Draft Technical Guidance for Assessing Environmental Justice in Regulatory Analysis

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Acronyms and Abbreviations

ADP	–	Action Development Process
CAFO	–	Concentrated Animal Feeding Operation
CDC	–	Centers for Disease Control and Prevention
CEQ	–	Council on Environmental Quality
CPI-U	–	Consumer Price Index
CRA	–	Cumulative Risk Assessment
DQO	–	Data Quality Objectives
DSW	–	Definition of Solid Waste
EGU	–	Electric Generating Utility
EJ	–	Environmental Justice
EO	–	Executive Order
EPA	–	Environmental Protection Agency
GAO	–	Government Accountability Office
GHG	–	Greenhouse Gas
GIS	–	Geographic Information System
HHRA	–	Human Health Risk Assessment
HIA	–	Health Impact Assessment
HUD	–	Housing and Urban Development
IQG	–	Information Quality Guidelines
IRIS	–	Integrated Risk Information System
MATS	–	Mercury and Air Toxics Standards
MDI	–	Mental Development Index
NAAQS	–	National Ambient Air Quality Standards
NATA	–	National Air Toxics Assessment
NEPA	–	National Environmental Policy Act
NESHAP	–	National Emission Standards for Hazardous Waste Pollutants
NHANES	–	National Health and Nutrition Examination Survey
NPDES	–	National Pollution Discharge Elimination System
NRC	–	National Research Council
NYCHANES	–	New York City Health and Nutrition Examination Survey
OAR	–	EPA Office of Air and Radiation
OMB	–	White House Office of Management and Budget
OPP	–	EPA Office of Pesticide Programs
PM	–	Particulate Matter
RAF	–	EPA Risk Assessment Forum
RCRA	–	Resource Conservation and Recovery Act
SES	–	Socioeconomic Status
SPM	–	Supplemental Poverty Measure

Overview and Background

What is the Purpose of this Guidance?

Executive Order (E.O.) 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, calls on each Federal agency to make achieving environmental justice (EJ) part of its mission "by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations."[1,2]

In July 2010, the United States Environmental Protection Agency (EPA or the Agency) released its *Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action* (*ADP Interim Process Guide*) to assist staff in considering potential EJ concerns during the development of actions.[3] The *ADP Interim Process Guide* aims to "explicitly integrate EJ considerations into the fabric of EPA's ADP [Action Development Process] – through all stages leading to promulgation and implementation."

This document, *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (*EJ Technical Guidance*), is a technical complement to the *ADP Interim Process Guide* and represents an important step toward ensuring that Agency regulatory actions appropriately consider EJ issues.[4] Specifically, this guidance document will help Agency staff conduct analyses to evaluate potential EJ concerns associated with EPA regulatory actions. This document is intended for use alongside other relevant Agency guidance on human health risk assessment and economic analysis (see Appendix A).[5] Together, the *ADP Interim Process Guide* and the *EJ Technical Guidance* provide direction on how regulatory actions can be responsive to E.O. 12898 as well as EPA's EJ policies and *Plan EJ 2014*, the Agency's roadmap for integrating environmental justice into EPA programs and policies (U.S. EPA, 2011b).[6]

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[1] E.O. 12898 (issued February 11, 1994) is available in full at: http://www.archives.gov/federal-register/executive-orders/pdf/12898.pdf.

[2] The term "effects" is typically interpreted within the EPA as a reference to risks, exposures, and outcomes and is sometimes used interchangeably with the term, "impacts."

[3] EPA's *Interim Guidance on Considering Environmental Justice During the Development of an Action* can be found at http://www.epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf. It applies generally to all "Agency actions," which include rules, policy statements, risk assessments, guidance documents, models that may be used in future rulemakings (for more on the ADP see http://intranet.epa.gov/adplibrary). This technical guidance document is designed to apply to analyses conducted mainly in direct support of a rule or regulation.

[4] E.O. 12866 defines a regulatory action as "any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

[5] Also see *Plan EJ 2014 Legal Tools* for a review of legal authorities under the environmental and administrative statutes administered by EPA that may contribute to the effort to advance environmental justice (U.S. EPA, 2011a). (http://www.epa.gov/compliance/environmentaljustice/resources/policy/plan-ej-2014/ej-legal-tools.pdf).

[6] Existing EPA EJ policy is summarized at: http://www.epa.gov/environmentaljustice/resources/policy/. EPA's historical EJ policies include: *The EPA's Environmental Justice Strategy* (U.S. EPA, 1995); *Environmental Justice Implementation Plan* (U.S. EPA, 1996); *Environmental Justice: Guidance Under the National Environmental Policy Act* (Council on Environmental Quality, 1997); *Final Guidance for Incorporating Environmental Justice Concerns in EPA's NEPA Compliance Analyses* (U.S. EPA,1998a); *Toolkit for Assessing Potential Allegations of Environmental Justice* (U.S. EPA, 2004); Memo from Stephen L. Johnson: *Reaffirming the U.S. EPA's Commitment to Environmental Justice* (U.S. EPA, 2005); and Memo from Lisa P. Jackson: *Next Steps: Environmental Justice and Civil Rights* (U.S. EPA, 2009).

Who is the Audience for this Technical Guidance?

This guidance document is intended primarily to assist Agency analysts, including risk assessors, economists, and other analytic staff, in evaluating potential EJ concerns in the context of rule development (i.e., regulatory actions). Senior EPA managers, decision makers, rulewriters, and workgroup chairs will also find this document useful for understanding analytic expectations and ensuring that potential EJ concerns are appropriately considered.

How is this Guidance Document Organized?

The first three sections of this guidance establish the principles, priorities, context, and definitions that drive the assessment of potential EJ concerns in support of EPA regulatory actions:

- **Section 1: Introduction** outlines the main objectives for analysis of potential EJ concerns. In addition, the section presents EPA's six main recommendations to guide assessments of EJ for EPA rules and regulations. Appendix A provides a list of relevant additional guidance that may be helpful to the analyst when assessing potential EJ concerns
- **Section 2: Key Analytic Principles and Definitions** reviews the analytic principles that guide the analysis of potential EJ concerns. The section also introduces and discusses key EJ concepts highlighted in Executive Order 12898 (e.g., population groups of concern, disproportionate impacts, meaningful involvement) that may interact with analytic considerations.
- **Section 3: Contributors and Drivers of Potential Environmental Justice Concerns** identifies important human health risk and economic factors that contribute to potential EJ concerns, and highlights the key reasons why health risks may be unevenly distributed across population groups.

The main technical sections (Sections 4 and 5) provide guidance for considering EJ in two specific contexts: planning for a human health risk assessment (Section 4) and development of a regulatory analysis (Section 5). The final section of the document (Section 6) identifies near-term research priorities related to the analysis of EJ.

- **Section 4: Considering Environmental Justice when Planning a Human Health Risk Assessment** provides technical guidance on how to incorporate consideration of potential EJ concerns into the planning phase of a human health risk assessment. The section describes empirical methodologies and tools that are currently available, and discusses how information can be clearly and transparently presented to decision makers. Appendix B provides examples of approaches for incorporating EJ into the planning stages of exposure and dose-response assessments.
- **Section 5: Conducting Regulatory Analyses To Assess Potential Environmental Justice Concerns** provides technical guidance on how to integrate potential EJ concerns into regulatory analyses. In particular, this section discusses how to evaluate what level of analysis is feasible; what types of information should be included in an assessment of potential EJ concerns; what methods and tools can be used to generate this information; a discussion of other analytic considerations that could affect the results of the assessment; and information on when to consider costs and non-health impacts.
- **Section 6: Key Near-Term Research Priorities to Fill Key Data and Methodological Gaps** provides information on longer-term research goals to improve assessment of EJ at the EPA. [NOTE: this section will be drafted based on Agency, public, and peer review input and will be added at a later date]

While planning for a human health risk assessment (Section 4) and development of a regulatory analysis (Section 5) are often carefully coordinated in the rulemaking context, they also may occur in isolation or in parallel. This guidance therefore assumes that an analyst may wish to consult only one of the two sections to address a specific context. As a result, the sections present some parallel information about key concepts and methods. This overlap is by design, and is appropriate given that different analytic experts will access and rely on different sections of the document for different purposes within the larger context of EPA regulatory action development.

Disclaimer: This document identifies internal Agency policies and recommended procedures for EPA employees. This document is not a rule or regulation and it may not apply to a particular situation based upon the circumstances. This guidance does not change or substitute for any law, regulation, or any other legally binding requirement and is not legally enforceable. As indicated by the use of non-mandatory language such as "guidance," "recommend," "may," "should," and "can," it identifies policies and provides recommendations and does not impose any legally binding requirements.

Section 1: Introduction

The United States Environmental Protection Agency defines environmental justice as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies."[7] EPA further defines the term "fair treatment" to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies" (U.S. EPA, 2012a). In implementing its EJ-related efforts, the Agency has expanded the concept of fair treatment to consider not only the distribution of burdens across all populations, but also the distribution of reductions in risk from EPA actions. For example, the Agency's *ADP Interim Process Guide* encourages Agency staff to evaluate the distribution of burdens by paying special attention to populations that have historically borne a disproportionate share of environmental harms and risk. At the same time, it encourages Agency staff to examine the distribution of positive environmental and health outcomes from regulatory and other Agency activities (U.S. EPA, 2010a).

The *ADP Interim Process Guide* describes the statutory and policy framework for considering EJ, identifies concepts central to determining whether an action involves a potential EJ concern, and discusses how they fit into each step of the ADP. It provides a limited discussion of possible analytical tools and methodologies available for evaluating the impacts of Agency actions on minority, low-income or indigenous populations (U.S. EPA, 2010a). The *EJ Technical Guidance* complements the *ADP Interim Process Guide*. It outlines particular approaches and methods to help Agency analysts, including economists, risk assessors, and other analysts, evaluate potential EJ concerns. Together, these documents provide guidance on how regulatory actions can be responsive to E.O. 12898 as well as consistent with EPA's EJ policies and Plan EJ 2014 (U.S. EPA, 2011b).

It is important to note that this technical guidance will evolve with the state of the science, data, and analytic methods available to Agency analysts. In particular, with regard to risk assessment, this technical guidance is limited to a discussion of how to integrate EJ into the planning phase of a human health risk assessment. EPA's Risk Assessment Forum (RAF) is currently developing guidance for the Agency on a variety of relevant topics including exposure assessment, effects assessment and cumulative risk assessment. The *EJ Technical Guidance* will be updated to integrate these analytical frameworks when they are completed.

1.1 Overarching Questions and Objectives for Analysis of Potential EJ Concerns

The *ADP Interim Process Guide* recommends that rule-writers, analysts, and decision makers "respond to three basic questions throughout the action development process (U.S. EPA, 2010a):

1. How did your public participation process provide transparency and meaningful participation for minority, low-income and indigenous populations, and Tribes?

[7] For instance, see Administrator Whitman's August 9, 2001 memo on EPA's commitment to environmental justice at http://yosemite.epa.gov/opa/admpress.nsf/89745a330d4ef8b9852572a000651fe1/41a2df9798d627a185256aaf0067e435!OpenDocument .

2. How did you identify and address existing and new disproportionate environmental and public health impacts on minority, low-income and indigenous populations during the rulemaking process?

3. How did actions taken under #1 and #2 impact the outcome or final decision?"

This technical guidance primarily will aid analysts in providing information to Agency decision makers that can be used to address Questions 2 and 3 from the *ADP Interim Process Guide*. Question 1 is expected to be addressed as part of broader public outreach during the rulemaking process.[8] Senior EPA managers will also find this technical guidance useful for understanding analytic expectations and ensuring that potential EJ concerns are appropriately considered and, when feasible, addressed in the development of regulatory actions.

The *ADP Interim Process Guide* introduces and defines the concept of "EJ concerns" as "disproportionate impacts on minority, low-income or indigenous populations that exist prior to or that may be created by the proposed action" (the term "disproportionate" is discussed in Section 2).[9] Analysis of EJ for regulatory actions should therefore address the following two questions:

- Is a potential EJ concern associated with the affected environmental stressors prior to the rulemaking?[10]
- For each of the regulatory options under consideration, is a potential EJ concern created or mitigated for these affected environmental stressors?

To ascertain the extent to which a potential EJ concern is associated with the affected environmental stressors prior to the rulemaking, the analyst should, when feasible:

1. Assess exposures, relevant health and environmental outcomes, and other relevant effects by population group in the baseline;[11] and

2. Assess differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups in the baseline.

For each regulatory option under consideration, to inform the extent to which a potential EJ concern is created or mitigated for the affected stressors, the analyst should, when feasible:

3. Assess exposures, relevant health and environmental outcomes, and other relevant effects by population group for each option;

4. Assess differences in these exposures , relevant health and environmental outcomes, and other relevant effects across population groups for each option; and

[8] Note that the EPA's *Toolkit for Assessing Potential Allegations of Environmental Injustice* differs from this technical guidance document in that it is mainly designed to help investigate allegations of environmental injustice in a particular geographic area, for instance as a result of a permitting or enforcement decision that pertains to a particular facility. This technical guidance document has a much broader scope, to aid analysts in evaluating potential EJ concerns that may arise due to EPA rulemakings.
[9] For analytic purposes, the term "EJ concern" refers to "disproportionate impacts on minority, low-income or indigenous populations that exist prior to or that may be created by your proposed action" (U.S. EPA, 2010a). It can also indicate the actual or potential lack of fair treatment or meaningful involvement of minority, low-income or indigenous populations in the development, implementation, and enforcement of environmental laws, regulations, and policies. The *ADP Interim Process Guide* (U.S. EPA, 2010a) focuses on identifying potential or actual EJ concerns related to the two latter uses of the term, while the Technical Guidance focuses on the former.
[10] The general term "environmental stressor" (or "stressor") is used to encompass the range of chemical, physical or biological agents, contaminants, or pollutants that may be subject to a rulemaking.
[11] The White House Office of Management and Budget (OMB) defines the baseline as "the best assessment of the way the world would look absent the proposed action" (OMB, 2003). See Section 5 of this document for more information.

5. Assess how estimated differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups increase or decrease as a result of each option compared to the baseline.[12]

This document is designed to provide analysts with information on how to address these analytic objectives, and to identify: (1) which adverse health and environmental outcomes and other relevant effects are associated with the regulated stressor or source for the population groups of concern (i.e., minority, low-income or indigenous populations)[13] relative to a comparison population group; (2) whether these outcomes are differentially distributed across population groups; and (3) whether any differences are potentially disproportionate. The extent to which an analysis is able to address all of these objectives will vary. Comparison population groups are discussed in greater detail in Section 2.3. The term "disproportionate" and the role of an analyst in this regard are discussed in Section 2.4.

While the main focus of this technical guidance is on tools analysts may use to evaluate differences in health outcomes across population groups of concern, the distribution of non-health and environmental outcomes are also important to consider. For instance, some population groups may place a higher cultural value on the environmental quality or ecological condition of particular places. Likewise, some regulatory options may imply uneven changes in access to particular aquatic amenities for recreation across population groups. While the distribution of non-health and environmental outcomes may be difficult to quantify, analysts should strive to qualitatively discuss those outcomes relevant to the particular regulatory action.

1.2 Recommendations to Guide Assessments for Potential EJ Concerns

The technical guidance makes six main recommendations designed to ensure consistency across assessments of potential EJ concerns for regulatory actions. These recommendations are not intended to be prescriptive and do not mandate the use of a specific approach. Rather, they encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time and resource constraints, and analytic challenges will vary across media and with the specific regulatory context.

1. For regulatory actions where impacts or benefits will be quantified, some level of quantitative analysis for EJ is recommended (see Section 5.1).
   - When feasible, analysts should present information on estimated health and environmental risks, exposures, outcomes, benefits and other relevant effects disaggregated by race/ethnicity and income.
   - When such data are not available, it may still be possible to evaluate risk or exposure using other metrics (e.g., prevalence of affected facilities as a function of race/ethnicity or income, evidence of unique or unusual (i.e., atypical) consumption patterns or contact rates).
2. When impacts or benefits will not be quantified or disaggregated by race/ethnicity or income, analysts should present information that is insightful with regard to potential EJ concerns (e.g., basic demographic information, and evidence of differential exposure) (see Section 5.1).
   - Analysts should use their best professional judgement to determine what combination of quantitative and qualitative analysis is possible.
3. Analysts should integrate applicable scoping questions during the planning stages of a risk assessment when one is being conducted for the regulatory action (see Section 4.3.2).

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[12] Draft Chapter 10 of the *Guidelines for Preparing Economic Analyses*, which discusses how to evaluate potential EJ concerns when doing regulatory analysis for economically significant rules, presents these as three questions (U.S. EPA, 2012b).
[13] The term "population groups of concern" is used instead of subpopulations to be inclusive of "population groups that form a relatively fixed portion of the population (e.g., groups based on ethnicity)." See http://yosemite.epa.gov/ochp/ochpweb.nsf/content/lifestage.htm.

4. Analyses should use the same baseline and regulatory option scenarios as other types of regulatory analyses (e.g., benefit-cost and economic impact analyses) conducted in support of the rulemaking (see Section 5.2).[14]

5. Analysts should follow identified best practices when feasible and applicable. Text Box 1.1 outlines current best practices that may be helpful for evaluating potential EJ concerns (see Sections 4.3 and 5.3)

6. Analysts should consider the distribution of costs associated with implementing a regulatory option from an EJ perspective when appropriate and relevant (see Section 5.5.1).[15]

Text Box 1.1: Current Best Practices that May be Helpful for Evaluating Potential EJ Concerns

- Use the latest demographic data available.
- Show changes in potential differences in impacts (i.e., analyze and compare effects in baseline and across policy scenarios).
- Carefully select and justify the choice of comparison group (discussed further in Sections 2 and 5).
- Present summary metrics (e.g. risk ratios and measures of statistical significance) for relevant population groups of concern and the comparison group, not just data on each population group or area.
- Characterize the distribution of risks, exposures, or outcomes across individuals, lifestages, gender, or other relevant categories within each population group when feasible, not just average impacts.
- Disaggregate data to reveal important spatial differences (e.g., demographic information for each facility/place), not just in aggregate, when feasible and appropriate.
- Conduct sensitivity analysis for key assumptions or parameters that may affect findings when feasible.
- Present available evidence on other environmental stressors that may contribute to increased vulnerability or susceptibility for population groups of concern.

[14] Because analyses of potential EJ concerns are often conducted separately from an assessment of benefits and costs (i.e., benefit-cost analysis evaluates efficiency, while analyses of potential EJ concerns evaluate whether impacts are distributed differently), it is important that the same baseline and options be used to ensure an apples-to-apples comparison when the decision maker weighs various policy objectives (e.g., aggregate net benefits and equity).

[15] See the *Economic Guidelines* (U.S. EPA, 2010b) for information on defining costs.

Section 2: Key Analytic Principles and Definitions

The purpose of a regulatory analysis is to "anticipate and evaluate the likely consequences of rules" in a way that informs the public and decision makers (OMB, 2003).[16,17] For this reason, an assessment for EJ is most meaningful and useful to the decision maker when it is consistent with the basic assumptions underlying other parts of the regulatory analysis that may be conducted (for instance, the benefit-cost analysis, economic impact analysis, or risk assessment). This section reviews the key analytic principles and concepts that are central to assessing EJ concerns.

2.1 Key Analytic Principles

The basic principles that guide analysis of potential EJ concerns are the same as those used to guide all aspects of regulatory analysis at the Agency. In general, analyses should:

- Be designed to inform the pending decision;
- Rely on generally accepted procedures for conducting risk assessment and economic analysis;
- Integrate consideration of EJ into existing analytical efforts;
- Use existing frameworks and data from other parts of the regulatory analysis, supplemented as appropriate;
- Be transparent with regard to data sources, assumptions, analytic techniques, and results; and
- Use the best available science and data.

In addition to adhering to these general principles, analyses of potential EJ concerns should also aim to:

- *Identify EJ objectives early in the process:* Decision makers are encouraged to communicate early in the process whether certain aspects of E.O. 12898 or applicable EPA policies or statutes are particularly important when evaluating EJ within the context of the regulatory action.

[16] " Important goals of regulatory analysis are (1) to establish whether federal regulation is necessary and justified to achieve a social goal and (2) to clarify how to design regulations in the most efficient, least burdensome, and most cost-effective manner." (OMB, 2003).

[17] Note that E.O. 12866, *Regulatory Planning and Review* (1993), expects agencies to consider "distributive impacts" and "equity" when choosing among alternative regulatory approaches, unless prohibited by statute. OMB's Circular A-4 also states that "regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects of economic efficiency…Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups" (OMB, 2003). However, Circular A-4's focus is on benefits and costs, while the focus of E.O. 12898 is on human health or environmental effects, which is generally at least one step prior to monetization of benefits and precludes certain other benefit categories covered in the EPA's *Economic Guidelines*.

- *Understand the root causes and contributors to potential EJ concerns early in the process:* Recognizing the underlying causes and contributors that may lead to EJ concerns (see Section 3) is important for properly assessing them and can aid in the design of regulatory options.
- *Identify data, methods and analytical needs early in the process:* Decisions about data and methodological needs and how to meet these needs are made early on in the planning phase of every regulatory analysis. Data and methods availability influences the scope and complexity of an assessment, and may even determine the extent to which potential EJ concerns are considered in the decision-making process. Analysts should evaluate data and methodological needs for an analysis of potential EJ concerns early in the planning process to ensure that such needs are duly considered and reasonably accommodated.
- *Identify the population groups of concern early in the process:* E.O. 12898 identifies relevant population groups of concern. An early priority of analysts should be to define these population groups within the context of a particular regulatory action, so that this definition can inform data collection and analysis, and the development of reliable inferences from the results of the assessment.
- *Identify the comparison group early in the process:* The selection of a comparison group should allow for a credible evaluation of whether disproportionate impacts are borne by minority, low-income, or indigenous populations relative to other demographic groups. Like the population groups of concern, the comparison population for the analysis of potential EJ concerns should be identified early in the process because it can inform decisions related to data collection and analytic approaches (see Sections 2.3 and 5.4.2).
- *Use baseline and regulatory options consistent with other parts of the regulatory analysis:* As stated in Recommendation 4 (Section 1.2), use of a consistent baseline and regulatory option scenarios ensures that analysis of potential EJ concerns remains relevant in the decision making process.

