risk reduction) would be about $200,000/yr (1982 dollars). While this additional cost is small, it is disproportionately large in comparison to the small additional emission and risk reduction achieved.

After considering all of these factors, EPA judged that the existing level of controls provides an ample margin of safety. In addition, EPA decided not to set standards to mandate the existing level of controls. Existing controls in the EB/S industry are in the form of product recovery devices or the routing of emissions to the process unit's boilers or other boilers onsite to

conserve energy (less fuel would be required due to the energy content of the waste stream). Thus, there is no incentive for removal of existing controls.

Additionally, there is no incentive for new sources to waste product or energy, and major new sources would be subject to other EPA requirements (e.g., new source review [NSR], prevention of significant deterioration [PSD]). Thus, less effective controls are not expected in the future. For these reasons, EPA has concluded that Federal standards mandating these controls are not warranted.

Benzene Storage Vessels

Background: This source category covers vessels used to store benzene. These vessels are typically located at petroleum refineries, chemical plants, and bulk storage terminals. As of 1984, 126 facilities with benzene storage vessels had been identified. As noted in the July 28, 1988, Federal Register notice, nationwide baseline (i.e., no NESHAP) emissions from benzene storage vessels are estimated to be about 620 to 1,290 Mg/yr. The range of emissions reflects uncertainty about the presence of shingled seals versus continuous seals on existing vessels with IFR's; the lower end of this range reflects the assumption that all storage vessels have continuous seals, while the upper end is based on the assumption that some vessels (17 percent of the existing IFR vessels) are equipped with shingled seals, which emit more benzene than continuous seals. The baseline incidence associated with these emission estimates is estimated to be 1 case every 10 to 20 years (0.1 to 0.05 case/year). The baseline MIR ranges from 4×10^{-5} to 4×10^{-4}.

Decision on Acceptable Risk: The baseline MIR (4×10^{-5} to 4×10^{-4}), while ranging above the presumptive risk of approximately 1×10^{-4}, is judged to be within the acceptable range after consideration of the following factors.

First, the upper end of the range (4×10^{-4}) is very likely an overestimate of the MIR because it assumes that all storage vessels have shingled seals at the plants that would also have the highest MIR's if all vessels in the industry had continuous seals. Based on information received from industry in 1978, EPA estimated that 12 percent of the nationwide benzene storage capacity was in vessels with shingled seals. This was estimated to be only about 17 percent of the existing IFR vessels that store benzene. The EPA believes that shingled seals have not been installed on new vessels for the past several years as general industry practice. Accordingly, the number of vessels equipped with shingled seals is decreasing over time; consequently the associated risk is also decreasing as existing vessels are replaced by new vessels. Therefore, the assumption that all vessels in the worst-case plant have shingled seals for the upper end of the MIR range is a unique conservative assumption for this source category. In addition, the emission estimate for storage vessels equipped with shingled seals is overstated for the following reason. The only test series of IFR vessels with shingled seals had testing irregularities, resulting in inaccurately high emission estimates. These test irregularities are described in detail in the EPA document "Benzene Emissions from Benzene Storage Tanks -- Background Information for Proposal to Withdraw Proposed Standards" (EPA-450/3-84-004, March 1984). Because there is

no way to determine the proportion of emissions attributable to the use of shingled seals versus the test methodology, the emission estimate for shingled-seal vessels continues to reflect all the uncertainty from that test series (49 FR 23563, June 6, 1984). While EPA is unable to quantify these uncertainties, EPA qualitatively considered the effect of these uncertainties (as well as other uncertainties in its risk assessment) in its judgment of acceptability.

Second, even if the MIR were not overestimated, EPA estimated that only 10 people (out of the total modeled population of 70 million) are at risks greater than or equal to 1×10^{-4}, and virtually no cancer incidence is associated with this risk level. In estimating these risk levels, EPA has not found that co-location of plants significantly influences the magnitude of the MIR or other risk levels. Where two or more of the model plants used for the analysis might occur at one site (e.g., both a producer and a consumer of benzene), the risks were calculated from their total emissions. In addition, EPA estimated that the majority of the people (about 99 percent) exposed to benzene from this source category would be exposed to a risk level of less than 1×10^{-6}, reflecting 1 cancer incidence every 12 years (0.08 case/year), and that 900,000 people would be exposed at a risk level between 1×10^{-4} and 1×10^{-6}, reflecting 1 cancer incidence every 50 years (0.02 case/year). The baseline incidence is estimated to be 1 incidence every 10 to 20 years (0.1 to 0.05 cancer case/year). This range reflects the range of emission estimates (620 to 1,290 Mg/yr). Virtually all of the incidence is associated with the population at a risk of less than 1×10^{-5}. Thus, even though one end of the range of the EPA's MIR estimate for this source category is above 1×10^{-4}, it is important to consider that almost all of the exposure to benzene from storage vessels is associated with risks well below the benchmark of approximately 1×10^{-4}.

The EPA also considered the noncancer health effects associated with benzene exposures at levels comparable to the baseline MIR range. Noncancer health effects have been associated with exposure to benzene, but the levels reported to produce such effects are two to three orders of magnitude above exposures comparable to the MIR range of 4×10^{-5} to 4×10^{-4}, especially with the likely overstatement of the top end of the range.

After considering all these factors, EPA judged that the baseline emission level is acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a level of emissions more stringent than the level associated with acceptable risk in providing an ample margin of safety for this source category. This would require all vessels to have emission reduction equipment that many vessels already have. Specifically, it would require the use of an IFR with continuous primary seals on each existing fixed roof vessel, and more effective continuous primary seals on any new vessel with an IFR. It would also require improvements to fittings (e.g., gaskets) on the roofs of all IFR vessels. On each vessel with an EFR, this option would require secondary seals. These are similar controls to those that are required for volatile organic liquid (VOL) storage vessels (including benzene vessels) in 40 CFR 60 Subpart Kb, which affects vessels constructed or rebuilt after July 23, 1984. This level of control was labeled Option 2 in the July 28, 1988, proposal (53 FR 28496).

Control Option 2 would reduce the estimated MIR to 3×10^{-5} from the baseline range of 4×10^{-5} to 4×10^{-4}. Because no facility could have vessels with shingled seals, which represent the upper end of the baseline range, all vessels would be required to have continuous seals under the control option and the risks are not expressed as a range. Thus, no one would be potentially exposed to a risk of greater than or equal to 1×10^{-4}. The number of people estimated to be exposed to a risk level between 1×10^{-4} and 1×10^{-6} would be reduced from 900,000 at baseline to 100,000 with this control option. The majority of the modeled exposed population (greater than 99 percent) would be exposed to a risk level less than 1×10^{-6} with Option 2. While EPA was unable to estimate the cancer incidences associated with various risk levels after control to this option for this source category, the cancer incidences for the higher risk levels would occur infrequently, and for the lower levels would occur about once every 25 years (0.04 case/year). Overall, the total nationwide incidence would be reduced from a range of 1 incidence every 10 to 20 years (0.1 to 0.05 case/year) to 1 incidence every 25 years (0.04 case/year). In addition, levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the levels expected under Option 2.

Control Option 2 would reduce benzene emissions by a range between 20 to 60 percent (110 to 780 Mg/yr) in comparison to the emissions without standards. To achieve this emission reduction (and consequent risk reduction) would cost $0.1 million/yr (1982 dollars). This cost is considered to be relatively small.

The EPA also considered a more stringent control level, which would require the controls in Option 2 and additionally require secondary seals for IFR vessels (Option 1 in the July 28, 1988, proposal notice, 53 FR 28496). This additional control would not result in any additional reduction in the MIR beyond that achieved by Option 2. The number of people estimated to be exposed to a risk level greater than 1×10^{-6} is estimated to be reduced from 100,000 (Option 2) to 80,000 (Option 1). In both cases, the vast majority of the exposed population (greater than 99 percent) is at a risk of less than 1×10^{-6}. Overall, the total nationwide incidence would only be reduced from 1 incidence every 25 years (0.04 case/year) for Option 2 to 1 incidence every 33 years (0.03 case/year) for Option 1. This additional incidence reduction is associated mainly with the population exposed to risk levels below 1×10^{-6}. Levels of exposure reported to produce noncancer health effects are at least three orders of magnitude above the levels of exposure expected for Option 1, just as for Option 2. The additional cost of Option 1 over Option 2 would be $1.2 million/yr (1982 dollars).

