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Technical Guidance for Assessing Environmental Justice in Regulatory Analysis

Second Edition

Office of Policy
National Center for Environmental Economics

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Version

This document updates and supersedes the 2016 *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* and reflects advancements in the state of the science, new peer-reviewed Agency economic and risk assessment guidance, and lessons learned from conducting environmental justice analysis for EPA rulemakings since publication of the original guidance.

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Contributors

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Public Comment and Tribal Consultation

The draft revision of this document was published in the Federal Register for a 60-day public comment period, which was then extended for an additional 14 days. The EPA also conducted a Tribal consultation process concurrent with the public comment period.

Peer Review

The revised technical guidance was peer reviewed by external and independent experts through the EPA's Science Advisory Board (SAB). For information on the SAB process and the final report, see https://sab.epa.gov/ords/sab/r/sab_apex/sab/advisoryactivitydetail?p18_id=2642&clear=18&session=6657841334402.

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Glossary

The purpose of the Glossary is to aid analysts in understanding terms used throughout the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis*. The EPA recognizes that many definitions will continue to evolve and may be updated.[1]

Agency action: includes rulemakings and issuance of policy statements, orders, licenses, permits, and other actions (Administrative Procedure Act, 1946).

American Indian or Alaska Native: an individual with origins in any of the original peoples of North, Central, and South America (OMB, 2024).

Ancestry: a person's ethnic origin or descent, "roots," or heritage, or the place of birth of the person or the person's parents or ancestors before their arrival in the United States (U.S. Census Bureau, 2024).

Background exposures: potential exposures to stressors due to background levels of both naturally occurring and anthropogenic sources (U.S. EPA, 2024l).

Baseline: an analytically reasonable forecast of the way the world would look absent the regulatory action being assessed, including any expected changes to current conditions over time (OMB, 2023b).

Bioaccumulation: a process by which chemicals are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemical (U.S. EPA, 2010b).

Comparison population group: the effects of a regulatory action on population groups of concern need to be presented in relation to another group, which can be defined as individuals with similar socioeconomic characteristics in areas of the state, region, or nation unaffected by the regulatory action (i.e., within-group comparison) or as individuals with different socioeconomic characteristics within the affected areas (i.e., across-group comparison).

Contaminant: any physical, chemical, biological, or radiological substance found in air, water, soil, or biological matter that can have a harmful effect on people, animals, or plants. Also, see *stressor*.

Cumulative impact assessment: the process of accounting for cumulative impacts in the context of problem identification and decision-making (U.S. EPA, 2022c).

Cumulative impacts: the totality of exposures to combinations of chemical and nonchemical stressors and their effects on health, well-being, and quality of life outcome throughout a person's lifetime (U.S. EPA, 2022c).

Cumulative risk assessment: an analysis, characterization, and possible quantification of the combined risks to human health and/or the environment from multiple agents and/or stressors (U.S. EPA, 2003a).

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[1] Additional information about relevant EJ-related terminology is available at https://www.epa.gov/environmentaljustice/learn-about-environmental-justice.

Difference or differential: in this document, an analytically discernible (or measurable) distinction in effects or risks across population groups.

Disability: an individual with a disability is someone who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment (Americans with Disabilities Act, 1990).

Disproportionate: in this document, differences in effects or risks that are extensive enough that they may merit Agency action and should include consideration of cumulative impacts or risks where appropriate (U.S. EPA, 2022a).

Distributional analysis: characterizing how benefits and costs of a regulation are ultimately experienced across the population and economy, divided up in various ways (OMB, 2023b).

Dose: the amount of a substance that enters a target in a specified period of time after crossing an exposure surface (U.S. EPA, 2019a).

Dose-response assessment: analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or target population and the changes developed in that organism, system, or target population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population (U.S. EPA, 2019a).

Effects: risks, exposures, and outcomes caused by a chemical, activity, or process as it comes into contact with humans or the environment, sometimes used interchangeably with *impacts*.

Effect-modifier: another variable that when present causes the effect of the exposure on the outcome to differ (U.S. EPA, 2005a).

Environmental justice: the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision-making and other Federal activities that affect human health and the environment so that people are fully protected from disproportionate and adverse human health and environmental effects (including risks) and hazards, including those related to climate change, the cumulative impacts of environmental and other burdens, and the legacy of racism or other structural or systemic barriers; and have equitable access to a healthy, sustainable, and resilient environment in which to live, play, work, learn, grow, worship, and engage in cultural and subsistence practices (E.O. 14096).

Environmental justice concern: the actual or potential lack of just treatment or meaningful involvement of any population group, community, or geographic area (e.g., associated with differences in income, race, color, national origin, Tribal affiliation, or disability status) in the development, implementation, and enforcement of environmental laws, regulations, and policies (U.S. EPA, 2015a). For analytic purposes, it refers specifically to disproportionate and adverse health and environmental effects that may exist prior to or be created by the regulatory action. See *environmental justice*.

Environmental stressor: In this document, the range of chemical, physical, or biological agents, contaminants, or pollutants that may be subject to a rulemaking.

Equity: the consistent and systematic treatment of all individuals in a fair, just, and impartial manner, including individuals who belong to communities that often have been denied such treatment (E.O. 14091).

Exposure: human contact with environmental contaminants in media including air, water, soil, and food through inhalation, ingestion, or direct contact with the skin or eye.

Exposure assessment: the process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent and the size and characteristics of the population exposed (U.S. EPA, 2019a).

Exposure pathway: the course a chemical or contaminant takes from its source to the person being contacted (U.S. EPA, 2019a).

Extrinsic factors: factors or conditions acquired over a person's lifetime (e.g., socioeconomic status, disease status, stress, nutrition, lifestyle, workplace, geography, previous or ongoing exposure to multiple chemicals) that may contribute to increased vulnerability (U.S. EPA, 2022b).

Fit-for-purpose: the concept that risk assessments and associated products should be suitable and useful for their intended purpose(s), particularly for informing choices among risk management options (U.S. EPA, 2014b).

Hazard: inherent property of an agent, contaminant, or situation having the potential to cause adverse effects when an organism, system, or population is exposed to that stressor (U.S. EPA, 2011a).

Hazard identification: the process of determining whether a stressor has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances (U.S. EPA, 2014b).

Health impact assessment: a systematic process that uses an array of data sources and analytic methods and considers input from stakeholders to identify the potential effects of a proposed policy, plan, program, or project on the health of a population and the distribution of those effects within the population. HIA also provides recommendations on monitoring and managing those effects (NRC, 2011a).

Hot spot: a geographic area with a high level of pollution/contamination within a larger geographic area of more "normal" environmental quality (U.S. EPA, 2022i).

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 or other stressors in contaminated environmental media, now or in the future (https://www.epa.gov/risk/human-health-risk-assessment).

Indigenous Knowledge/Traditional Ecological Knowledge: a body of observations, oral and written knowledge, innovations, practices, and beliefs developed by Tribes and Indigenous Peoples through interaction with and experience with the environment (OSTP and CEQ, 2022).

Indigenous Peoples: includes state-recognized Tribes; Indigenous and Tribal community-based organizations; individual members of federally recognized Tribes, including those living on a different reservation or living outside Indian country; individual members of state-recognized Tribes; Native Hawaiians; Native Pacific Islanders; and individual Native Americans (U.S. EPA, 2014a).

Intrinsic factors: biological conditions or factors that cannot be altered (e.g., age, gender, genetic conditions) that may contribute to increased vulnerability (U.S. EPA, 2022b).

Lifestage: a temporal stage of life with distinct anatomical, physiological, behavioral, or functional characteristics that contribute to potential differences in vulnerability to environmental exposures (U.S. EPA, 2019a).

Low-income: individuals, households, or populations characterized by limited economic resources. The OMB has designated the U.S. Census Bureau's annual poverty measure as the official metric for program planning and analysis (OMB, 1978), although other definitions exist and may be appropriate as supplemental measures.

Meaningful involvement or Engagement: actions that agencies take to engage persons or communities with EJ concerns that are potentially affected by Federal activities by: providing timely opportunities for members of the public to share information and concerns and participate in decision-making processes; fully considering public input provided as part of decision-making processes; seeking out and encouraging the involvement of persons and communities affected by Federal activities; and providing technical assistance, tools, and resources to assist in facilitating meaningful and informed public participation, whenever practical and appropriate (E.O. 14096).

Non-environmental stressor: factors found in the built, natural, and social environments that can directly or indirectly adversely affect health or increase vulnerability to environmental stressors (Tulve et al., 2016)

Overburdened: in this document, population groups, communities, or geographic areas that potentially experience disproportionate environmental harms and risks due to greater vulnerability to environmental hazards, lack of opportunity for public participation, or other factors.

Participatory science: engages the public in advancing scientific knowledge by formulating research questions, collecting data, and interpreting results. This includes a broad and inclusive range of activities, from those originating in academic and government institutions that enlist the public in data collection to create knowledge, to community-led projects intended to identify potential EJ issues and community concerns (U.S. EPA, 2022e).

Peer review: a documented process conducted to ensure that activities are technically supportable, competently performed, properly documented, and consistent with established quality criteria (U.S. EPA, 2014b).

People of color: populations or individuals who list their racial status as a race other than White alone and/or list their ethnicity as Hispanic or Latino. That is, all people other than non-Hispanic White-alone individuals. The word *alone* in this case indicates that the person is of a single race, not multiracial. The term *people of color* is intended to be interchangeable with the term *minority populations*, as that term appears in numerous federal documents and statutes. (U.S. EPA, 2024c).

Plain language: writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience (The Plain Writing Act of 2010, Public Law 111-274).

Private costs: the costs that the purchaser of a good or service pays the seller (U.S. EPA, 2024f).

Pollutant: any substance introduced into the environment that may adversely affect the usefulness of a resource or the health of humans, animals, or ecosystems. For most environmental media, this term is commonly understood to refer to substances introduced by human activities. Also, see *stressor* (U.S. EPA, 2021e).

Population groups of concern: in this document, any population groups being analyzed for actual or potential EJ concerns related to the regulatory action, including cases where specific demographic or socioeconomic characteristics correlate with increased vulnerability to environmental exposure, such as race, ethnicity, national origin, low-income, Tribal affiliated and Indigenous populations, and disability status in the United States and its territories and possessions.

Proximity-based analysis: analytic approach using geospatial data that uses proximity to or distance from the source(s) of an environmental stressor to indicate a population group’s likelihood of risk or exposure when direct measurement is unavailable.

Quantitative methods: analysis of numerical data using statistical techniques that include simply describing the phenomenon of interest or looking for differences between groups or relationships among variables (Tashakkori et al., 2020).

Qualitative methods: encompasses a wide range of methods, such as interviews, case studies, discourse analysis, and ethnographic research. A key distinction from quantitative methods is that qualitative methods do not necessarily collect numerical data, and therefore frequently cannot provide numerical results (Taherdoost, 2022; Tashakkori et al, 2020).

Regulatory action: 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 (E.O. 12866; E.O. 14094).

Regulatory analysis: a tool used to anticipate and evaluate the likely consequences of regulatory actions. It compares the baseline scenario to one or more regulatory or policy scenarios. Economic and other effects of policies or regulations are then measured as the differences between these two scenarios (OMB, 2023b).

Regulatory options: the alternatives under consideration for a specific regulatory action.

Risk: the probability of an adverse effect in an organism, system, or population caused under specified circumstances by exposure to a contaminant or stressor (U.S. EPA, 2024l).

Risk analyst/assessor: one who plans and conducts a risk assessment. In particular, the risk analyst 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 characterization: the integration of information on hazard, exposure, and dose-response to provide an estimate of the likelihood that any identified adverse effects will occur in exposed people (U.S. EPA, 2024l).

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 (U.S. EPA, 2024l).

Social context: refers 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 (WHO, 2024).

Social cost: the total burden a regulation will impose on the economy. The bearers of social costs can be either specific individuals or society at large (U.S. EPA, 2024f).

Source: the origin of potential contaminants or environmental stressors; frequently a facility or site (U.S. EPA, 2019a).

Statistical significance: the probability that a result is not likely to be due to chance alone (U.S. EPA, 2024l).

Stressor: any chemical, physical, or biological entity that induces an adverse response (U.S. EPA, 2019a).

Structural and systemic racism: forms of racism that are pervasively and deeply embedded in systems, laws, written or unwritten policies, and entrenched practices and beliefs that produce, condone, and perpetuate widespread unfair treatment and oppression of people of color, with adverse health consequences (Braverman et al., 2022).

Subsistence: dependence on indigenous fish, vegetation, and/or wildlife as the principal portion of one’s diet (CEQ, 1997).

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

Uncertainty: imperfect knowledge or lack of precise knowledge of the real world, either for specific values of interest or in the description of the system. Although numerous schemes for classifying uncertainty have been proposed, most focus on parameter uncertainty and model uncertainty (U.S. EPA, 2014b).