2.2 Population Groups of Concern Highlighted in E.O. 12898

Executive Order 12898 identifies a number of population groups of concern, including: minority, low-income and indigenous populations. It also mentions "populations who principally rely on fish and/or wildlife for subsistence," a group that may overlap with minority, low-income or indigenous populations by virtue of unique exposure pathways. This section provides information for analysts on how to define the population groups of concern specifically mentioned in the Executive Order.[18]

It may be useful in some contexts to analyze these categories in combination – for example, low-income minority populations – or to evaluate these categories based on diversity within the population groups of concern (e.g., lifestages, gender) when some individuals are at greater risk for experiencing adverse effects (i.e., are particularly vulnerable or susceptible). Analysts should rely on the White House Office of Management and Budget (OMB) or other official Federal agencies (e.g., United States Census Bureau) for definitions of these population groups when available. Note that analysis of additional population groups is not a substitute for examining the populations explicitly mentioned in the Executive Order.

2.2.1 Minority and Indigenous Populations

OMB provides minimum standards for "maintaining, collecting, and presenting data on race and ethnicity for all Federal reporting purposes…The standards have been developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies" (OMB, 1997). OMB defines six race and ethnic categories:

[18] This section borrows extensively from Chapter 10 of EPA's *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2012b).

- American Indian or Alaska Native;
- Asian;
- Black or African American;
- Native Hawaiian or Other Pacific Islander;
- White; and
- Hispanic or Latino.

Note that these categories are not all additive; for example, Hispanic or Latino is an ethnic category and, as such, may overlap with several categories based on race. Statistical data collected by the Federal government, such as the Census Bureau, adhere to this classification system.[19]

While OMB does not define the term indigenous, it defines someone who identifies as an American Indian or Alaska Native as a person "having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment" (OMB, 1997).

OMB also does not define what constitutes a minority population. The Council on Environmental Quality's (CEQ) *Environmental Justice: Guidance Under the National Environmental Policy Act* (EJ Guidance for NEPA) provides guidance on how to do so based on the Federal race and ethnicity classifications (CEQ, 1997). It defines the term "minority" as "individual(s) who are members of the following population groups: American Indian or Alaskan Native; Asian or Pacific Islander; Black, not of Hispanic origin; or Hispanic." A population is identified as minority if "either (a) the minority population of the affected area exceeds 50 percent or (b) the minority population percentage of the affected area is meaningfully greater than the minority population percentage in the general population or other appropriate unit of geographic analysis." The term "meaningfully greater" is not defined. CEQ's EJ Guidance for NEPA also notes that a minority population exists "if there is more than one minority group present and the minority percentage, as calculated by aggregating all minority persons, meets one of the above-stated thresholds." Finally, the guidance states that analysts "may consider as a community either a group of individuals living in geographic proximity to one another, or a geographically dispersed/transient set of individuals (such as migrant workers or Native Americans), where either type of group experiences common conditions of environmental exposure or effect."

2.2.2 Low-Income Populations

OMB has designated the Census Bureau's annual poverty measure, produced since 1964, as the official metric for program planning and analysis by all Executive branch Federal agencies in *Statistical Policy Directive No. 14*, though it does not preclude the use of other measures (OMB, 1978). CEQ's EJ Guidance for NEPA also suggests analysts use "annual statistical poverty thresholds from the Bureau of the Census' Current Population Reports, Series P-60 on Income and Poverty" to define low-income populations. As with minority populations, CEQ's EJ Guidance for NEPA allows low-income populations to be defined as a geographically dispersed group of individuals that experience common environmental exposure conditions or effects.

The Census Bureau's annual poverty measure uses a set of income thresholds that vary by family size and composition to determine the households that live in poverty. If a family's total income falls below the

[19] See http://www.whitehouse.gov/omb/fedreg_1997standards/ for the OMB definitions. Beginning with the 2000 Census, the Federal government began to collect more detailed information on race. Respondents could select more than one category. OMB provides guidance on how to aggregate from 63 different race categories to a smaller subset to yield the first five categories listed above and four frequently-reported double race categories (OMB, 2000).

threshold, then that family and every individual in it is defined as being in poverty. This measure of poverty has remained essentially unchanged since its inception.[20] It does not vary geographically though it is updated for inflation using the Consumer Price Index (CPI-U). It also does not take into account capital gains or non-cash benefits (such as public housing, Medicaid, and food stamps) (U.S. Census, 2011a).

The ability of the official poverty measure to adequately capture differences in economic well-being has been the subject of ongoing debate. In particular, the National Research Council (NRC) recommended that the official measure be revised because "it no longer provides an accurate picture of the differences in the extent of economic poverty among population groups or geographic areas of the country, nor an accurate picture of trends over time" (Citro and Michael, 1995). In response, OMB convened an interagency group in 2009 to define a supplemental poverty measure based on the NRC recommendations. A Supplemental Poverty Measure (SPM) was included in the Current Population Reports, Series P-60, for the first time in 2010 (U.S. Census, 2011b). Unlike the official poverty measure, it accounts for "co-resident unrelated children (such as foster children) and any cohabiters and their children," and uses a broader resource measure to account for out-of-pocket medical expenses and in-kind benefits, for example. It also improves on the traditional measure of poverty by adjusting for differences in housing prices by metropolitan statistical area, as well as family size and composition.[21]

Unlike its treatment of poverty, the Census Bureau does not provide an official definition of "low income." An analyst may characterize low-income more broadly than just those that fall below the poverty threshold (e.g., to include families whose income is above the poverty threshold but still below the average household income for the U.S.). Additional socioeconomic characteristics typically collected by U.S. statistical agencies (e.g., Census Bureau), such as educational attainment, baseline health status, and health insurance coverage, may also be useful for characterizing low-income populations. Another possible measure is the percent of people who are chronically poor versus those that experience poverty on a more episodic basis (Iceland, 2003).[22]

Finally, cross-tabulations often are available through the Census Bureau between many of these poverty measures and other socioeconomic characteristics of concern such as race, ethnicity, age, sex, education, and work experience.

2.2.3 Populations that Principally Subsist on Fish and Wildlife

E.O. 12898 also identifies the need to analyze the human health risks of "populations with differential patterns of subsistence consumption of fish and wildlife" when practical and appropriate. This category identifies populations based on particular pathways of exposure, and may overlap with those defined on the basis of income and race/ethnicity.[23]

CEQ's EJ Guidance for NEPA describes the two main components of this definition: differential patterns and subsistence consumption. "Differential patterns" are "differences in rates and/or patterns of subsistence consumption by minority populations, low-income populations, and Indian tribes as compared to

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[20] The U.S. Census Bureau produces single-year estimates of median household income and poverty by state and county, and poverty by school district as part of its *Small Area Income and Poverty Estimates*. It also provides estimates of health insurance coverage by state and county as part of its *Small Area Health Insurance Estimates*. These data are broken down by race at the state level and by income categories at the county level.

[21] The NRC recognizes that income-based measures such as the official or supplemental poverty thresholds are not necessarily the best measure of relative poverty since it does not account for differences in accumulated assets across households. The SPM tries to capture inflows of income and outflows of expenses, which are likely correlated with short-term poverty since many assets are not easily convertible to cash in the short run (Short, 2012).

[22] This type of measure is reported in the U.S. Census Bureau's *Survey of Income and Program Participation*.

[23] The overlap between populations that principally subsist on fish and wildlife and minority or low-income populations is an important consideration in an evaluation of potential EJ concerns in a risk assessment. As part of a risk assessment, analysts are expected to evaluate as appropriate all consumption/contact patterns and rates that are relevant from an EJ perspective, including those associated with populations that subsist on fish and wildlife.

rates and patterns of consumption of the general population." The term "subsistence consumption" is defined as "dependence by a minority population, low-income population, Indian tribe or subgroup of such populations on indigenous fish, vegetation and/or wildlife, as the principal portion of their diet."

While Federal statistical agencies do not specifically track individuals and population groups who subsist on fish or wildlife, EPA has conducted consumption surveys in specific geographic areas to inform policy formulation. If fish and wildlife consumption is a substantial concern for a particular regulatory action, analysts should refer to existing EPA guidance on fish and wildlife consumption surveys when collecting these data (U.S. EPA, 1998b). Analysts may also investigate whether these types of survey data are available from other Federal agencies, or state or local governments. However, they should verify that any survey data used in an EJ analysis is in accordance with the appropriate parameters and methodology (U.S. EPA, 1998b).

2.3 Selecting a Comparison Group

To assess whether a potential EJ concern exists, an analyst should compare impacts experienced by the population groups of concern to those of a comparison group (sometimes referred to as a reference group). From the perspective of E.O. 12898 and EPA EJ policies, a between-group comparison (i.e., comparison to population groups with different socioeconomic characteristics) is generally the most relevant to policy assessment. It is unlikely, however, that the same comparison group will be appropriate in every instance. For example, it may make sense in some contexts to define the comparison group at a sub-national level to reflect differences in socioeconomic composition across geographic regions (see Text Box 2.1 for a few examples from recent rulemakings).

Text Box 2.1: Choosing a Comparison Group – Recent Examples

There are a variety of ways to define a comparison group. For the final Mercury and Air Toxics Standards (MATS) Rule (U.S. EPA, 2011c), analysts examined mortality risk associated with fine particulate matter by race, income, and poverty level for people living in high risk counties (i.e., in the top 5 percent). The comparison group was defined as people living in counties not facing a high mortality risk.

For the proposed (but now withdrawn) Reporting Rule for Concentrated Animal Feeding Operations (U.S. EPA, 2011d), analysts began by comparing the socioeconomic characteristics of census tracts with concentrated animal feeding operations (CAFOs) to an average U.S. census tract without a CAFO. However, "data on minority and low-income populations were heavily dominated by populations in urban census tracts." Because CAFOs are located in rural areas of the country, EPA decided it was appropriate to exclude urban census tracts and instead compared the socioeconomic characteristics of each census tract with a CAFO to the characteristics of the average rural census tract.

Sources: Regulatory Impact Analysis for the Final Rule for the Mercury and Air Toxics Standard (U.S. EPA, 2011c), and Analysis to Address Environmental Justice for National Pollution Discharge Elimination System (NPDES) Concentrated Animal Feeding Operation (CAFO) Rule (U.S. EPA, 2011d).

The comparison group definition can have important implications for evaluating the distribution of risk, exposure, and health outcomes across population groups of concern in the baseline and under various policy options. In selecting a comparison group, an analyst should evaluate how the use of different comparison groups affects the way information is conveyed to the decision maker.[24] Analysts should also

[24] For example, a comparison group of all minorities in the United States, while informative about the burden of risk among minorities, will not directly provide information about whether this burden is *higher* among minorities relative to non-minorities.

carefully document the criteria used to choose the comparison group for a particular regulatory action. When appropriate and practicable, an analyst may wish to conduct sensitivity analysis using alternate definitions of the comparison group (see Section 5.4.2 for further discussion).

2.4 Disproportionate Impacts Under E.O. 12898

E.O. 12898 calls for each Federal agency to "make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects…of its policies, programs, and activities." In the context of regulatory analysis two steps are important in this regard: (1) identifying differences in impacts, and (2) determining whether there are potentially disproportionate impacts that may merit Agency action (see Text Box 2.2).

The term "disproportionate" is not specifically defined in E.O. 12898, and it is not defined in EJ guidance developed to implement the Executive Order. However, CEQ's EJ Guidance for NEPA discusses several factors that the decision maker may consider when determining whether human health effects are disproportionately high and adverse (CEQ, 1997):[25]

- "Whether the health effects, which may be measured in risks and rates, are significant (as employed by NEPA), or above generally accepted norms;"
- "Whether the risk or rate of hazard exposure by a minority population, low-income population, or Indian tribe to an environmental hazard is significant (as employed by NEPA) and appreciably exceeds or is likely to appreciably exceed the risk or rate to the general population or other appropriate comparison group;" and
- "Whether health effects occur in a minority population, low-income population, or Indian tribe affected by cumulative or multiple adverse exposures from environmental hazards."

Text Box 2.2: Distinguishing between Difference in and Disproportionate Impacts

For this guidance document, the terms "differential risks" or "differences in impacts" refer to a distinct concept from "disproportionate" impacts or risks.

Specifically, the terms difference or differential are used to indicate an analytically measurable distinction in impacts or risks across population groups. The term disproportionate is used to refer to differences in impacts or risks that are substantial enough that they may merit Agency action.

These factors may also be useful to consider in an EPA rulemaking context (though what constitutes "significant" may differ from how it is defined under NEPA). An analyst should provide the decision maker with the best available information (both quantitative and qualitative) for the baseline and policy options to aid in evaluating whether there is a disproportionate impact that may merit Agency action. What data are available and relevant will vary with the specific circumstances of the regulatory action; analysts should be transparent about data limitations, time and resource constraints, and analytic challenges.[26]

Examples of the kinds of information that may be useful to provide to decision makers include:

[25] The EJ guidance for NEPA (CEQ, 1997) also discusses similar factors to consider when evaluating the potential for disproportionately high and adverse environmental effects.
[26] In addition, the decision maker also may need other kinds of information to aid the selection of a regulatory option, including:
- The extent to which available options reduce exposure or risk differences,
- How the regulatory options produce benefits (usually in the form of reduced health impacts) for each of the relevant population groups, and
- When relevant, how the economic costs of these options are borne by each relevant population.

- The severity and nature (i.e., biological significance) of the health consequences for which differences between population groups have been estimated.
- The magnitude of the estimated differences in impacts between population groups of concern and the appropriately defined comparison group (e.g., a measure of statistical significance when relevant and appropriate).
- Mean or median exposures or risks to relevant population groups (or acceptable surrogates when such data are not available).
- Distributions of exposure or risk to relevant population groups – while average exposure or risk estimates are helpful, it may be the case that differences between population groups only occur in the tail of the distribution.
- Characterization of the uncertainty surrounding various aspects of the analysis.
- A discussion of factors that may make population groups of concern more vulnerable to exposure (e.g., unique pathways, cumulative exposure, behavioral or biological factors).

The relative weight of these or additional criteria will likely vary with the specific attributes of the rulemaking under consideration. It is important to note that the role of an analyst is to assess and present differences in anticipated impacts across population groups of concern to the decision maker and the public. The determination of whether there is a disproportionate impact that may merit Agency action is ultimately a policy judgment informed by analysis, and is the responsibility of the decision maker.[27] See Text Box 2.3 for examples of the way in which differences in impacts are characterized in a rulemaking to allow the decision maker discretion regarding a finding of disproportionate impacts.

Additionally, as EPA's *Interim ADP Process Guide* notes, "the Agency's statutory and regulatory authorities provide a broader basis for protecting human health and the environment and do not require a demonstration of disproportionate impacts in order to protect the health or environment of any population, including minority, low-income and indigenous populations. Thus, consistent with its mission, the Agency may address adverse impacts in the context of developing an action without the need for showing that the impacts are disproportionate" (U.S. EPA, 2010a).

[27] This is not meant to prevent analysts from using their expert judgment to determine whether enough of a risk exists to merit moving from one stage of the analysis to the next.

Text Box 2.3: Characterizing Differences in Impacts for a Rule or Regulation

Phrases that have been used to characterize differences in impacts (e.g., in the baseline or as a result of a rule) in recent rulemakings include "the potential for disproportionate impacts," "overrepresentation of minority, low-income or indigenous populations near sources," and "notably higher."

For instance, the proposed rulemaking for the Definition of Solid Waste (U.S. EPA, 2011e) states that, "In general, some communities will have a higher percentage [of minority and/or low-income members] than the comparison population and some will have a lower percentage. As long as these differences have a regular distribution, they would not indicate disproportionate impact. However, if the number of communities with a higher percentage of minority and/or low-income population is greater than that of the comparison populations, then there is a potential for disproportionate impact. The higher the average difference between the potentially affected communities and the comparison group, the greater the potential disproportionality."

The proposed National Emission Standards for Hazardous Air Pollutants (NESHAP) for Polyvinyl Chloride (U.S. EPA, 2011f) describes its analysis as follows: "An analysis of demographic data shows that the average percentage of minorities, percentages of the population below the poverty level, and the percentages of the population 17 years old and younger, in close proximity to the sources, are similar to the national averages, with percentage differences of 3, 1.8, and 1.7, respectively, at the 3-mile radius of concern. These differences in the absolute number of percentage points from the national average indicate a 9.4-percent, 14.4-percent, and 6.6-percent over-representation of minority populations, populations below the poverty level, and the percentages of the population 17 years old and younger, respectively."

Another example comes from the Advanced Notice of Proposed Rulemaking on Lead Emissions from Piston-Engine Aircraft Using Leaded Aviation Gasoline (U.S. EPA, 2010c): "Demographic factors that can affect risk of lead-related effects in children include residential location, poverty, and race. As noted in previous EPA actions on lead, situations of elevated exposure, such as residing near sources of ambient lead, as well as socioeconomic factors, such as reduced access to health care or low socioeconomic status can also contribute to increased blood lead levels and increased risk of associated health effects from air-related lead. Additionally, as described in the National Ambient Air Quality Standard (NAAQS) for Lead, children in poverty and black, non-Hispanic children have notably higher blood lead levels than do economically well-off children and white children, in general."

Sources: Environmental Justice Analysis of the Definition of Solid Waste Rule (U.S. EPA, 2011e); National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production (U.S. EPA, 2011f), and Advance Notice of Proposed Rulemaking on Lead Emissions From Piston-Engine Aircraft Using Leaded Aviation Gasoline; Proposed Rule (U.S. EPA, 2010c).

2.5 Meaningful Involvement

The term "meaningful involvement" means that "1) potentially affected community members have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; 2) the public's contribution can influence the regulatory agency's decision; 3) the concerns of all participants involved will be considered in the decision-making process; and 4) the decision makers seek out and facilitate the involvement of those potentially affected" (U.S. EPA, 2010a; U.S. EPA, 2012a).

Ensuring meaningful involvement in the rulemaking process as a whole is not the focus of this guidance document, but intersects with analytic considerations in several key respects. First, if the analysis of potential EJ concerns is explained in plain language, then key assumptions, methods, and results will be more transparent and easier to understand. This can further a clear understanding of the potential EJ implications of a regulatory action and allow for more substantive engagement by community members and other interested parties during public comment periods. Second, it may be possible for analysts to request information early on in the process (for instance, by asking for public comment in the proposal) regarding unique exposure pathways or end points of concern, as well as data sources that could improve the analysis of potential EJ concerns. Text Box 2.4 highlights several examples of how activities taken to ensure meaningful involvement have been described in the analysis of EJ issues for recent rulemakings.

See EPA's Public Involvement Policy (U.S.EPA 2013b) and EPA's *ADP Interim Process Guide* (U.S. EPA, 2010a) for more examples and guidance on how to meaningfully engage environmental justice stakeholders in the rulemaking process. Section 4.3.2.5 also discusses meaningful involvement in the context of risk communication.

Text Box 2.4: Meaningful Involvement

As part of the proposed rulemaking for National Emission Standards for Hazardous Waste Pollutants (NESHAP) in the chromium electroplating industry (U.S. EPA, 2011f), EPA asked for public comment on the analysis of EJ issues:

"The EPA offers the demographic analyses in this rulemaking as examples of how such analyses might be developed to inform such consideration and invites public comment on the approaches used and the interpretations made from the results, with the hope that this will support the refinement and improve utility of such analyses for future rulemakings."

The regulatory impact analysis for the Final Mercury and Air Toxics Standards (MATS) Rule (U.S. EPA, 2011c) also describes activities taken to ensure meaningful involvement:

"The EPA defines 'environmental justice' to include meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. To promote meaningful involvement, the EPA publicized the rulemaking via newsletters, EJ listserves, and the internet, including the Office of Policy's Rulemaking Gateway Web site (http://yosemite.epa.gov/opei/RuleGate.nsf/). During the comment period, the EPA discussed the proposed rule via a conference call with communities, conducted a community-oriented webinar on the proposed rule, and posted the webinar presentation on-line. The EPA also held three public hearings to receive additional input on the proposal."

"Once this rule is finalized, affected electric-generating utilities (EGUs) will need to update their Title V operating permits to reflect their new emission limits, any other new applicable requirements, and the associated monitoring and recordkeeping from this rule. The Title V permitting process provides that when most permits are reopened (for example, to incorporate new applicable requirements) or renewed, there must be opportunity for public review and comments. In addition, after the public review process, the EPA has an opportunity to review the proposed permit and object to its issuance if it does not meet CAA [Clean Air Act] requirements."

Sources: National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production (U.S. EPA 2011f, and Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards (U.S. EPA, 2011c).

Section 3: Contributors and Drivers of Potential Environmental Justice Concerns

The purpose of this section is to briefly highlight the key reasons why health risks may be unevenly distributed across population groups. In addition, this section provides an overview of select contributors to and drivers of the uneven distribution of health risks that often occur among communities with potential environmental justice concerns.

3.1 Social Context and Risk

Minority, low-income and indigenous populations experience greater exposure and disease burdens that can increase their risk of adverse health effects from environmental stressors.[28] For example, many studies have established that sources of environmental hazards tend to be located and concentrated in areas that are dominated by minority, low-income or indigenous populations (Bullard et al., 2007; Faber and Krieg, 2002; Faber and Krieg, 2005; GAO, 1983; Maantay, 2001; United Church of Christ, 1987; and Wilson et al., 2002). In addition, studies show that these population groups experience higher exposures to environmental hazards associated with where they live, work and play (Apelberg et al., 2005; Marshall, 2008; Morello-Frosch and Jesdale, 2006; Morello-Frosch et al., 2001; Sexton et al., 2007; Thompson et al., 2003; and Woodruff et al., 2003). These population groups also tend to be most burdened with adverse health conditions such as cardiovascular disease, preterm birth, low birth weight, and asthma that either have environmental triggers or affect similar target physiological systems as environmental pollution (Akinbami, 2006; Akinbami et al., 2012; Glover et al., 2005; Keenan and Rosendorf, 2011; Lara et al., 2006; Martin, 2011; and Martin et al., 2010). Pre-existing disease and adverse health conditions likely increase susceptibility in response to exposure to environmental hazards (Schwartz et al., 2011a).[29]

Both high exposures to environmental stressors and increased individual susceptibility can drive higher responses to environmental hazards (Schwartz et al. 2011). Therefore, the combination of higher exposures and pre-existing disease among minority, low-income or indigenous population groups may lead to a predisposition to higher health risks. As a result, in an assessment of potential EJ concerns it is important to assess both the potential for higher exposures to a given environmental stressor, and the potential for higher susceptibility in response to exposure for population groups of concern. Potential contributors to disproportionate health risk and adverse health impacts can thus be identified based on how they may increase exposure or increase susceptibility in response to exposure.