Based on the factors discussed above, EPA decided that the level of control reflected by Option 2 provides an ample margin of safety. Although the emissions associated with the baseline risks are considered to be acceptable, they can be reduced further, achieving additional risk reductions, at a reasonable cost using the control technology included in Option 2. Selecting Option 2 also ensures that any existing shingled seals are replaced with continuous seals, thus addressing one of the uncertainties associated with the EPA's risk assessment. In addition, EPA concluded that additional controls beyond Option 2 are not warranted. The costs of additional controls beyond Option 2 are disproportionately high considering the small reductions in risk and incidence which are achievable.

Coke By-product Recovery Plants

Background: The risk analysis was revised after the July 1988 proposal based on comments that the industry's operating status should be updated. There are now 36 coke by-product recovery plants. The nationwide baseline benzene emissions are estimated to be 17,000 Mg/yr. The revised baseline estimates of health risk indicate an MIR of 7×10^{-3} and an annual cancer incidence of 1 case every 6 months (2 cases/year). More information regarding the updated estimates can be found in Section IV of this preamble and in the BID.

Decision on Acceptable Risk: The baseline risk of 7×10^{-3} is unacceptable for benzene, a known human carcinogen. In considering the decision on acceptable risk for this source category, EPA focused on control to a level that would result in an estimated MIR of 2×10^{-4}. The EPA considers this MIR to be in the acceptable range after considering several factors.

First, the long-term emissions and, therefore, the MIR are likely to be overstated because EPA assumed that coke batteries operate at full capacity for 70 years. In fact, presently not all plants are continuously operating at full capacity (including some of the plants with the highest risks). In addition, the decline in the domestic coke industry makes it likely that the EPA's estimate overstates the long-term emissions. There is considerable uncertainty in predicting the utilization of coke batteries. Therefore, EPA made the assumption of full capacity for 70 years, recognizing the effect of this assumption (as well as other assumptions) on its risk assessment. Thus, EPA believes the MIR is not likely to be much different than the benchmark of approximately 1×10^{-4} even though EPA is unable to quantify these uncertainties and, therefore, adjust the MIR for this source category. However, EPA considered this likely overestimation qualitatively in its judgment of acceptability. Furthermore, over time, the residual emissions from one group of sources in this category (equipment leaks) may decrease as operators use better equipment (e.g., improved valve packing) in addition to the required work practice program.

Second, EPA estimated that 100 people (out of the total modeled population of 70 million) potentially would be exposed to risks of 1×10^{-4} or greater, with 1 cancer incidence every 5,000 years among this group of 100 people (0.0002 case/year). In estimating these risk levels, EPA has not found that co-location of coke by-product recovery plants significantly influences the magnitude of the MIR or other risk levels. In addition, EPA estimated that the vast majority of the modeled population (greater than 99 percent) exposed to benzene from this source category would be exposed to a risk level of less than 1×10^{-6} reflecting 1 cancer incidence every 25 years (0.04 case/year), and that 300,000 people would be exposed at a risk level between 1×10^{-4} and 1×10^{-6} reflecting 1 cancer incidence every 100 years (0.01 case/year). Of the total cancer incidence (1 cancer incidence every 20 years, i.e., 0.05 case/year), 80 percent is associated with the large population at risks of less than 1×10^{-6}. Thus, even though EPA estimates an MIR of about 2×10^{-4} for this option, it is important to consider that almost all the exposure to benzene from this source category is associated with risks well below the benchmark of approximately 1×10^{-4}.

The EPA also considered the noncancer health effects associated with benzene exposures at levels comparable to an MIR level of 2 X 10^{-4}. Noncancer health effects have been associated with exposure to benzene, but the probability is unlikely of the effects occurring at exposures comparable to an MIR level of 2 X 10^{-4}. Levels of benzene reported to produce such effects are three orders of magnitude higher than the concentrations comparable to an MIR of 2 X 10^{-4}.

After considering all these factors, EPA judged the emission level associated with an MIR of 2 X 10^{-4} to be acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a level of emissions more stringent than the level associated with acceptable risks in providing an ample margin of safety for this source category. This option (Option 1) would require additional control over the acceptable risk level (Option 2) of storage vessels at foundry coke by-product recovery plants and would also require use of dual mechanical seals on pumps and sealed bellows valves (i.e., assumed to be 100 percent control) at both furnace and foundry coke by-product recovery plants. The control technologies and their estimated impacts are presented for each emission point in Table 1 for Options 1 and 2. It should be noted that EPA has not concluded that leakless valves/sealed bellows valves will always effectively eliminate emissions or that they are available for all sizes and types of equipment in benzene service. Nevertheless, EPA evaluated Option 1 to determine if it should be selected to reflect an ample margin of safety even though there would be technological feasibility issues in implementing this option.

Table 1 – Controls Included in Each Option[a]

Emission points	Control technology efficiency (%)	Option 1		Option 2	
		Furnace	Foundry	Furnace	Foundry
Final cooler, cooling tower; napthalene processing/handling	Wash-oil final cooler (100)	X	X	X	X
Tar decanter, tar intercepting sump and flushing-liquor circulation tank	Gas blanketing (98[b])	X	X	X	X
Tar storage and tar-dewatering tanks	Gas blanketing (98)	X	X	X	X
Light-oil condenser, light-oil decanter, wash-oil decanter, and wash-oil circulation tanks	Gas blanketing (98)	X	X	X	X
Excess ammonia-liquor storage tank	Gas blanketing (98)	X	X	X	
Light-oil and BTX storage tanks	Gas blanketing (98)	X	X	X	
Benzene storage tanks	N 2 gas blanketing (98)	X	X	X	
Light-oil sump	Cover (98)	X	X	X	X
Pumps	Monthly inspections (83)			X	X
	Dual mechanical seals (100)	X	X		
Valves	Monthly inspections (73)			X	X
	Sealed-bellows valves (100)	X	X		
Exhausters	Quarterly inspections (55)			X	X
	Degassing reservoir vents (100)	X	X		
Pressure-relief devices	Rupture disc system (100)	X	X	X	X
Sampling connection systems	Closed-purge sampling (100)	X	X	X	X
Open-ended lines	Cap or plug (100)	X	X	X	X

[a] The control options analyzed to determine an ample margin of safety are the same as those analyzed for the July 1988 proposal (53 FR 28496), except that control options less stringent than Option 2, the level determined to be in the acceptable range, are not shown on the table. The impacts associated with these control options have been revised since the July 1988 proposal to reflect updated information on the industry operating status. These revisions are explained in greater detail in Section 6 of the BID.

[b] 95-percent efficiency for tar decanter.

In comparing Options 1 and 2, EPA found that they provide essentially the same level of safety. Each reflects significant risk reduction in comparison to the baseline risks. Although the estimated number of people exposed to a risk level greater than or equal to 1 X 10^{-4} would be reduced from 100 to 50 under Option 1, EPA estimates that Option 1 would not reduce the MIR below the Option 2 level of 2 X 10^{-4}. The number of people exposed to a risk level between 1 X 10^{-4} and 1 X 10^{-6} would be reduced from 300,000 to 200,000 under Option 1. Under both options, the vast majority of the exposed population (greater than 99 percent) would be at risk levels of less than 1 X 10^{-6}. For the population exposed to a risk level between 1 X 10^{-4} and 1 X 10^{-6}, the incidence would change from 1 case every 100 years (0.01 case/year) under Option 2 to 1 case every 140 years (0.007 case/year) under Option 1; for the population exposed to risks below 1 X 10^{-6}, the incidence would change only from 1 case every 25 years (0.04 case/year) under Option 2 to 1 case every 33 years (0.03 case/year) under Option 1. Overall, the total nationwide incidence would be reduced from 1 case every 20 years (0.05 case/year) to 1 case every 33 years (0.03 case/year) or only by an additional 0.02 case/year. Most (about 80 percent) of this additional reduction in incidence in Option 1 compared to Option 2 occurs in the population exposed to risks in the 1 X 10^{-6} range or lower. In addition, levels reported to produce noncancer health effects are about three orders of magnitude above levels expected under either option.