Underserved: populations as well as geographic communities that have been systematically denied the opportunity to participate fully in aspects of economic, social, and civic life (E.O. 14091).

Variability: inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population (U.S. EPA, 2014b).

Vulnerability: characteristics of individuals or populations that place them at increased risk of an adverse health effect (U.S. EPA, 2019a).

Acronyms and Abbreviations

ACS – American Community Survey
AHS – American Housing Survey
BIE – Bureau of Indian Education
CCR – Coal Combustion Residuals
CEQ – Council on Environmental Quality
CIA – Cumulative Impact Assessment
CPI-U – Consumer Price Index for all Urban Consumers
CRA – Cumulative Risk Assessment
E.O. – Executive Order
ECHO – Enforcement and Compliance History Online
EDGE – Education Demographic and Geographic Estimates
EJ – Environmental Justice
EPA – Environmental Protection Agency
HFC – Hydrofluorocarbon
HHRA – Human Health Risk Assessment
HIA – Health Impact Assessment
HOLC – Home Owner’s Loan Corporation
IQ – Intelligence Quotient
IRP – Integrated Review Plan
ISA – Integrated Science Assessment
MU – Management Unit
NAAQS – National Ambient Air Quality Standards
NEJAC – National Environmental Justice Advisory Council
NHANES – National Health and Nutrition Examination Survey
NOX – Nitrogen Oxide
NRC – National Research Council
NSTC – National Science and Technology Council
OMB – Office of Management and Budget
ORD – Office of Research and Development
OSTP – Office of Science and Technology Policy
PFAS – Per- and Polyfluoroalkyl Substances
PM – Particulate Matter
RCRA – Resource Conservation and Recovery Act
RIA – Regulatory Impact Analysis
RSEI – Risk Screening Environmental Indicators
SAB – Science Advisory Board
SES – Socioeconomic Status
SI – Surface Impoundment
TRI – Toxics Release Inventory
U.S. – United States

Chapter 1: Introduction

The purpose of this document, the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (*EJ Technical Guidance*), is to outline analytic expectations and technical approaches that can be used by Agency analysts to evaluate environmental justice (EJ) concerns for United States Environmental Protection Agency (EPA) regulatory actions.[2] The term *analyst* is intentionally broad because an evaluation of EJ concerns may be conducted by economists, risk assessors, and others, often as a team. Senior EPA managers will also find this document useful for understanding what role analysis can play in ensuring that EJ concerns are appropriately considered in the development of regulatory actions, to the extent practicable and consistent with applicable law.

Recommendations and best practices highlighted in the guidance are intended to bring greater consistency across EJ analyses, while recognizing the need for flexibility to reflect policy considerations and technical challenges within a particular regulatory context. Conducting EJ analysis is valuable, whether it informs further Agency action or is conducted for informational purposes only, as it provides the public with information on the distribution of environmental and health effects and risks and furthers the EPA's mission of integrating environmental justice into its activities and processes.[3]

The guidance recommends that early in the rulemaking process analysts identify the extent to which a regulatory action may raise EJ concerns that need further evaluation, including the level of analysis that is feasible and appropriate (see Sections 3.2 and 6.1). This helps ensure that EJ concerns are given due consideration, including informing how to avoid, minimize, or mitigate disproportionate and adverse human health and environmental effects through regulatory design and the proposed options; information provision; opportunities for retrospective analysis; the leveraging of statutory authorities; and monitoring, compliance, and enforcement, among others. Based on the initial evaluation, analysts can choose from a suite of methods depending on the data and resources available, time needed to conduct the analysis, and other technical challenges. When conducting these evaluations, the EPA not only considers the distribution of reductions in environmental and health effects and risks but also the distribution of positive outcomes (U.S. EPA, 2015a).

This document is intended for use alongside other Agency guidance, including guidance on human health risk assessment (HHRA) and economic analysis (see Appendix A).[4] It will evolve with advances in the state of the science, data, and analytic methods available to Agency analysts. Regarding risk assessment, this technical guidance currently is limited to a discussion of how to integrate EJ into the planning of an HHRA. The EPA has developed and continues to refine methods and guidance on a variety of topics relevant to conducting analyses of EJ concerns in the context of a regulatory action.

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[2] Though not the focus of this guidance, the approaches and methods described here may also be useful for analyses that precede and are ultimately used in support of regulation.

[3] Circular A-4 (2023) states that regulatory analysis "provides a formal way of organizing the evidence on the key effects of the various alternatives that should be considered in developing regulations. A high-quality regulatory analysis is designed to inform policymakers, other government stakeholders, and the public about the effects of alternative actions. Regulatory analysis can help agencies in developing regulations by clarifying the likely effects of a regulation under consideration, and it is meant to inform the public about the anticipated consequences of government action (and alternatives)."

[4] See also *EPA Legal Tools to Advance Environmental Justice: Cumulative Impacts Addendum* (U.S. EPA, 2023a), *EPA Legal Tools to Advance Environmental Justice: Executive Order 14096 Addendum* (U.S. EPA, 2023b), and *EPA Legal Tools to Advance Environmental Justice* (U.S. EPA, 2022a),, available at: https://www.epa.gov/ogc/epa-legal-tools-advance-environmental-justice.

Such references are noted throughout the document, and future updates to the *EJ Technical Guidance* may include more detail on these topics.

The Executive Orders (E.O.s) that underpin the EPA's efforts to incorporate EJ analyses into rulemakings are summarized in Table 1.1.

Table 1.1 Executive Orders with Implications for EJ Analysis of Federal Rulemakings

Executive Order	Year	Main Directives Pertaining to EJ Analysis for Rulemakings
12898	1994	"To the greatest extent practicable and permitted by law, make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the U.S."
14094	2023	"Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law."
14096	2023	Identify, analyze, and address: (1) "disproportionate and adverse human health and environmental effects…, including those related to climate change and cumulative impacts of environmental and other burdens on communities with environmental justice concerns;" (2) "historical inequities, systemic barriers, or actions related to any Federal regulation, policy, or practice that impair the ability of communities with environmental justice concerns to achieve or maintain a healthy and sustainable environment;" and (3) "barriers related to Federal activities that impair the ability of communities with environmental justice concerns to receive equitable access to human health or environmental benefits..."

Note: This is not an exhaustive list of the directives contained within these E.O.s that pertain to rulemakings or to Federal activities more generally.

1.1 How Is This Guidance Document Organized?

The first four chapters of this guidance establish the objectives, definitions, main analytic considerations, and context for an assessment of EJ concerns in support of EPA regulatory actions:

- **Chapter 1: Introduction** (this chapter) provides background and outlines the main objectives of the *EJ Technical Guidance*.
- **Chapter 2: Key Definitions** reviews key EJ concepts that are expected to influence analytic considerations. In particular, the chapter discusses how to define the concepts of an EJ concern; disproportionate effects; race, ethnicity, national origin, low-income, and disability; Tribal affiliated and Indigenous populations; subsistence practices; and meaningful involvement or engagement.

Text Box 1.1 Overarching Recommendations to Analysts

1. When risks, exposures, outcomes, or benefits are quantified, some level of quantitative EJ analysis is recommended.
2. Analysts should integrate EJ into the planning of a risk assessment conducted for the regulatory action.
3. Analysts should strive to characterize the distribution of risks, exposures, or outcomes within each population group, not just average effects.
4. Analysts should follow best practices appropriate to the analytic questions at hand.
5. As relevant, analysts should consider any economic challenges that may be exacerbated by the regulatory action for relevant population groups of concern.

- **Chapter 3: Key Analytic Considerations** discusses three questions analysts should strive to answer when evaluating EJ concerns, outlines the key steps of an EJ analysis, and presents overarching recommendations (Text Box 1.1) and best practices to guide assessments of EJ concerns for EPA regulatory actions. Appendix A provides links to additional EPA guidance that may be helpful when assessing EJ concerns.

- **Chapter 4: Contributors to Environmental Justice Concerns** identifies factors that can result in differential patterns of exposure to environmental hazards for some population groups, and/or a greater response of some individuals to a given level of exposure.

By design, Chapters 5 and 6 present some overlapping information about key concepts and methods under the assumption that analysts may consult only one of the technical chapters. These technical chapters provide guidance for considering EJ in two specific contexts:

- **Chapter 5: Considering Environmental Justice when Planning a Human Health Risk Assessment** provides guidance on incorporating EJ concerns into the planning of an HHRA, including descriptions of available methodologies and tools. Appendix B provides examples of approaches for incorporating EJ concerns into the planning of exposure and effects assessments.

- **Chapter 6: Conducting Regulatory Analyses to Assess Environmental Justice Concerns** discusses how to identify and evaluate the feasibility and appropriateness of different analytic approaches and tools for assessing EJ concerns; the types of information that should be included in the assessment; other analytic considerations that could affect results; and how to consider costs and non-health effects in the assessment.

The final chapter describes identified near-term research needs related to the analysis of EJ concerns:

- **Chapter 7: Research Priorities to Fill Key Data and Methodological Gaps** provides information on research goals to improve assessment of EJ at the EPA.

Chapter 2: Key Definitions

For purposes of this document, an *EJ concern* is the actual or potential lack of just treatment or meaningful involvement of any population group, community, or geographic area (e.g., associated with differences in income, race, color, national origin, Tribal affiliation, or disability status) in the development, implementation, and enforcement of environmental laws, regulations, and policies.[5] For analytic purposes, this concept refers specifically to disproportionate and adverse health and environmental effects that may exist prior to or be created by the regulatory action.[6]

This chapter defines and discusses key terms and concepts from E.O.s 12898 and 14096 that are important for analysts to understand before conducting an analysis of EJ concerns. These key terms and concepts include *disproportionate*; *race*, *ethnicity*, *national origin*, *low-income*, and *disability*; *Tribal affiliated and Indigenous populations*; *subsistence practices*; and *meaningful involvement or engagement*.[7]

2.1 Disproportionate

For this technical guidance, the term *disproportionate* is used to refer to differences in effects or risks that are extensive enough that they may merit Agency action and should include consideration of cumulative impacts or risks where appropriate and consistent with applicable law (U.S. EPA, 2022a).[8] In general, the determination of whether a difference in effects or risks is disproportionate is ultimately a policy judgment which, while informed by analysis, is the responsibility of the decision-maker.[9] The terms *difference* or *differential* indicate an analytically discernible (or measurable) distinction in effects or risks across population groups. It is the role of the analyst to assess and present differences in anticipated effects across population groups for both the baseline and regulatory options, using the best available information (both quantitative and qualitative) to inform the decision-maker and the public. See Text Box 2.1 for examples of how differences in effects have been characterized for a regulatory action.

2.2 Population Groups of Concern

At an early stage of the analysis, analysts need to identify the population groups of concern relevant to a specific regulatory context.[10] The concept of vulnerability can be used to help identify population

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[5] The term *EJ concern* was first defined in U.S. EPA (2015a) and used in the 2016 version of this technical guidance. While consistent with those earlier definitions, it has been revised slightly here to reflect E.O. 14096.

[6] What constitutes an adverse effect will likely vary by regulatory context and statute.

[7] While the Justice40 Initiative uses the term *disadvantaged*, it is not typically used at the EPA for purposes of identifying and/or evaluating populations or communities with EJ concerns in the context of rulemaking. For information on the Justice40 Initiative, see: https://www.whitehouse.gov/wp-content/uploads/2021/07/M-21-28.pdf.

[8] The definition of *disproportionate* is consistent with U.S. EPA (2022a) and builds on what was used in the 2016 version of this technical guidance.

[9] A finding of disproportionate and adverse effects is neither necessary nor sufficient for the EPA to address environmental risks. The Agency's statutory and regulatory authorities provide a broad basis for protecting human health and the environment and do not require a demonstration of disproportionate effects to protect the health or environment of any population.

[10] The term *population groups of concern* is used instead of the term *subpopulations* to include "population groups that form a relatively fixed portion of the population (e.g., based on ethnicity)." See the EPA's Early Lifestages website: http://www.epa.gov/children/early-life-stages.

groups of concern.[11] For example, analysts can combine available data on baseline health, demographic, socioeconomic, or other relevant indicators (including those related to cumulative impacts, historic inequities and systemic barriers, and lack of access) to identify characteristics in affected communities that correlate with increased vulnerability to environmental exposure or lack of opportunity for public participation (Fann et al., 2011). See Chapter 4 for a discussion of underlying contributors to increased vulnerability. Further discussion about considering vulnerability and exposure factors in risk assessment is found in Section 5.3 and Appendix B.