Differences in exposure to stressors, and resulting adverse health outcomes among certain population groups (e.g., low income, minority) underscores the importance of social context. Social context refers broadly to all social and political mechanisms that generate, configure and maintain social hierarchies. These mechanisms can include the labor market, the educational system, political institutions and cultural and societal values (Solar and Irwin, 2010). Social context has been recognized as a critical root cause of societal stratification into different social positions (e.g., race/ethnicity, income, occupation). Social

[28] The term "racial/ethnic minority" is often used in the literature upon which this section is based to define what is referred to in Executive Order 12898 as "minority populations."

[29] An individual who is susceptible is one who is more responsive to exposure (Schwartz et al., 2011a).

stratification in turn results in differential exposure and vulnerability to stressors, and differential consequences (Solar and Irwin 2010). Social context and social stratification together can shape determinants of health such as:

- material circumstances (e.g., neighborhood and housing conditions/quality, green space, walkability, access to fresh foods, and the work environment);
- behavioral and biological factors (e.g., nutrition, smoking, genetic factors);
- the health care system (e.g., access to and interaction with it); and
- psychosocial circumstances (e.g., stressful living conditions and relationships, availability of coping and support mechanisms) (Solar and Irwin, 2003).

The literature has proposed a number of conceptual frameworks to explicitly integrate social context drivers and contributors to disproportionate health risks/impacts into the exposure-disease paradigm, and highlight potential pathways through which these drivers and contributors may interact with environmental exposures to yield health differences (Gee and Payne-Sturges, 2004; Morello-Frosch and Jesdale, 2006). Though the proposed pathways in these frameworks have not all been tested, they are insightful and offer integrated approaches for considering pathways through which multiple factors may increase exposure or susceptibility.

3.2 Contributors to Higher Exposure

The steps for performing an exposure assessment are to: (1) identify the source of the environmental stressor and the media that transports it; (2) determine the contaminant concentration; (3) determine the exposure scenarios, and pathways and routes of exposure; (4) determine the exposure factors related to human behaviors that define time, frequency, and duration of exposure; and (5) identify the exposed population. Exposure factors are related to human behavior and characteristics, and determine an individual's exposure to an agent (U.S. EPA, 2011g).

The terms "exposure" and "dose" are very closely related and are therefore often confused (Zartarian et al., 2007). Dose is the amount of a chemical substance or agent that enters a target (e.g., an organ of the body) in a specified period of time after crossing a contact boundary (e.g., the skin or lining of the intestine). An exposure does not necessarily lead to a dose, but there cannot be a dose without a corresponding exposure (U.S. EPA, 2011g, and Zartarian et al., 2007).

Contributors to higher exposure status among minority, low-income or indigenous populations include:

- Proximity to emission sources;
- Unique exposure pathways;
- Physical infrastructure (e.g., housing conditions, water infrastructure);
- Exposure to multiple stressors/cumulative exposures; and
- Community capacity to participate in decision making (Nweke et al., 2011; U.S. EPA, 2007).

3.2.1 Proximity to Emission Sources

Proximity to emission sources is the most studied indicator of high exposure in the environmental justice literature. As noted earlier in this section, several studies have found that the location of pollution emission sources correlates positively with the location's composition of minority, low-income or indigenous populations. For instance, studies have shown that disproportionate numbers of low-income and/or minority populations are located in close proximity to emission sources like high traffic roadways (Apelberg et al., 2005; Guinier et al., 2003). Additionally, residents in these areas may experience increased concentrations of contaminants due to damaged structural and building conditions and inadequate ventilation systems. Residential proximity does not, however, imply that exposures and health risks are occurring but only that the potential for exposure is increased (NRC, 1991).

Proximity to an emission source is not a complete surrogate exposure measure because it does not incorporate key exposure determinants such as time-activity patterns. Nonetheless, several studies have found positive associations between residents living near a pollution emissions source such as a hazardous waste site, high traffic roadway, or industrial site and adverse health outcomes (Brender et al., 2011).

3.2.2 Unique Exposure Pathways

Unique exposure pathways are non-traditional pathways through which exposure to a given stressor occurs. Exploring unique exposure pathways means identifying behaviors that are unique to a specific group of individuals who have shared ideas, values, learned traditions and life experiences that are embedded in socially grounded processes. The social constructs of culture and ethnicity may to varying extents capture shared learned traditions and/or life experiences, and therefore provide a window for viewing how exposure pathways may vary across social groups (NRC, 2002). Specific examples of exposure pathways for environmental stressors that relate to cultural context or ethnicity are documented in the academic literature (Anderson and Rice, 1993; Ernst, 2002a, b; Ernst and Thompson Coon, 2001; McKelvey et al., 2011; Peterson et al., 1994). In addition, a detailed review of unique exposure pathways and a conceptual model to aid the identification of such pathways are discussed in detail elsewhere (Burger and Gochfeld, 2011; Gochfeld and Burger, 2011). Examples of shared behavior that may yield atypical pathways of exposure to environmental stressors and potentially higher exposures include subsistence fishing, consumption of ayurvedic (i.e., alternative) medicines among Asians, and sweat baths among Native Americans (Gochfeld and Burger, 2011).[30]

Unique exposure pathways can also be identified based on other factors, such as behavioral and physiological stages of growth and development which may occur during a particular lifestage (U.S. EPA, 2011g). For example, individuals in all populations alter their eating patterns as they grow older, (e.g., infants' diets consists primarily of milk products). Breastfeeding, object-to-mouth behavior, and crawling are examples of behaviors that are associated with infants and toddlers (U.S. EPA, 2013a). Such behavior increases exposure to environmental stressors that may exist in higher concentrations in breast milk, in toys, and in contaminants that accumulate on floors or carpets, for example.

3.2.3 Physical Infrastructure

Physical infrastructure is an important source of environmental stressors. Housing, in particular, has been well studied as a potential contributor to environmental exposure. Housing in the United States built before 1978 may contain lead-based paint, exposure to which can impair cognitive function in children and lead to lower IQ. In addition, substandard housing conditions such as water leaks, poor ventilation, dirty carpets and pest infestation can lead to an increase in mold, dust mites and other allergens associated with poor health (Commission to Build a Healthier America, 2008; U.S. Housing and Urban Development, 2001; Thorne et al., 2009). A higher proportion of minorities live in substandard housing (Jacobs, 2011).

[30] Ayurvedic medicines are taken as part of a Hindu traditional medicine practice of the same name.

Therefore, examining how housing may increase exposure to a given stressor is helpful for uncovering whether particular minority, low-income or indigenous populations may experience higher exposures. Other types of infrastructure such as transportation and drinking water infrastructure may also be associated with increased exposure to environmental stressors. For example, in Southern California, minority and low-income neighborhoods have twice the traffic density of the rest of region, meaning that their potential for greater exposure to hazards from traffic is higher than in other neighborhoods (Houston et al., 2004). Differential exposure related to drinking water infrastructure is less examined. However, there is some evidence of the potential for differential exposure burdens for some stressors based on access to piped water and shared water systems and residence in older housing, which may have lead pipes (VanDerslice, 2011). When to examine exposure through the lens of physical infrastructure will depend on the stressors.

3.2.4 Exposure to Multiple Stressors

Exposures to multiple stressors from one or more sources or pathways over time can result in one or multiple effects (U.S. EPA, 2003a). Exposure to a specific stressor from a given source when viewed in isolation can inaccurately characterize the potential for health risks if the populations for which risk is being estimated are also exposed to a stressor from multiple sources. For example, each source might emit low levels of a stressor, but when considered across all sources to which a population is exposed emissions may pose a significant health risk. Emission sources for environmental pollution have been found to be concentrated in locations dominated by minority, low-income or indigenous populations (Bullard et al., 2007; United Church of Christ, 1987). This is further complicated when non-chemical stressors are present, such as crime, which may exacerbate the effects of chemical exposures (e.g., changes in immunological response due to increased presence of stress hormones (Gee and Payne-Sturges, 2004)).

3.2.5 Community Capacity to Participate in Decision Making

Community capacity is a multidimensional concept that includes factors such as leadership, participation, skills, resources, community power, and social and organizational networks (Freudenberg et al., 2011). ICommunities with a relatively high proportion of minority, low-income or indigenous populations may have lower community capacity, and this may contribute to EJ concerns. The capacity of communities to participate in the decision making process is a crucial determinant of the success of civic engagements in terms of preventing high burdens of emitting sources and exposure to environmental stressors. Political mechanisms, for instance, can influence the potential for exposure to environmental stressors at the community level, given the role of such mechanisms in facility siting and permitting. Political mechanisms give rise to opportunities for civic engagement such as zoning meetings, which provide communities with opportunities to participate in decisions pertaining to the quality of their environment. When communities are unable to participate effectively in decision making, they may be more likely to be the recipients of negative environmental consequences, including emission sources.

Though meaningful involvement is related to the community's capacity to participate in the decision making process, these topics are not discussed in depth in this guidance document. Some additional information about meaningful involvement can be found in Section 2.5, Section 4.3.2.5, and Text Box 2.4 (see also U.S. EPA, 2010a).

3.3 Contributors to Higher Susceptibility in Response to Exposure

An individual's susceptibility to an environmental stressor is an important determinant of the occurrence of and severity of an adverse effect. Some factors that may influence susceptibility include genetics, diet, nutritional status, pre-existing disease, psychological stress, co-exposure to similarly acting toxics, and cumulative burden of disease resulting from exposure to all stressors throughout the course of life (Schwartz et al., 2011). Also known as risk or effect-modifiers, these factors influence the outcome of exposure through biological interactions at the individual level. Another noteworthy risk-modifier is socioeconomic status, which in and of itself does not elicit a biological interaction. Socioeconomic status has a complex and robust association with many health states (Schwartz et al., 2011b), and may operate by influencing factors such as diet, nutrition, and access to health care, hence health status. Several examples of how these risk modifiers interact with environmental exposures to increase risk are discussed in papers by Schwartz et al. (2011a, b).

Some individuals within minority, low-income or indigenous populations may also experience higher susceptibility given exposure to stressors compared to other individuals in these population groups. This greater susceptibility often reflects age and the stages of physiological and behavioral growth and development, referred to as lifestages (U.S. EPA, 2011g). Highly susceptible individuals can include children, the elderly, pregnant women and/or women of childbearing age, as well as workers in certain occupations. To determine if an individual may experience higher susceptibility, one should consider both the lifestage in question and the target health endpoint. For example, unborn babies, infants and children under the age of six are more likely to experience adverse neurological health effects if exposed to certain levels of lead (U.S. EPA, 2013a). As previously stated, these individuals may also have unique exposure pathways (e.g., breast-fed infants) or may be exposed to multiple exposure sources (e.g., workers that are both exposed occupationally and also reside in neighborhoods with high ambient concentrations of air pollution) that when combined with higher susceptibility can lead to increased risk for adverse health effects. Text Box 3.1 gives an example of how the concepts of susceptibility and vulnerability can be used to identify population groups of concern. Further discussions of considering susceptibility and exposure factors in risk assessments for EJ analyses can be found in Section 4.3 and Appendix B.

Text Box 3.1: Identifying Population Groups Based on Varying Definitions of Susceptibility and Vulnerability

The concepts of susceptibility and vulnerability can be used to identify population groups consistent with dose-response functions found in the literature. Fann et al. (2011) note, "to the extent that certain attributes contributing to either susceptibility or vulnerability can be detected among the population, then a profile of susceptible and vulnerable individuals can be constructed and the geographic distribution of these populations determined." These profiles combine available data on baseline health and demographic information to identify susceptible population groups and then use various combinations of demographic, education, poverty, and air quality data to describe them.

Section 4: Considering Environmental Justice when Planning a Human Health Risk Assessment

4.1 Introduction

The purpose of this section is to provide guidance to Agency analysts on integrating the consideration of potential EJ concerns into the planning phase of a human health risk assessment (HHRA) conducted to support a regulatory action. Senior EPA managers and decision makers may also use this section to help establish expectations for information that analysts should provide about potential EJ concerns, and to ensure that appropriate provisions are made to evaluate potential EJ concerns in the development of regulatory actions.

This guidance recommends that, to the extent possible, evaluation of potential EJ concerns be integrated into an HHRA rather than conducted as an add-on or separate analysis of potentially disproportionate risks across population groups of concern. This integration ensures that EPA can more effectively consider differential health risks for minority, low-income or indigenous populations that are associated with differences in exposure, vulnerability and susceptibility to risk. This recommendation is also consistent with EPA's *Draft Framework for Human Health Risk Assessment to Inform Decision Making* (U.S. EPA, 2012c), which identifies EJ as one of several overarching considerations for which "early consideration and discussion … can enhance the utility of the risk assessment."[31]

An analyst planning an HHRA in support of a regulatory action should seek information early in the process relevant to the five analytic objectives outlined in Section 1.1 (and repeated here), to the extent feasible.

To ascertain the extent to which a potential EJ concern is associated with the affected environmental stressors prior to the rulemaking, the analyst should, when feasible:

1. Assess exposures, relevant health and environmental outcomes, and other relevant effects by population group in the baseline; and
2. Assess differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups in the baseline.

For each regulatory option under consideration, to inform the extent to which a potential EJ concern is created or mitigated for the affected stressors, the analyst should, when feasible:

3. Assess exposures, relevant health and environmental outcomes, and other relevant effects by population group for each option;
4. Assess differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups for each option; and

[31] EPA's *Draft Framework for Human Health Risk Assessment to Inform Decision Making* has not yet been finalized.

5. Assess how estimated differences in these exposures, relevant health and environmental outcomes , and other relevant effects across population groups increase or decrease as a result of each option compared to the baseline.

These objectives help an analyst evaluate whether a potential EJ concern already exists and whether, for each of the regulatory options under consideration, a potential EJ concern is likely to be created or mitigated by the affected stressors. The role of an analyst is to plan and conduct an HHRA that presents results – and the appropriate context for those results – in a transparent manner so that the decision maker can incorporate consideration of differential risks across population groups into risk management decisions (see Section 2.2.4).

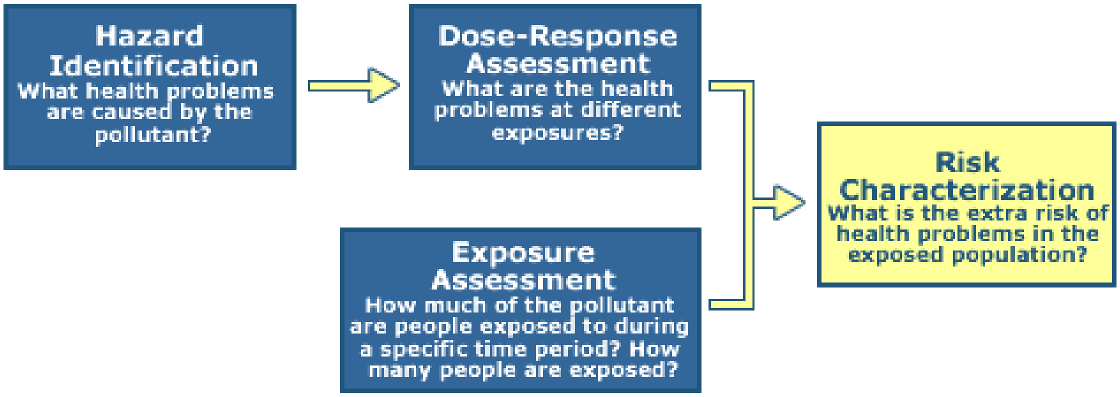
This technical guidance focuses on the planning phase of an HHRA, but is designed to allow analysts to incorporate new information on risk assessment as it becomes available through EPA research efforts. EPA's Risk Assessment Forum (RAF) is currently developing guidance on key topics such as cumulative risk assessment, dose-response assessment, and exposure assessment that will expand the tools and approaches available for analyses of potential EJ concerns. EPA is also involved in ongoing research activities designed to advance risk assessment; these efforts are specifically focused on better understanding the impact of susceptibility and variability on dose-response and how various risk factors beyond chemical exposures (e.g., poor nutrition, stress, access to health care, lower socioeconomic status) may be utilized in HHRA to improve the scientific basis for estimating risks at the community level. Once these guidance documents are completed, this technical guidance will be updated to integrate these analytical frameworks.

The remainder of this section is organized into two parts. Section 4.2 provides an overview of key concepts. Section 4.3 reviews the specific processes involved in considering EJ when planning an HHRA. Additional information on this topic can be found in Appendix B, which provides examples of ways to incorporate potential EJ concerns into the planning stages of exposure and dose-response assessments.

4.2 Overview of Key Concepts

Figure 4.1 depicts EPA's analytic risk assessment process. A careful planning phase informs each of the first three steps (hazard identification, dose-response assessment and exposure assessment). The final step in the process, risk characterization, provides the basis for communicating the results to decision makers to inform policy. Using the same basic analytic process, an HHRA can be used to characterize the nature, probability and magnitude of current or future risks of adverse human health effects related to exposure to environmental stressors (e.g., chemical, physical or biological agents; contaminants; or pollutants). An HHRA can include both quantitative and qualitative expressions of risk (NRC, 1983; U.S. EPA, 2011h).

Figure 4.1: The Four Step Risk Assessment Process



Source: http://www.epa.gov/risk_assessment/health-risk.htm

A traditional risk assessment estimates risks associated with exposure to stressors using a “bottom-up” approach. This approach employs a source-to-effects paradigm, and typically begins with exposure information (Figure 4.2). This approach is often used to assess the risks associated with exposure to one stressor at a time. However, addressing EJ is particularly challenging when using a bottom-up approach because this approach does not capture joint effects of a population group’s exposure to multiple stressors. While not the focus of this technical guidance, Text Box 4.1 discusses a multiple stressor or cumulative risk assessment approach.[32]

Textbox 4.1: Cumulative Risk Assessment

Multi-stressor or cumulative risk assessment (CRA) is important for characterizing how risks may disproportionately affect one group relative to another. EPA defines CRA as the evaluation of the combined risks from aggregate exposure to multiple agents or stressors (both chemical and non-chemical) (U.S. EPA, 2003a). Though current applications of CRA focus largely on chemical mixtures and/or single chemicals from multiple sources, several key CRA concepts may be more broadly applicable in evaluating the range of both chemical and non-chemical stressors relevant to EJ concerns.

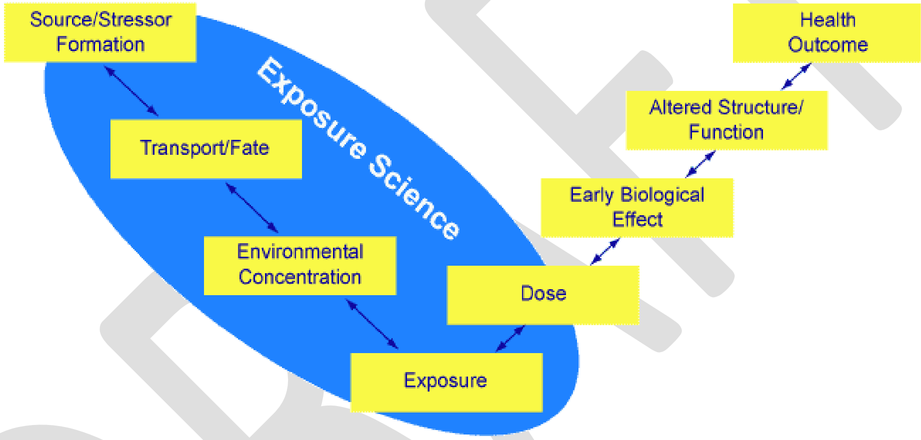
A “top-down” approach using epidemiological data to focus first on health outcomes may better enable analysts to examine the potential impacts of such exposures. While epidemiology studies may not isolate individual effects of numerous co-occurring stressors, an analyst can use these studies, when available, to characterize the cumulative impacts of multiple stressors (Levy, 2008). The use of stratification in epidemiology to identify effect modification is an important illustration of this concept; it can provide data on the risk of an adverse outcome from exposure to a regulated stressor, given co-exposure to another stressor that may be of concern when evaluating potential EJ concerns.

[32] While this broader definition of cumulative risk considers multiple agents or stressors (both chemical and non-chemical), it is important to acknowledge that the Food Quality Protection Act also requires EPA to evaluate aggregate risks of one chemical from multiple sources and/or cumulative exposures to multiple chemicals with similar mechanisms of toxicity (U.S. EPA, 2002a).

To ensure that an HHRA sufficiently identifies and characterizes differential and potentially disproportionate risks, an analyst should:

1. Identify those types of individuals or population groups likely to experience higher risks relative to the average or comparable individuals in the general population;
2. Clearly state the reasons why an identified population group (or lifestage within a population group) may potentially experience higher risk than the average person;
3. Estimate and characterize the potential for differences in risk for at-risk groups; and
4. Present the results to decision makers in a complete and transparent manner.

Figure 4.2: The Source to Effects Paradigm



Source: http://www.epa.gov/heasd/basic.html

4.3 Considering EJ when Planning a Human Health Risk Assessment

To implement E.O. 12898 and EPA's EJ policies, it is important that HHRAs conducted in support of regulatory actions explicitly consider health risks that may disproportionately accrue within minority, low-income or indigenous populations since these demographic attributes may reflect underlying vulnerability and susceptibility to environmental stressors. Also, the burden of health problems and potentially disproportionate environmental exposures associated with race/ethnicity and income may overlap with other susceptibility factors such as lifestage, genetic predisposition, or pre-existing health conditions (see Section 3 for further discussion).[33]

[33] For example, the burden of environmental exposures and resulting health problems is often borne disproportionately by children from low-income communities and minority communities (Israel et al., 2005).

The risk assessment planning process (also referred to as the "planning and scoping" process or phase) encompasses three key priorities that occur in an iterative process. The "fit for purpose" principle governs the development of an HHRA methodology. Central to the planning phase is the "planning and scoping" process itself; this provides a structure to the analysis and ensures that data collection and the approach are appropriate ("fit") for the intended purpose of the risk assessment, considering the context and use of the final results (NRC 2009).[34] Finally, the "problem formulation" step builds on planning and scoping and focuses on the specific hypotheses and technical approach of the HHRA. The effective interaction of these three priorities is essential to producing a sound risk assessment that serves its intended purpose (U.S. EPA, 2012c). As discussed below, the consideration of EJ in each part of the risk assessment planning process is important to ensuring an effective assessment of potential EJ concerns.

4.3.1 Fit for Purpose

An overarching principle guiding the planning process is ensuring that the risk assessment results will be fit for the purpose of informing a specific policy decision, for example addressing local environmental health concerns. Consistent with E.O. 12898 and EPA's EJ policies, one part of the "fit for purpose" planning discussion should be ensuring that the analysis will provide useful information about how the policy options under consideration might affect distribution of risks across population groups of concern.