Option 1 reduces benzene emissions by about 98 percent, whereas Option 2 reduces benzene emissions by about 97 percent in comparison to the emissions that would occur without the standards. This reflects only an additional 1 percent reduction for Option 1. Also, the relative difference between these options may be even smaller than estimated. This is due to the uncertainty that sealed bellows valves would actually achieve the assumed 100 percent reduction in Option 1 and the potential for higher emission reduction than estimated for the equipment leak detection and repair program under Option 2. To achieve this emission reduction (and consequent risk reduction), Option 1 would increase the annualized cost by about $6 million/yr (1984 dollars). While this additional cost is relatively small overall, it is disproportionately large in comparison to the small additional emission and health risk reductions associated with Option 1 in comparison to Option 2.

In conclusion, EPA decided that Option 2 provides an ample margin of safety. The EPA judged the risk reductions for Options 1 and 2 to be essentially the same and the greater control cost of Option 1 to be high in relation to the small additional emission and risk reduction achieved. In doing so, EPA considered the likely overstatement of long-term emissions and risks and the question of technical feasibility.

Benzene Equipment Leaks

Background: This source category covers emissions of benzene from pieces of equipment handling process streams that contain greater than 10 percent benzene, by weight. These equipment pieces include pumps, pipeline valves, open-ended valves, flanges, compressors, pressure-relief valves, sampling connections, process drains, and product accumulator vessels. In 1984, there were an estimated 131 facilities in this source category.

When Subpart J of Part 61, the benzene equipment leaks NESHAP, was promulgated in 1984, EPA estimated that this regulation would reduce emissions from about 7,900 Mg/yr to 2,500 Mg/yr (a 69 percent reduction). As noted in the July 28, 1988, Federal Register notice, EPA viewed the estimate of 2,500 Mg/yr for current emissions as being an upperbound estimate, and recognized that actual emissions may be substantially lower. The EPA reached this conclusion after reviewing compliance report information from facilities subject to the existing standards and other information for facilities handling toxic compounds. Information obtained since proposal has further substantiated this conclusion. The basis for this conclusion is summarized below and is discussed in more detail in section IV and in the BID.

During the consideration of the public comments, EPA examined compliance reports from 1987 and 1988 for a randomly-selected sample of 25 facilities subject to the benzene NESHAP. This review showed many facilities had no leaking valves or pumps (0.0 percent) and no facilities had more than 1.5 percent leaking valves. The average leak rate for valves was 0.27 percent. This performance is better than an average expected leak rate of about 3 to 5 percent. In addition to the compliance reports, EPA also reviewed a limited amount of comprehensive data for a few process units with equipment in benzene service. These data show emission rates a factor of 20 to 30 below levels predicted by the earlier EPA studies. However, these more recent results do not provide a basis for developing new emission factors that would be generally applicable to all facilities. To rederive the emission estimates will require additional information and analysis of current industry practices. As this information has been received only recently, EPA has not been able to conduct the necessary studies and analyses in time to revise the emission estimates for benzene equipment leaks. The EPA has initiated a negotiated rulemaking to develop a new regulatory approach that will result in quantifiable emission levels, give credit for good original plant design, and motivate innovation (54 FR 17944, April 25, 1989). This effort is expected to require at least 6 months to complete. Consequently, the emission and risk estimates remain essentially as presented in the July 28, 1988, Federal Register notice.

Decision on Acceptable Risk: Based on 1984 emission estimates, the MIR is estimated to be 6×10^{-4}. However, as discussed previously under "Background" (and as discussed in detail in section IV, in response to comments), EPA considers the emission estimates to be overstated by roughly a factor of 5 to 20, or more. If actual emissions could be quantified and modeled in the exposure analysis, the risk estimates would decrease proportionately to the emissions, and would be comparable to the presumptive risk benchmark. An additional factor in this overstatement of emissions is that the analysis was developed assuming facilities continued to operate at the estimated emission rate for 70 years. However, EPA expects that, over time, emissions may continue to decrease due to improved control of air toxics through use of better design, operation, and maintenance of facilities. Given all these factors, EPA concludes that the MIR for this category is more likely to be less than the benchmark of approximately 1×10^{-4}, and will use this in its judgment on acceptability.

The estimated annual cancer incidence (based on the overstated emission estimates) is 1 case every 5 years (0.2 case/year) in a total modeled population of 200 million. The estimated incidence among the 2,000 people predicted to be at lifetime risks greater than 1×10^{-4} is only 1

case every 200 years (0.005 case/year). In estimating these risk levels, EPA has not found that co-location of facilities significantly influences the magnitude of the MIR. In addition, EPA estimated the majority of the population (greater than 99 percent) exposed to benzene from this source category would be exposed to risk levels below 1×10^{-6}. The incidence predicted for the population exposed to risks smaller than 1×10^{-6} is 1 case every 5 years (0.2 case/year), and the incidence for the population exposed to risks greater than 1×10^{-6} is 1 case every 20 years (0.05 case/year).

The EPA also considered the noncancer health effects associated with benzene exposures at current levels of exposure from this source category. Benzene concentrations reported to produce noncancer health effects are two to three orders of magnitude above the exposures predicted for these sources.

After considering all of these factors, especially the substantial overstatement of emissions, EPA judged that the present, controlled level of emissions and risks are acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a level of emissions more stringent than the level associated with the existing standards. The additional control of Option 1 reflects the use of dual mechanical seals for pumps, and sealed bellows valves. For the purpose of this analysis, this equipment is considered to be leakless (i.e., 100 percent control). However, it is not known if leakless valves/sealed bellows valves will effectively eliminate emissions or if they are available for all sizes and types of equipment in benzene service. Thus, it should be noted that EPA has not concluded that leakless valves/sealed bellows valves will effectively eliminate leaks. Information is needed on the magnitude of emissions released when a sealed bellows valve fails, failure rates of these valves, and appropriate procedures for monitoring valves for failures before any conclusions are made. In addition, a better understanding of the factors affecting equipment leaks and development of new regulatory approaches is needed before significant further reductions in exposures will be assured. Nevertheless, EPA considered Option 1 to determine if it should be selected to provide an ample margin of safety even though there would be technological feasibility issues in implementing this option.

Under Option 1, the estimated MIR would be reduced by roughly a factor of three, and the nationwide incidence would be reduced from 1 case every 5 years (0.2 case/year) under the current NESHAP baseline to 1 case every 10 years (0.1 case/year). As discussed under the "Decision on Acceptable Risk," EPA views the estimate of the MIR for this source category as significantly overstated. The number of people exposed to a risk level between 1×10^{-4} and 1×10^{-6} would be reduced from about 1 million to 300,000 under Option 1. For the people exposed to these risk levels, the incidence would change from 1 case every 200 years (0.005 case/year) to 1 case every 1,000 years (0.001 case/year) and from 1 case every 25 years (0.04 case/year) to 1 case every 100 years (0.01 case/year), respectively. The number exposed to a risk level less than 1×10^{-6} would be the same under Option 1 and the existing standards, with more than 99.5 percent of the total population of 200 million exposed to these risk levels. Most (about 90 percent) of the additional reduction in incidence in Option 1 compared to the existing standards

would occur in the population exposed to risks in the 1 X 10^{-6} range or lower. In addition, benzene concentrations reported to produce noncancer health effects are at least two to three orders of magnitude above the concentrations expected under Option 1 or the existing standards.