While the EPA does not have rigid criteria for identifying population groups of concern, this section defines and describes characteristics from E.O.s 12898 and 14096: race, ethnicity, national origin, low-income, disability status, Tribal affiliated and Indigenous populations, and those engaged in cultural or subsistence practices. Note that population groups of concern may be clustered within specific communities or geographically dispersed (e.g., unhoused populations, migrant workers). Underserved communities or populations also may warrant consideration.[12]

It may be useful in some contexts to analyze population groups in combination or to evaluate additional aspects of diversity within a specific population group of concern (e.g., by lifestage, gender), particularly when some individuals within a population group may be at greater risk for experiencing disproportionate and adverse effects (e.g., due to unique exposure pathways).

In addition to the information below, analysts should rely on the Office of Management and Budget (OMB) or other federal statistical agencies (e.g., U.S. Census Bureau), when available, to define relevant population groups (or combinations thereof) for a specific regulatory action. Note that analysis of additional population groups is not a substitute for examining the population groups explicitly mentioned in the E.O.s.

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[11] Note that specific terminology and definitions related to the term *vulnerability* may be provided by statute.

[12] Examples of other characteristics that may be relevant in some regulatory contexts include linguistic isolation, occupation, rurality, and employment status, among others.

Text Box 2.1 Characterizing Differences in Effects for a Regulation

Regulatory actions have described differences in the size, type, or distribution of environmental and health effects among population groups or communities, both in the baseline and for the regulatory options. Terminology varies with specific context. Below are three examples.

The final rule for the Phasedown of Hydrofluorocarbons (HFC) (U.S. EPA, 2021a) states:

"EPA finds evidence of environmental justice concerns near HFC production facilities from cumulative exposure to existing environmental hazards in these communities. However, given uncertainties about where and in what quantities HFC substitutes will be produced, EPA cannot determine the extent to which this rule will exacerbate or reduce existing disproportionate adverse effects on communities of color and low-income people."

The final rule for the National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emission Standards for Sterilization Facilities Residual Risk and Technology Review (U.S. EPA, 2024a) describes its baseline demographic analysis as follows:

"A total of 17.3 million people live within 10 km of the 88 facilities that were assessed. The percent of the population that is Hispanic or Latino is substantially higher than the national average (36 percent versus 19 percent), driven by the seven facilities in Puerto Rico, where an average of 99 percent of the 658,000 people living within 10 km of the facilities are Hispanic or Latino. The proportion of other demographic groups living within 10 km of commercial sterilizers is similar to the national average. The EPA also conducted a risk assessment of possible cancer risks and other adverse health effects, and found that prior to the implementation of this regulation, cancer risks are unacceptable for several communities."

The final Per-and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Standard rule (U.S. EPA, 2024b) states that the EPA's EJ analysis:

"…demonstrates that some communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population… The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. Across all hypothetical regulatory thresholds, elevated exposure—and thus reductions in exposure under the hypothetical regulatory scenarios—is anticipated to occur in communities of color and/or low-income populations."

2.2.1 Race, Ethnicity, Tribal Affiliated and Indigenous Populations, and National Origin[13]

The OMB provides minimum reporting standards for "maintaining, collecting, and presenting race and ethnicity data for all Federal information collection and reporting purposes. The categories in these standards are understood to be socio-political constructs and are not an attempt to define race and

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[13] Where data shows a higher concentration of health and environmental effects among specific population groups—such as among groups of a particular race, national origin or sex—the EPA uses race-neutral criteria to address such actual or potential risks/harms and to ensure environmental justice for all. The EPA does not distribute governmental benefits or burdens based on race, color, national origin, or sex; however, such data are important for understanding the distribution of environmental and health effects and risks, as well as to measure the impact of race-neutral EPA decision-making on these distributions.

ethnicity biologically or genetically. These standards… provide a common language for uniformity and comparability in the collection and use of race and ethnicity data by Federal agencies" (OMB, 2024).

Within this context, the OMB defines seven minimum categories for data on race and ethnicity:

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

Note that these categories are not mutually exclusive and cannot simply be added to estimate a total population. For example, Hispanic or Latino is an ethnic category and, as such, an individual may identify as both Hispanic or Latino and as one or more races.

While the OMB does not use the terms *Tribal affiliation* or *Indigenous*, it defines someone who identifies as an American Indian or Alaska Native as an individual "with origins in any of the original peoples of North, Central, and South America" (OMB, 2024). The EPA defines Indigenous Peoples in the *EPA Policy on Environmental Justice for Working with Federally Recognized Tribes and Indigenous Peoples* (U.S. EPA, 2014a) to include state-recognized Tribes; Indigenous and Tribal community-based organizations; individual members of federally recognized Tribes, including those living on a different reservation or living outside Indian country; individual members of state-recognized Tribes; Native Hawaiians; Native Pacific Islanders; and individual Native Americans.

National origin refers to where a person or their family is from originally and may encompass birthplace, ethnicity, ancestry, culture, and language. In addition, national origin may refer to a specific country or to a part of the world. While potentially inclusive of national origin, the race and ethnicity categories in the U.S. Census do not distinguish individuals based on national origin (U.S. Census Bureau, 2024).

The U.S. Census asks about an individual's ancestry, which is defined as "a person's ethnic origin or descent, 'roots,' or heritage, or the place of birth of the person or the person's parents or ancestors before their arrival in the United States." In addition, it may encompass identities that originate in geographic areas outside the United States or from within the United States (U.S. Census Bureau, 2024). Up to two ancestries are tabulated per respondent. Note that some ancestries may not be reported to protect confidentiality. In addition, the U.S. Census Bureau collects data on foreign-born individuals living in the United States, which includes anyone who is not a U.S. citizen at birth (U.S. Census Bureau, 2024).

2.2.2 Low-Income Populations

The OMB has designated the U.S. 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 the OMB does not preclude the use of other measures (OMB, 1978). The Council on Environmental Quality (CEQ) also suggests analysts use "annual statistical poverty thresholds from the Census Bureau's Current Population Reports, Series P-60 on Income and Poverty" to define low-income populations (CEQ, 1997).[14]

The U.S. Census Bureau's annual official 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 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.[15] It does not vary geographically, though it is updated for inflation using the Consumer Price Index for All Urban Consumers (CPI-U).[16] It also does not account for capital gains or non-cash benefits such as public housing, Medicaid, and food stamps (U.S. Census Bureau, 2022).

The ability of the official poverty measure to adequately capture regional and other 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, the OMB convened an interagency group in 2009 to define a supplemental poverty measure based on the NRC recommendations. The U.S. Census Bureau has produced a Supplemental Poverty Measure annually since 2011 (Fox and Burns, 2021). Unlike the official poverty measure, it accounts for "co-resident unrelated children" (such as foster children), any cohabiters and their children, and uses a broader resource measure to account for out-of-pocket medical expenses and in-kind benefits. It also improves on the traditional measure of poverty by adjusting for differences in housing prices and family size by metropolitan statistical area.[17] However, since the Supplemental Poverty Measure is based on survey data and available only at a relatively aggregate geographic spatial scale, it should not supplant the use of official poverty measures in an analysis of EJ concerns.[18]

Unlike its treatment of poverty, the U.S. Census Bureau does not provide an official definition of *low income*. For screening purposes, the EPA's EJScreen tool uses the "number or percent of a block group's population in households where the household income is less than or equal to twice the federal poverty level" to identify low-income populations (U.S. EPA, 2024c). However, analysts may characterize low-income populations more broadly than just those that fall below a certain income level

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[14] Federal agencies may also identify low-income populations relevant to their mission. For example, the Federal Reserve Board, under the Community Reinvestment Act, designates a low-income community as one where median family income is less than 50 percent of the area median income. The U.S. Department of Agriculture defines as *limited resource* a farmer or rancher "with direct or indirect gross farm sales not more than the current indexed value in each of the previous two years, and who has a total household income at or below the national poverty level for a family of four, or less than 50 percent of county median household income in each of the previous two years." See https://www.federalreserve.gov/consumerscommunities/cra_resources.htm and https://lrftool.sc.egov.usda.gov/.

[15] The U.S. Census Bureau produces single-year estimates of median household income and poverty by state and county and poverty by school district in its *Small Area Income and Poverty Estimates*. It also provides estimates of health insurance coverage by state and county in 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.

[16] See https://www.bls.gov/cpi/questions-and-answers.htm for a discussion of the limitations of the Consumer Price Index.

[17] 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 they do not account for differences in accumulated assets across households. The Supplemental Poverty Measure 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).

[18] See Congressional Research Service (2022) for more information on the Supplemental Poverty Measure, including limitations and outstanding issues.

(e.g., include families with income above the poverty threshold but still below the average U.S. household income). Additional socioeconomic characteristics typically collected by U.S. statistical agencies, such as educational attainment, baseline health status, and health insurance coverage, may also be useful for characterizing low-income populations. Measures that capture the dynamics of poverty, such as the percent of people who are chronically poor versus those who experience poverty on a more episodic basis, are also available in other U.S. Census Bureau data products (Iceland, 2003).[19]

Finally, the U.S. Census Bureau makes available several cross-tabulations between poverty measures and other socioeconomic characteristics of interest such as race, ethnicity, age, sex, education, and work experience; these can be useful in developing more specific population descriptions.

2.2.3 Disability Status

The Federal government defines an individual with a *disability* as someone who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment (Americans with Disabilities Act, 1990).

Beginning in 2008, the U.S. Census Bureau asked respondents of the American Community Survey (ACS) about six types of disability:[20]

- Hearing difficulty: deaf or having serious difficulty hearing.
- Vision difficulty: blind or having serious difficulty seeing, even when wearing glasses.
- Cognitive difficulty: having difficulty remembering, concentrating, or making decisions because of a physical, mental, or emotional problem.
- Ambulatory difficulty: Having serious difficulty walking or climbing stairs.
- Self-care difficulty: Having difficulty bathing or dressing.
- Independent living difficulty: having difficulty doing errands alone such as visiting a doctor's office or shopping because of a physical, mental, or emotional problem.

Several other agencies also collect statistical information on disability status based on the same six disability categories listed above. For instance, the Bureau of Labor Statistics collects information on the employment status of persons with disabilities as part of the Current Population Survey. The Centers for Disease Control and Prevention includes disability status in several population surveys about a wide range of demographic, socioeconomic and health indicators.[21]

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[19] This type of measure is reported in the U.S. Census Bureau's *Survey of Income and Program Participation.* For more information, see https://www.census.gov/programs-surveys/sipp.html.

[20] In 2013, the U.S. Census Bureau produced the first set of five-year estimates on disability status for all geographies including tracts and block groups. See https://www.census.gov/topics/health/disability/guidance/data-collection-acs.html for more information. Note that these data exclude people in institutions such as nursing or retirement homes, correctional facilities, and inpatient hospice care.

[21] For more information, see https://www.cdc.gov/ncbddd/disabilityandhealth/datasets.html.

2.2.4 Populations that Rely on Cultural and Subsistence Practices

E.O. 12898 identifies the need to analyze the human health effects and risks of Agency programs, policies, and activities for "populations with differential patterns of subsistence consumption of fish and wildlife … whenever practical and appropriate." E.O. 14096 also highlights the importance of analyzing differences in consumption patterns related to the cultural and subsistence practices of Tribal and Indigenous populations. Tribal and Indigenous populations often rely on traditional diets of indigenous fish, vegetation, and/or wildlife. Access to medicinal plants and natural resources is also often integral to Tribal cultural practices, traditions, and customs (also referred to as lifeways) and helps define them as peoples (U.S. EPA, 2019a).

The CEQ (1997) describes the two main components of subsistence practices: differential patterns of consumption of natural resources and subsistence consumption. *Differential patterns* of consumption of natural resources are "differences in rates and/or patterns of fish, water, vegetation and/or wildlife consumption among minority populations, low-income populations, or Indian Tribes, as compared to rates and patterns of consumption of the general population." The term *subsistence consumption* is defined as dependence "on indigenous fish, vegetation and/or wildlife, as the principal portion of their diet." Both differential patterns and subsistence consumption can result in higher exposure to environmental stressors. For example, Tribal and Indigenous populations may be exposed to higher concentrations of environmental contaminants due to greater reliance on indigenous fish, vegetation and/or wildlife in their diets and cultural practices compared to the general population. See Section 4.1.2 for a discussion of unique exposure pathways.[22] Note that this category identifies populations based on specific pathways of exposure and may overlap with those defined based on income, race/ethnicity, and national origin.[23]

While federal statistical agencies do not specifically track the cultural and subsistence practices of individuals and population groups, the EPA has conducted consumption surveys and exposure assessments in specific geographic areas to inform policy formulation (see U.S. EPA (2011a) for examples). If differential patterns of indigenous fish, vegetation, and wildlife consumption are a substantial concern for a specific regulatory action, analysts should refer to existing EPA guidance when collecting and using these data for analysis (e.g., U.S. EPA, 2019a; 2016a; 2011a).