Addressing the "fit for purpose" question early and revisiting it throughout the planning and scoping process and the HHRA itself helps ensure that the assessment adequately addresses community concerns and provides data to decision makers regarding the distribution of risk across population groups. The specific risk assessment methods used to consider EJ will vary with the environmental problem being addressed (e.g., a local or national environmental issue). The scope of the HHRA also will be affected by statutory mandates and any limitations in data, methods, time and resources.

4.3.2 Planning and Scoping

The following discussion outlines important elements of this process, and identifies the issues relevant to integrating EJ into each of them. Consistent with EPA guidance, the elements of planning and scoping include the following:

- Identify the Context, Purpose, and Scope of the Risk Assessment (Section 4.3.2.1)
- Define Responsibilities for Assessing and Communicating Risks and Allocate Resources (Section 4.3.2.2)
- Identify Data, Models, Tools and Other Technical Resources (Section 4.3.2.3)
- Conduct a Scientific Peer Review (Section 4.3.2.4)
- Ensure Meaningful Public, Stakeholder and Community Involvement When Possible (Section 4.3.2.5)

Each step of planning and scoping for an HHRA is discussed briefly here. Risk assessors and other analysts should consult EPA guidance documents on risk assessment for more information (see Appendix A, and U.S. EPA, 2012c; U.S. EPA, 1997).

[34] There are other assessment approaches for determining differential risks across population groups apart from a HHRA, such as a health impact assessment (HIA). HIA is an approach for evaluating the potential public health consequences of a project, plan, or policy. It can encompass a traditional HHRA approach, but also typically considers a broad spectrum of health determinants such as the quality of housing, access to services and social cohesion, and exposure to contaminants (NRC, 2011).

4.3.2.1 Identify Context, Purpose, and Scope of the Risk Assessment

For HHRA planning and scoping, an analyst should consider how to proceed in assessing risks in a way appropriate to the context of the analysis. Specifically, analysts should identify the regulatory context and objectives, and scientific objectives that are driving and defining the analysis. In addition, in this step analysts should develop a high-level review of data needs and limitations to ensure that the results will adequately inform decision makers (NRC, 2009). Context, risk management and analytic objectives, and scope are key elements in this step.

Regulatory, Risk, and Social Context

EPA risk assessments occur in specific policy contexts that inform the scope, purpose and risk management objectives. In some cases, the purpose, scope, and risk management objectives should be linked: the purpose of a risk assessment is often articulated through risk management objectives, and the related scope of the assessment is then articulated through analytical objectives that support the risk management objectives (U.S. EPA, 2002b). Early attention to context enables an analyst to make timely decisions about the scope of the risk assessment to ensure that potential EJ concerns are appropriately addressed during the rulemaking process.

An analyst should identify any complementarities between the triggering statutory authority and E.O. 12898 regarding identifying and addressing potentially disproportionate risks. In addition to the policy context, other contexts may help frame an evaluation of potential EJ concerns within an HHRA. For example, background exposure from multiple sources to the environmental stressor being regulated or background risks for a relevant adverse health outcome are important contexts for assessing differential risk. Similarly, communities with potential EJ concerns may experience differential risks due to higher susceptibility (e.g., due to lifestage or pre-existing health conditions) to the stressor being regulated. Finally, historical and social contexts may reveal drivers or contributors to differential exposures that contribute to potentially disproportionate risks in some locations and among some population groups (e.g., behavioral patterns or diet). See Section 3 for additional discussion of social and risk context.

Defining Risk Management and Analytic Objectives

While risk management objectives typically reflect regulatory and decision-making contexts and focus on the pending decision, the related analytical objectives of an HHRA employ contextual information to identify the technical and scientific actions that are required to meet regulatory objectives. As risk managers and analysts develop risk management and analytic objectives for assessing potential EJ concerns, it is important to frame them so they generate responses to the main EJ objectives from Section 1.1 (see Text Box 4.2 for an example).

To ensure that an HHRA generates useful information, risk managers and analysts should develop concise statements of risk management and analytical objectives that incorporate potential EJ concerns. The risk management objectives should present EPA's perspective on how the pending decision will affect potentially disproportionate human health risks among minority, low-income or indigenous populations. Related analytical objectives for evaluating potential EJ concerns within an HHRA should clearly identify anticipated outputs of the assessment. Analytical objectives should concisely identify the nature of evidence to be collected; the direction and structure of the planned evaluation for potential EJ concerns; the analytical methods to be employed (e.g., between socioeconomic group comparisons); the type of data required; and the scope of the analysis (e.g., national versus local scale).

Key Scoping Questions for Analysis of Potential EJ Concerns

Scoping is an important step in the planning process for a risk assessment. It refers to establishing the boundaries of the assessment (e.g., determining what population groups, health effects, chemicals, and exposure pathways will be included in the assessment). The scope, in combination with the context and purpose, is a major factor in developing a detailed plan for an HHRA (U.S. EPA 2012c).

Analysts should integrate applicable scoping questions during the planning stages of a risk assessment when one is being conducted for the regulatory action. (Recommendation 3 in Section 1.2.)

Text Box 4.2: Incorporating Potential EJ Concerns for the Definition of Solid Waste Rule; Examples of Risk Management and Analytic Objectives (U.S. EPA, 2011e).

Regulatory Context: The Resource Conservation and Recovery Act (RCRA) gives EPA the authority to regulate hazardous wastes (see, e.g., RCRA, 1976, sections 3001–3004). Hazardous wastes may (1) cause, or significantly increase mortality or serious irreversible or incapacitating reversible illness, or (2) pose a substantial present or potential hazard to human health or the environment when improperly managed (see RCRA, 1976, section 1004(5)). Hazardous wastes are a subset of solid wastes; materials that are not solid wastes are not subject to regulation as hazardous wastes.

Thus, the definition of "solid waste" plays a key role in defining the scope of EPA's authority under RCRA. EPA has historically interpreted "solid waste" to include certain materials that are destined for recycling (see U.S. EPA, 1980). Under the 2008 RCRA Hazardous Waste Definition of Solid Waste Rule (DSW rule), EPA sought to clarify how the definition of solid waste applies to hazardous secondary material recycling in a way that both encourages recycling, and is protective of human health and the environment (U.S. EPA, 2008a).

Risk Management Objective for EJ Concerns: Review the 2008 DSW rule to determine the potential for increased risk to human health and the environment from discarded hazardous secondary materials intended for recycling.

Translating Risk Management Objective to Questions: (1) What hazards could pose risks to human health and the environment from recycling of hazardous secondary materials, including accidental releases of hazardous secondary materials resulting in potentially disproportionate risks to minority, low-income or indigenous populations? and (2) What is the likelihood of such hazards occurring under the requirements of the 2008 DSW rule as compared to the pre-2008 DSW hazardous waste regulations?

Analytical Objectives for EJ Concerns: (1) Evaluate whether the populations potentially affected by the 2008 DSW rule have different socioeconomic characteristics (i.e., minority and/or low-income) than the general population; (2) Evaluate whether other factors that affect the potential for disproportionate risk to minority and/or low-income communities are present under the 2008 DSW rule.

Translating Analytical Objectives to Questions: (1) Do communities surrounding facilities potentially affected by the 2008 DSW rule have a higher percentage of minority and/or low-income population compared to the comparison population (i.e., national or state population)? (2) Are the communities potentially affected by the 2008 DSW rule also affected by other potential sources of pollution (e.g., industrial facilities, landfills, transportation-related air emissions, lead-based paint, leaking underground storage tanks, pesticides, incompatible land uses)? (3) Are there other factors that may contribute to higher susceptibility (e.g., lifestages, nursing mothers) among minority and/or low-income populations? (4) Does the 2008 DSW rule reduce the ability for potentially impacted communities to participate in the decision making process?

Examples of questions that can aid in scoping for EJ are provided below (also see Text Box 4.3).

- **Which population groups, as defined by attributes such as geographic location, ethnicity or race, gender, or baseline health status, should be part of the assessment?** While an evaluation of EJ focuses on minority, low-income and indigenous populations, in some instances diversity within these population groups due to the presence of effect-modifying factors (i.e., factors that alter an individual's reaction to exposure such as pre-existing disease conditions or lifestage) may mean that some types of individuals are at greater risk for experiencing adverse effects. In identifying target population groups for the assessment of potentially disproportionate risks, an analyst should consider the extent to which effect-modifying factors may explain demographically defined differences. If an analyst decides to assess population groups defined by effect-modifying factors, the rationale for this decision and the associated methods should be transparently documented.

- **What health endpoints are to be addressed by the assessment?** Defining health endpoints clearly in the planning phase of the HHRA focuses the risk assessment and increases the transparency of the process. When selecting health endpoints, an analyst should consider whether specific health endpoints may be significant in population groups of concern. In making this selection, it is important to evaluate whether health endpoints for a given exposure differ across population groups. This type of information is most often found in epidemiology and toxicology studies, such as those focused on the modifying effects of social context on environmental risk. It may not be possible to identify all health endpoints upfront. Some information found in toxicity assessments may only define the potential for an adverse health outcome for specific stressors.

- **What exposure routes and pathways are relevant, are there specific exposure pathways that may lead to specific effects, and what exposure scenarios should be modeled?** In determining the scope of the evaluation for potential EJ concerns, an analyst should evaluate whether population groups of concern may have different exposure routes, pathways, or contact scenarios from the general population. Scoping for an exposure assessment should include timing of exposure, both historical and current. Unique exposure pathways based on lifestages and other relevant categories may also be considered. Different pathways of exposure (e.g., inhalation, dermal, ingestion) may produce different effects with varying levels of severity.

Depending on the nature of the assessment, it can be helpful to consult with representatives from affected population groups and other stakeholders when identifying exposure routes, pathways and other information for constructing exposure scenarios for an HHRA.[35] Community and stakeholder knowledge may provide information not known to an analyst or undocumented in the literature (e.g., unusual pathways or unique behavior patterns that may alter exposure to an environmental stressor, and may affect estimates of intake or pathways to be examined from a source to the exposed population). EPA has developed extensive guidance on community and stakeholder involvement for this purpose (U.S. EPA, 2013b). In addition, Section 2.5 and the *Interim Process Guide* also discuss how to effectively engage the community in the rulemaking process.

At the completion of the scoping step, analysts will have a set of boundaries for the HHRA that can be incorporated into problem formulation (see Section 4.3.3) to produce a detailed plan for the assessment.

[35] The Paperwork Reduction Act requires that an Information Collection Request (ICR) be submitted for collecting information (e.g., surveys) from more than nine people (44 U.S.C. 3501).

Text Box 4.3: Example of Scoping Questions for Integrating EJ Considerations into Exposure and Dose-Response Assessments

To explicitly consider EJ in exposure assessment, risk assessors should consider scoping questions such as:

- Based on the use and release patterns of the environmental stressor of concern, are there population groups that might be more highly exposed?
- Are exposure variabilities predominantly a spatial phenomenon (e.g., due to contaminant hot spots)? Is proximity to source a reasonable proxy for estimating exposure to stressors of concern?
- Can exposure variability be estimated using ambient contaminant concentrations, either measured or modeled? Are data available or can data be modeled at a reasonable spatial scale appropriate for available demographic data?
- Are bio-monitoring data available for the population groups of concern, including those with potentially elevated exposure?
- Do the physical and/or chemical properties of the stressor indicate a potential for long range transport (e.g., volatile, persistent), especially stressors that may also bioaccumulate?
- Are there population groups that may experience greater exposure to stressors because of their unique food consumption patterns, behaviors or use of certain cosmetics?

To explicitly consider EJ in dose-response assessment based on available epidemiological data, risk assessors should consider scoping questions such as:

- What demographic and population groups are most relevant from a risk perspective for the stressor in question?
- Do population-specific dose-response functions exist for particular minority, low-income or indigenous populations?
- Are the spatial and temporal scales of the studies supplying the dose-response function comparable to the spatial and temporal scales of the assessment of potential EJ concerns, from both an exposure and outcome perspective?

4.3.2.2 Define Responsibilities for Assessing and Communicating Risks and Allocate Resources

The HHRA planning phase includes assigning responsibilities for analysis and clarifying how analysts will interact with decision makers and stakeholders. This process also includes describing or establishing the available and required resources, including staffing, budget, and time needed for the assessment.

Consideration of EJ is cross-disciplinary in nature due to its cultural, economic, and demographic elements. Early identification of skill sets needed for the assessment enables managers to identify the most appropriate analytical team at the outset of the planning process. Areas of expertise that may be pertinent to EJ (but not necessarily to a more general HHRA) include social epidemiologists and experts on cumulative risk.

4.3.2.3 Identify Data, Models, Tools and Other Technical Resources

A central challenge for an analyst in the HHRA planning process is identifying the data, tools and models available or that need to be generated to complete an assessment for EJ. Data selection should be based on the context, risk management and analytic objectives, and scope of the analysis. (Appendix B provides sample questions to help identify data and model needs when planning for exposure assessment and dose-response assessment.)

Data Identification. As previously mentioned, a key planning element for identifying data relevant to EJ analyses is consultation with stakeholders, including communities that may have access to data useful for improving the characterization of exposure and risk. Other data that can be used to evaluate EJ within an HHRA include exposure data, epidemiological data, toxicity including susceptibility data, and fate and transport data. Relevant data can be location-specific or population group-specific, or, ideally, both. Relevant data may also include ambient concentration data (e.g. from air monitoring stations and water quality measures), or public health data such as disease incidence.

Exposure data may include intake data such as consumption or contact rates, routes of exposure, behavior data for estimating contact rates, concurrent exposures to other stressors that are of toxicological relevance, biomonitoring data, or emissions data. Extensive discussion about use of exposure data in the EJ context is available in the peer reviewed literature. Burger and Gochfeld (2011), for example, discuss the types of unique exposure pathways that may occur in population groups of concern, and suggest that the first step in improving risk methodology is to recognize and account for unique exposure sources (e.g., native tattoos and sweat baths, culturally significant toys, mercury used in religious practices) and the corresponding exposure pathways. If a chemical bioaccumulates in fish, for example, it would pose greater risks to populations who eat more local fish for subsistence or cultural reasons (see Fitzgerald et al., 2005 for another example).

Health risk data could include incidence data specific to populations with potential EJ concerns, historical population specific disease or illness rates, toxicological data, such as that which can be found in EPA's Integrated Risk Information System (IRIS) database.

Model and Tool Identification. Risk assessment employs a range of models and tools to estimate ambient concentrations of stressors, exposure, amounts of stressors likely to reach the target organ (e.g., effective dose), risks for a specific health endpoint, locational vulnerability to health impacts, and other key factors. EPA's traditional models for estimating exposure and risk remain relevant for an evaluation of potential EJ concerns within an HHRA.

> *"An exposure pathway is the course a chemical takes from its source to the person being contacted."* (U.S. EPA, 1992)

The challenge in incorporating EJ into an HHRA is to evaluate input parameters for these models to ensure that they are representative of population groups of concern. Traditional defaults used for inputs in HHRAs may not adequately reflect the demographic characteristics of these population groups. Within the research community and among state and local agencies, several new tools and models reflect recent methodological advances for addressing potential EJ concerns. EPA also has developed improved models and tools with a specific focus on EJ, such as Environmental Benefits Mapping and Analysis Program (BenMAP). BenMAP is designed to provide the type of input that is particularly useful in a regulatory analysis and can be adjusted to highlight particular population groups. More recently, the Agency has been developing EJSCREEN, a Census tract-level mapping tool that organizes demographic and environmental data that could prove useful to HHRA planning for evaluating potential EJ concerns. Text Box 4.4 identifies several recent tools that can be used to support EJ planning within an HHRA. Section 5 also discusses analytic approaches that can be used to address data needs.

Identifying Data Quality and Data Gaps. Because assessing potential EJ concerns relies on rapidly developing data and tools, it is essential that the HHRA planning process pair data and tool identification with a clear and integrated discussion of data available to characterize key uncertainties, data quality, and lack of data that may affect methodology development and/or affect results.

Text Box 4.4: Examples of Models, Tools and Technical Resources for Evaluating Potential EJ Concerns within a Human Health Risk Assessment

Data Resources

- Geospatial Platform http://www.geoplatform.gov
- U.S. Census American Fact Finder http://factfinder2.census.gov/
- EPA Report on the Environment http://www.epa.gov/roe/
- America's Children and the Environment Report, Third Edition http://www.epa.gov/ace/
- Centers for Disease Control (CDC) Tracking Program-Funded State and Local Health and Environmental Tracking http://ephtracking.cdc.gov/showStateTracking.action
- CDC Environmental Public Health Indicators http://ephtracking.cdc.gov/showIndicatorsData.action
- National Air Toxics Assessment (NATA) (EPA Office of Air and Radiation (OAR)) http://www.epa.gov/ttn/atw/natamain/
- EPA's Air Quality System http://www.epa.gov/ttn/airs/airsaqs/
- EPA's IRIS Database http://www.epa.gov/IRIS/
- National Library of Medicine, Toxicology and Environmental Health Information Program https://www.nlm.nih.gov/pubs/factsheets/tehipfs.html
- State or county public health and environmental databases
- County Health Ranking and Roadmaps http://www.countyhealthrankings.org/
- Superfund site information http://www.epa.gov/superfund/sites/cursites/
- RCRAInfo http://www.epa.gov/enviro/facts/rcrainfo/search.html
- State databases for state-regulated facilities

Guidance and References

- EPA Risk Assessment Portal http://epa.gov/risk/
- EPA Community Action for a Renewed Environment http://www.epa.gov/care/
- Air Toxics Risk Assessment Reference Library http://www.epa.gov/ttn/fera/risk_atra_main.html
- Recent state legislation on a broad range of environmental issues http://www.ncsl.org/issues-research/energyhome/energy-environment-legislation-tracking-database.aspx
- Recent state legislation on environmental justice http://www.uchastings.edu/public-law/docs/ejreport-fourthedition1.pdf
- Cal EPA Cumulative Impacts Assessment Methodology http://oehha.ca.gov/ej/cipa123110.html
- CDC Health Disparities and Inequalities Report: http://www.cdc.gov/minorityhealth/CHDIReport.html

Models and Tools

- Office of Pesticide Programs (OPP) Tools - see http://www.epa.gov/oppt/exposure/
- BenMAP (OAR) http://www.epa.gov/air/benmap/
- Community-Focused Exposure and Risk Screening Tool (C-FERST) (under development by Office of Research and Development) http://www.epa.gov/heasd/c-ferst/
- EJSCREEN (under development by Office of Policy; currently for internal use only)
- Community Cumulative Assessment Tool (under development by Office of Research and Development) http://www.epa.gov/research/healthscience/health-ccat.htm
- Council of Regulatory and Environmental Modeling (CREM) tools http://www.epa.gov/crem/index.html

In some cases, lack of data may prompt a decision to limit the scope of an evaluation for EJ within an HHRA. Any decisions to limit an evaluation of potential EJ concerns for data availability reasons should be clearly documented. Documentation is particularly important in an EJ context because stakeholders often provide comments about how to proceed when data needs are identified.

To further promote the quality of data used in planning risk assessments, risk analysts should review EPA's Information Quality Guidelines (IQG) and Data Quality Objectives (DQO) (U.S. EPA, 2012d). IQGs and DQOs help increase the integrity, objectivity, and quality of data when analyzing potential EJ concerns.[36]

4.3.2.4 Conduct a Scientific Peer Review

EPA encourages and expects independent peer review of scientific and technical information intended to inform or support Agency decisions.[37] When an HHRA that incorporates potential EJ concerns is subject to scientific peer review, it is important to identify key expertise needed and potential experts, including community representatives with technical expertise and public health scientists with community and EJ experience. This step also involves planning the peer review process so that it is interactive to ensure that stakeholders have the opportunity to participate effectively in the review process.

4.3.2.5 Ensure Meaningful Public, Stakeholder and Community Involvement When Possible

Stakeholder involvement (http://www.epa.gov/stakeholders/) is integral to both the HHRA process and to the broader consideration of potential EJ concerns. As previously mentioned, engaging stakeholders in the HHRA process may help analysts identify stressor sources, highlight adverse health effects, and address risk perception issues. To foster meaningful participation of members of communities with potential EJ concerns in the highly technical HHRA process, EPA should recognize and work to overcome conditions that reduce or hinder a community's ability to participate fully in the rulemaking process, such as time and resource constraints, lack of trust, lack of information, language barriers, and difficulty in accessing and understanding complex scientific, technical, and legal resources. See Section 2.5 and the *ADP Interim Process Guide* (U.S. EPA, 2010a) for more details on meaningful involvement.

A key element of successful public involvement is effective risk communication. EPA's *Seven Cardinal Rules of Risk Communication* begins with two basic tenets: people and communities have a right to participate in decisions that affect their lives; and the goal of risk communication is to produce an informed public that is involved, interested, reasonable, thoughtful, solution-oriented, and collaborative (U.S. EPA, 1998c). Effective risk communication is essential to identify and address potential EJ concerns, and to ensure that relevant information is accessible to affected communities and population groups of concern, who may not be familiar with the data and analyses used by EPA to evaluate public health risks.

The Presidential/Congressional Commission on Risk Assessment and Risk Management suggests using the following questions to identify potential stakeholders:[38]

- Who might be affected by the assessment?
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?

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[36] For more information on IQGs and DQOs , visit http://epa.gov/quality/informationguidelines/index.html and http://www.epa.gov/QUALITY/qs-docs/g4-final.pdf.

[37] Guidelines for the peer review process are available in EPA's Peer Review Handbook: http://www.epa.gov/peerreview/.

[38] See http://www.riskworld.com/riskcommission/default.html .

- Who might reasonably or unreasonably feel they should be included?

It is recommended that analysts and risk managers consult *The Framework Implementing EPA's Public Involvement Policy* (U.S. EPA, 2003b) for general guidance for scoping a public involvement process.[39] When EPA actions or decisions may affect tribes, EPA has instituted a Tribal Consultation Policy that provides clear guidance for when, how and on what issues consultations with tribal governments should occur (U.S. EPA, 2011i). To ensure that stakeholders participate meaningfully in the HHRA the approach for soliciting information should be specific, involve interactive dialogue that is designed to elicit specific responses, and include accommodations for population groups with limited English proficiency. Elements of such a dialogue could include specific questions about the types of data or models that are needed for analysis of potential EJ concerns.