Option 1 is estimated to reduce benzene emissions by about 50 percent from the level of the standards. The relative difference between the two control levels may be substantially smaller than this estimate. This is due to the uncertainty that sealed bellows valves would actually achieve the assumed 100 percent reduction in Option 1 and the greater than predicted reductions observed with the current standards' leak detection and repair program. Because of the large uncertainty in the emission levels under the current standards, the likely additional emission reduction cannot be estimated. Implementation of the requirements of Option 1 would increase the annualized control cost by $52.4 million/yr (1979 dollars). (Docket No. A-79-27, Item V-A-1). The majority of the estimated cost is from the cost of sealed bellows valves.

Although Option 1 shows some additional emission and risk reduction may be achievable, the control cost is disproportionately large when compared to the small reductions in risk which could be achieved. If the actual emission reduction were known and used, the option would likely be even less effective. Recognizing the uncertain bias in the emission estimates, the large proportion of the incidence associated with lifetime risks less than 1 X 10^{-6}, the questions regarding technical feasibility, and the costs of additional controls, EPA judged the emission levels associated with the existing NESHAP to protect public health with an ample margin of safety. Therefore, additional control beyond the existing NESHAP is not warranted and will not be required.

Appendix C

Schedule for Source Category MACT Standards

Exhibit C-1
EPA - Clean Air Act - Title III
2-Year MACT Standards

MACT Standard / Source Categories	Number of Source Categories	CFR Subparts	Statutory Date	Administrator Signed Promulgation	Fed Register Publication and Citation	Initial Compliance Date
DRY CLEANING	5	M	11/15/92	09/13/93	09/22/93 (58FR49354)	12/20/93
Commercial dry cleaning dry-to-dry						
Commercial drycleaning transfer machines*						
Commercial drycleaning transfer machines						
Industrial drycleaning dry-to-dry						
Industrial drycleaning transfer machines						
HAZARDOUS ORGANIC NESHAP	1	F, G, H, I	11/15/92	02/28/94	04/22/94 (59FR19402)	10/24/94

Key Legend:
* = denotes area source category
Admin signed date = actual date EPA Administrator signed package

Exhibit C-2
EPA - Clean Air Act - Title III
4-Year MACT Standards

MACT Standard / Source Categories	Number of Source Category	CFR Subparts	Statutory Date	Administrator Signed Promulgation	Fed Register Publication and Citation	Initial Compliance Date
AEROSPACE INDUSTRY	1	GG	11/15/94	07/31/95	09/01/95 (60FR45948)	09/01/98
ASBESTOS (delisted)	1	--	11/15/94	11/14/95	11/30/95 (60FR61550)	11/30/95
CHROMIUM ELECTROPLATING	6	N	11/15/94	11/22/94	01/25/95 (60FR49848)	01/25/96 decor; 01/25/97 others
Chromic Acid Anodizing						
Chromic Acid Anodizing*						
Decorative Chromium Electroplating						
Decorative Chromium Electroplating*						
Hard Chromium Electroplating						
Hard Chromium Electroplating*						
COKE OVENS	1	L	12/31/92	10/23/93	10/27/93 (58FR57898)	11/15/93
COMMERCIAL STERILIZERS	2	O	11/23/94	11/22/94	12/06/94 (59FR62585)	
Commercial Sterilization Facilities						
Commercial Sterilization Facilities*						
DEGREASE ORGANIC CLEANERS	2	T	11/15/94	11/15/94	12/02/94 (59FR61801)	12/02/97
Halogenated Solvent Cleaners						
Halogenated Solvent Cleaners*						
INDUSTRIAL COOLING TOWERS	1	Q	11/15/94	07/30/94	09/08/94 (59FR46339)	03/08/96
MAGNETIC TAPE	1	EE	11/15/94	11/22/94	12/15/94 (59FR64580)	12/15/96
MARINE VESSELS	1	Y	11/15/94	07/28/95	09/19/95 (60FR48388)	09/19/99
OFF-SITE WASTE TREATMENT	1	DD	11/15/94	05/28/96	07/01/96 (61FR34139)	07/01/99
PETRO REFINERIES	1	CC	11/15/94	07/28/95	08/18/95 (60FR4344)	08/18/98

Exhibit C-2 (continued)
EPA - Clean Air Act - Title III
4-Year MACT Standards

MACT Standard / Source Categories	Number of Source Category	CFR Subparts	Statutory Date	Administrator Signed Promulgation	Fed Register Publication and Citation	Initial Compliance Date
PRINTING/PUBLISHING	1	KK	11/15/94	05/15/96	05/30/96 (61FR27132)	05/30/99
POLYMERS & RESINS I	9	U	11/15/94	07/15/96	09/05/96 (61FR46906)	03/05/97
Butyl Rubber						
Epichlorohydrin Elastomers						
Ethylene Propylene Rubber						
Hypalon (TM) Production						
Neoprene Production						
Nitrile Butadiene Rubber						
Polybutadiene Rubber						
Polysulfide Rubber						
Styrene-Butadiene Rubber & Latex						
POLYMERS & RESINS II	2	W	11/15/94	02/28/95	03/08/95 (60FR12670)	03/03/98
Epoxy Resins Production						
Non-Nylon Polyamides Production						
POLYMERS & RESINS IV	6	JJJ	11/15/94	05/15/96	09/12/96 (61FR48208)	03/12/97
~Acrylonitrile-Butadiene-Styrene						
~Methyl Methacrylate-Acrylonitrile+						
Methyl Methacrylate-Butadiene++						
~Polystrene						
Styrene Acrylonitrile						
Polyethylene Terephthalate						
SECONDARY LEAD SMELTERS	1	X	11/15/94	5/31/95	06/23/95 (60FR32587)	06/23/97
SHIPBUILDING MACT	1	II	11/15/94	11/14/95	12/15/95 (60FR64330)	12/16/97
STAGE I GASOLINE DISTRIBUTION	1	R	11/15/94	11/23/94	12/14/94 (59FR64303)	12/15/97
WOOD FURNITURE	1	JJ	11/15/94	11/14/95	12/07/95 (60FR62930)	11/21/97
total sources	40					

Exhibit C-2 (continued)
EPA - Clean Air Act - Title III
4-Year MACT Standards

Table Legend:
* area source categories
+ Methyl Methacrylate-Acrylonitrile-Butadiene-Styrene
++ Methyl Methacrylate-Butadiene-Styrene Terpolymers
Admin signed date = actual date EPA Administrator signed package

Exhibit C-3
EPA - Clean Air Act - Title III
7-Year MACT Standards

Statutory date - 11/15/97 (42 Source Categories)

7-YEAR STANDARDS	PROPOSE			PROMULGATE		
Source Category	**Administrator signature**	**Actually proposed in FR**	**FR citation for proposed rule**	**Administrator signature**	**Actually promulgated in FR**	**FR citation: promulgated rule**
Pesticide Active Ingredients^^^	10/27/97	11/10/97	62FR60566	3/99		
Acrylic/Modacrylic Fibers (GMACT)	9/16/98	10/14/98	63FR55178	12/98		
Manuf. of Tetrahydrobenzaldehyde^^	8/15/97			5/1/98		
Chlorine Manuf.	11/99			11/2000		
Chromium Chemicals Manuf.	--			delisted 5/17/96		
Cyanide Chemicals Production (3)*	11/99			11/2000		
EAF: Stainless & Non-Stainless Steel (2)	--			delisted 5/17/96		
Ferroalloys Production	7/23/97	8/4/98	63FR41509	8/98		
Flexible Polyurethane Foam Prod.	12/09/96	12/27/98	61FR68408	9/15/98	10/7/98	63FR53980
Mineral Wool	4/29/97	5/8/97	62FR25370	4/98		
Nylon 6 Production	--			to be delisted		
Oil & Natural Gas Production	11/23/97	2/6/98	63FR6288	10/98		
Petroleum Refineries	8/25/98	9/11/98	63FR48890	3/99		
Pharmaceuticals Production	03/20/97	4/2/97	62FR15754	7/30/98	9/21/98	63FR50280
Polycarbonates Production (GMACT)	9/16/98	10/14/98	63FR55178	12/98		
Polyether Polyols Production	8/15/97	9/4/97	62FR48804	9/98		
Polymers & Resins III (2)*	9/30/98			7/99		
Portland Cement	3/9/98	3/24/98	63FR14182	9/98		
Publicly Owned Treatment Works (POTW)	11/12/98	12/1/98	63FR66085	1/99		
Primary Aluminum	08/22/96	9/26/96		9/19/97	10/7/97	62FR52384
Primary Copper	4/9/98	4/20/98	63FR19582	6/98		
Primary Lead Smelting	4/9/98	4/17/98	63FR19201	8/98		
Pulp & Paper (non-combust) MACT I^	12/17/93			11/14/97	4/15/98	63FR18504
Pulp & Paper (combustion) MACT II^	11/14/97	4/15/98	63FR18754	7/98		
Pulp & Paper (non-chem) MACT III^	2/29/96			11/97	4/15/98	
Reinforced Plastic Composites Prod.	10/99			11/2000		
Secondary Aluminum Prod.	3/98			3/99		
Steel Pickling	8/28/97	9/18/97	62FR49052	4/98		
Wood Treatment MACT	--			delisted 5/17/96		