Analysts may also investigate whether data collected via consumption surveys or exposure assessments are available from other federal agencies or from state, Tribal, or local governments. Per EPA guidance, it is important to verify that any survey data used in an EJ analysis accords with appropriate parameters and methodology for that specific analysis (U.S. EPA, 2016a). Note, it is essential to gain permission from a Tribe to gather and use information on cultural practices (e.g., Indigenous Knowledge, also referred to as Traditional Ecological Knowledge).[24] Because Tribes retain

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[22] For example, over 40% of non-Hispanic Asian populations in the United States eat seafood at least twice per week compared to a national average of 20% between 2013 and 2016 (Terry et al., 2018). This can result in elevated mercury levels that can affect neurodevelopment in children and the risk of cardiovascular disease in adults (e.g., Buchanan et al., 2015).

[23] The overlap between populations that principally subsist on indigenous fish, vegetation, and wildlife and other population groups based on race, ethnicity, income, or other factors is an important consideration when evaluating EJ concerns in a risk assessment. As part of a risk assessment, analysts are encouraged 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 indigenous fish, vegetation, and wildlife.

[24] While Indigenous Knowledge is used here, a variety of terms, including Traditional Ecological Knowledge, Traditional Knowledge, Indigenous Traditional Knowledge, Native science, and related terms are used and preferred by different Tribes and Indigenous Peoples. For more information, see OSTP and CEQ (2022).

ownership of these data and can decide who and how they are used, it is important that the EPA be transparent about statutory requirements that may limit its ability to protect sensitive information from public disclosure.[25] For these reasons, data collection, storage, and sharing should be discussed with Tribes early in the process (see Section 2.3).[26]

2.3 Meaningful Involvement or Engagement

The EPA strives to meaningfully involve or engage members of the public that are potentially affected by Federal activities by:

- Providing timely opportunities for members of the public to share information and concerns and participate in decision-making processes,
- Considering public input provided as part of decision-making processes,
- Seeking out and encouraging the involvement of persons and communities potentially affected by federal activities; … [and]
- Providing technical assistance, tools, and resources to help facilitate meaningful and informed public participation, whenever practical and appropriate (U.S. EPA, 2024d).

The EPA can seek out and encourage public involvement by sharing information in a way that is accessible to individuals with limited English proficiency and people with disabilities; providing notice of and reaching out to communities or groups of people who are potentially affected and who might not regularly participate in federal decision-making; and addressing other barriers to participation that individuals may face, to the extent practicable and appropriate. (U.S. EPA, 2024d).[27] In addition, the EPA continues to respect Tribal sovereignty and support self-governance by ensuring that Tribal Nations are consulted on Federal actions that have Tribal implications. The EPA consults with federally recognized Tribes consistent with the *EPA Policy on Consultation with Indian Tribes* (U.S. EPA, 2023f) and E.O. 13175.[28]

While opportunities for engaging the public differ across agency activities and take time and resources, there are three steps recommended for planning and providing opportunities to meaningfully engage the public that can be tailored to the decision context: (1) understand the EPA action and key issues the public can inform; (2) identify the expected level of participation; and (3) identify the appropriate engagement tools and practices. Details on how to actualize these steps, as well as best practices,

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[25] Statutory requirements include the Freedom of Information Act and Administrative Procedures Act.

[26] See the EPA's *Policy on Environmental Justice for Working with Federally-Recognized Tribes and Indigenous Peoples* (https://www.epa.gov/environmentaljustice/epa-policy-environmental-justice-working-federally-recognized-tribes-and). For more information on practices around Tribal data sovereignty, see Carroll et al. (2020).

[27] The terms *meaningful involvement* and *meaningful engagement* are often used interchangeably. For the remainder of this document, we use the term meaningful engagement to align with U.S. EPA (2024d).

[28] The EPA's policy is to consult on a government-to-government basis with federally recognized Tribes when EPA actions or decisions may affect Tribes. Tribal consultations are separate and distinct from the EPA's obligations to engage the public as required by federal environmental laws and regulations and the EPA's work to address the environmental concerns of non-federally recognized Tribes, individual Tribal members, Tribal community-based organizations, and other Indigenous stakeholders. The *EPA Policy on Consultation with Indian Tribes* (U.S. EPA, 2023f) is available at: https://www.epa.gov/system/files/documents/2023-12/epa-policy-on-consultation-with-indian-tribes-2023.pdf.

examples, and other resources are available in the EPA's *Meaningful Engagement Policy* (U.S. EPA, 2024d).[29]

While the EPA's *Meaningful Engagement Policy* does not create new legal requirements or mandatory obligations, the recommendations are designed to enhance meaningful engagement opportunities within Agency actions, including rulemaking. The EPA is committed to providing timely, accessible, and accurate information to the public about its regulatory actions and recognizes the importance of providing "opportunities for participation that foster a spirit of mutual trust, confidence, and openness between the EPA and the public" (U.S. EPA, 2024d). Within the regulatory context, the OMB (2023a) recommends that agencies engage communities through trust-based, long-term, and two-way relationships throughout the regulatory process.[30]

Meaningful engagement intersects with analytic considerations in several important respects. First, providing the analysis of EJ concerns in a timely fashion and using plain language to improve accessibility makes key assumptions, methods, and results more transparent and easier to understand.[31] This can further a clear understanding of the EJ implications of a regulatory action and allow for more substantive engagement by community members and other interested parties during the rulemaking process. Second, analysts play a role in ensuring meaningful engagement by evaluating possible differences in opportunities for ongoing public input and feedback, the ability to identify and resolve compliance issues, and ways implementation may be improved once a regulation is in place for the regulatory options under consideration. Third, it may be possible for analysts to request data and other information early in the process regarding unique exposure pathways or end points of concern that could improve the analysis of EJ concerns. This includes the possible use and consideration of Indigenous Knowledge (also referred to as Traditional Ecological Knowledge) and data and information collected via participatory science (U.S. EPA, 2024d).[32] Communities with EJ concerns have unique knowledge of their goals, needs, and vulnerabilities.

Through early involvement, the EPA can obtain information and improve understanding of issues affecting these populations in the context of the regulatory action.[33] Text Box 2.2 highlights several examples of activities taken to ensure meaningful engagement on EJ issues for regulatory actions. Section 5.3.1.2 discusses meaningful engagement in the context of a human health risk assessment.

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[29] The EPA's National Environmental Justice Advisory Council (NEJAC) issued updated recommendations on public participation in 2013, *Model Guidelines for Public Participation*, available at https://www.epa.gov/environmentaljustice/model-guidelines-public-participation. See also U.S. EPA (2015b).

[30] EPA staff should also hold early, transparent discussions about Freedom of Information Act with public participants prior to seeking public input, exchanging information, obtaining recommendations, entering into collaborations or agreements, conducting community-based participatory research, and working together. Sharing the EPA's limitations with participants enables communities to assess how they intend to share information or knowledge with the Agency prior to engagement as well as facilitates trust and relationship building.

[31] The Plain Writing Act of 2010 (Public Law 111-274) defines *plain language* as "writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience." For Federal plain language guidelines, see https://www.plainlanguage.gov/guidelines/.

[32] The Agency's network of Tribal Partnership Groups facilitates the exchange of technical information and communication between Tribes and the EPA. The National EPA-Tribal Science Council works to integrate and increase tribal involvement in the EPA's scientific activities, while the National Tribal Toxics Council provides Tribal input on issues related to toxic chemicals and pollution prevention. Assessors should engage with these partnership groups, through the EPA's Tribal Program, to better understand Tribal lifeways and to discuss and collaborate on data and research needs.

[33] Note that the Paperwork Reduction Act requires that an Information Collection Request be submitted for collecting information (e.g., focus groups, interviews, surveys) from more than nine people (44 U.S.C. 3501).

Text Box 2.2 Examples of Meaningful Engagement for EPA Regulatory Actions

To inform the proposed Supplemental Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category, the EPA characterized the environmental and socioeconomic characteristics of communities that are expected to be impacted by discharges from steam electric plants to prioritize outreach and engagement. The EPA then met with community members in five identified communities either virtually or in a hybrid format.

“Two broad themes were conveyed consistently across communities. First, community members conveyed several perceived harmful impacts from steam electric power plants and their desire for more stringent regulations to reduce these harmful impacts. Second, community members expressed the desire for more transparency and communication to overcome their decreasing trust in the regulated power plants and state regulatory agencies and, thus, a corresponding skepticism that their community would be protected from these harmful impacts. In addition to these broad themes, commenters also raised concerns unique to each community. For example, members of the Navajo Nation discussed with EPA the spiritual and cultural impacts to the community from pollution related to steam electric power plants. In Jacksonville, Florida, community members raised concerns regarding tidal flows of pollution upstream and storm surges during extreme weather events which cause additional challenges in their community” (U.S. EPA, 2023c).

In addition to imposing more stringent requirements to limit discharges from steam electric power plants, the final rule responds to the feedback received at these outreach meetings by:

“…requiring posting of required reports to a publicly available website to improve transparency. In addition, the EPA recently added a new feature called ECHO Notify to the Enforcement and Compliance History Online (ECHO) website. ECHO Notify provides weekly email notifications of changes to enforcement and compliance data in ECHO. Notifications are tailored to the geographic locations, facility IDs, and notification options that users select” (U.S. EPA, 2024e).

For the Petroleum Refineries Risk and Technology Review, the EPA conducted EJ-relevant outreach activities with communities living near refineries in the two years prior to proposing the rule. It was in the context of this outreach that the possibility of fenceline monitoring was first raised as a regulatory option. In response to public comments asking for more data on refinery emissions that may affect nearby communities, the EPA changed several aspects of its proposed electronic reporting requirements: it required data collection no later than two years from the effective date of the final rule instead of the originally proposed three years and required submission of fenceline monitoring data on a quarterly instead of a semi-annual basis.

In addition, the EPA stated that it “will continue to work with communities to better understand their unique concerns and needs. We will seek opportunities to enhance education and engagement around our rules, including the best way to make the monitored data required by this rule accessible and digestible by those who need to understand what the data means” (U.S. EPA, 2015c). Subsequent public outreach and solicitation of input specifically asked for feedback from the public:

- “What information needs to be included on the web page to understand the data?
- Within context of the rule, what information and data on benzene do you want to see on the web page?
- Do you have ideas for other ways to share the information besides a web page?
- What other information would be helpful for you? Other EPA information about air toxics? Links to EPA environmental justice tools?
- Is there other training or support that might be helpful?” (U.S. EPA, 2016b).

Chapter 3: Key Analytic Considerations

This chapter provides an overview of the questions analysts should aim to evaluate and the main steps of an analysis of EJ concerns. It also offers five broad recommendations and a list of best practices to enhance consistency across assessments.

3.1 Questions to Evaluate When Analyzing EJ Concerns

The analysis of EJ concerns for regulatory actions should address three questions:[34]

- **Baseline:** Are there existing EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern?
- **Regulatory options:** For the regulatory option(s) under consideration, are there potential EJ concerns associated with environmental stressors that are affected by the regulatory action for population groups of concern?
- **Mitigation or exacerbation of effects:** For the regulatory option(s) under consideration, are EJ concerns exacerbated, mitigated, or unchanged compared to the baseline?

The term *environmental stressor* encompasses the range of chemical, physical, or biological agents, contaminants, or pollutants that may be subject to a regulatory action. *Baseline* is defined as "an analytically reasonable forecast of the way the world would look absent the regulatory action being assessed, including any expected changes to current conditions over time" (OMB, 2023b).[35] Section 6.2 of this document provides more information on characterizing the baseline for a regulatory action. Note that characterizing the baseline may include consideration of other relevant environmental or non-environmental stressors that increase a community or population group's vulnerability. This may include considering the cumulative effects of exposure to multiple stressors on human health and well-being and those related to climate change. See Chapter 4 for a discussion of vulnerability.

3.2 Identifying Objectives, Data, and Other Information

The purpose of a regulatory analysis is to "anticipate and evaluate the likely consequences" of a regulatory action in a way that informs the public and decision-makers (OMB, 2023b).[36] To help fulfill

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[34] These analytic questions are intended to prompt assessment of differences in anticipated effects across population groups for the baseline and regulatory options, and to prompt presentation of these results to decision-makers to support determinations of potentially actionable disproportionate and adverse effects. Differences in effects or risks may include differential exposures, differential health and environmental outcomes, or other relevant effects.

[35] "In some cases, it may be reasonable to forecast that the world absent the regulation will resemble the present. In other cases, particular attention should be paid to ways in which conditions will change absent the regulation—e.g., technological advances, demographic changes, changes in the economy, or alterations to the climate—that will significantly affect the estimated effects of the regulation… If a harm addressed by a regulation is expected to become more severe over time, the baseline should reflect that trend" (OMB, 2023b).