4.3.3 Problem Formulation

Problem formulation, a key step in risk assessment planning, is a process for generating and evaluating preliminary hypotheses about why health effects may occur due to specific stressors. Through problem formulation an analyst systemically identifies the major factors to be considered in the risk assessment. Problem formulation therefore provides the foundation for the entire risk assessment and also provides a process for refining risk assessment objectives. It draws from the regulatory, decision-making, and policy contexts to inform the technical approach of the HHRA. Effective problem formulation helps ensure that an analyst develops a clear set of goals and endpoints for the HHRA and that all relevant risks are identified and addressed in the assessment (U.S. EPA, 2012c).

In considering EJ, problem formulation focuses on determining whether minority, low-income or indigenous populations experience potentially disproportionate risks relative to the general population or other appropriate comparison groups (see Sections 2.3, 2.4, and 5.4.2). Specifically, this involves: 1) clarifying the source and characteristics of the stressors that are relevant to potential disproportionate risks, 2) identifying factors that may influence exposures that contribute to those risks, and 3) characterizing susceptibilities or vulnerabilities of the populations with potential EJ concerns that may exacerbate differences in exposure or risk. Key products of problem formulation are the assessment endpoints, a conceptual model, and an analysis plan. Since planning and scoping is an interactive, nonlinear process, substantial re-evaluation is an anticipated step in the development of all problem formulation products.

Text Box 4.5 presents examples of questions that may be raised during problem formulation in the context of proximity to sources of pollution. For additional sample problem formulation questions, see EPA's *Lessons Learned in Planning and Scoping for Environmental Risk Assessments* (U.S. EPA, 2002b).

[39] EPA's public involvement website (www.epa.gov/publicinvolvement) provides guidance documents, case studies, and resources helpful in planning outreach activities. EPA also provides specific recommendations regarding outreach to Tribes at: www.epa.gov/tribalportal/consultation/index.htm.

Text Box 4.5: Examples of Questions to Consider During Problem Formulation

Characteristics Related to Proximity to a Stressor or Source

- What are the sources of the stressor?
- Is the source being potentially regulated located in geographic areas with greater minority, low-income or indigenous populations?
- Are other sources of the stressor more prevalent in geographic areas with greater minority, low-income or indigenous populations?
- Are there historical releases or uses of the stressor in such areas?
- Is the concentration of the stressor in the relevant ambient media higher in geographic areas with greater minority, low-income or indigenous populations?

Potentially Disproportionate Exposures to a Stressor

- Do minority, low-income or indigenous populations have higher body burdens of the contaminant?
- Are these population groups more likely to experience current or historically higher exposures to the stressor from sources other than the one under consideration?
- Are there particular lifestages within these population groups that may be more at risk to higher exposure to the stressor?
- Are there products/consumer goods that contain the stressor?
- Are these products/consumer goods used at disproportionately higher rates among minority, low-income or indigenous populations?
- Are there cultural practices that are unique to these population groups versus the general population?
- What is the frequency of occurrence of the cultural practice and its duration?
- What is the frequency of occurrence of an atypical activity and its duration?
- Is proximity to the emitting source an important factor in the assessment?
- What geographic scale is important to highlight different exposures between demographic groups for the pollutant in question (e.g., U.S. Census tract, block, or county)?

Population Characteristics

- What are the rates of the adverse health outcome of concern among minority, low-income or indigenous populations?
- Are the rates of the adverse health outcome of concern higher among these population groups?
- What factors or conditions are known to modify the effect of the regulated contaminant?
- How are these modifying factors or conditions distributed across demographic groups?
- Do minority, low-income or indigenous populations have a higher prevalence of modifying effects or conditions?
- Are there more members of these population groups employed in specific professions known to have higher risks of the adverse health outcome?

4.3.3.1 Characterizing the Stressor and its Sources

The properties of the stressor and its sources and their relationships to differential risks are important inputs to the HHRA. Although HHRAs typically collect information on the general characteristics of stressors and their sources, analysts also should incorporate relevant information specific to potential EJ concerns (e.g., the likelihood that the source of the stressor is located in areas where minority, low-income or indigenous populations live relative to areas where other population groups live). Analysts should also identify the distribution of any additional sources of the stressor that are not the focus of the regulatory action, because these sources may contribute to potentially disproportionate risks. For example, a stressor may be present in environmental media due to background concentrations (e.g., historical or past industrial activity, or naturally occurring) in areas with minority, low-income or indigenous populations.

4.3.3.2 Identifying Differences in Exposures that May Lead to Disproportionate Risks

Differential exposures can be an important indicator of potentially disproportionate risks. Differences in exposures across population groups may arise from many causes, including those described earlier such as proximity to pollution sources, employment in certain occupations, or exposures to multiple sources of a specific stressor (Brender et al., 2011; Burger and Gochfeld, 2011). For example, if other sources tend to be co-located with the source in question, it may contribute to important differences in patterns of exposure to the stressor. Even in situations where a regulated source of the stressor is not disproportionately located in geographic areas primarily consisting of minority, low-income or indigenous populations, other sources of the stressor may contribute to differential exposures, and ultimately, to potentially disproportionate risks.

Patterns of exposure can be location-specific or population group-specific depending on the scale of the assessment and the types of data available. Analysts identifying differences in exposure should investigate issues such as relevant cultural practices, consumer products use, group differences in body burdens of the contaminant, and co-exposures to multiple stressors that may affect the body's ability to detoxify a particular contaminant (e.g. factors that may influence metabolism). Social patterns related to exposure could also be evaluated across other characteristics of population groups of concern such as lifestage or gender or within multiple social strata (e.g., low income minority) to yield unique and important perspectives on population groups most at risk. For example, exposure patterns for blood lead show that non-Hispanic black children between the ages of 1 and 5 who live below poverty level have the highest median blood lead concentration in the United States (U.S. EPA 2013a).

Background exposure may be evaluated using bio-monitoring data, when available. In the United States, the primary source of national bio-monitoring data on chemical hazards is the National Health and Nutrition Examination Survey (NHANES). NHANES is designed to collect data on the health and nutritional status of the U.S. population. The NHANES is a representative sample of the civilian, non-institutionalized population in the U. S. based on age, gender, and race/ethnicity (Centers for Disease Control (CDC), 2009). Due to its sample design, NHANES cannot be used to provide exposure data for small geographic units or co-located individuals (U.S. EPA, 2003c). Nevertheless, it is an important information resource for identifying differences in exposure.[40] For more detailed information on using bio-monitoring data to evaluate exposure differences, see the exposure assessment examples in Appendix B.

For some stressors that are dispersed locally in ambient media (e.g., air toxics), exposure may be effectively captured using proximity to the source.[41] Section 5 discusses use of proximity methods for evaluating potential EJ concerns.

In some cases, a screening analysis using measured or estimated concentrations of a stressor in ambient media that are correlated with race/ethnicity or income can identify differential exposures. For example, analysts may have information from ambient air quality monitors or estimated ambient air concentration data averaged over a period of time. However, in some cases monitoring data may not be adequate to evaluate differences in exposure for small geographic units (e.g., Census tracts). See Appendix B for an example of estimating exposure using ambient concentration data.

In some cases, states, Tribes, and local governments may have relevant monitoring data. Case studies may also offer some insight into potential impacts when data are not available for all areas affected by the regulatory action.

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[40] Some limitations of data available through NHANES can be addressed by locale-specific surveys such as the New York City Health and Nutrition Examination Survey (NYCHANES) and other site- and population specific surveys that may be conducted for reasons other than EJ considerations. Some limitations to the availability of primary site- and population-specific surveys are cost and the amount of time required for to conduct these surveys.

[41] Methods for estimating exposure using the concept of proximity are well developed and are extensively reviewed in Chakraborty et al., 2011.

In the problem formulation step, it is essential to clearly articulate how population groups of concern may be exposed to a stressor. Unique exposure pathways are often important in assessing potential EJ concerns.[42] In some cases, new pathways can be identified during or after planning as new data become available. For example, bio-monitoring data acquired during scoping and problem formulation may suggest the presence of unexpected differences, resulting in a focused inquiry.

Alternatively, analysts may seek new information about unique exposure pathways to ensure a comprehensive evaluation of the range of exposures in the population groups of concern. Conceptual frameworks of the type discussed in section 3 may be useful for identifying and collecting data on these exposure pathways. Examples of questions that are helpful for extracting information about unique exposure pathways also are presented in Text Box 4.5.[43]

"Populations who face environmental inequities may be identified in national exposure databases but may not be located in discrete spatial communities. Such databases might identify [population groups] who face a disproportionate adverse health outcome, but unless they live in a community that is spatially identified, it is difficult to address common exposures using conventional risk assessment approaches… Broad-scale surveys, site-specific surveys, and national databases are beneficial, and can be used to identify environmental inequities among [groups] that are not spatially related" (Burger and Gochfeld, 2011).

4.3.3.3 Population Characteristics

Population characteristics refer to those attributes shared by individuals within a population group that influence the likelihood of exposure to the stressor and the risk of adverse health outcome that may result from this exposure. These factors or conditions range from those with direct effects such as pre-existing disease conditions, chronic disease, age, medication status, and immune status to those with more indirect influences such as a lack of access to resources (e.g., health care), negative social conditions, age of housing as a function of race/ethnicity and income, a specific type of occupation, income status, access to transportation, and poor educational status.

Understanding population characteristics is an important step toward identifying factors that may affect an individual's resilience, i.e., their ability to withstand or recover from exposure to a stressor. Such information also highlights how these characteristics are distributed in the population groups of concern from an EJ perspective. Appendix B provides examples of integrating these characteristics into a dose-response assessment.

Information on population characteristics can be identified in the literature, including epidemiological and toxicological studies of effect-modifying factors. For example, if education modifies an adverse health outcome from exposure to a stressor such that population groups with lower educational status have higher risk, this information could be used in the risk assessment to identify potentially disproportionate risks. Sample questions to guide collection of information on population characteristics are presented in Text Box 4.5.

[42] Examples of documented unique exposure pathways include exposure to heavy metals from the use of non-traditional medicines (Ernst and Thompson Coon, 2001; Ernst, 2002a, b), exposure to mercury from high consumption rates of fish (Anderson and Rice, 1993; Peterson et al., 1994), exposure to pesticides tracked into homes by family members from their places of work (Simcox et al., 1995), and exposure to inorganic mercury from the use of contaminated cosmetic products for body maintenance purposes (McKelvey et al., 2011).

[43] The *Exposure Factors Handbook* also has exposure factors data stratified by race/ethnicity (U.S. EPA, 2011g).

4.3.3.4 Building a Conceptual Model

Information from the problem formulation process should assist in the development of a conceptual model. The model should explain how and to what degree identified risk factors contribute to differences in exposure and/or risk; communicate the strength and direction of relationships between these factors and exposure and/or risk; identify data needs by characterizing relationships as low, medium and high uncertainty; and ultimately inform the scope of an assessment for EJ given current scientific understanding.

A conceptual model includes both a written description and a visual representation of the stressor(s), the exposed population(s), actual or predicted relationships between population groups of concern and the regulated stressor to which they may be exposed, and the endpoint(s) that will be addressed in the risk assessment as well as the relationships among them (U.S. EPA, 2012c). The specific challenges of integrating EJ into the risk assessment should be addressed in the conceptual model.

4.3.3.5 Developing an Analysis Plan

The analysis plan is the final stage of problem formulation. It describes decisions made during the planning process and provides details on incorporating EJ into the scope of the assessment, including: (a) the assessment design and rationale for which relationships are addressed; (b) a description of the data and information, methods and models to be used in the analyses (including uncertainty analyses); and (c) the associated data gaps, needs, and limitations.

Section 5: Conducting Regulatory Analyses To Assess Potential Environmental Justice Concerns

This section discusses how to assess whether there are existing EJ concerns or are likely to be EJ concerns based on information generated from a human health risk, exposure, or other assessments.[44] In particular, it discusses methods that may be useful for answering the analytic objectives from Section 1.1 of this document, which are repeated here:

To ascertain the extent to which a potential EJ concern is associated with the affected environmental stressors prior to the rulemaking, the analyst should, when feasible:

1. Assess exposures, relevant health and environmental outcomes, and other relevant effects by population group in the baseline; and
2. Assess differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups in the baseline.

For each regulatory option under consideration, to inform the extent to which a potential EJ concern is created or mitigated for the affected stressors, the analyst should, when feasible:

3. Assess exposures, relevant health and environmental outcomes, and other relevant effects by population group for each option;
4. Assess differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups for each option; and
5. Assess how estimated differences in these exposures, relevant health and environmental outcomes, and other relevant effects across population groups increase or decrease as a result of each option compared to the baseline.

This section is organized as follows.[45] Section 5.1 discusses how to evaluate the feasibility of conducting a quantitative or qualitative assessment of potential EJ concerns; Section 5.2 defines baseline and incremental changes for an analysis of potential EJ concerns; Section 5.3 summarizes a number of methods for assessing differences in impacts across population groups; Section 5.4 discusses analytic issues, including how to define comparison groups and geographic issues relevant for analyses where the source of emissions is identifiable and health effects are fairly localized and spatially distinguishable; and Section 5.5 discusses costs and non-health impacts.

[44] While the focus in this section is on population groups mentioned in E.O. 12898, the methods discussed may be applied to any population group of concern.

[45] The material discussed in this section is generally consistent with draft Chapter 10 of the *Guidelines for Preparing Economic Analysis*, though there are a few key differences. First, the *Economic Guidelines* apply to regulatory analyses for economically significant rules (i.e., rules with benefits or costs in excess of $100 million in any year); the *EJ Technical Guidance* applies to a broader array of regulatory actions. Second, Chapter 10 says little about the generation of underlying information, such as from a risk assessment (U.S. EPA., 2012b).

5.1 Evaluating the Feasibility of an Assessment of Potential EJ Concerns

For policies that strengthen an environmental standard, EPA regulatory analyses have often assumed there are no EJ concerns because the regulation is expected to reduce overall environmental burden. However, this assumption may lead to erroneous conclusions. A basic analysis should support conclusions with regard to potential distributional effects to improve the transparency of the rulemaking process and provide the decision maker and public with more complete information regarding the expected effects of the policy.

The main purpose of analyzing the effects of a regulation on population groups of concern is to examine how changes in risk to human health or indicators of environmental quality are distributed across and, when relevant and feasible, within (e.g., lifestages, gender) population groups. A quantitative analysis is generally preferred to a qualitative assessment since it allows for more rigorous evaluation of the way in which emissions, risk, and/or health effects are distributed among population groups.

> *For regulatory actions where impacts or benefits will be quantified, some level of quantitative analysis for EJ is recommended.* (Recommendation 1 in Section 1.2.)

When information on risk and incidence by groups is available, an analyst may be able to characterize the baseline and likely response to a change in exposure quantitatively for each policy option. When feasible, analysts should present benefits information disaggregated by race/ethnicity and income.[46]

When direct quantitative information on risk is unavailable, analysts may consider using surrogate quantitative information, such as prevalence or concentration of affected facilities as a function of race/ethnicity or income. For instance, the distribution of ambient environmental quality indicators (e.g., pollutant concentrations) or stressors from regulated sources may be a useful proxy. In other cases, proximity-based analysis may provide some insight into distributional impacts. However, analysts should be aware that the conclusions that can be drawn from these analyses will necessarily be limited. There may be considerable uncertainty regarding how a reduction in emissions from a given source translates into ambient environmental quality and how it, in turn, translates into the human health impacts that are the ultimate objective of the analysis. This is particularly problematic if these uncertainties differ across population groups. For instance, if an overexposed population group is also more susceptible – meaning, it experiences greater health effects per unit of exposure – then using exposure as a proxy will underestimate the actual health risk posed by a stressor to that group. If, on the other hand, local proximity to a pollutant source is used as a proxy for risk that is much more widely distributed, it could overestimate potential differences in risk.

If the available scientific literature and data do not allow an analyst to characterize how risk/exposure or health outcomes are distributed across population groups of concern, an analyst should qualitatively characterize the issue and discuss any evidence, key limitations and sources of uncertainty highlighted in the published literature (U.S. EPA, 2010b). See Text Box 5.1 for an example of a qualitative discussion of potential EJ concerns from a recent EPA rulemaking.

> *When impacts or benefits will not or cannot be quantified or disaggregated by race/ethnicity or income, analysts should present information that is insightful with regard to potential EJ concerns (e.g., basic demographic information, evidence of differential exposure).* (Recommendation 2 in Section 1.2.)

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[46] As discussed in greater detail in Section 4, analysts should engage risk assessors early on in the process to identify data needed for evaluating potential EJ concerns that could be generated by the risk assessment.

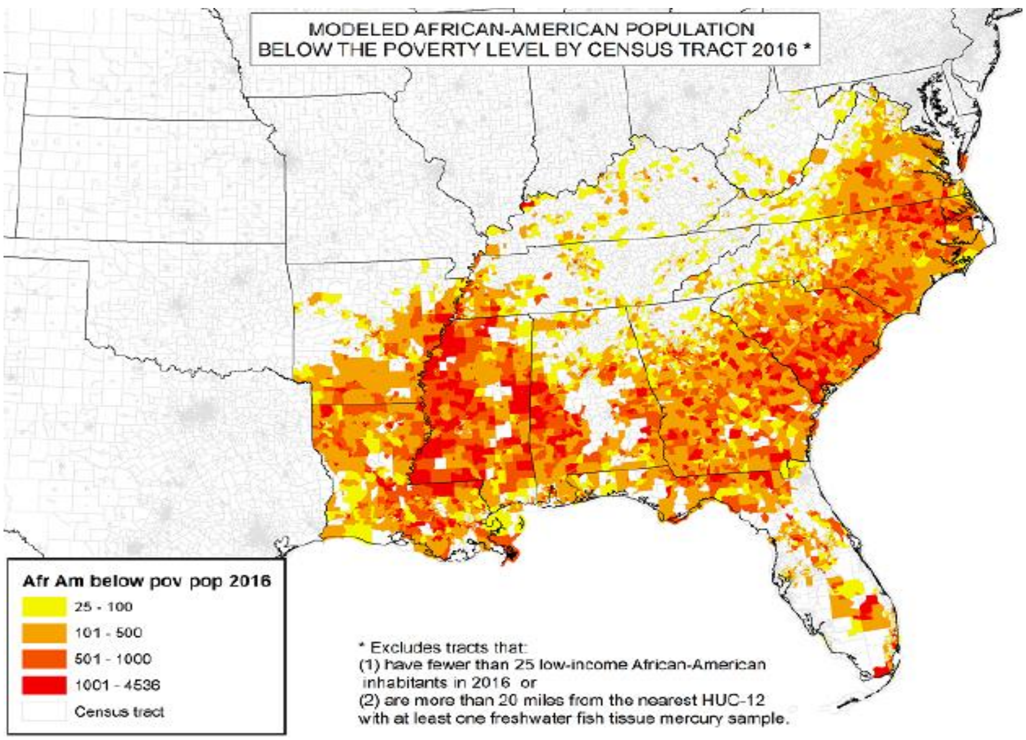
Analysts should use their best judgement when determining the appropriate use of quantitative and qualitative information for analysis of potential EJ concerns.

Text Box 5.1: Qualitative Assessment of Unique Mercury Exposure Pathway in the Final Mercury and Air Toxics Standards (MATS) (U.S. EPA, 2011c)

In addition to the quantitative assessments described in Text Box 5.5, analysts for MATS include a qualitative assessment of the effects of the rule on population groups with a high potential risk of mercury exposure due to a unique exposure pathway – high rates of fish consumption.

The analysis reviews the literature to identify which populations groups are likely to fall into the high risk category for mercury exposure based on higher than average daily fish consumption. Six high risk population groups are identified (e.g., Laotian subsistence fishers, low-income African-American recreational and subsistence fishers) and the results of the studies summarized, including sample size, mean and median fish consumption, and 90th and 95th percentiles.

The analysis then uses projections of county-level growth to estimate the number of individuals in each population group at highest risk for mercury exposure in 2016 absent the rule (i.e., in the baseline) and presents this information in a series of maps, one of which is presented below.



Source: Figure 7-1 in the Regulatory Impact Analysis for the Final Mercury and Air Toxics Standard (U.S. EPA, 2011c).

Analysts could also consider using case studies, anecdotal information about unique exposure pathways, and qualitative relationships (e.g., some low-income populations are known to rely on subsistence fishing), information on impacts of facility closures, and general information about demographics to describe the expected distributional effects of outcomes when quantitative data are unavailable or would require significant resources to collect. Text Box 5.2 provides another example of a qualitative discussion when stressors are dispersed widely.

Text Box 5.2: Qualitative Discussion of EJ Concerns from Final Rule to Establish Greenhouse Gas (GHG) Emission Standards for Medium-Heavy Duty Trucks (U.S. EPA, 2011j)

Climate Change Discussion: "Within communities experiencing climate change, certain parts of the population may be especially vulnerable; these include the poor, the elderly, those already in poor health, the disabled, those living alone, and/or indigenous populations dependent on one or a few resources. In addition, the U.S. Climate Change Science Program stated as one of its conclusions: 'The United States is certainly capable of adapting to the collective impacts of climate change. However, there will still be certain individuals and locations where the adaptive capacity is less and these individuals and their communities will be disproportionally impacted by climate change.' Therefore, these specific population groups may receive benefits from reductions in GHGs. For non-GHG co-pollutants such as ozone, $PM_{2.5}$, and toxics, EPA has concluded that it is not practicable to determine whether there would be disproportionately high and adverse human health or environmental effects on minority and/or low income populations from these rules."

Non-GHG Air Pollution Discussion: "There is a large population in the United States living in close proximity of major roads. According to the Census Bureau's American Housing Survey for 2007, approximately 20 million residences in the United States, 15.6 percent of all homes, are located within 300 feet (91 meters) of a highway with 4+ lanes, a railroad, or an airport. Therefore, at current population of approximately 309 million, assuming that population and housing are similarly distributed, there are over 48 million people in the United States living near such sources. The HEI [Health Effects Institute] report also notes that in two North American cities, Los Angeles and Toronto, over 40 percent of each city's population live within 500 meters of a highway or 100 meters of a major road. It also notes that about 33 percent of each city's population resides within 50 meters of major roads. Together, the evidence suggests that a large U.S. population lives in areas with elevated traffic-related air pollution. People living near [major] roads are often socioeconomically disadvantaged. According to the 2007 American Housing Survey, a renter-occupied property is over twice as likely as an owner-occupied property to be located near a highway with 4+ lanes, railroad or airport. In the same survey, the median household income of rental housing occupants was less than half that of owner-occupants ($28,921/$59,886). Numerous studies in individual urban areas report higher levels of traffic-related air pollutants in areas with high minority or poor populations.