Exhibit C-3 (continued)
EPA - Clean Air Act - Title III
7-Year MACT Standards

7-YEAR STANDARDS	PROPOSE			PROMULGATE		
Source Category	**Administrator signature**	**Actually proposed in FR**	**FR citation for proposed rule**	**Administrator signature**	**Actually promulgated in FR**	**FR citation: promulgated rule**
Wool Fiberglass	2/25/97	3/31/97	62FR15228	3/98		
Acetal Resins (GMACT)	9/16/98	10/14/98	63FR55178			
Natural Gas Transmission and Storage	11/23/97	2/6/98	63FR6288			

Key Legend:
* = Standards with more than one Source Category (see below for breakdown)
^^^ = formerly known as Agriculture Chemicals Production
^^ = formerly known as Butadiene Dimers Production
^ = projects are part of the Pulp and Paper rule

7 YEAR STANDARD: BREAKDOWN OF SOURCE CATEGORIES

CYANIDE CHEMICALS PRODUCTION:
- Sodium Cyanide Production
- Hydrogen Cyanide Production
- Cyanuric Chloride Production

POLYMERS & RESINS III:
- Amino Resins
- Phenolic Resins

PULP & PAPER:
- MACT I - non-combustion
- MACT II - combustion (kraft, soda, sulfite)
- MACT III - non-chemical
- NESHAP for Combustion Sources in the Semichemical Pulping Industry

Exhibit C-4
EPA - Clean Air Act - Title III
10-Year MACT Standards

Statutory date - 11/15/00 (87 Source Categories)

10-YEAR STANDARDS	PROPOSE			PROMULGATE
Source Category	**Administrator Signature**	**Actually proposed in FR**	**FR citation for proposed rule**	
Aerosol Can-Filling Facilities	potential			delisting
Alumina Processing	11/99			11/2000
Ammonium Sulfate Production	11/99			11/2000
Antimony Oxides Manufacturing	potential			delisting
Asphalt Concrete Manufacturing	11/99			11/2000
Asphalt Roofing & Processing	08/98			08/99
Asphalt/Coal Tr Application-Metal Pipes	11/99			11/2000
Auto & Light Duty Truck (surface ctg.)	11/99			11/2000
Boat Manufacturing	12/99			12/2000
Carbon Black	11/99			11/2000
Carbonyl Sulfide (COS) Production via Carbon Disulfide	11/99			11/2000
Clay Products Manufacturing	11/99			11/2000
Coke By-Products	covered by 40CFR61 subpart L			
Coke Oven: Pushing, Quenching...	11/99			10/2000
Dry Cleaning (Petroleum Solvent)	potential			delisting
Engine Test Facilities	11/99			11/2000
Ethylene Processes	11/98			11/99
Flat Wood Paneling	11/99			11/2000
Flexible Poly Foam Fabrication Operations	03/99			06/2000
Friction Products Manufacturing	05/99			04/2000
Fume Silica Production	11/99			11/2000
Hydrogen Chloride Production	11/99			11/2000
Hydrogen Fluoride Production (GMACT)	9/16/98	10/14/98	63FR55178	12/98
Industrial Combustion Coord. Rule +	11/99			11/2000
Integrated Iron & Steel	11/99			11/2000
Iron & Steel Foundries	11/99			11/2000

Exhibit C-4 (continued)
EPA - Clean Air Act - Title III
10-Year MACT Standards

10-YEAR STANDARDS	PROPOSE			PROMULGATE
Source Category	**Administrator Signature**	**Actually proposed in FR**	**FR citation for proposed rule**	
Lead Acid Battery Manufacturing	--			delisted 5/17/96
Leather Tanning & Finishing Operations	11/99			11/2000
Lime Manufacturing	4/99			04/2000
Manufacuring of Nutritional Yeast	10/7/98	10/19/98	63FR55183	06/99
Marine Vessel Loading Operations	--			7/28/95
Metal Can	11/99			11/2000
Metal Coil	11/99			11/2000
Metal Furniture	7/99			11/2000
Miscellaneous Cellulose +	12/99			11/2000
Miscellaneous Metal Parts	11/99			11/2000
Municipal Landfills	11/99			11/2000
Misc. Organic NESHAP (MON) +	11/99			11/2000
Nitrile Resins Production ^^	--			05/15/97
Non-Clay Refractories Manuf.	5/99			05/2000
Organic Liquids Distribution (Non-Gas)	11/99			11/2000
Paint Strippers	11/99			11/2000
Paper & Other Webs (Surface Ctg)	11/99			11/2000
Phosphoric Acid/ Phosphate Fertilizers ^	11/21/96	12/27/96		12/97
Plastic Parts & Products	11/99			11/2000
Plywood/Particle Board Manuf.	11/99			11/2000
Polyvinyl Chloride & Copolymers Prod	11/99			11/2000
Primary Magnesium	5/99			05/2000
Printing, Coating, & Dyeing of Fabrics	11/99			11/2000
Quaternary Ammonium Comp. Prod.	11/99			11/2000
Rocket Engine Test Firing	11/99			11/2000
Rubber Tire Production	3/99			12/99
Secondary Lead Smelters	--			5/31/95
Semiconductor Manuf.	11/99			11/2000

Exhibit C-4 (continued)
EPA - Clean Air Act - Title III
10-Year MACT Standards

10-YEAR STANDARDS	PROPOSE			PROMULGATE
Source Category	**Administrator Signature**	**Actually proposed in FR**	**FR citation for proposed rule**	
Sewage Sludge Incinerators	4/99			05/2000
Spandex Production	11/99			11/2000
Taconite Iron Ore Processing	11/99			11/2000
Uranium Hexafluoride Prod.	11/99			11/2000
Vegetable Oil Production	11/99			11/2000

Table Legend:
+ = standards with more than one source category (see below for breakdown)
^ = two source categories being worked on together as one project
^^=Part of Polymers & Resins IV

BREAKDOWN OF SOURCE CATEGORIES FOR 10 YEAR MACT

MISCELLANEOUS CELLULOSE MACT
- Carboxymethylcellulose Production
- Cellulose Ethers Production
- Cellulose Food Casing Manufacturing
- Cellophane Production
- Methylcellulose Production
- Rayon Production

INDUSTRIAL COMBUSTION COORDINATING RULEMAKING
- Industrial Boilers
- Institutional/Commercial Boilers
- Process Heaters
- Stationary Internal Combustion Engines
- Stationary Turbines