[36] E.O. 12866 (1993) directs agencies to consider distributional effects when choosing among alternative regulatory approaches, unless prohibited by statute. A distributional analysis is one that characterizes "how the benefits and the costs of a regulatory action are ultimately experienced across the population and economy, divided up in various ways (e.g., across

this purpose, analysts need to communicate with decision-makers early in the process on how the relevant Executive Orders and other applicable EPA policies or statutes interact with the evaluation of EJ concerns for a regulatory action. Identifying the objectives of the EJ analysis is a key input into the analytic plan, including how to frame the questions, which datasets to use, which analyses to perform, and how to synthesize and interpret results.

To help decide what level of analysis of EJ concerns is feasible and appropriate, analysts need to identify the quantitative and qualitative data and methodological needs to ensure that they are duly considered and reasonably accommodated. Data and methods availability influence the scope and complexity of an assessment and may inform the extent to which EJ concerns are considered in the decision-making process (see Sections 5.3, 6.3, and 6.4). Feasibility is based on a technical evaluation of the data and methods that are available or can be reasonably collected (e.g., the availability of disaggregated data, data quality, and the quality of evidence from the peer-reviewed literature, community input, and other information). Appropriateness is informed by relevant policy, budgetary, and statutory considerations (see Chapter 6). Text Box 3.1 provides an overview of the criteria by which the EPA assesses the quality of scientific and technical information used in support of Agency decisions. When possible, it is recommended that analysts also identify the population groups of greatest relevance within the context of a specific regulatory action early in the process to inform data collection and analysis.

In some circumstances, available data may not be sufficient to perform a quantitative evaluation, but it may be possible to conduct a meaningful qualitative analysis or rely on a mix of quantitative and qualitative information (see Sections 6.1 and 6.3).[37] Documentation of the process for identifying what level of analysis is feasible is encouraged and ensures transparency when communicating with the public. It is also recommended that analysts coordinate with the Office of Policy when determining the level of EJ analysis undertaken for a specific regulatory action.

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income groups, race or ethnicity, sex, gender, sexual orientation, disability, occupation, or geography; or relevant categories for firms, including firm size and industrial sector). The benefits and costs of a regulation may also be distributed unevenly over time, resulting in regulatory benefits and costs falling on different individuals or different groups of individuals" (OMB, 2023b). Note that while the concepts and objectives of distributional analysis and EJ analysis overlap, they are distinct. See Wolverton (2023) for more discussion.

[37] The EPA also receives information that is voluntarily submitted by or collected from other federal, state, Tribal, local, and international agencies; national laboratories; academic and research institutions; business and industry; and public interest organizations. Although the EPA's existing quality systems are not applied at the time this information is generated, the EPA "does apply appropriate quality controls when evaluating this information for use in Agency actions and for its dissemination consistent with the EPA" data quality guidelines (U.S. EPA, 2012a).

Text Box 3.1 The Quality and Relevance of Scientific and Technical Information

To evaluate the quality and relevance of scientific and technical information used to support Agency actions, the EPA assesses five factors:

Soundness - The extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for, and consistent with, the intended application.

Applicability and Utility - The extent to which the information is relevant for the Agency's intended use.

Clarity and Completeness - The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations, and analyses employed to generate the information are documented.

Uncertainty and Variability - The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods, or models are evaluated and characterized.

Evaluation and Review - The extent of independent verification, validation, and peer review of the information or of the procedures, measures, methods, or models.

See U.S. EPA (2012a) for examples of the types of questions that could be considered to assess each of these factors. OMB (2019) and U.S. EPA (2002b) also are helpful resources.

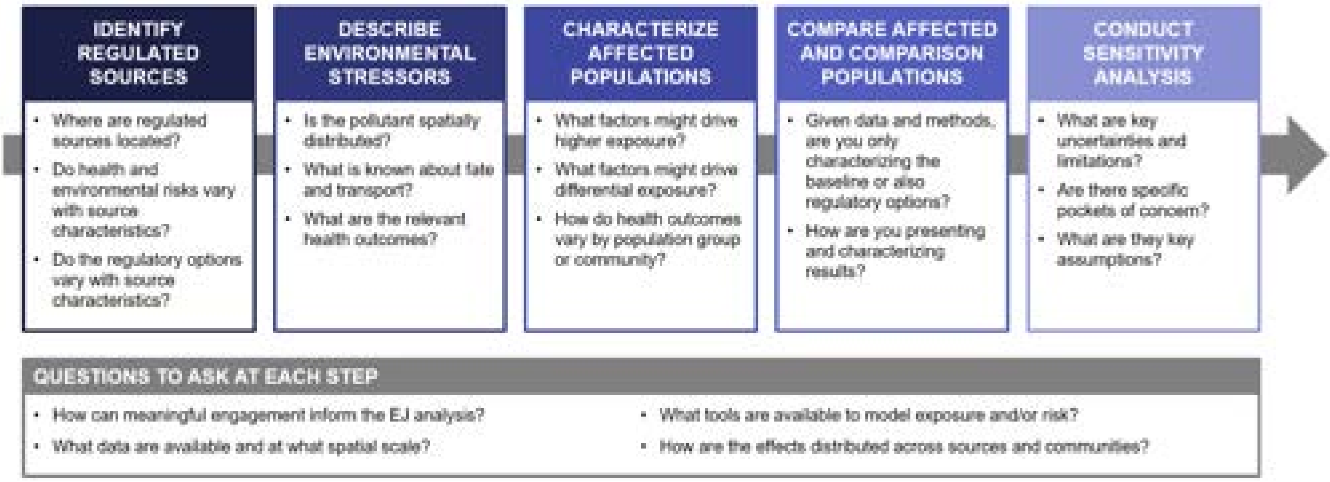
3.3 Main Steps of an EJ Analysis

Conducting a preliminary analysis may be a useful first step to identifying what level of assessment is feasible and appropriate to support the regulatory action. In addition, it can help identify the extent to which a regulatory action may raise EJ concerns that need further evaluation. While there is no single recommended approach for conducting a preliminary analysis, Section 6.1 discusses the types of factors and tools analysts may consider as part of a preliminary analysis.

In cases where there is a need for further evaluation, and the data and methods support it, an in-depth analysis should be conducted. The extent to which an in-depth analysis can address all three questions from Section 3.1 will vary due to data limitations, time and resource constraints, and other technical challenges that vary by media and regulatory context. The EPA encourages analysts to document key reasons why a particular question cannot be addressed to help identify future priorities for filling key data and research gaps. A lack of existing data and methods does not mean there is no EJ concern, so identifying such gaps is important.

While Offices may develop program-specific approaches to evaluating EJ concerns for regulatory actions to reflect their specific methodological, regulatory, and resource constraints, an EJ analysis typically includes five main steps (Figure 3.1). We briefly describe each step and refer the reader to more detailed discussion in Chapter 6.

Figure 3.1 Main Steps of an EJ Analysis



IDENTIFY REGULATED SOURCES

- Where are regulated sources located?
- Do health and environmental risks vary with source characteristics?
- Do the regulatory options vary with source characteristics?

DESCRIBE ENVIRONMENTAL STRESSORS

- Is the pollutant spatially distributed?
- What is known about fate and transport?
- What are the relevant health outcomes?

CHARACTERIZE AFFECTED POPULATIONS

- What factors might drive higher exposure?
- What factors might drive differential exposure?
- How do health outcomes vary by population group or community?

COMPARE AFFECTED AND COMPARISON POPULATIONS

- Given data and methods, are you only characterizing the baseline or also regulatory options?
- How are you presenting and characterizing results?

CONDUCT SENSITIVITY ANALYSIS

- What are key uncertainties and limitations?
- Are there specific pockets of concern?
- What are they key assumptions?

QUESTIONS TO ASK AT EACH STEP

- How can meaningful engagement inform the EJ analysis?
- What data are available and at what spatial scale?
- What tools are available to model exposure and/or risk?
- How are the effects distributed across sources and communities?

1. **Identify the sources being regulated:** Before analysts can identify the populations and communities being affected by a regulatory action, it is important to first characterize the regulated sources: where are they located? Are there particular characteristics of the regulated sources that contribute to higher exposure and/or risk of health effects? Do the regulatory options vary with these characteristics? For instance, are some sources subject to greater stringency or other regulatory requirements that would be important to account for in the EJ analysis?

2. **Describe the environmental stressor:** The spatial distribution of health and welfare outcomes is a relevant consideration for some regulatory actions. In these cases, evidence on the fate and transport of the environmental stressor can help determine the populations and communities potentially exposed. In other cases, the regulatory action's effects may be more widespread (see Section 6.5.3). It is also important to understand which specific health effects are of greatest relevance for a given regulatory context. The benefits analysis and, when conducted, the human health risk and exposure assessments can be important sources for this information (see Chapter 5 and Appendix B).

3. **Characterize affected populations:** It is important to understand what factors may contribute to EJ concerns. How are individuals being exposed? Are there unique pathways or other factors that drive higher exposures for some population groups? Recognizing underlying contributors within a specific regulatory context is important for properly assessing EJ concerns and can aid in the design of regulatory options. This may include evidence of already overburdened communities, including the cumulative effects of exposure to multiple environmental or non-environmental stressors on human health and well-being (see Chapter 4, Chapter 5, and Appendix B).

4. **Compare the affected and comparison groups:** To answer each of the three questions in Section 3.1, analysts need to characterize the exposure and risk of health effects for population groups of concern in the baseline and for the regulated action relative to a comparison population group (see Section 6.5.2). This allows analysts to gauge the extent to which effects for the affected population are similar or different than they are for the comparison group and how they vary across population groups.

5. **Conduct sensitivity analysis:** Due to the inherent limitations and uncertainties associated with analyses of EJ concerns, conducting sensitivity analysis around key assumptions is particularly important for clearly communicating results to the public (see Chapter 6).

In addition, Figure 3.1 identifies four overarching questions that are relevant throughout the EJ analytic process:

How can meaningful engagement inform the EJ analysis?

As discussed in Section 2.3, meaningful engagement can help analysts to identify and sometimes help fill information and data needs. It can also help analysts to identify factors such as unique pathways or pre-existing vulnerabilities that may contribute to exposure and/or risk for affected populations.

What data are available and at what spatial scale?

As mentioned in Section 3.2, the quality and availability of data are key determinants in the scope and complexity of the EJ analysis. In some cases, analysts will have data at the individual level for the environmental stressor being regulated, allowing for a detailed, rigorous analysis. In other cases, analysts may need to rely on proxies for individual-level effects. Data relevant to the EJ analysis may include, but are not limited to, the demographic and socioeconomic characteristics of populations that may be exposed to environmental stressors from regulated sources, what each regulated source is emitting or discharging, and pre-existing health conditions or other environmental and non-environmental stressors that increase the vulnerability and therefore the risk of experiencing a health effect for some population groups (see Sections 5.3.3.2 and 6.3).

What tools are available to model exposure and/or risk?

Analysts have a choice among several scientifically defensible methods to assess EJ concerns associated with a regulatory action (see Section 5.3.3.2, Section 6.4, and Appendix B), including proximity-based analysis, exposure and risk modeling, and combining qualitative and quantitative approaches. The choice of a specific analytic method for the EJ analysis is often driven by data availability. Together, the data and methods utilized directly influence what conclusions can be drawn regarding EJ concerns for specific population groups or communities.

How are the effects distributed across sources and communities?

In some cases, extensive differences in effects among population groups of concern may occur in only a few geographic locations. Referred to as *hot spots*, these locations are typically exposed to localized concentrations of emissions from one or more sources along with other stressors. In these cases, it may be appropriate to tailor the analysis to evaluate effects in a few specific areas. Identifying the potential for hot spots early helps analysts develop appropriate sources of data and analytic approaches, which may differ from those used for a broader analysis (see Section 6.5.5).

3.4 Recommendations for Analyses of EJ Concerns

This technical guidance makes five overarching recommendations to ensure a high-quality EJ analysis, while also recognizing the need for flexibility to reflect policy considerations and technical challenges within a particular regulatory context. The recommendations are intended to bring greater consistency across EJ analyses as they strive to answer the three analytic questions from Section 3.1 but are not prescriptive and do not mandate the use of a specific approach. Analysts should use their best professional judgement to decide on the type of analysis that is feasible and appropriate within a specific regulatory context.

While these recommendations and best practices are intended as a starting point, they should not be interpreted as limiting the scope of the EJ analysis. It is recommended that analysts thoughtfully tailor their analysis to the rule context and incorporate new data and methods as they become available. Ultimately, the EPA strives to innovate and improve upon EJ analyses as the state of science continues to evolve. The five overarching recommendations are:

1. When risks, exposures, outcomes, or benefits of the regulatory action are quantified, some level of quantitative EJ analysis is recommended (see Chapter 6).
    - Analysts should present information on estimated health and environmental risks, exposures, outcomes, benefits, or other relevant effects disaggregated by race, ethnicity, income, and other relevant demographic and socioeconomic categories when feasible and appropriate.
    - When such data are not available, it may still be possible to evaluate potential risk or exposure using other metrics (e.g., proximity to affected facilities, cancer or asthma prevalence, or evidence of unique exposure pathways for specific population groups) in a scientifically defensible way.
    - When health and environmental outcomes or benefits are not quantified or disaggregated by race, ethnicity, income, or other relevant demographic and socioeconomic categories, analysts should present available quantitative and/or qualitative information that sheds light on EJ concerns that may arise.