Students may also be exposed in situations where schools are located near major roads. In a study of nine metropolitan areas across the United States, Appatova et al. (2008) found that on average greater than 33 percent of schools were located within 400 meters of an Interstate, U.S., or state highway, while 12 percent were located within 100 meters. The study also found that among the metropolitan areas studied, schools in the Eastern United States were more often sited near major roadways than schools in the Western United States. Demographic studies of students in schools near major roadways suggest that this population is more likely than the general student population to be of non-white race or Hispanic ethnicity, and more often live in low socioeconomic status locations. There is some inconsistency in the evidence, which may be due to different local development patterns and measures of traffic and geographic scale used in the studies."

5.2 Evaluating Baseline and Incremental Changes

To address the analytic objectives listed above, an analyst needs to isolate the effects of the regulatory action from other changes that could occur in the future. To accomplish this, the incremental or additional effects are measured relative to a baseline. OMB (2003) defines the baseline as "the best assessment of the way the world would look absent the proposed action." In particular, OMB notes that an analyst may need to consider the evolution of the market, compliance with other regulations, and the future effect of current government programs and policies, as well as other relevant external factors.

> *Analyses should use the same baseline and regulatory option scenarios as other types of regulatory analyses (e.g., benefit-cost, economic impact analyses) conducted in support of the rulemaking* (Recommendation 4 in Section 1.2.).

Defining a consistent baseline allows an analyst to determine how aggregate effects are distributed across population groups of concern and to assess whether some groups are more or less affected. See Chapter 5 of EPA's *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2010b) for a more detailed discussion of baseline issues.

When evaluating how incremental impacts are distributed across population groups of concern, it is important to understand the difference between how a regulatory action *changes the baseline distribution* of health and environmental outcomes across population groups and the *distribution of changes* in outcomes across population groups. For example, consider a regulatory action that reduces emissions of an asthma-causing stressor. An analysis of the *change in the distribution* of outcomes compares the baseline distribution of outcomes across population groups with the projected distribution of outcomes when the regulation is in place. In other words, the analysis tries to identify differences in the baseline incidence of asthma induced by the stressor and determine if the distribution increases or decreases differences. In contrast, an analysis of the *distribution of change* identifies the total reduction in asthma cases due to the regulation and then determines how this reduction in cases is distributed across population groups.[47]

The first type of comparison is more relevant for evaluating potential EJ concerns. For example, suppose that minority populations have a higher number of asthma cases per capita compared to non-minority populations in the baseline. Now suppose that the proposed new policy results in a 10 percent reduction in asthma cases for both population groups. While the distribution of the change in asthma incidence may appear neutral from an EJ standpoint (i.e., both see an equal percentage reduction), it would be incorrect to conclude based on this information that there is no potential difference in asthma rates among minority and non-minority populations. An analyst needs to know the distribution of outcomes under the regulation as well as the distribution of baseline incidence to understand whether this is actually the case. Since minority populations have a higher number of asthma incidences than non-minority populations in the baseline, reducing asthma incidence by 10 percent actually results in a larger reduction in the number of asthma cases for minority populations than for non-minority populations, which represents a decrease in the difference in asthma incidence.[48]

The difference between these two measures – the distribution of change in health and environmental outcomes, and the change in the distribution of health and environmental outcomes – also can affect analysis of the distribution of monetized benefits. Unlike physical environmental indicators such as health risk or ambient pollutant concentrations, it is not possible to estimate each affected individual's total monetized welfare in the baseline and under each regulatory option. Instead, economists often estimate society's willingness to pay for a *change* in environmental quality. Thus, although the distribution of the

[47] See Maguire and Sheriff (2011) for more information.
[48] As discussed in Section 2.4, how to use the information on differences and making a determination of a disproportionate impact that merits Agency action is ultimately a policy decision and the responsibility of the decision maker.

change in monetized benefits across groups may be of concern in its own right, in isolation it does not inform the question of whether the policy increases or reduces pre-existing differences.

Analysis of non-monetized physical indicators when there are multiple health and environmental outcomes brings challenges of aggregation, particularly if various policy options affect end points to different degrees. It is not appropriate to sum over physical units because it necessarily entails normative value judgments regarding the weight to be given to each component (e.g., how many asthma cases are equivalent to a heart attack), which implicitly requires use of a social welfare function (see Chapter 10 of the *Economic Guidelines* for more information; U.S. EPA, 2012b).

While the use of a social welfare function that explicitly weighs one individual's preferences relative to another's is generally not recommended,[49] in some circumstances it may be possible to multiply the incidence of each outcome for each population group by the value of society's willingness to pay to avoid the outcome and sum up across all outcomes in each policy scenario.[50]

5.3 Methods to Assess Potential EJ Concerns

This section describes a variety of transparent, scientifically sound approaches for presenting EJ information on regulatory actions for the public and decision makers: specifically, the evaluation of whether there is a potential pre-existing EJ concern and whether any new concerns are created for population groups of concern.

In general, the scope and complexity of the information presented hinges upon the quality and specificity of the input data available. Text Box 5.3 gives an example of how data quality may affect the level of analysis in an air quality context. Such input data may include:

- Demographic characteristics (e.g., age/sex/race/ethnicity);
- Baseline health data (e.g., hospital and emergency admissions; race/ethnicity-stratified mortality rates; race/ethnicity/age-stratified asthma prevalence rates);
- Income data (e.g., median income or population count below poverty level);
- Risk coefficients stratified by socio-economic variables (e.g., education, race/ethnicity);
- Distribution of health effects (or the available proxy such as emissions, ambient concentrations, biomarkers, proximity) in the baseline and under each regulatory option; and
- Distribution of costs, when relevant (see Section 5.5.1).

When data are available, an analyst should present basic summary information for the baseline and each regulatory option for the relevant endpoints for the population groups of concern relative to a comparison

[49] The use of a social welfare function requires decisions regarding the ranking of alternative outcomes (i.e., society's preferences for more or less equal distributions). There is no consensus regarding such rankings. Hence a universally accepted social welfare function does not exist.

[50] The EPA's current approach to valuing damages associated with carbon emissions may make it difficult to conduct a quantitative analysis of how domestic effects associated with the pollutant are distributed across population groups of concern. Difficulty parsing the effects across particular groups is due to estimation of a comprehensive measure of climate change damages resulting from a marginal change in emissions as opposed to the typical outcome-by-outcome approach employed by EPA, and the use of a global instead of domestic value of willingness to pay.

group (see Sections 2. 3 and 5.4.2). This basic information can be supplemented with other approaches described below when a screening analysis indicates that a more careful evaluation is needed.[51]

Regardless of the analytic methods used, information should be presented in a transparent way so that the decision maker can determine whether any identified differences across population groups constitute a disproportionate impact. Analysts should clearly present:

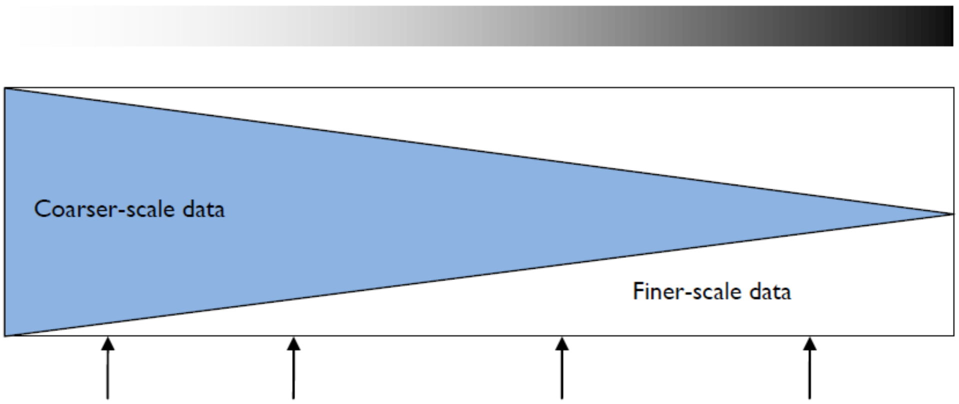
- Who is affected by the regulatory action;
- Main exposure pathways and expected health and environmental outcomes;
- Evidence for why risk, exposure, or outcomes may vary by population group;
- Relevant geographic scale;
- Main methods of analysis used;
- Summary statistics for the baseline and each regulatory option;
- An easy-to-understand description of what the summary statistics show;
- Conclusions based on the information available;
- Robustness of results across options presented, and
- Data quality and limitations that affect conclusions regarding potential disparate impacts.

In cases where limited quantitative data are available, an analyst should discuss any information that sheds light on whether minority, low-income or indigenous populations may be more susceptible to the regulated stressors, may be exposed through unique pathways, and how that may change with the regulation.[52] There may be cases where an analyst is also able to provide information on how population groups of concern are distributed in relation to where baseline emissions occur.

[51] The Interim Guidance on *Considering Environmental Justice During the Development of an Action* (U.S. EPA, 2010a) suggests conducting a screening analysis for determining when an action may require detailed evaluation.
[52] The terms susceptible and vulnerable are discussed in Section 3.

Text Box 5.3: Data Quality and Spatial Resolution in the Context of Air Regulations

Confidence in analysis (darker = higher level of confidence)



Examples of data used:	**(A)** Emission changes by source type; basic demographic data	**(B)** Source-level dispersion modeling; income by tract; state- or county-level baseline health data	**(C)** Regional photochemical air quality modeling; county-level health data; $PM_{2.5}$ & O_3 effect coefficients stratified by education/race	**(D)** Local-scale air quality modeling; ZIP or tract-level health data; city-level effect coefficients; projected incidence rates

An analyst's ability to address how a regulation changes the distribution of risk across population groups of concern hinges directly on the quality and spatial resolution of the data available. Finer-scale air quality, health and socioeconomic data allow one to assess the distribution of air pollution impacts across key population groups of concern and to have greater confidence in the conclusions drawn from these data. When air quality data are lacking or only available at a coarse-level, the ability to assess change in risk across populations and other conclusions are more limited.

An example in limited data environments: Using race-stratified county-level mortality and morbidity, one can calculate population-weighted mortality rates by county. One can then utilize a highly aggregated baseline air quality modeling projection (e.g., 12 or 36 km) to identify population groups most exposed to air pollution. Using GIS, it is possible to combine the two sources of data. The coarse geographic scale of air quality information may inhibit the ability to detect meaningful differences in impacts among and between groups. When risk coefficients are unavailable, it is not possible to estimate health impacts separately for each population group.

An example in data rich environments: Using finely resolved air quality data, one can identify at a highly disaggregated level (e.g., 1 km) population groups that experience the highest exposure to air pollution. One can also identify population groups who exhibit the highest baseline incidence or prevalence rates for air pollution health impacts at the zip code-level. Using geographic information system (GIS) modeling tools, one can join the two data sources. Using race-specific or standard risk coefficients one can then estimate health impacts for each population group.

5.3.1 Summary Statistics

Simple summary measures are a useful way to characterize potential differences in baseline and regulatory options across population groups of concern relative to appropriate comparison groups. A variety of measures can be used to characterize a regulatory action's health and environmental effects for population groups of concern (e.g., averages, ratios). This information should be sufficiently disaggregated so that the public can discern how risk, exposure, and/or health effects vary for different types of individuals within a population group, to the extent that such a detailed presentation is supported by underlying data. For instance, exposure or health outcomes can be presented for income quantiles in addition to presenting this information for those above or below a particular poverty threshold. Likewise, information on risk, exposure, and/or health effects can be presented for the average-exposed individual in each population group as well as a maximally exposed individual (for example, see Text Box 5.4). If particular communities are substantially affected, summary statistics can be shown at a locally disaggregated level as well as for the nation as a whole.

> *Analysts should follow identified best practices when feasible and applicable*. (Recommendation 5 in Section 1.2.)

Current practices – previously outlined in Text Box 1.1 - that may be helpful for evaluating potential EJ concerns include using the latest demographic data available; presenting information that shows the change in the difference in impacts across population groups; careful selection and justification of comparison group, presenting summary metrics for relevant population groups of concern and the comparison group; and characterizing the distribution of risks, exposures, or outcomes across individuals, lifestages or other relevant categories within each population group, not just average impacts. It is also recommended that analysts present disaggregate data to reveal important spatial differences (e.g., demographic information for each facility/ place), not just in aggregate, when feasible and appropriate. Analysts should conduct sensitivity analysis for important assumptions and parameters (e.g., resolution of demographic data) that may affect findings, when feasible and appropriate, and present available evidence on other relevant environmental stressors that may contribute to increased vulnerability or susceptibility for population groups of concern.

5.3.2 Additional Analytic Methods

As previously mentioned, the appropriate way to capture differences in health effects is to use information on risk and incidence disaggregated by groups to characterize the baseline and likely response to a change in exposure. Analysts should engage risk assessors early in the process to identify data needed for assessing potential EJ concerns that could be generated as part of the risk assessment (see Section 4 for a discussion of how to integrate EJ into a risk assessment). For an example of an analysis of potential EJ concerns that makes use of information on differences in mortality risk across population groups in the air quality context, see Text Box 5.4. The remainder of Section 5.3 discusses several possible analytic methods for evaluating impacts across population groups of concern: visual displays, proximity-based analysis, and methods that use exposure or risk information.

Text Box 5.4: Quantitative Approaches Used in the Final Rule for the Mercury and Air Toxics Standard (MATS) (U.S. EPA, 2011c)

Overall, this regulation will reduce emissions of hazardous and criteria air pollutants from electric generating units (EGUs). But because of possible shifts in electricity generation across EGUs, some communities could experience small increases in emissions. To evaluate how these changes in emissions and associated human health risks are distributed among population groups, the analysis uses two quantitative approaches.

First, the analysis utilizes a proximity-based approach to compare the aggregate average demographic composition (i.e., by ethnicity/race, age, and education) of communities within a 5 kilometer radius of specific EGUs covered by the rule to the national average. This approach is used as a proxy for exposure to hazardous air pollutants such as nickel and chromium, for which the health effects are expected to be localized.

Second, the analysis characterizes the distribution of mortality risk associated with fine particulate matter ($PM_{2.5}$) in the baseline and after implementation of the final rule. Proximity-based analysis is not a good proxy in this case because criteria air pollutants often travel long distances from sources, and because the formation of $PM_{2.5}$ is governed by a series of complex reactions in the atmosphere. Using methods generally consistent with those used in other parts of the regulatory analysis, mortality risk associated with $PM_{2.5}$ in the baseline is examined across population groups by county. There are two differences in methodology: First, the baseline mortality rates differ from what is used in the regulatory analysis in order to stratify by race. Second, mortality risk coefficients differ to allow for variation by education level (instead of applying the same risk coefficient across all socioeconomic groups).

Using a photochemical grid model and BenMAP (a GIS-based tool that estimates health impacts based on air pollution concentrations), EPA estimates changes in mortality risk in the baseline and after implementation of the final rule for individuals living in counties with the highest $PM_{2.5}$ mortality risk in 2005 (defined as the top 5 percent), stratified by race, income, and educational attainment. Finally, the analysis compares the change in risk for people living in "high risk" counties to that for people living in other counties. An example of a table used to present this information is included below. It shows the estimated change in the percentage of all deaths attributable to $PM_{2.5}$ before and after implementation of MATS in 2015 for each population, by race. Populations that are living in "high risk" counties experience reductions in mortality risk that are at least as great as for those populations living in other counties, and this occurred regardless of race.

Estimated Change in the Percentage of All Deaths Attributable to PM2.5 Before and After Implementation of MATS by 2016 for Each Populations, Stratified by Race

Year	Race			
	Asian	Black	Native American	White
Among populations at greater risk				
2016 (pre-MATS rule)	4.3%	4.4%	4.4%	4.5%
2016 (post-MATS rule)	4.1%	4.1%	4.2	4.3%
Among all other populations				
2016 (pre-MATS rule)	3.2%	3.1%	3.1%	3.3%
2016 (post-MATS rule)	3.0%	2.9%	2.9%	3.1%

Source: Table 7-17 in the Regulatory Impact Analysis for the Final Mercury and Air Toxics Standard (U.S. EPA, 2011c)

5.3.2.1 Visual Displays

Visual displays such as maps, charts, and graphs are commonly used as a way to present information when the stressor and demographic groups are geographically distributed. Visual displays can be helpful in displaying baseline levels of air pollutants or clusters of hazardous waste sites, and then overlaying the demographic profile and baseline health status of various population groups of concern. In this way, analysts can identify any potential "hot spots" where high levels of pollution are found in communities with minority, low-income or indigenous populations.

Visual displays are a useful way to communicate large amount of information in an easily digestible form (see Text Boxes 5.1 and 5.5 for examples). However, these displays have been criticized for leading to erroneous conclusions regarding impacts. For instance, it is difficult to discern differences between baseline and regulatory options unless differences are large. However, smaller differences – for instance, those not discernible on a map - could still be important.[53] For this reason, visual displays are only suggestive of potential effects and should be combined with more precise analytic techniques to further refine conclusions.

5.3.2.2 Proximity-Based Analysis

Proximity- or distance-based analysis is an approach commonly used in the literature as a surrogate for a direct measure of risk or exposure when such information is not available (United Church of Christ, 1987; Baden and Coursey, 2002; Cameron and Crawford, 2003; Wolverton, 2009). Using this approach, it is possible to compare the demographic and socioeconomic characteristics of population groups affected by a particular source (e.g., a waste site or permitted facility) to the demographic and socioeconomic characteristics of population groups unaffected by the source. Text Boxes 5.4 and 5.6 illustrate how it has been used in a rulemaking context at EPA. It is important to note that proximity-based approaches should not be used if the risks associated with the stressor of concern are not reasonably correlated with the geographic location of its source.

For practical reasons, the boundary of an "affected" versus "unaffected" area is usually based on a Census-defined geographic area (e.g., census tract) or a GIS-defined concentric buffer (e.g., a specified radius around a site that reflects the distance a particular pollutant may travel). When mapping the location of polluting sources, it is clearly paramount to have accurate spatial information on sources. Analysts should decide what distance from the facility most accurately reflects the community's exposure to a stressor. Buffer-based approaches around an emissions source can be chosen such that they more closely approximate actual risk and exposure, though it must be uniform around each source. It is also possible to use more continuous measures of distance such as distance to the nearest polluting site or, when additional information is available, an emission-weighted distance measure. In some cases, it may be possible to use dispersion models to select a buffer that approximates the effect of atmospheric conditions (for instance, wind direction and weather patterns) on exposure, though these types of models are data-intensive.[54] Regardless of how the boundary is defined, the proximity-based approach assumes that the effects of the stressor only occur within the designated boundary (i.e., people located outside the boundary do not suffer ill effects from the stressor) and that all individuals residing within the boundary are equally exposed.[55]

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[53] See Chakraborty and Maantay (2011) for further discussion of the limitations of using GIS for EJ analyses.

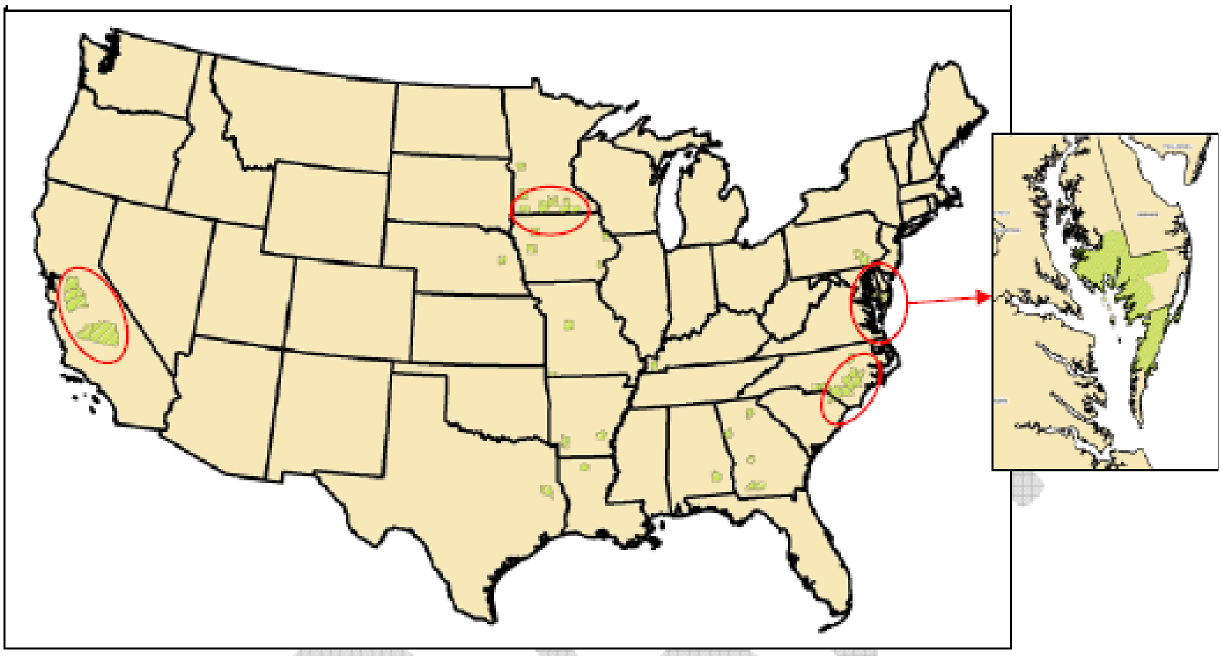
[54] For an overview of proximity analysis, including a discussion of various spatial analysis techniques used in the literature, see Chakraborty and Maantay (2011) and Mohai and Saha (2007).

[55] Chakraborty and Maantay (2011) identify another assumption: that communities with more than one pollutant source are treated the same as those with only one source. One can account for this through the use of a count regression technique. However, each pollutant source is treated as identical with regard to its effect on the health of the surrounding community. In reality, these sources could vary widely in size, age, and production techniques resulting in differing amounts of pollution released into the environment.

Text Box 5.5: Use of Visual Displays to Characterize EJ Concerns in the Proposed Reporting Rule for Concentrated Animal Feeding Operations (U.S. EPA, 2011d)

The objective of this proposed rule was to collect facility information from concentrated animal feeding operations (CAFOs). This rulemaking addressed reporting requirements rather than technical operations at CAFOs, and thus did not include an assessment of water quality impacts deriving from the proposed requirements. For this reason, the analysis of EJ concerns only focused on outreach to potentially affected communities regarding the content and utility of the new data. (Note: EPA ultimately withdrew this rule.)