MISCELLANEOUS ORGANIC NESHAP (MON)
- Alkyd Resins Production
- Benzyltrimethylammonium Chloride Production
- Carbonyl Sulfide Production
- Chelating Agents Production
- Chlorinated Paraffins Production
- Ethyllidene Norbomene Production
- Explosives Production
- Hydrazine Production
- Maleic Anhydride Copolymers Production
- Manufacture of Paints, Coatings, & Adhesives
- OBPA/1,3-diisocyanate Production
- Photographic Chemicals Production
- Phthalate Plasticizers Production
- Polyester Resins Production
- Polymerized Vinylidene Chloride Production
- Polymethyl Methacrylate Resins Production
- Polyvinyl Acetate Emulsions Production
- Polyvinyl Alcohol Production
- Polyvinyl Butyral Production
- Rubber Chemicals Production
- Symmetrical Tetrachloropyridine Production

Appendix D

Summary of Response to Science Advisory Board's (SAB) Review of EPA's April 14, 1998 Draft Residual Risk Report to Congress

Appendix D
Summary of Response to Science Advisory Board's (SAB) Review of EPA's April 14, 1998 Draft Residual Risk Report to Congress

Introduction

This appendix includes a summary of EPA's response to the Science Advisory Board (SAB) comments to EPA's April 14, 1998 draft Residual Risk Report to Congress (Report). The SAB is a public advisory group, comprised of non-EPA scientists, that provides extramural scientific information and advice to EPA. At EPA's request, the Residual Risk Subcommittee of SAB convened on August 3, 1998 to review the Report. The SAB found the Report to be overall a good draft of a strategy document; however, the Subcommittee indicated that certain areas of the Report should be strengthened before it can be applied to actual residual risk assessments. The Subcommittee was highly supportive of the Agency's plan to inform the SAB in 1999 with examples in which the Report's strategy has been applied to specific areas. The SAB endorsed the underlying risk assessment (RA)/risk management (RM) approach described in the Report. However, the SAB added that the following issues needed to be addressed more directly and explicitly before finalizing the Report.

(1) The Report should more carefully convey the limitations of the data, models, and methods that are described or that would be needed to carry out the residual risk assessment activities.

(2) The Report should contain or cite specific examples to clarify what some of the bold, but vague, language is intended to convey.

(3) There needs to be a more clearly described screening approach that will prioritize stressors for assessment and will husband (i.e., conserve) Agency resources.

(4) The Report should be more explicit about how the residual risk assessments will be used to make risk management decisions.

Executive Summary of SAB's Review

The following is the full text of the executive summary of SAB's review of EPA's draft Residual Risk Report to Congress.

Section 112(f)(1) of the Clean Air Act (CAA), as amended, directs EPA to prepare a Residual Risk Report to Congress (Report) that describes the methods to be used to assess the risk remaining, (i.e., the residual risk) after maximum achievable control technology (MACT)

standards, applicable to emissions sources of hazardous air pollutants (HAPs), have been promulgated under Section 112(d). The Report presents EPA's proposed strategy for dealing with the issue of residual risk and reflects consideration of technical recommendations in reports by the National Research Council ["Science and Judgment"] (NRC, 1994) and the Commission on Risk Assessment and Risk Management (CRARM, 1997). As a strategy document, the Agency's Report describes general directions, rather than prescribed procedures. The announced intent is to provide a clear indication of the Agency's plans while retaining sufficient flexibility that the program can incorporate changes in risk assessment methodologies that will evolve during the 10-year lifetime of the residual risk program.

In June, 1998, the Science Advisory Board (SAB) was asked to review the Agency's April 14, 1998 draft Report to Congress on Residual Risk. The Board was asked to focus primarily on the five specific charge questions that are addressed in the report:

a) Has the Residual Risk Report to Congress (Report) properly interpreted and considered the technical advice from previous reports, including:

   (1) The NRC's 1994 report "Science and Judgment in Risk Assessment", and

   (2) The 1997 report from the Commission on Risk Assessment and Risk Management, in developing its risk assessment methodology and residual risk strategy?

b) Does the Report identify and appropriately describe the most relevant methods (and their associated Agency documents) for assessing residual risk from stationary sources?

c) Does the Report provide an adequate characterization of the data needs for the risk assessment methods?

d) Does the Report provide adequate treatment of the inherent uncertainties associated with assessment of residual risks?

e) Does the Report deal with the full range of scientific and technical issues that underlie a residual risk program?

An SAB Subcommittee of the Executive Committee met in public session on August 3, 1998 at the USEPA main auditorium in Research Triangle Park, NC. Written comments prepared before and after the meeting by Subcommittee members form the basis for this report. Those comments are included in Appendix A for the edification of the Agency as an illustration of the issues identified by the Subcommittee members and the range of views expressed.

In short, the SAB found the Report to be a generally good draft of a strategy document, but one that must be strengthened in a number of important places prior to its submission to

Congress. The Subcommittee was highly supportive of the approach that the Agency described in terms of coming back to the SAB in 1999 with examples in which the Report's strategy is applied to specific cases.

Overall, the Report utilizes the risk assessment(RA)/risk management (RM) framework, endorsed by the SAB and others. It emphasizes the dynamic and evolving nature of the RA process by not being overly prescriptive, while also providing some bounds to the process in both the areas of RA and RM. The Agency has clearly studied the National Research Council and Commission on RA/RM reports that related to this topic and has addressed many of the concerns and suggestions that they raised. At the same time, there are additional points that should be confronted more directly, including the following:

(1) *The Report gives a misleading impression that more can be delivered than is scientifically justifiable, given the data gaps and limited resources (e.g., time, funding) for conducting the residual risk assessments. The Subcommittee recommends that the Report more carefully convey the limitations of the data, models, and methods that are described or that would be needed to carry out the residual risk assessment activities.*

The task of conducting so many assessments of the risks remaining after implementation of MACT controls is daunting, but doable. While the Report describes a general strategy for accomplishing this task, it does not address many of the outstanding, practical difficulties that will have to be overcome in carrying out the strategy. For example, there will likely be many situations in which the data implied in the strategy are absent. Although a number of options exist, it is not clear what the Agency will do in such cases. Other problems that need attention include: computer models that have had only limited independent testing for their application to a particular problem and/or have not been adequately validated for its general applicability across a wide array of situations, information in important toxicological databases that is outdated or has had limited peer review, and special limitations in information and tools for ecological risk assessment. The Congress and the public, on the basis of reading this Report, may have unrealistically high expectations of what the Agency can, in fact, deliver in terms of the accuracy, precision, and timeliness of residual risk assessments.

(2) *The Report should contain or cite specific examples to clarify what some of the bold, but vague, language is intended to convey.*

The Report lacks any specific examples and/or citations of existing examples to illustrate its discussion of the many complex and difficult issues involved, such as, but not limited to, the following:

a) Involving stakeholders in the process, which is particularly important when it comes to sharing information among the Federal and State Governments and industry.

b) Determining the criteria for when to use other than default assumptions.

c) Addressing background contamination and competing sources of risks (e.g., mobile and area sources).

d) Dealing with the trade-off between risks from HAPs and possible risks posed by measures to reduce the HAPs risks.

e) Assessing risks in the face of significant limitations in the available data, the lack of validation of existing and emerging computer models, and the need to consider uncertainty in the results.

f) Employing screening tiers and emerging risk assessment methodologies in such a way that scarce resources are targeted on the most important assessments and are not expended on resource-intensive, low-information-yield analyses.

g) Providing a public health perspective to these issues.

(3) *There needs to be a more clearly described screening approach that will prioritize stressors for assessment and will conserve Agency resources. The Report should more clearly present the approach by which the Agency will perform the screening and prioritization.*

There is the potential that the Residual Risk program could evolve into a large, resource-intensive activity unless there is an appropriate and well-supported screening approach in place to prioritize assessments among the 188 pollutants and 174 source categories. The screening methods should be such that they avoid generating a large number of "false positives" -- that would drain scarce RA resources -- or "false negatives" -- that could result in leaving high risk situations unaddressed. Unless the Agency carefully prioritizes its assessments and conserves its resources, the program could evolve either into a wide, but shallow, program that fails to adequately quantify and target residual risks or into a program that fails to address a sufficient number of pollutants and sources, due to over-analysis of just a few cases.