2. Analysts should integrate EJ into the planning of a risk assessment conducted for the regulatory action (see Chapter 5).

3. Analysts should strive to characterize the distribution of risks, exposures, or outcomes within each population group, not just average effects (see Section 6.5.5).
    - In particular, analysts should pay attention to whether populations in the upper tail of the distribution face the highest adverse risks, exposures or health effects.

4. Analysts should follow best practices appropriate to the analytic questions at hand.
    - Text Box 3.2 outlines best practices for evaluating EJ concerns. If it is not feasible for analysts to follow these best practices, analysts should explain their use of different approaches.

5. As relevant, analysts should consider any economic costs or challenges that may be exacerbated by the regulatory action for relevant population groups of concern.
    - For instance, it may be appropriate to consider how low-income populations are affected by price changes or to consider the distribution of economic costs (i.e., private and social costs) more broadly from an EJ perspective (see Section 6.7.1).[38]

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[38] See the EPA's *Guidelines for Preparing Economic Analyses*, hereafter referred to as the *Economic Guidelines* (U.S. EPA, 2024f), for information on defining costs.

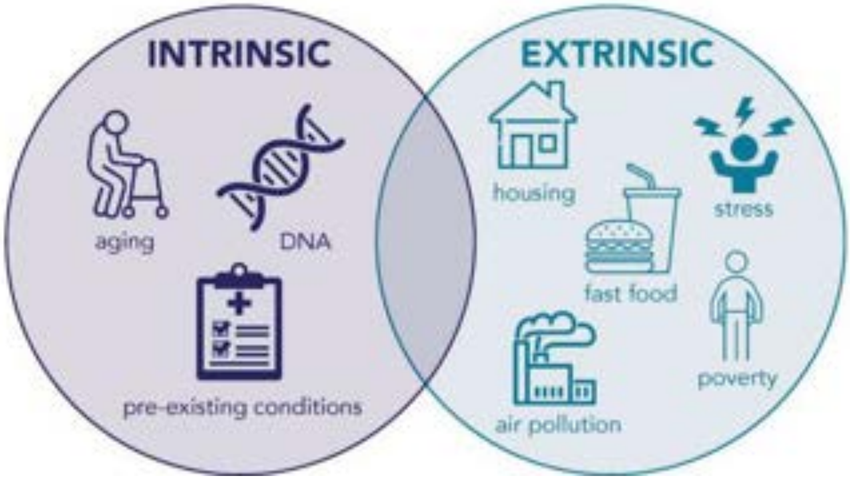
Text Box 3.2 Current Best Practices for Evaluating EJ Concerns

- Use the best available science while relying on current, generally accepted Agency procedures for conducting risk assessment and economic analysis.
- Use existing frameworks and data from other parts of the regulatory analysis, supplemented as appropriate.
- Be consistent with the basic assumptions underlying other parts of the regulatory analysis, such as using the same baseline and regulatory option scenarios.
- Use the highest quality and most relevant data available. Discuss the overall quality and main limitations of the data (see Text Box 3.1 and Section 6.3).
- Identify relevant population groups of concern and discuss available evidence of factors that make them vulnerable to adverse effects (e.g., unique pathways; cumulative exposure to multiple stressors; behavioral, biological, or environmental factors) (see Chapter 4).
- Consider unique pathways for individuals that rely on cultural or subsistence practices and relevance for Tribal or Indigenous populations, when practicable (see Section 2.2.4).
- Carefully select and justify the choice of comparison population group (see Section 6.5.2).
- Carefully select and justify the choice of the geographic unit of analysis and discuss any challenges or aggregation issues related to the choice of spatial scale (see Section 6.5.3).
- Analyze and compare effects in baseline and across policy scenarios to show differences in effects (see Section 6.2).
- Present summary metrics for each population group and the comparison population group and characterize differences between them (see Section 6.6.1).
- When data allow, characterize the distribution of risks, exposures, or outcomes within each population group, not just average effects (see Section 6.5.5).
- Disaggregate data to reveal important spatial differences (e.g., demographic information for each source/place) when feasible and appropriate (see Sections 6.5.4 and 6.5.5).
- Clearly describe data sources, assumptions, analytic approaches, and results (see Sections 6.4, 6.5, and 6.6).
- Summarize the main conclusions of differences in exposure or health risk between analyzed population groups based on the available evidence (see Section 6.6).
- Discuss key sources of uncertainty or potential data biases (e.g., sample size, proximity as a surrogate for exposure) and how they may influence the results (see Section 6.6.3).
- When possible, conduct sensitivity analysis for key assumptions or parameters that may affect findings (see Section 6.5).
- Qualitatively describe behavioral responses not accounted for in the analysis that could affect the level or distribution of exposure or health risks (e.g., dynamic spatial or temporal effects, averting or adaptive behavior) (see Section 6.5).
- Make elements of the EJ analysis as straightforward and easy for the public to understand as possible (see Section 2.3).

Chapter 4: Contributors to Environmental Justice Concerns

Increased vulnerability may be attributable to differences in *intrinsic* (meaning, biological) factors (e.g., age, lifestage, sex, pre-existing disease, genetic predisposition) or *extrinsic* (meaning, acquired or external) factors over a person's lifetime. Extrinsic factors consist of both environmental stressors (e.g., previous or ongoing exposure to chemicals; the impacts of climate change) and non-environmental stressors (e.g., socioeconomic status, stress, nutrition, lifestyle, racism, discrimination, culture) from the built, natural, and social environment across the locations in which individuals spends their time (e.g., work, home, school, community).[39, 40, 41]

Figure 4.1 Examples of Sources of Human Variability and Vulnerability to Health Risks from Exposure to Environmental Stressors



(Source: Varshavsky et al., 2023)[42]

Intrinsic and extrinsic factors interact in complex ways that can result in differential patterns of exposure to environmental hazards for some population groups, and/or a greater response of some individuals to a given level of exposure to an environmental stressor (Figure 4.1). These factors can ultimately result

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[39] It is important to note that race/ethnicity is a social construct that captures the complex interplay of social vulnerability factors that drive environmental health risk. Belonging to a race/ethnic or low-income group does not on its own influence how a stressor causes adverse health effects; rather, it is an upstream factor in a causal chain for which there may be little or no data (Morello-Frosch et al., 2011).

[40] Extrinsic factors may relate to current and historical mechanisms that operate through the labor market, real estate market, educational system, political institutions, and cultural and societal values to reinforce social hierarchies based on race, ethnicity, income, occupation, age, or other characteristics (NASEM, 2016; Solar and Irwin, 2010).

[41] Differences in outcomes due to extrinsic factors related to socioeconomic, demographic, cultural, psychological, and physical factors are sometimes also referred to as non-chemical or, more broadly, non-environmental stressors (NASEM, 2023).

[42] Used under Creative Commons license (https://creativecommons.org/licenses/by/4.0/). No changes were made to the original figure.

in higher cumulative risk and incidence of adverse health effects for these population groups and communities.[43, 44]

4.1 Contributors to Higher Exposure to Environmental Hazards

Important extrinsic factors that contribute to higher exposure among population groups of concern include:

- Proximity to emissions and discharges from nearby sources (U.S. EPA, 2022b; Morello-Frosch et al., 2011);
- Unique exposure pathways (Burger and Gochfeld, 2011; Solar and Irwin, 2010);
- Physical infrastructure (e.g., housing conditions, water infrastructure) (Solar and Irwin, 2010);
- Exposure to multiple stressors/cumulative exposures (U.S. EPA, 2022c; Morello-Frosch et al., 2011; Brender et al., 2011);
- Differential monitoring, compliance, and regulatory enforcement (Banzhaf et al., 2019a); and
- Community capacity to meaningfully participate in decision-making (U.S. EPA, 2011b).

4.1.1 Proximity to Emissions and Discharges from Nearby Sources

It is well documented that sources of environmental hazards are often concentrated in communities with higher proportions of people of color, low-income populations, Indigenous populations, or persons with disabilities (Chakraborty et al., 2020; Chakraborty et al., 2016; Mohai et al., 2009).[45] Researchers have pointed to a variety of explanations for these spatial patterns, including the legacy of historically discriminatory land-use siting decisions (e.g., highway placement, redlining, other zoning practices) and other systemic barriers (Lane et al., 2022; Shkembi et al., 2022; Grove et al., 2017; Mohai and Saha, 2015).

Not surprisingly, given their proximity to concentrated sources of environmental hazards, these populations often experience higher levels of exposure.[46] Exposure is a function of what or how much is being emitted or discharged from a nearby source, how and where the pollutant travels as it moves through the environment (i.e., fate and transport), the time-activity patterns of individuals, as well as other key determinants (Banzhaf et al., 2019a; NRC, 1991). See Section 6.4.1 for further discussion of proximity-based analysis.

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[43] See Cain et al. (2024); WHO (2023); Knapp et al. (2023); Ding et al. (2023); Tessum et al. (2021); Bekkar et al. (2020); Colmer et al. (2020); Deere and Ferdinand (2020); U.S. EPA (2019a); McHale et al. (2018); Manuck (2017); Akinbami et al. (2016); Tulve et al. (2016); Wilson et al. (2015); Currie et al. (2013); and Morello-Frosch et al. (2011).

[44] The World Health Organization (2006) defines *vulnerability* as "a matrix of physical, chemical, biological, social, and cultural factors that result in certain communities and subpopulations being more susceptible to environmental factors because of greater exposure to such factors or a compromised ability to cope with and/or recover from such exposure."

[45] Other studies documenting environmental stressors in communities with higher proportions of non-White populations include Bullard et al. (2008), Faber and Krieg (2005, 2002), Wilson et al. (2002), and Maantay (2001).

[46] See Morello-Frosch and Obasogie (2023), Di Fonzo et al. (2022), Jbaily et al. (2022), Pace et al. (2022), Grineski and Collins (2018), and Ash and Boyce (2018).

4.1.2 Unique Exposure Pathways

Exposure pathways describe the means by which exposure to a given stressor occurs. Environmental hazards and risks are not uniformly distributed throughout a population; biological factors and social context intersect to create unique exposure pathways that put some individuals at higher exposure risk (Burger and Gochfeld, 2011). At the community level, groups of individuals may be exposed to certain stressors through shared cultural or social practices, learned traditions, values, and life experiences. For example, subsistence fishing is more prevalent in some communities, leading to potential exposure through handling and ingesting fish with high levels of mercury or other chemicals (U.S. EPA, 2023d). Occupation-related pathways are also relevant to consider, such as potential exposures from pesticide drift faced by farmworkers or from “take home” chemical residues on clothing (Kalweit et al., 2020; Hyland and Laribi, 2017).

Exposure pathways are also related to lifestages (U.S. EPA, 2011a). For example, object-to-mouth and crawling behaviors in infants and toddlers could increase exposure to contaminants such as lead dust that accumulate on floors or carpets (U.S. EPA, 2013a). Other lifestages, such as persons of childbearing age or old age, are associated with other exposure pathways; the EPA provides exposure assessment tools for different lifestages.[47]

4.1.3 Physical Infrastructure

For some environmental stressors, physical infrastructure (or lack thereof) may contribute to increased exposure. For instance, housing in the United States built before1978 is more likely to contain lead-based paint, exposure to which can impair cognitive function in children (U.S. EPA, 2024g). Likewise, older homes may have leaded pipes and result in exposure via drinking water (Triantafyllidou et al., 2021). Substandard structural and building conditions such as dampness, poor ventilation, dust collection, and pest infestation can also trigger asthma or other negative health effects (U.S. EPA, 2021b; Stephens, 2016). Living near highways, airports, railroads, or pipelines may also result in increased exposure to specific stressors (e.g., particulate matter, lead, noise, odors) (Tessum et al., 2021; Woodburn, 2017; Rowangould, 2013).

4.1.4 Exposure to Multiple Stressors and Cumulative Exposures

People of color and low-income populations are often impacted by exposure to environmental hazards from multiple industrial sources, such as contaminants from manufacturing facilities, landfills, and leaking underground tanks; transportation-related air pollution; and consumer products (e.g., Bakkensen et al., 2024; Banzhaf et al., 2019a; California Environmental Protection Agency, 2015). Rural and Tribal communities may be exposed to higher levels of contaminants that naturally occur in the soil or groundwater (e.g., radon, uranium, arsenic) via groundwater or economic activities such as mining or energy production (Erickson et al., 2024). The uneven distribution of the effects of climate change, such as increased risk of wildfires, droughts, flooding, and other extreme weather events, can further compound these differences in exposure (Nolte et al., 2018; Lall et al., 2018).