In particular, the analysis identified areas in the United States with large numbers of CAFOs as well as high concentrations of minority or low-income populations. The location of large livestock operations was identified at the county level from custom tabulations of U.S. Census of Agriculture data and used as a proxy for CAFOs. The analysis combined this data on CAFOs with information on minority or low-income populations at the Census tract level from the U.S. Census of Population and Housing. Because CAFOs are located in rural areas, urban census tracts were excluded from the dataset. Using geographic information system (GIS) modeling tools, information from these two data sources are overlaid and presented visually. Areas circled in red on the map identify communities with both a high number of CAFOs and population groups of concern.



Source: Figure 3 in Analysis to Address Environmental Justice for National Pollution Discharge Elimination System (NPDES) Concentration Animal Feeding Operation (CAFO) Rule (U.S. EPA 2011d). Note this proposed rule has been withdrawn.

The results of proximity-based analyses also often depend on the choice of the geographic unit of analysis (e.g., Ringquist, 2005; Mohai and Saha, 2007). For this reason, an analyst should explore alternative geographic units or distances when defining proximity to a source.

The two groups – individuals located near and far from the source – can be compared on the basis of simple statistical or regression estimation techniques. Statistical tests on summary data can be used to identify whether, on average, there are statistically discernible differences in the characteristics of the two groups. Regression techniques such as a binary logit also can be used to formally make this comparison (where 1 indicates areas where one or more sources are located, and 0 indicates areas with no sources of the stressor). A significant coefficient on a demographic variable such as poverty indicates a statistically measurable difference in the variable across geographic areas with and without stressor sources.

Text Box 5.6: Proximity-Based Analysis in the Definition of Solid Waste Proposed Rule (U.S. EPA, 2011e)

This proposed regulation would allow recycling of hazardous secondary materials, and implies that some facilities may process higher amounts of hazardous material than was the case prior to the rule. After identifying potential hazards that could pose risks to human health from the recycling of hazardous materials and the likelihood that they could occur under the new requirements, the analysis uses a proximity-based approach to evaluate the potential for EJ concerns. First, the analysis identifies the location and type of facilities that may handle secondary recycled materials (both existing and those that may come on-line in the future). Using GIS tools, the analysis then draws a 3 kilometer radius boundary around each facility to compare the average demographic characteristics of communities within the buffer to those outside of it at the state and national level. State-level comparisons are included to account for differences in the way Resource Conservation and Recovery Act (RCRA) programs are implemented (which is done at the state-level). The demographic characteristics used to make these comparisons are minority, American Indian/Alaskan Native, persons below poverty, and children under five years old.

The analysis uses several types of summary statistics for these comparisons. First, it evaluates whether communities with a particular type of facility have higher or lower percent minority or low-income populations on average, and the degree to which they differ from communities without a facility. Second, the analysis generates two types of ratios to determine whether (1) there is a substantially greater probability that minority or low-income populations will be affected in comparison to non-minority or non-low income populations (referred to as an "affected population ratio"), and (2) minority or low-income populations comprise a greater proportion of the affected population than the unaffected population (referred to as a "demographic ratio"). Each of these metrics is also calculated separately for urban and rural populations (based on Census definitions that use population density to determine a rural or urban area) to examine whether the propensity for hazardous material recycling facilities to locate in urban areas affects the results. The analysis then evaluates whether statistically distinguishable differences exist for each metric.

In addition, the analysis qualitatively discusses factors that may affect the vulnerability of affected populations to pollutants associated with recycling of hazardous materials at nearby facilities. The analysis ends with a discussion of potential strategies to prevent non-compliance and ways to mitigate the potential adverse impacts identified in the analysis.

5.3.2.3 More Advanced Methods

When data are available, analysts may want to use emissions or ambient concentration data combined with fate and transport modeling to examine distributional effects at a disaggregated level. For instance, criteria air pollutants are monitored nationally while data on hazardous air pollutants are available through EPA's National Air Toxics Assessment (NATA). These monitoring data can be combined with demographic data and dispersion models to generate baseline and regulatory distributions of pollutants by population groups of concern. Appendix B discusses this in more detail.

In cases where disaggregated information is available on the types of activities that result in differences in exposure across population groups of concern, it may be possible to characterize differences in various health effects due to the regulatory action. In some cases it also may be possible to combine exposure data with information on differences in risk across population groups (see Text Box 5.4).

5.4 Analytical Considerations

Regardless of the analytic approach taken, there are a number of key decisions that an analyst needs to make that can have a substantial effect on the results, including: the geographic scope of the analysis; the comparison group; and, for regulatory actions where health effects have distinct spatial distributions, how to spatially identify and aggregate effects across affected and unaffected (i.e., comparison group) populations.

5.4.1 Geographic Scope

The geographic scope of analysis for an EPA regulatory action is often the entire country since requirements typically apply nationally. However, there may be circumstances under which a regulatory action's effects occur mainly at a sub-national level. For example, some regulatory actions are more regional in scope or have effects that are expected to be concentrated in particular regions or states. In such cases, it may make sense for an analyst to also analyze and present differences in health and environmental outcomes across population groups of concern at a sub-national level.

5.4.2 Comparison Group

As previously discussed in section 2.3, for decision makers to determine whether impacts on population groups of concern are disproportionate, an analyst needs to present them with information that compares changes experienced by one group to those of a comparison group. The way the comparison group is defined can have important implications for evaluating changes in health, risk, or exposure effects across population groups of concern relative to the baseline.

It is possible to define the comparison group as individuals with similar socioeconomic characteristics unaffected by the regulation (i.e., within-group comparison) or as individuals that are also affected by the regulation but have different socioeconomic characteristics (i.e., between-group comparison). From the perspective of E.O. 12898 and EPA's EJ policies, a between-group comparison is probably more relevant because it is the differences across groups that is of primary importance.

As with geographic scope, some have argued (e.g., Bowen, 2001) that restricting the comparison group to a sub-national level may be more defensible than a national level comparison in some instances, given heterogeneity in industrial development and economic growth and inherent differences in socioeconomic composition across geographic regions (e.g., relatively more Hispanics reside in the Southwest). However, Ringquist (2005) notes that placing restrictions on comparison groups may "reduce the power of statistical tests by reducing sample sizes" or bias the results against finding disproportionate impacts because such restrictions reduce variation in socioeconomic variables of concern.

Since results often are sensitive to the comparison group chosen, analysts should consider conducting sensitivity analysis regarding how the comparison group is defined.

5.4.3 How to Spatially Identify and Aggregate Effects

Spatial distribution of health outcomes is a relevant consideration for some regulations, such as those that reduce emissions from point sources that have fairly localized effects. In other cases, the regulation's effects may be more wide spread. For instance, the effects of a national regulation on a chemical product does not hinge on the spatial distribution of health and environmental outcomes but instead on variation in the purchase, use, transport, and disposal of this product. Text Box 5.2 provides an example of qualitative discussions for disperse stressors.

When human health outcomes are spatially distributed, analysts need to determine how to spatially identify and aggregate affected and unaffected (i.e., comparison group) populations. The nature of the stressor should guide an analyst's choice of the geographic area of analysis. Some air pollutants, for example, may travel long distances, affecting individuals hundreds of miles away from the source, making it appropriate to choose a relatively large geographic area. In contrast, water pollutants or waste facilities may have more localized effects, making it appropriate to select relatively small areas for analysis. Likewise, an assessment of local impacts from point sources may call for more spatially resolved air quality, demographic and health data than those that affect regional air quality. The quality and type of data available also affect the spatial resolution of the analysis. Using more than one geographic area of analysis to examine the robustness of results may also be useful since effects are unlikely to be neatly contained within geographic boundaries and results may be sensitive to the choice of the geographic area of analysis (Mohai and Bryant, 1992; Baden et al., 2007).

Census-based definitions often reflect topographical features such as rivers, highways, and railroads. As a result, they may exclude a portion of the affected population who, although separated by some physical feature, have the same adverse impacts. While Census-based definitions are easily accessible and offer many options with regard to geographic scale, use of geographic information system (GIS) software allows for a potentially more flexible approach. GIS-based methods enable analysts to define spatial buffers around an emissions source that are more uniform in size and that are easier to customize to reflect the appropriate scale and characteristics of the emissions being analyzed (e.g., fate and transport) for a given policy action.[56]

5.4.4 Statistical Significance

The extent to which a finding of statistical significance can be interpreted as evidence of differential impacts depends on a number of factors. First, a statistical difference does not necessarily indicate that the difference is meaningful from a policy perspective. For instance, suppose an analyst finds that poor households are more likely to locate near a pollution source than wealthier households and that this effect is statistically significant. This indicates that the effect is statistically distinguishable from zero (i.e., not due to sampling error). However, the difference in likelihood between these types of households could still be quite small. Analysts will need to examine what the coefficent estimate implies (e.g., how different is poverty across these geographic areas). Second, many of the demographic and socioeconomic characteristics that are often included in these types of regressions are highly correlated with each other, making it difficult to interpret the meaning of a coefficient on any given variable. Third, it is important that analysts consider other factors aside from demographic and socioeconomic characteristics that may have influenced the location of stressor sources. Regression techniques are able to partially control for these factors, while the use of statistical tests on summary data cannot. Finally, it is important that analysts be aware of the biases and limitations that are introduced when proximity or distance is used as a substitute for risk and exposure modeling and that these limitations be clearly discussed (see Chakraborty and

[56] There are a number of challenges typical of geospatial data. Some statistical techniques rely on assumptions that are regularly violated by these types of data (Chakraborty and Maantay, 2011). For instance, when data are spatially autocorrelated – locations in closer proximity are more highly correlated than those further away – they violate the assumption that underlies some regression and statistical techniques that error terms are independently distributed.

Maantay, 2011). Given the analytic challenges associated with proximity-based analysis, analysts may only be able to draw limited conclusions regarding the possibility of differences across populations groups.

5.5 Assessing the Distribution of Costs and Other Impacts

This section covers the following topics: when it may be appropriate to evaluate the distribution of costs across population groups of concern; and the evaluation of non-health impacts.

5.5.1 The Distribution of Costs

This technical guidance focuses on providing information to decision makers so that they can assess the potential for disproportionate health impacts of regulations on population groups of concern. However, certain directives (e.g., E.O. 13175 and OMB Circular A-4) identify the distribution of economic costs as an important consideration. While health or environmental improvements may benefit certain population groups of concern, their costs may be borne by others.

> *Analysts should consider distribution of costs associated with implementing a regulatory option from an EJ perspective when appropriate and relevant.* (Recommendation 6 in Section 1.2.)[57]

Consideration of the distribution of costs in the context of EJ is not always necessary.[58] Often, the costs of regulation are passed onto consumers as higher prices that are spread fairly evenly across many households. When these price increases are small, the effect on an individual household also will likely be relatively small and not warrant further analysis. However, there may be situations where further exploration of the distribution of costs is warranted. Whether to undertake such an analysis is a case-by-case determination. Examples when such consideration is warranted include: costs to consumers may be concentrated among particular types of households such that they impose a noticeable burden (see Text Box 5.7, for example); identifiable plant closures or relocation of facilities; or behavioral changes in response to a rule or regulation. When this is the case, analysts should consider including an analysis of costs when evaluating potential EJ concerns.

Data or methods may not exist to fully examine the distributional implications of costs across population groups of concern. For example, an analyst may not have information on whether assistance is available to low-income consumers to offset any differences in cost or whether consumption patterns differ substantially by race/ethnicity and income. Absent such data, it is difficult to precisely predict the regulatory action's impact on different population groups of concern. In these instances, the issue can be qualitatively discussed.[59]

[57] Recommendation 5 from Section 1.2 pertains to the use of scoping questions in the planning of a human health risk assessment and therefore is referenced in Section 4.3.2.1.

[58] By costs we refer to the direct and indirect costs to consumers. There may be other impacts of a rule (e.g., employment effects), but understanding how all impacts vary across population groups of concern may not be feasible. For example, data on the distribution of changes in employment across low-income and minority populations may be difficult to assess.

[59] Under some environmental statutes, EPA performs "affordability analyses," the purpose of which is to evaluate how increased costs of a regulatory action are passed through in the price of a household good or service and how this affects the purchase decision. For instance, the increased costs to a rural water system of new effluent requirements could affect a household's decision to purchase a new home. Because affordability analyses often differentiate purchase decisions by income, they may be a good starting point for information useful for evaluating potential EJ concerns.

Text Box 5.7: Example of Qualitative Discussion of Costs from Lead Renovation, Remodeling, and Painting Final Rule (U.S. EPA 2008)

This rule requires renovators to adhere to certain work practices that reduce risk of exposure to lead dust and is expected to raise the cost of renovations. The analysis includes a qualitative assessment of how minority or low-income households could be affected by the rule in terms of both cost and human health impacts. Excerpts are included below:

"Because these disadvantaged groups are more likely to reside in rental and older housing, they are more likely to be affected under the options that emphasize regulating older and/or rental housing. In addition, individuals and children with food insecurity (i.e., those who do not have healthy diets or do not eat enough because of poverty) are more susceptible to ill health effects from lead dust. Thus, they stand to accrue greater benefits under all of the options considered.

Following the work practice, cleaning, and cleaning verification steps specified in the rule will increase the costs for renovation, repair and painting activities covered by the rule. These additional costs may lead some lower income homeowners or some landlords of properties in lower income neighborhoods to avoid using certified renovators or recommended practices. The incremental costs of the rule's work practices are typically below $200. These costs are likely to be a small part of the total cost of the renovation, repair, and painting projects. EPA believes that these costs are unlikely to result in significant changes in consumer behavior. If however, the increased costs result in more projects being undertaken by uncertified firms or by do-it yourselfers, the risks in these instances would be the same as in the baseline and would not constitute new risks resulting from the rule. EPA believes that the rule would result in new risks only if the increased costs caused individuals to delay work such as painting until lead-based paint began peeling and chipping, creating a lead hazard. This is expected to occur infrequently given the rule's low cost per event."

5.5.2 Other Impacts

Non-health endpoints may be unevenly distributed across population groups. Alternatively, some population groups may place a higher cultural value on the environmental quality or ecological condition of particular places. Data on the distribution of baseline conditions by non-health endpoints are often not easily available or are difficult to quantify. For instance, data on ecosystem services in the United States is of much poorer quality than data for identifying baseline criteria air pollution levels and mortality incidence. Likewise, data and models to assess how various regulatory options affect non-health endpoints may not be available.

Given these challenges, analysts should identify any non-health endpoints that may be affected by the regulatory action, noting any that are of cultural importance for population groups of concern, and discuss how they may be distributed across population groups in the baseline. Conditions under various policy options and their effect on non-health endpoints should be qualitatively discussed if feasible. When data are available, analysts should use them in the evaluation.

Section 6: Key Near-Term Research Priorities to Fill Key Data and Methodological Gaps

This section will be added at a later date and will summarize identified data and methodological gaps in conducting analyses of EJ concerns based on internal and external peer review comments.

Glossary

Adverse effect: a biochemical change, functional impairment, or pathological lesion that either singly or in combination adversely affects the performance of the whole organism or reduces an organism's ability to respond to an additional environmental challenge.

Agency actions: includes rules, policy statements, risk assessments, guidance documents, and models that may be used in future rulemakings, and strategies that are related to regulations.

Background exposures: potential exposures due to background levels of both naturally occurring and anthropogenic sources.

Baseline: describes an initial, status quo scenario that is used for comparison with one or more alternative scenarios. In typical economic analyses, the baseline is defined as the best assessment of the world absent the proposed regulation or policy action.

Comparison group: see Sections 2.3 and 5.4.2.

Contaminant: a substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects. Also see "stressor."

Cumulative risk assessment: an analysis, characterization, and possible quantification of the combined risks to human health or the environment from multiple agents or stressors.

Disproportionate risk: see Section 2.4.

Dose: the amount of a substance that enters a target in a specified period of time after crossing an exposure surface.

Dose-response assessment: a determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or as the probability of occurrence within a population.

Effects: refers to risks, exposures, and outcomes and is sometimes used interchangeably with the term, "impacts."

Effects modifier: factors that may influence susceptibility, and may include genetics, diet, nutritional status, pre-existing disease, psychological stress, co-exposure to similarly acting toxics, and cumulative burden of disease resulting from exposure to all stressors throughout the course of life.

Environmental justice: the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.

Environmental justice concern: In this document, potentially disproportionate impacts on minority, low-income, or indigenous populations that exist prior to or that may be created by a proposed action. It can also indicate the actual or potential lack of fair treatment or meaningful involvement of minority, low-income, or indigenous populations in the development, implementation, and enforcement of environmental laws, regulations, and policies.

Exposure: human contact with environmental contaminants in media including air, water, soil, and food.

Exposure Assessment: an identification and evaluation of the human population exposed to a toxic agent, describing its composition and size, as well as the type, magnitude, frequency, route and duration of exposure.

Fair treatment: no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.

Hazard: inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or population is exposed to that agent.

Human health risk assessment (HHRA): the process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future.

Lifestage: a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth.

Low-income: see Section 2.2.2.

Meaningful involvement: occurs when 1) potentially affected community members have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; 2) the public's contribution can influence the regulatory agency's decision; 3) the concerns of all participants involved will be considered in the decision-making process; and 4) the decision makers seek out and facilitate the involvement of those potentially affected.

Minority: see Section 2.2.1.

Pollutant: an emitted substance that is regulated or monitored for its potential to cause harm to the health of individuals or to the environment.

Population groups of concern: in this document, minority, low-income and indigenous populations in the United States and its territories and possessions.

Proximity analysis: see section 5; analytical approach using spatial data to estimate a populations' risk or exposure to a stressor when direct measurement of risk or exposure is unavailable.

Reference group: see Sections 2.3 and 5.4.2. (synonym for comparison group).

Regulatory action: a subset of Agency actions conducted in direct support of a rulemaking; means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

Regulatory analysis: a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules.

Risk: the probability of an adverse effect in an organism, system, or population caused under specified circumstances by exposure to an agent.

Risk analyst/assessor: plans and conducts a risk assessment. provides a transparent description of all aspects of the risk assessment (e.g., default assumptions, data selected and policy choices) to make clear the range of plausible risk associated with each risk management option.

Risk management: in the context of human health, a decision making process that accounts for political, social, economic and engineering implications together with risk-related information in order to develop, analyze and compare management options and select the appropriate managerial response to a potential chronic health hazard.

Source: the origin of potential contaminants.

Susceptibility: increased likelihood of an adverse effect, often discussed in terms of relationship to a factor that can be used to describe a population group (e.g., life stage, demographic feature, or genetic characteristic). In this document, the term refers to an individual who is more responsive to exposure.

Stressor: a stressor is any physical, chemical, or biological entity that can induce an adverse response. Stressors may adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact. In this document, the term is used to encompass the range of chemical, physical, or biological agents, contaminants, or pollutants that may be subject to a rulemaking.

Stakeholders: broadly defined as the interested parties who are concerned with the decisions made about how a risk may be avoided, mitigated, or eliminated, as well as those who may be affected by regulatory decisions.

Summary statistics: see Section 5; descriptive statistics which provide an overview of available data and may include the mean, median, mode, interquartile mean, range, and/or standard deviation, etc.

Vulnerability: physical, chemical, biological, social, and cultural factors that result in certain communities and population groups being more susceptible or more exposed to environmental toxins, or having compromised ability to cope with and/or recover from such exposure.

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Appendix A: Select Examples of EPA Guidance, Guidelines, and Policy Documents that May Be Helpful When Evaluating Potential EJ Concerns for Regulatory Actions

Topic Area	Title	Publication Year	Weblink
Economics	Guidelines for Preparing Economic Analyses	2010	http://yosemite.epa.gov/ee/epa/eed.nsf/pages/guidelines.html
Action Development Process	EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action	2010	http://www.epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf
Human Health Risk Frameworks	Framework for Human Health Risk Assessment to Inform Decision Making (Draft)	2012	http://www.epa.gov/raf/frameworkhhra.htm
	Framework for Assessing Health Risk of Environmental Exposures to Children	2006	http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363
Other Health Risk Guidance	Guideline for Microbial Risk Assessment: Pathogenic Microorganisms with Focus on Food and Water	2012	http://www.epa.gov/raf/microbial.htm
	Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens	2005	http://www.epa.gov/ttnatw01/childrens_supplement_final.pdf
	Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures	1986	http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533
Exposure Assessment	Exposure Factors Handbook	2011	http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252
	Exposure Assessment Guidelines	1992	http://www.epa.gov/raf/publications/guidelines-for-exposure-assessment.htm
Risk Characterization	Risk Characterization Handbook	2000	http://www.epa.gov/spc/2riskchr.htm
Cumulative Risk Assessment	Considerations for Developing a Dosimetry-Based Cumulative Risk Assessment Approach for Mixtures of Environmental Contaminants (Final Report)	2009	http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=172725
	Concepts, Methods, and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document (Final Report)	2008	http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=190187
	Framework for Cumulative Risk Assessment	2003	http://www.epa.gov/raf/publications/framework-cra.htm
	Cumulative Risk Planning and Scoping Guidance	1997	http://www.epa.gov/spc/2cumrisk.htm

Appendix B: Example Approaches to Address Potential EJ Concerns When Conducting Exposure and Dose-Response Assessments

The planning and scoping process provides a key opportunity to ensure that potential EJ concerns are incorporated into a risk assessment. This appendix provides several key EJ-specific questions to consider when designing an exposure or dose-response assessment, describing the implications of each question for the data and analytic work that may be necessary to address it. Also included are examples of analyses from the peer-reviewed literature and/or U.S. government analyses that may suggest approaches for an analyst to consider during planning and scoping.

Planning for an Exposure Assessment

Patterns of exposure to stressors across population groups of concern may vary for a number of reasons: it may be predominantly a spatial phenomenon, if exposure is highest within close proximity to pollution sources and that is where the population group of concern is most likely to reside; it may reflect variation in behaviors (e.g., subsistence anglers) or exposures due to specific dietary or cultural practices of a population group (e.g., exposures to pesticides in reeds used for basket weaving); it may reflect unique aspects of the use or application of the chemical (e.g., exposures to pesticide applicators); or it may be due to still other factors that vary by population group. Text Box B.1 illustrates how the five scoping questions (below) for integrating EJ into an exposure assessment could be posed to evaluate dietary risks from pesticide residues.

Questions and Key Considerations

1. Based on the use and release patterns of the environmental stressors of concern, are there population groups that might be more highly exposed?