(4) *The Report should be more explicit about how the residual risk assessments will be used to make risk management decisions.*

The Subcommittee recognizes that the Report is a description of a strategy for RA, not for RM, per se. However, as S&J and the CRARM report each emphasize, there should be open communication between risk assessors and risk managers at the beginning of the process, so that it is clear how the RA will fit into the RM process. If the Residual Risk program is, indeed, to be "science-based", then it is important that there be, even in a strategy document, some discussion of what type of RA is needed and how its results will be factored with other legitimate risk management factors during the final stages of decision making.

The Subcommittee strongly encourages the Agency to implement their plan to bring to the SAB for review in 1999 some applications of the Residual Risk strategy as specific illustrations of how these complex issues will be addressed. This approach will permit more detailed discussion of many of the implementation issues that members felt will arise when residual risk assessments are made.

Considering a larger issue beyond its specific Charge, the Subcommittee expressed some concern about the manner in which risks from HAPs are being addressed, when compared with the risks posed by Section 109 Criteria Air Pollutants (CAPs). There are differences in the wording of the Clean Air Act Amendments as to the level of risk avoidance that should be provided. This incongruity is puzzling and suggests that it may be useful to reevaluate how risks are assessed and managed for these two types of airborne pollutants. We recognize that the current legislation requires that these two classes of pollutants be treated separately. However, since the Agency was specifically asked to suggest changes in the legislation, there is an opportunity to propose a more comprehensive framework upon which to build the assessment and management of the risks from both HAPs and CAPs. Such a broader public health perspective would result in greater improvements in health and environmental benefits for a given expenditure of resources. The Agency has taken some steps towards a comprehensive view of HAPs and CAPs in its Report to Congress on the Costs and Benefits of the Clean Air Act, 1970-1990 (EPA 1997) that has been reviewed earlier by the SAB (SAB 1997, 1996) and those steps should be continued. The contrast in relative benefits of the two programs was revealing.

In addition, the Agency Staff should consider outlining a number of the most important Residual Risk issues in a policy memo to top management; e.g., the limitations on what science can deliver and the comparison between the Section 112 (HAPs) program and the Section 109 (CAPs) program. These managers should be made aware of the problems involved and be given the opportunity to provide the kind of guidance that would clarify these matters for the benefit of those both inside and outside of the Agency.

In summary, the Agency's Report is a useful strategic document that will help guide the Agency as it moves ahead with the Residual Risk program. However, the Subcommittee recommends that the Agency be more candid with Congress and the public about what can be accomplished with existing limitations in data, models, methods, time, and resources. The Subcommittee has pointed out many areas that will require more thought, more documentation, and more articulation before the program is actually implemented.

Response to SAB Comments

In this section, EPA addresses SAB's four major comments.

1. The report should more carefully convey limitations of data, models, and methods that are described or that would be needed to carry out residual risk assessment activities.

RESPONSE

The report has been revised to clarify the current availability of data and tools relevant to air toxics risk assessment, the resultant limitations of the risk assessments, and plans for data and tool development to improve this situation. The more obvious limitations include the lack of dose-response assessments and ecological criteria for many HAPs. This situation significantly handicaps our risk assessment for those HAPs, thus limiting the scope of some source category risk assessments. This leads to a greater level of uncertainty regarding residual risks than if all data gaps were filled.

Sections detailing the availability of data, methodology, or models, as appropriate, have been included in the report following the discussion of each of the the various components of the risk assessment process. In addition to describing the current availability and completeness of data or methodology, and how that may affect the limitations and uncertainties associated with risk assessments, plans to improve that situation (i.e., data and tool development activities and priorities) are also presented.

2. The report should contain or cite specific examples to clarify what some of the "bold, but vague language" is intended to convey.

RESPONSE

General discussion of some topics in the Report is necessary given that the Agency is in the initial stages of the residual risk assessment process and that evaluation of the process following initial analyses may lead to changes. However, clarifying language has been incorporated to provide the reader with a better understanding of the methods and general process presented.

A new subsection on stakeholder involvement has been added to highlight ways in which stakeholders may be involved in the risk assessment process. Additional text has been added to describe the term "default options." In the restructured chapter on the general risk assessment framework for residual risk, differences between the screening and refined tiers are more clearly described. A major difference between the two tiers is the use of conservative assumptions in the screening tier. In the refined tier, additional data or more refined modeling are relied upon to replace the conservative assumptions. That

is, the specificity and complexity (and consequently resource intensiveness) increases with each tier. Additionally, experience from case studies will inform the problem formulation stage in later source category assessments.

The section describing the risk characterization step for both human health and ecological risk assessments is strengthened regarding presentation of calculated risks in context of uncertainties associated with the analysis and, as data are available, risk posed by background concentrations. Additional available public health information may also be presented in this step for final risk assessment iterations (i.e., those supporting regulatory risk management decisions). The section of the Report addressing Clean Air Act section 112(f)(1)(B) discussion of uncertainties in the risk assessment methodology and analysis of uncertainties in air toxics risk assessment has been substantively revised.

As risk management decisions are made regarding the need for residual risk standards, information specific to each source category regarding risks associated with implementation of controls can be considered.

To improve clarity of descriptions of ecological risk assessment methodology, examples have been added to the report.

3. There needs to be a more clearly described screening approach that will prioritize stressors for assessment and will conserve Agnecy resources.

RESPONSE

The chapter on the general framework for the residual risk risk assessment process has been restructured to better describe the screening and refined tiers of assessment. The screening tier provides the ability to identify those source categories or subcategories and HAPs that may need to move into the refined assessment tier. The risk estimates derived in the screening tier can be used in conjunction with information on available data and other relevant information to set priorities for refined analyses. The Report is not meant to provide a detailed description of data, assumptions, and analyses within each tier, i.e., the Report is not meant to be a guidance document. Rather, it provides a description of the general framework for the risk assessment process. Use of the tiered approach allows EPA to efficiently and effectively use resources and available data. The screening tier is less resource intensive, and more likely overly conservative, while the refined tier requires more resources and relies on more realistic assumptions. The decision made with results of the screening analysis is “no further action” or “refine analysis,” while the decision made with results of the more refined analyses is “no further action” or “consider additional emissions control.”

4. The Report should be more explicit about how the residual risk assessments will be used to make risk management decisions.

RESPONSE

As EPA's process for conducting residual risk assessments and consideration of those results in risk management decision is evolving, the Report is not intended to provide details regarding risk management decisions. The Report includes general descriptions of risk management decision points within the risk assessment framework, e.g., during problem formulation and scoping phases and in consideration of iterative assessment results.

Appendix E
Summary of MACT Standards and Control Technologies

Table I - Summary of MACT for Process Vents Under Promulgated NESHAP [a]
MACT Control Level for Affected Sources

40 CFR 63 Subpart	Industry Source Category	HAP Emission Control Standard	Alternative Standards Established by Subpart
Subpart G	HON	HAP control efficiency ≥ 98%	Vent to a flare, or Vent to control device with HAP outlet concentration ≤ 20 ppmv
Subpart M	Perchloroethylene Dry Cleaning	Vent to refrigerated condenser, carbon adsorber, or "equivalent control device" as applicable to machine [b]	none specified
Subpart O	EO Sterilization	Ethylene oxide (EO) control efficiency ≥ 99%	Achieve aeration room vent EO concentration ≤ 1 ppmv
Subpart U	Group I Polymers and Resins	Continuous process HAP control efficiency ≥ 98% and Batch process HAP control efficiency ≥ 90%	Vent to a flare, or Vent to control device with HAP outlet concentration ≤ 20 ppmv
Subpart W	Group II Polymers and Resins	HAP control efficiency ≥ 98% [c]	Achieve mass emission limit ≤ 5,000 lb HAP / yr [c]
Subpart CC	Petroleum Refineries	HAP control efficiency ≥ 98%	Vent to a flare, or Vent to control device with HAP outlet concentration ≤ 20 ppmv[d]
Subpart DD	Off-Site Waste and Recovery	HAP control efficiency ≥ 95% [e]	Vent to a flare, or Vent to combustion control device with HAP outlet concentration ≤ 20 ppmv
Subpart EE	Magnetic Tape Manufacturing	HAP control efficiency ≥ 95%	none specified
Subpart JJJ	Group IV Polymers and Resins	Continuous process HAP control efficiency ≥ 98% [f] and Batch process HAP control efficiency ≥ 90% [f]	Alternative standards available for process vents in certain subcategories under conditions selected in rule. These options include (not all options are allowed in all cases): achieve HAP emission limit per unit of product produced; vent to control device with HAP outlet concentration ≤ 20 ppmv; and vent to a flare.