An analysis that considers risks from only one source can inaccurately characterize the potential health risks faced by a population group if they are also exposed to stressors from other sources. The presence of other stressors, such as lost access to culturally important subsistence practices, structural

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[47] See https://www.epa.gov/expobox/exposure-assessment-tools-lifestages-and-populations-lifestages.

and systemic racism, or other life events, may also exacerbate the effects of some chemical exposures for vulnerable communities (e.g., increased likelihood of adverse health outcomes due to increased presence of stress hormones from psychological factors) (Swope et al., 2022; Padula et al., 2020).

4.1.5 Monitoring, Compliance, and Enforcement

The monitoring activities, compliance efforts, and enforcement of existing environmental regulations can also contribute to differences in exposure. The difficulty and cost of siting and maintaining monitoring equipment often limits the amount of environmental sampling performed. This can lead to an underestimate of the emissions generated by regulated sources (Hoyt and Raun, 2015). Given that industrial activity tends to be clustered in communities with EJ concerns, insufficient information about what is being emitted by both regulated and unregulated sources can further mask the magnitude of potential exposure faced by these communities.

Differential compliance across sources can also exacerbate pre-existing disparities (e.g., Fedinick et al., 2019; Allaire et al., 2018; Balazs et al., 2012). For instance, drinking water systems that serve low-income, Indigenous, and rural communities and communities of color have been found to have higher levels of drinking water violations and poorer water quality (Martinez-Morata et al., 2022; Mueller and Gasteyer, 2021; McDonald and Jones, 2018). The way environmental policies are enforced may also differ across local governments, states, and Tribal lands (Switzer, 2019; Teodoro et al., 2018).[48]

4.1.6 Community Capacity to Meaningfully Participate in Decision-Making

The capacity to meaningfully participate in decision-making varies widely across communities and depends on a variety of factors such as leadership, skills, resources, community power, and social and organizational networks (Freudenberg et al., 2011). Removing barriers related to disability, language access, and lack of resources is particularly important for facilitating meaningful engagement in decision-making. For example, community planning meetings that make facility siting and permitting decisions without translating key materials and discussion limit the ability of a non-English speaking community to participate. Other factors that can affect a community’s capacity to participate are lack of broadband internet access, particularly in rural areas and Tribal lands (U.S. FCC, 2020), and lack of technology fluency. When communities are unable to participate effectively in decision-making due to these types of barriers, they may be more likely to experience negative environmental consequences.

Though meaningful engagement is related to a community’s capacity to participate in the decision-making process, these topics are not discussed in depth in this guidance document. Information about how meaningful engagement can inform EJ analysis is found in Sections 2.3 and 5.3.1.2.

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[48] Enforcing federal environmental regulations is a shared responsibility of federal and state governments and Tribal Nations. This requires cooperative, periodic, and early joint planning and regular communication between the EPA, states, and Tribal governments on the sharing of enforcement responsibilities. Several federal environmental laws authorize the EPA to treat eligible federally recognized Tribes as a state for the purpose of implementing and managing certain federal environmental programs and functions. That said, the EPA is ultimately “responsible for fair and effective enforcement of federal requirements. If a state partner is not taking timely or appropriate action to address threats to public health and the environment, [the] EPA has the authority and responsibility to take direct action” (U.S. EPA, 2023e).

4.2 Contributors to Increased Consequences of Exposure

An individual's biological response to an environmental stressor is an important determinant of both the occurrence and severity of an adverse health effect. Potentially relevant current and historical intrinsic and extrinsic factors that may influence this response include, but are not limited to:

- Pre-existing diseases and health conditions (e.g., asthma, disability) (Varshavsky et al., 2023);
- Material circumstances (e.g., neighborhood quality and housing conditions, green space, walkability, access to fresh foods and high-quality schools; access to credit) (Jimenez et al., 2021);
- Behavioral and biological factors (e.g., nutrition, smoking, genetic factors) (Varshavsky et al., 2023);
- Access to health care (e.g., interaction with health care providers and resources; lack of health insurance or access to preventative care) (Varshavsky et al., 2023);
- Psychosocial circumstances (e.g., stressful living conditions and relationships, low socioeconomic status, racism, discrimination, lack of coping and support mechanisms) (Padula et al., 2020; McEwen and Tucker, 2011; Couch and Coles, 2011);
- Limited capacity to adapt to the effects of climate change and other natural disasters (World Health Organization, 2023); and
- Co-exposure to similarly acting toxics or chemicals, and cumulative burden of disease resulting from exposure to all stressors throughout the course of life (McPartland et al., 2022; Schwartz et al., 2011a, 2011b).[49]

Also known as risk- or effect-modifiers, these factors may influence health outcomes from exposure through biological interactions at the individual level. Socioeconomic status, which does not by itself elicit a biological interaction, has a complex and robust association with many health states (Mani et al., 2013), and may influence factors such as diet, nutrition, and access to health care and consequently health status (Christensen et al., 2022; Munoz-Pizza et al., 2020; Clougherty et al., 2014).[50]

Some individuals within population groups may be more vulnerable to the effects of some stressors due to their stage of physiological and behavioral growth and development, referred to as *lifestage* (U.S. EPA, 2011a). Vulnerable individuals based on lifestage can include children, the elderly, and pregnant women. Workers in certain occupations (e.g., farmworkers) may also be more vulnerable depending on the health endpoint and stressor. These groups may also have unique exposure pathways 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 responsiveness, can further increase the risk for adverse health effects. Text Box 4.1 provides an overview of the literature on increased vulnerability to the effects of climate change.

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[49] Several conceptual frameworks explicitly integrate social context into the exposure-disease paradigm to highlight how these factors may interact with environmental exposures to yield health differences (Morello-Frosch and Jesdale, 2006; Gee and Payne-Sturges, 2004).

[50] See Schwartz et al. (2011a, 2011b) for several examples of how these risk- or effect-modifiers may increase risk.

Text Box 4.1 Increased Vulnerability to the Effects of Climate Change

Changes in global temperatures due to climate change are expected to result in changes in average annual temperatures in the U.S. For instance, global warming of 2°C by 2100 is projected to result in average annual temperature increases of between 3°C and 4°C for large portions of the country (U.S. EPA, 2021c). These changes in temperature and other changes to our natural systems are expected to affect human health in myriad ways over the coming decades. These effects are due to changes in the frequency, duration, intensity, timing, and location of extreme events such as heat waves, floods, wildfires, and droughts. These extreme events can also affect human health through their effects on vector-, food-, and waterborne infectious diseases, through changes in temperature-related mortality, climate-driven air pollution exposure, flooding-related property damage, and effects on labor productivity, to name a few. These effects are not expected to be evenly distributed across the U.S. population (U.S. EPA, 2021c; USGCRP, 2018).

Low-income and predominantly non-White communities are especially vulnerable to these and other effects of climate change because of their limited adaptive capacity; dependence on climate-sensitive resources, such as local water, fish, and food supplies; and inadequate access to information and recovery resources (USGCRP, 2023; USGCRP, 2018; IPCC, 2018; NASEM, 2017; USGCRP, 2016; IPCC, 2014; NRC, 2011b). For example, low-income households typically have limited access to healthcare and often do not have adequate insurance. Workers in outdoor occupations such as agriculture or construction may not be able to avoid working on high-temperature days without significant loss of income. Non-English speaking and disabled individuals may have more difficulty accessing flood or fire hazard alerts, evacuating safely, or accessing aid after natural disasters (U.S. EPA, 2021c; USGCRP, 2016).

In addition, health conditions such as cardiovascular or respiratory illnesses that occur at higher rates in many socially and economically vulnerable communities may also be exacerbated by the effects of climate change (USGCRP, 2023; USGCRP, 2016). Outdoor workers, who frequently are comprised of already at-risk groups, are also more likely to be exposed to poor air quality and extreme temperatures (U.S. EPA, 2021c). Low-income households may also face increased food insecurity as climate change reduces food availability and increases prices (USGCRP, 2018; USGCRP, 2016).

Chapter 5: Considering Environmental Justice Concerns When Planning a Human Health Risk Assessment

This chapter provides guidance to Agency analysts on integrating EJ concerns into the planning of a human health risk assessment (HHRA) conducted to support a regulatory action. As noted in the EPA's *Framework for Human Health Risk Assessment to Inform Decision-Making* (referred as the *HHRA Framework*) (U.S. EPA, 2014b), EJ concerns are a key consideration in the early stages of HHRA, including planning and scoping, and problem formulation.

5.1 Introduction

Human health risk assessment is a complex, iterative, and multidisciplinary process intended to inform decision-makers about the effects of environmental stressors on human health and to support the formulation of policy actions that impact these stressors. EPA risk assessment has well-established procedures, methods, and tools to inform regulatory decision-making, but it also evolves with experience and the advance of new scientific capability (U.S. EPA, 2014b). The following questions, outlined in Section 3.1 (and repeated here), are important to consider during HHRA planning to help ensure that the HHRA provides relevant information about differences in risks for population groups of concern that can then be used as inputs into the EJ analysis for a regulatory action (see Chapter 6):

- **Baseline:** Are there existing EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern?
- **Regulatory options:** For the regulatory option(s) under consideration, are there potential EJ concerns associated with environmental stressors that are affected by the regulatory action for population groups of concern?
- **Mitigation or exacerbation of effects:** For the regulatory option(s) under consideration, are EJ concerns exacerbated, mitigated, or unchanged compared to the baseline?

Even when methods and data relevant to these questions are not available, their consideration can highlight where additional data or research are needed. HHRA and the science and practices that support it continue to evolve. As new tools and information become available, incorporating EJ considerations into HHRA should also evolve to reflect improved risk assessment methodologies and guidance.

This chapter first provides an overview of modeling and data needs for evaluating EJ concerns (Section 5.2), then discusses how EJ concerns can be considered when planning a HHRA (Section 5.3). This discussion is guided by EPA's existing *HHRA Framework* and highlights considerations during the initial phases of risk assessment: planning and scoping, and problem formulation. The chapter concludes with a brief summary of possible approaches for considering the cumulative effects of multiple exposures (Section 5.4).

5.2 Overview of Modeling and Data Needs for Evaluating EJ Concerns

HHRA seeks to characterize the nature, probability, and magnitude of current or future risks of adverse human health effects related to exposure to environmental stressors. This can include both quantitative and qualitative characterizations of risk (U.S. EPA, 2014b; NRC, 1983) and may incorporate different approaches, methods, and metrics, depending on the nature of the decision that the assessment is intended to inform. The EPA has published guidance on all steps of the HHRA process, as well as the *HHRA Framework* (U.S. EPA, 2014b).

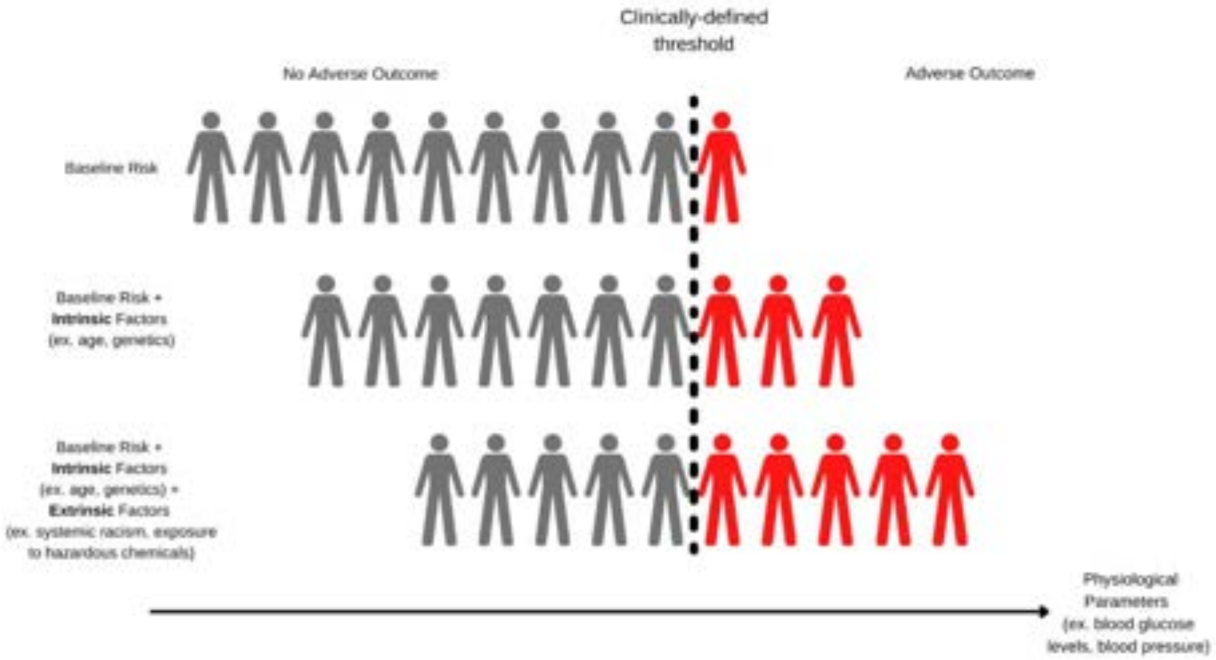
Analyzing EJ concerns as part of HHRA requires spatially and temporally resolved data, including environmental exposures, health data, and demographic information. However, information on EJ concerns is often qualitative and place specific, which results in several challenges when considering EJ in HHRA.