Environmental stressors may be used and released in a variety of circumstances. However, even when the stressor is intended for use in a particular circumstance or location, unintended releases can result. For instance, the stressor could migrate to an unintended location. One example of this is spray dust from pesticide applications that result in drift falling on "off-target" locations, which may lead to increased exposure to certain populations (e.g., farmers, migrant workers, children, sprayers). Text Box B.2 discusses how the potential risk for exposure due to pesticide application and residues can be calculated using drift modeling and other methods while accounting for evaporation of aerosols (i.e. volatization), and the potential effects to bystanders. Some factors for consideration when evaluating the use and release patterns of environmental stressors include evaluating the potential for risks due to intended use and potential migration of the stressor, prevalence of use, environmental fate, and the toxicological characteristics of the stressor.

2. Are exposure variabilities predominantly a spatial phenomenon (e.g., due to contaminant hot spots)? Is proximity to source a reasonable proxy for estimating exposure to stressors of concern?

For environmental stressors that are dispersed locally in ambient media, exposure may be effectively captured using proximity to the source as a surrogate measure. Further detail about these methods can be found in the recent review by Chakraborty et al. (2011) and Section 5.

Text Box B.1: Example of Scoping Questions for Integrating EJ Considerations into Assessments of Dietary Risk from Pesticide Residues

To ensure that EJ considerations are explicitly considered in dietary risk assessments for pesticides, risk assessors could consider the following scoping questions when determining whether risk concerns may exist:

- Based on the pesticide use patterns, are there population groups that might be more highly exposed to pesticide residues because of their unique consumption patterns (e.g., unusual ethnic diets; subsistence consumers)?
- Is it likely that the pesticide or its metabolites/degradates will bioaccumulate such that increased exposure and risk might be expected for certain population groups (e.g., lifestages; subsistence consumers of fish, shellfish, game.)?
- Is the pesticide used on, or likely to be found in, foods that are consumed in significantly higher amounts by certain ethnic or other population groups (e.g., lemon grass; quinoa grain; broccoli raab)?
- Does the pesticide have an atypical or unusual use pattern that could result in unusual exposures for certain population groups (e.g., use of straw that is woven into baskets by American Indians; use in non-traditional agriculture; locally-restricted use)?
- Do the physical and/or chemical properties of the pesticide indicate a potential for long range transport (e.g., volatile, persistent), especially pesticides that may also bioaccumulate?
- Are there other groups within the population groups of concern (e.g. based on lifestage) who might be more highly exposed through their diet to the pesticide?

3. Can exposure variability be estimated using ambient contaminant concentrations, either measured or modeled? Are data available or can data be modeled at a reasonable spatial scale appropriate for available demographic data?

Ambient concentrations can be used to identify and assess spatial variability in exposure that may contribute to exposure differences between population groups. Two types of ambient concentration data exist: data from ambient air quality monitors and modeled estimates of ambient concentrations averaged over a period of time. Monitoring data generally offer a more accurate estimate of the level of exposure to a stressor. However, obtaining monitoring data at a level of geospatial resolution that allows for the evaluation of differences may not be feasible for a number of reasons, including: (1) some environmental stressors may not be routinely monitored (e.g. consumer products); and (2) coverage for routinely monitored stressors is insufficient to provide the level of geospatial resolution required to discern differences as most monitoring data are available only down to the county level. This lack of detail is problematic given that both racial, ethnic, and income diversity, and differences in ambient concentrations could vary widely with the level of geospatial resolution. An example of an alternative strategy for evaluating multi-pollutant settings is provided in Text Box B.3.

Modeled data can sometimes serve as a surrogate for monitoring data. Ambient air quality modeling methods have been developed to estimate ambient concentrations of a plume beyond its point of release, based on relevant factors such as meteorology and chemical characteristics (e.g., reactivity and solubility). However, the predictive accuracy of models is not comparable across stressors. Important considerations for using modeled data should include the predictive accuracy of the model for the stressor in question, and the ability to predict ambient concentrations for smaller geospatial units such as Census tracts. Data provided at a larger geospatial scale than the census tract may not be able to discern differences in exposure. An analyst may consider the use of screening models to highlight concerns about exposure differences, which can be evaluated in greater detail with more sophisticated models at a later stage.

4. Are bio-monitoring data available for the population groups of concern, including those with potentially elevated exposures?

Although analysis using bio-monitoring data can be time consuming, it may be the most accurate way to estimate exposures for population groups of concern. A literature search for previous assessments of differential exposure using survey data should be conducted prior to commencing such an analysis. An important resource to consider is the National Report on Human Exposure to Environmental Chemicals generated by the United States Centers for Disease Control (CDC, 2009). Human exposure data in this report are presented by lifestage, race/ethnicity and income to the extent that such detailed breakouts are possible.

When using exposure biomarkers to draw inferences about exposure differences in the context of source-specific regulation, an analyst should carefully consider the extent to which measured levels reflect exposure, and also whether biomarkers represent total exposure to an environmental stressor from multiple sources. Comparisons at this stage are often focused on point estimates or, at most, deterministic models rather than complex probabilistic models. An analyst may use simple, well-established comparative methods such as ratios to examine between-population group comparisons, or apply more complex approaches such as analysis of variance or regression techniques as needed. Comparisons may focus on particular segments of the distribution, (e.g., 95th percentile of minorities compared to 95th percentile of non-minorities) or on the percent of a population group represented within a percentile group (e.g., percent minorities compared to percent non-minorities in the 10th percentile of the population). Sometimes, several years of data may need to be combined to obtain sufficient sample size to conduct analysis in the tail of the distribution, though this would be subject to possible resource, analytic, and data constraints.

As discussed in Section 4.3.3.2 of this document, use of biomonitoring data has both benefits and limitations. While a large population survey (e.g., NHANES) may suggest the existence of exposure difference, locale- or site-specific surveys (e.g., NYCHANES) can yield more detailed insights into the dimensions of the differences. For example, analysis of NHANES data from 1999-2004 demonstrated that total organic blood mercury levels among New Yorkers was on average three times higher than the U.S. population, and highest among Asian New Yorkers. The NYCHANES data provided the additional perspective that among Asians, the levels were highest among foreign-born Chinese New Yorkers (Kass 2009).[60]

5. Are there population groups that may experience greater exposure to stressors because of their unique food consumption patterns, behaviors or use of certain cosmetics?

When planning for an assessment of potential EJ concerns, an analyst should consider whether the population group of concern has higher levels of exposure to a stressor due to food consumption patterns that differ from those of the general population (e.g., unique ethnic diets or subsistence living), behaviors (e.g., pica), or through use of imported cosmetics (e.g. dyes used for kumkum and bindi body art). Understanding potential exposures from these types of sources will allow more accurate estimates of exposures to the stressor of concern. Differences in exposures from ingestion may be due to several factors, including regional variation in dietary habits, and cultural, ethnic or religious practices. A population group of concern may consume certain foods at higher rates than members of other groups or consume parts of animals or plants not commonly consumed by the general population. For example, children in tribal communities may consume as much as fifteen times more fish than children in the general population (U.S. EPA, 2011g). Additionally, some population groups may eat food predominantly from specific locations. Likewise, subsistence fishers may consume fish far more frequently and obtain it only from local waterways. If fish from these waterways have higher levels of a contaminant, subsistence fishers may have higher exposure levels both due to their increased consumption of fish and their dependence on particular water sources (U.S. EPA, 2011g). Similar to foods, some cosmetics may contain lead. An analyst should evaluate the exposure pathway (e.g. dermal or inhalation), frequency of use, and identify the populations most likely to use these products in unique ways (Burger and Gochfield, 2011).

[60] Combining inferences from different surveys should be done with a clear and cautious understanding of the key attributes of each survey, including its design, the intended use of the data, how this intended use may bias the sample, statistical characteristics of each survey, and use of validated laboratory methods, among other considerations.

Text Box B.2: Pesticide Spray Drift Risk Assessment to Bystanders

Farm workers and their families often live near the fields where they work, and can be exposed to pesticides in a manner different from other population groups because of this proximity. While direct measures of the degree of drift in the vicinity of fields may be difficult or impossible to obtain, potential exposure estimates from these residues may be calculated using drift modeling and methods employed for typical residential risk assessments.

Spray drift can be characterized as the movement of aerosols and volatile components away from a treated area as a result of the application process. Bystanders, defined as those who live on, work in or frequent areas adjacent to treated fields, can be exposed to spray drift directly or by contact with resulting deposited residues (e.g., children playing on lawns next to treated fields). The degree of such impacts is governed by many processes (e.g., application method, nozzles used, release height) and the conditions at the time of application (e.g., wind speed and direction).

To model potential high-end exposure to people living near treated agricultural fields (e.g., via deposition on residential turf), EPA used AgDRIFT (V2.1.1) and AgDISP (V8.26) to provide deposition values for residential lawns, as a fraction of the application rate, at different distances downwind of a treated field.[1] AgDRIFT is used to estimate air concentrations at different distances downwind of a treated field. Analysis of spray drifts also includes evaluation of risks from pesticides used on turf because this scenario represents the highest potential for exposure associated with spray drift and considers different lifestages, including children at different developmental stages. Data from pesticide studies that determined turf residue levels and dissipation rates after application are often available, and in the absence of these data, default assumptions can be used. This information is used in conjunction with the standard residential methods to estimate exposure from treated turf, including exposures from the oral, dermal, and inhalation routes for both adults and children.

Along with these types of exposures, airborne concentrations of pesticides are also defined and used to estimate risks from inhalation exposure. For this calculation, concentrations are defined in the breathing zone (area around the nose, ~ 3 to 5 feet above ground for this analysis) at the edge of a hypothetical 50 foot wide lawn closest to the treated field.

Conceptual Model for Spray Drift Modeling

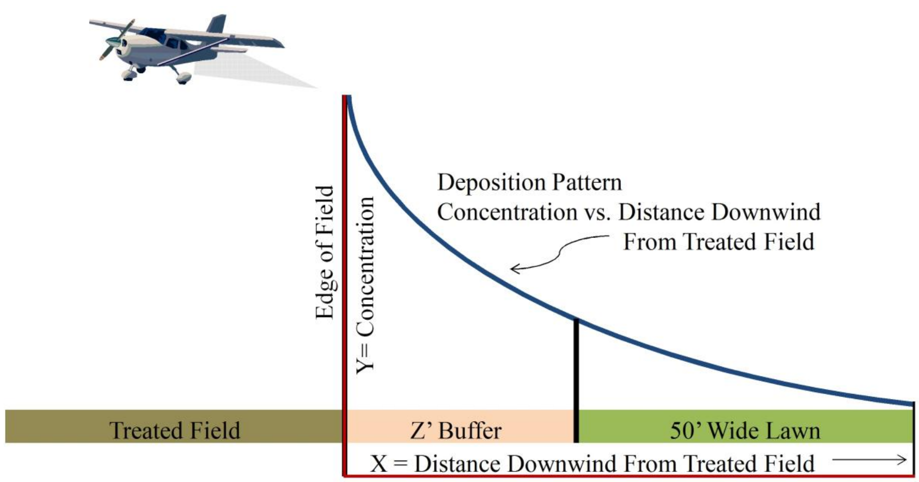


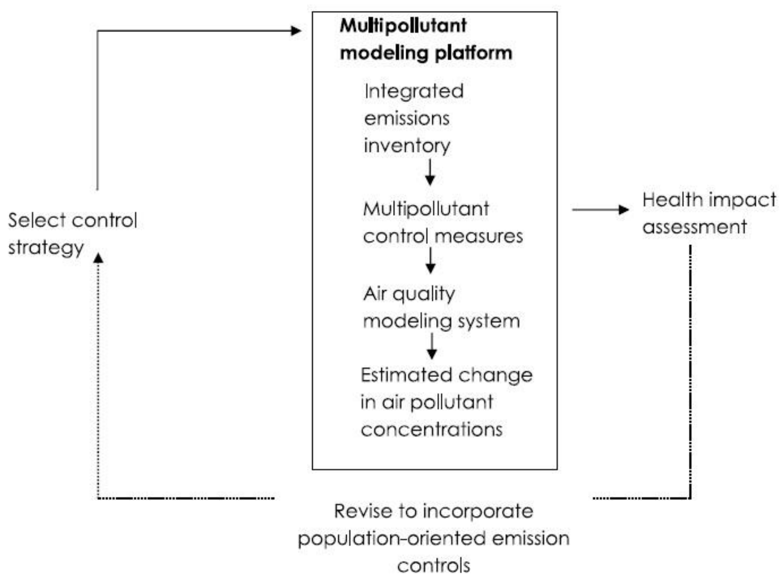
Figure may be found in *Chlorpyrifos, PC Code 059101, DP Barcode 399483 and 399485; Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures* (U.S. EPA, 2012g).

Text Box B.3: Detroit Multi-Pollutant Pilot Project Incorporating EJ

EPA conducted a peer-reviewed case study (Fann et al., 2011) to test whether a multi-pollutant, risk-based pollution control strategy - designed using spatially resolved air quality, population, and baseline health data in the Detroit metropolitan area - represented a viable alternative to a traditional pollutant-by-pollutant approach to air quality. The authors performed both within-group and between-group comparisons of exposure and risk. The objective of the case study was to demonstrate how states might design air quality attainment strategies that met multiple goals: (1) attaining a tighter National Ambient Air Quality Standard or NAAQS; (2) maximizing human health benefits of air quality improvements; and (3) achieving a more equitable distribution of air pollution-related risk.

The study characterized the costs, benefits and risk inequality implications of two alternative emission control scenarios constructed by Wesson et al. (2010) for the Detroit metropolitan area: a more traditional approach to pollution reduction for NAAQS compliance, and achieving compliance using a multi-pollutant strategy that maximized population risk reduction in the area. The assessment for potential EJ concerns followed four basic steps: (1) identify and model exposure to population groups susceptible and/or vulnerable to $PM_{2.5}$-related mortality and morbidity impacts in the baseline, based on fine scale air quality modeling and population characteristics including education attainment, race and poverty level; (2) design an emission control strategy that maximized air quality improvements among these population groups, primarily by reducing emissions of directly-emitted $PM_{2.5}$, which exhibits a strong spatial gradient; (3) compare the multi-pollutant, risk-based strategy with the traditional pollution control strategy for attainment by modeling the air quality impacts of each strategy and comparing the results with the baseline scenario; and (4) calculate the change in exposure/risk inequality from the baseline using economic measures to assess whether a multi-pollutant risk-based strategy results in a more equal distribution of exposure and risk than a traditional pollution control strategy. The findings from this study revealed that the population risk reduction approach produced greater net benefits.

Risk-Based, Multi-Pollutant Modeling Framework (Fann et al., 2011)



Additional information about the Detroit multi-stressor project can at: http://www.epa.gov/dears/info.htm

Planning For a Dose-Response Assessment

As part of the planning process, the dose-response assessment phase presents another opportunity to incorporate EJ concerns into a risk assessment. It plays a key role in identifying potential population groups of concern that may exhibit particular sensitivity to a stressor and in assessing how demographic characteristics might modify effects seen in the general U.S. population. If there are multiple stressors of concern for which a dose-response relationship has been drawn, the relationship of this dose-response to any susceptible population will be defined by whether there are factors particular to that population that may alter the dose-response relationship in question. For example, stress level is a recognized effect-modifer that may alter the dose-response curve for lead.

Below are a few key questions and sample responses that highlight the types and scale of analytic work that may be required to adequately integrate EJ concerns into a dose-response assessment.

Questions and Key Considerations

1. What demographic and population groups are most relevant from a risk perspective for the stressor in question?

The purpose of asking this question is two-fold: (1) defining the susceptible and vulnerable population groups and (2) considering what dose-response or concentration-response information is available for those population groups. The goal should be to achieve as close a match as possible between the information available in the literature and the dose-response function so that the information is not being stretched to fit a population group to which it does not apply. The answer to this question may involve stratification by race/ethnicity and income, or it might also include factors such as educational level, access to health care, and baseline disease prevalence (e.g., asthma).

2. Do population-specific dose-response functions exist for particular minority, low-income or indigenous populations?

   In answering this question, an analyst should investigate:

   - Are there known or identified effect modifiers?
   - For identified factors that modify risks of interest, how are they distributed among minority, low-income or indigenous populations?
   - Are different lifestages within population groups relevant to the distribution analyses?
   - Is the dose-response function the same for all population groups of concern?

To answer these questions, a thorough review of the relevant literature is necessary to identify potential sources of population group-specific dose-response information (see Text Boxes B.4 and B.5). An example of guidelines based on dose-response information is also provided in Text Box B.6.

Text Box B.4: Concentration-Response Functions Stratified by Demographic Factors

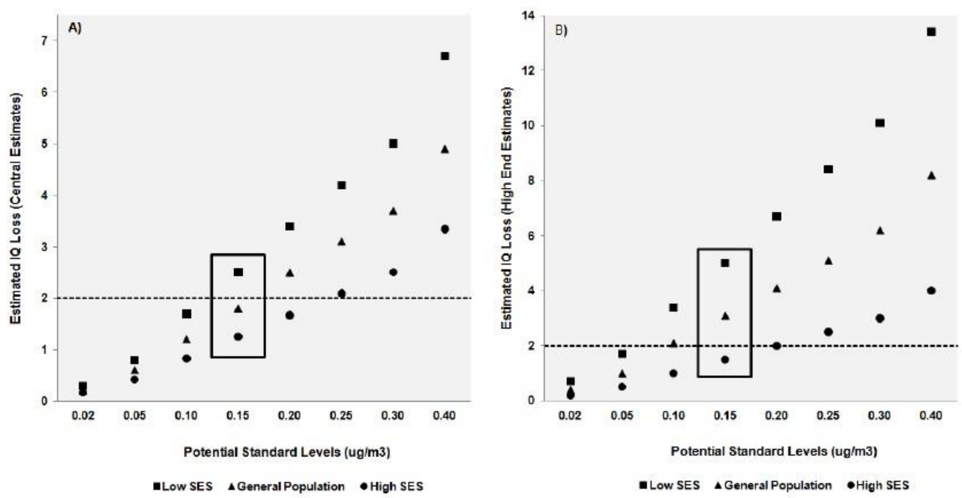
The literature on particulate matter (PM) provides examples of concentration-response functions stratified by demographic factors that may be indicative of socioeconomic status. In particular, the Regulatory Impact Analysis for the proposed PM NAAQS (U.S. EPA, 2012f) includes a distributional analysis of the estimated relative risk of $PM_{2.5}$-related mortality modified by race and educational attainment for counties projected to exceed baseline and rolled-back $PM_{2.5}$ standards. This analysis uses dose-response functions stratified by educational level from Krewski et al. (2000). Although dose-response functions modified by race were not available, the analysis relied on county-level baseline mortality rates stratified by race in place of race-specific functions. Similarly, Fann et al. (2011) incorporates educational attainment-specific dose-response functions from Krewski et al. (2009): "Krewski et al. find that educational attainment is inversely related to all-cause PM mortality risk, noting that '[a]lthough the reasons for this finding are unknown . . . level of education attainment may likely indicate the effects of complex and multifactorial socioeconomic processes on mortality or may reflect disproportionate pollution exposures" (Fann et al. 2011, pg. 912).

Text Box B.5: The Role of Socioeconomic Status as an Effect Modifier of Lead Neurotoxicity (Chari et al. 2012)

In this study the authors base their approach on a comprehensive literature review of available dose-response data on the human health effects of lead exposure for children ranging in age from 6 months to 13 years. "To identify candidate C[-]R [Concentration-Response] functions we relied on a previously conducted systematic review of studies assessing SES [socio-economic status] as an effect modifier of lead toxicity for neurocognitive, renal, and cardiovascular (hypertension) outcomes. C-R functions for neurocognitive outcomes were included in the present analysis if their associated studies focused on children, measured lead in blood, assessed global aspects of cognitive function (Mental Development Index (MDI) or IQ), and reported separate estimates for each socioeconomic level," (Chari et al. 2012). The Figure, reproduced from the Chari et al. paper, illustrates how SES modifies the effect of lead on IQ, with low-SES population groups exhibiting a greater response to a given level of lead exposure than the general population. Note that this study is only suggestive of the role of SES as an effect modifier of lead neurotoxicity due to study limitations (Murphy et al., 2013).

Central and High-End Estimates of IQ Loss for General Population and Susceptible Groups

Figure 2. Comparison of IQ loss estimates derived from general population and susceptible groups for two scenarios: (**A**) central estimates derived from median concentration-response (CR) functions; and (**B**) high-end estimates generated from the largest available CR function in each population (see Table 3). Differences across population groups are grouped according to potential standard level. Dotted line at 2 IQ points represents the acceptable risk level defined by EPA. A box surrounds estimates associated with the final standard.



3. Are the spatial and temporal scales of the study or studies supplying the dose-response function comparable to the spatial and temporal scales of the assessment of potential EJ concerns, from both an exposure and outcome perspective?

Ideally, the dose-response functions chosen should match as closely as possible the geographic scale of the proposed analysis for potential EJ concerns. An analyst may introduce measurement errors if dose-response functions from studies conducted over smaller geographic areas are applied at a more aggregate scale to evaluate potential EJ concerns. For example, if the study assigned each subject in the cohort a county-level average, the study could underestimate the true relationship between exposure and outcome for an analysis of potential EJ concerns at a finer spatial scale. Likewise, if the exposure in the study is acute, it cannot be applied directly to an analysis for potential EJ concerns where the exposure of interest is chronic; rather, the exposure duration being modeled in the regulatory analysis should be considered.

"[T]hese publications used coarse spatial resolution exposure measures to develop their concentration-response functions, which may result in exposure misclassification (and is not aligned with the fine spatial resolution of our exposure assessment). An analysis of a subset of the American Cancer Society cohort using more spatially refined exposure characterization… [indicates] that past studies may have underestimated the effects of PM2.5," (Levy et al., 2009, p.38).

Analysts may consider adjusting the geographic or temporal scope of an analysis for potential EJ concerns for this reason, and also may need to change the scope if detailed data on factors such as baseline health are available only at a certain scales (e.g., at the local urban level or at the acute exposure level).

Text Box B.6: Guidelines Based on Dose-Response Functions for Lead

The U.S. EPA's 2008 Lead Renovation, Repair, and Painting Program provides specific guidelines for population groups (e.g., children) whose dose-response functions for lead makes them exceptionally vulnerable to lead exposure: "Under this rule, a child-occupied facility is a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under 6 years of age, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least 3 hours and the combined weekly visits last at least 6 hours, and the combined annual visits last at least 60 hours. Child-occupied facilities may be located in public or commercial buildings or in target housing." (U.S. EPA, 2008b).