Table I (concluded)

TABLE NOTES:

(a) This is a summary table prepared to group the MACT standards by similar HAP emission points. It is **not** a comprehensive listing of the individual subpart requirements, and is **not** to be used to determine the applicability and compliance requirements under 40 CFR part 63 for a specific facility location.

(b) Under Subpart M, owner/operator has the option of venting the air-perchloroethylene vapor stream exhausted from existing dry-cleaning machine to carbon adsorber provided control device installed before 9/22/93.

(c) Under Subpart W process vents are included in the group of emission points that must be controlled to achieve an overall maximum emission limit standard for the resin or polyamine manufacturing process. The standard listed in this table applies only for resin manufacturing processes that are new sources.

(d) Under Subpart CC these emission limit standards are not explicitly stated as an alternative standard, but is applied implicitly through the applicability provision specifying the affected process vents requiring Organic HAP Emission Controls (see Table 6a).

(e) Under Subpart DD, an owner/operator may elect to meet this control efficiency standard by averaging emissions from all of the affected process vents.

(f) This is the minimum control efficiency for most subcategories.

Table II - Summary of MACT for Equipment Leaks Under Promulgated NESHAP [(a)]
MACT Control Level for Affected Sources

40 CFR 63 Subpart	Industry Source Category	Standards Established by Subpart for Affected Equipment (see Table 9a)
Subpart F/H	HON	• Implement leak detection and repair program for affected pumps, valves, and connectors. Monitoring interval established by performance requirements for a maximum allowable percentage of leaking components • Standards for compressors, open-ended lines, pressure relief devices, and sampling connections same as in 40 CFR 61 subpart V. • Alternative standards for batch processes and for equipment inside an enclosed building.
Subpart R	Gasoline Distribution	Monthly leak inspection of all affected equipment
Subpart U	Group I Polymers and Resins	Comply with 40 CFR 63 subpart H
Subpart CC	Petroleum Refineries	Existing Sources: comply with either 40 CFR 60 subpart VV or 40 CFR 63 subpart H New Sources: comply with 40 CFR 63 subpart H
Subpart DD	Off-Site Waste and Recovery	Comply with 40 CFR 61 subpart V (as an alternative owners/operators may comply with 40 CFR 63 subpart H)
Subpart JJJ	Group IV Polymers and Resins	Comply with 40 CFR 63 subpart H

(a) This is a summary table prepared to assist in grouping the MACT standards by similar HAP emission points. It is **not** a comprehensive listing of the individual subpart requirements, and is **not** to be used to determine the applicability and compliance requirements under 40 CFR part 63 for a specific facility location.

Table III - Summary of MACT for Organic Coating Application Operations Under Promulgated NESHAP [a]

40 CFR 63 Subpart	Industry Source Category	Affected Source	Standards Established by Subpart	
			Maximum Emission Limit	Alternative Standards
Subpart EE	Magnetic tape manufacturing	Magnetic tape coating application	≤ 180 grams HAP per liter of solids in coating	Achieve HAP control efficiency ≥ 95%
Subpart GG	Aerospace manufacturing and rework facilities	Primer paint application	≤ 350 grams HAP per liter of coating	Achieve HAP control efficiency ≥ 81%
		Topcoat paint application	≤ 420 grams HAP per liter of coating	Achieve HAP control efficiency ≥ 81%
		Milling maskant application	≤ 160 grams HAP per liter of coating	Achieve HAP control efficiency ≥ 81%
Subpart II	Shipbuilding and ship repair	Ship paint application	Meet either applicable limit: grams HAP per liter of coating [b] or grams HAP per liter of solids in coating [b]	none
Subpart JJ	Wood furniture manufacturing	Finish coating application	applicable limit in grams HAP per grams of solids in coating [b]	none
		Contact adhesive application	applicable limit in grams HAP per grams of solids in adhesive [b]	none
Subpart KK	Printing and publishing	Publication rotogravure printing [c]	≤ 8% total organic HAP applied by each press per month on mass basis	Achieve HAP control efficiency ≥ 92%
		Product and packaging rotogravure and wide-web flexographic printing [c]	≤ 4% total organic HAP applied by each press per month on mass basis	none

Table III (concluded)

TABLE NOTES:

(a) This is a summary table prepared to assist in grouping the MACT standards by similar HAP emission points. It is **not** a comprehensive listing of the individual subpart requirements, and is **not** to be used to determine the applicability and compliance requirements under 40 CFR part 63 for a specific facility location.

(b) Different numerical values are specified for different types of coatings and for existing sources and new sources.

(c) Rule distinguishes between a "printing operation" and a "coating operation," but both are included as part of the affected sources if a press is capable of printing or coating on the same substrate.

Table IV - Summary of MACT for Organic Solvent Cleaning Operations Under Promulgated NESHAP [(a)]

40 CFR 63 Subpart	Industry Category	Affected Source	Standards Established by Subpart
Subpart T	Halogenated solvent cleaning	Batch cold solvent cleaning machines	• Use tight-fitting covers except when adding or removing parts to be cleaned • Minimum machine freeboard ratio specified • Implement specific work practices requirements.
		Batch vapor and In-line cleaning machines	• Specific machine equipment design requirements • Install and operate one of the control options specified in the rule. Control options are different combinations of equipment (refrigeration or carbon adsorber devices), minimum machine freeboard ratios, and reduced room draft rates. Number of control options vary depending on solvent cleaning machine type and whether it is an existing or new source. • Meet machine idling emission limit expressed in terms of kg of the total halogenated HAP solvent emissions per hour per m^2 solvent/air interface. Numerical value varies depending on type of solvent cleaning machine. • Implement specific work practices requirements.
Subpart EE	Magnetic tape manufacturing	Wash sinks	• Implement one of the following options: Option 1: Achieve for each sink overall HAP control efficiency $\geq$ 88% Option 2: Maintain minimum freeboard ratio of 75%.
Subpart GG	Aerospace manufacturing and rework facilities	Solvent cleaning operations	• Implement specific work practice requirements
		Depainting operations	• Existing sources achieve overall HAP control efficiency $\geq$ 81% • New sources achieve overall HAP control efficiency $\geq$ 95% • Implement specific work practices requirements.

Table IV (concluded)

TABLE NOTES:

(a) This is a summary table prepared to assist in grouping the MACT standards by similar HAP emission points. It is **not** a comprehensive listing of the individual subpart requirements, and is **not** to be used to determine the applicability and compliance requirements under 40 CFR part 63 for a specific facility location.

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15. SUPPLEMENTARY NOTES

16. ABSTRACT

This report has been prepared in response to section 112(f)(1) of the Clean Air Act and provides the Congress and the public with a description of the methods and general framework that EPA will use to assess the public health and environmental risk which may remain after implementation of air toxics emissions standards required under section 112(d) of the Clean Air Act. This remaining risk is referred to as "residual risk." Air toxics, also known as hazardous air pollutants, are those pollutants known or suspected to cause cancer or other adverse health effects to humans or adverse environmental effects. This report also discusses specific issues relevant to the evaluation of residual risk and methods and costs of reducing such risk.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Residual Risk Air Toxics Hazardous Air Pollutants MACT Risk Assessment	Air Pollution control	

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