5.2.1 HHRA Requires Sufficient Data and Modeling Capabilities to Incorporate EJ Considerations

As noted by the NRC "the goal [of HHRA] of achieving accurate, highly quantitative estimates of risk…is hampered by limitations in scientific understanding and the availability of relevant data…" (NRC, 2009). These data requirements may be even greater when it comes to risk estimates to inform EJ considerations due to complexities of exposure and the existence of additional stressors. For example, modeling how non-environmental stressors (such as nutritional deficits and stress) interact with specific chemicals to exacerbate or mitigate individual health endpoints is still at a nascent stage of development. However, population-level vulnerability due to these types of non-environmental stressors can be informative for establishing increased susceptibility to exposures to pollutants.

Figure 5.1 illustrates how considering intrinsic and extrinsic factors, including both environmental and non-environmental stressors, can impact risk. The first row, baseline risk, depicts how exposure above a clinically defined threshold leads to adverse health outcomes in the general population. As we also consider intrinsic factors such as age and genetics, a greater proportion of the population experiences an adverse health effect. Adding extrinsic factors, such as systemic racism and exposure to hazardous chemicals results in a more accurate estimation of the population with an adverse health outcome. Though not depicted in the figure, this concept could be extended to broader characterizations of adverse outcomes (e.g., lost workdays).

Figure 5.1 How Intrinsic and Extrinsic Factors Influence Adverse Health Outcomes in a Population



(Source: Varshavsky et al., 2023)[51]

Data needed for HHRA to more fully consider EJ may be difficult to find, particularly given the importance of considering it within a holistic framework. For example, robust national studies of health outcomes, and their variability, are often limited because specific measurements of non-environmental stressors vary locally. Many studies target populations whose socioeconomic status is higher than the national average (e.g., White, male adults) and who reside in urban areas that have adequate monitoring and therefore may not be generalizable to populations with EJ concerns (Pelacho et al., 2021; Payne-Sturges, 2011).[52] That said, a growing literature is focused on vulnerable population groups, including Medicare populations (Di et al., 2017), Hispanics and Latinos (Letellier et al., 2022), Native Americans, Asians, and those who experience low income (Josey et al., 2023; Liu and Eichen-Miller, 2021).

National data can have limited utility for informing health disparities and there are limitations to extrapolating community-level data from national surveys (Dosemagen and Williams, 2022; Nweke et al., 2011). See Chapter 7 for a discussion of identified research priorities for improving the EPA analysis of EJ concerns, which elaborates upon these modeling and data gaps.[53]

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[51] Used under Creative Commons license (https://creativecommons.org/licenses/by/4.0/). No changes were made to the original figure.

[52] In the absence of scientific data to fully characterize the range of responses to chemical exposures, the EPA employs default assumptions, such as uncertainty factors used in non-cancer risk assessments, to account for human variability. See the EPA's risk assessment portal (www.epa.gov/risk) for guidance documents on these uncertainty factors. As noted by the EPA's Science Advisory Board (SAB, 2015), however, "…the use of uncertainty factors in developing dose-response assessments for an individual level chemical might address the general population as a whole but does not specifically address differential or disproportionate vulnerability."

[53] Varshavsky et al. (2023) notes that emerging tools and data "that better account for human variability and susceptibility include probabilistic methods, genetically diverse in vivo and in vitro models, and the use of human data to capture underlying risk and/or assess combined effects from chemical and non-chemical stressors."

5.2.2 It Can Be Difficult to Incorporate the Cumulative Effects of Multiple, Dissimilar Stressors into HHRA

Communities with EJ concerns are often exposed to many environmental and non-environmental stressors through multiple pathways. HHRA is most often conducted on a chemical-by-chemical basis using single exposure-to-effect pathways.[54] Broadening the scope of HHRA to incorporate other environmental and non-environmental stressors requires addressing challenging scientific and technical questions (e.g., what effect does exposure to pesticides have on rural or Indigenous populations? How does living near an environmental hazard affect vulnerability to other environmental concerns?).[55]

In addition, adoption and use of a framework for cumulative risk assessment (CRA) is rare among practitioners (Clougherty and Rider, 2020). Cumulative risk assessment that incorporates both environmental and non-environmental stressors requires more comprehensive data than traditional HHRA (e.g., information on background exposure or health status among specific populations).[56] While the EPA's SAB (SAB, 2015) continues to recommend use of HHRA, it encourages the EPA to develop further guidance for quantitative and/or qualitative evaluation of cumulative effects of exposure to multiple stressors on human health and well-being. See Section 5.4 for additional discussion.

5.2.3 HHRA Requires Effective Communication, Given its Highly Technical Nature

HHRA has been criticized for often having limited consideration of public perceptions of risk and, more broadly, for limiting public input into the process. Both factors are critical to the assessment of EJ concerns (Sexton and Linder, 2010).[57] The technical complexity of HHRA can also lead to a lack of transparency and accountability (SAB, 2015).

Effective communication about HHRA is therefore necessary for meaningful public involvement, which is not only a critical aspect of the HHRA process (see Figure 5.2) but is also essential for decision-making. Payne-Sturges (2011) notes that "when affected citizens actively participate in the process to better understand science and inform policy responses, better decisions emerge as a result." Risk communication can increase community involvement in decision-making processes, better inform risk assessors regarding community perceptions of risk, and provide opportunity for dialogue about the limits and opportunities of policymaking efforts (Barzyk et al., 2015). See Section 2.3 for further discussion of meaningful engagement and Section 5.3.1.2 for further discussion of risk communication in the context of environmental justice.

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[54] Some assessments have also evaluated the risk associated with exposure to multiple chemicals that act by similar mechanisms (Cattaneo et al., 2023; Backhaus and Faust, 2012).

[55] While there is limited quantitative data available on non-environmental stressors, how they interact with chemicals is a growing area of research (Aker et al., 2020; Payne-Sturges et al., 2018), including methods to combine multiple and dissimilar stressors (Bakkensen et al., 2024).

[56] While the literature often uses the terms *chemical* and *non-chemical stressors*, we use the terms *environmental* and *non-environmental stressors* in this report to capture the range of chemical, physical, or biological agents, contaminants, or pollutants that may be subject to a rulemaking.

[57] HHRA is framed in terms of the risk of an adverse outcome from a specific stressor or stressors, but EJ advocates and analysts are often interested in broader concepts of health (Barzyk et al., 2015). For example, HHRA as traditionally practiced does not quantify factors such as fairness, voluntariness, responsibility, control, trust, reversibility, and identifiable victims (Sexton and Linder, 2010; Corburn, 2002), though these factors may be identified and characterized as part of risk management discussions. HHRA methods also do not typically consider public attitudes toward risk or incorporate community insights and priorities around sources of risk (Sandman, 1989).

5.3 Considering EJ Concerns When Planning a HHRA

When considering EJ concerns, it is important that analyses conducted in support of regulatory actions explicitly consider both baseline health risks and whether changes in risk due to policy actions may accrue differentially within population groups of concern. Specific demographic and socioeconomic attributes (e.g., age, poverty) can be correlated with increased vulnerability to environmental stressors. Also, the burden of health problems and differential environmental exposures associated with race, ethnicity, income, or other relevant demographic and socioeconomic characteristics may overlap with other factors that influence vulnerability such as lifestage, genetic predisposition, or pre-existing health conditions (Shao et al., 2022). See Chapter 4 and Section 6.2 for further discussion.

5.3.1 Overview of the HHRA Process

The EPA's *HHRA Framework* provides an overview of the risk assessment process (Figure 5.2). The HHRA process is not strictly sequential; steps are often performed together in an integrative fashion, and EJ can be considered at multiple points in the HHRA process. Ultimately, the final step—risk characterization—synthesizes information from the other steps and provides the basis for communicating the results to decision-makers and the public.

The planning and scoping and the problem formulation phases are key initial elements of the *HHRA Framework*. At the planning and scoping phase, analysts define the process for conducting the risk assessment and establish its analytic scope. The problem formulation phase informs the HHRA technical approach. Important outcomes of this step are a conceptual model that describes the relationship between stressors, exposure pathways, exposed lifestages, populations, and health endpoints that will be addressed in the risk assessment, as well as an analysis plan for conducting the assessment (U.S. EPA, 2014b). The consideration of EJ throughout the risk assessment planning and scoping and the problem formulations phases is important to ensure an effective assessment.

Figure 5.2 also illustrates two key elements to consider throughout the risk assessment process, from initiation to informing decisions: fit-for-purpose and public and community involvement.

Figure 5.2 Framework for Human Health Risk Assessment to Inform Decision-Making

Adapted from U.S. EPA (2014b)

5.3.1.1 Fit-for-Purpose

Fit-for-purpose refers to the concept that risk assessments and associated products should be suitable and useful for their intended purpose(s), particularly for informing choices among risk management options (U.S. EPA, 2014b). Accordingly, throughout the process of planning and performing HHRAs, it is important to evaluate whether the assessment effectively addresses the information needs of decision-makers. This is primarily accomplished through transparent dialogue between risk assessors and risk managers early in the assessment process.

While the nature and scope of a HHRA may vary by statute and the type of problem being addressed (and will be limited by available data, methods, and resources), a robust fit-for-purpose process that includes consideration of its purpose in relation to evaluating EJ concerns will maximize the usefulness of the assessment. A clearly defined purpose informs many aspects of HHRA planning, including how to frame the questions, which datasets to use, which analyses to perform, and how to synthesize and interpret results.

Because fit-for-purpose will be continually evaluated throughout the risk assessment process, it is important to raise key questions early and even revisit questions that bear on whether the resulting risk characterization will be able to inform EJ concerns. These questions include:

1. What types of individuals or population groups face higher risks in the baseline relative to the average or comparable individuals in the general population?

2. What types of individuals or population groups could experience higher risks relative to the average or comparable individuals in the general population as a result of a regulatory option?
3. What are the reasons why an identified population group (or lifestage within a population group) may potentially experience higher risk than the average person?
4. What tools and data are available to estimate and characterize the potential for differences in risk for affected groups? (This is especially relevant when developing the HHRA analysis plan.)
5. How can information about differences in risk for affected groups, or the potential for these differences, be effectively communicated in the risk characterization?

5.3.1.2 Public and Community Involvement

Public and community involvement is integral to both the HHRA process and the broader consideration of EJ concerns. For example, engaging Tribes early in the process, as relevant, may lend new insights into how they define human health (U.S. EPA, 2019a) and allow for consideration of Indigenous Knowledge (also referred to as Traditional Ecological Knowledge). See Section 2.3 for more discussion of meaningful engagement.

To enable communities to meaningfully participate, it is important to recognize and address conditions that could reduce or hinder their ability to participate in the HHRA and regulatory process. These could include time and resource constraints; barriers due to limited English proficiency or disability; lack of trust; lack of information; and difficulty in accessing and understanding complex scientific, technical, and legal resources. Public participation may also be hindered by socio-political dynamics that serve to weaken democratic processes, which raises the importance of finding approaches that function in contexts of social distrust and creating positive participatory experiences (Webler and Tuler, 2021). For instance, some forms of public participation may favor individuals with more political influence and do not necessarily lead to more equitable outcomes. It is therefore paramount that the EPA is intentional about creating opportunities for meaningful public involvement so that risk-based decisions do not lead to unsatisfactory community outcomes (Sexton, 2013).

See Chapter 3 of the *HHRA Framework* (U.S. EPA, 2014b) on how to involve the public and the broader community in the risk assessment process. Text Box 5.1 also highlights the potential role of participatory science in further enhancing data available for HHRA. See Section 2.3 for more discussion of meaningful involvement in the context of analysis.

In planning a HHRA, information gained through public involvement can be particularly valuable for constructing exposure scenarios in scoping (Section 5.3.2) and for identifying both data and data gaps as part of the analysis plan (Section 5.3.3.2).

Text Box 5.1 Participatory Science

Participatory science engages the public in advancing scientific knowledge by formulating research questions, collecting data, and interpreting results. This includes a broad and inclusive range of activities, from those originating in academic and government institutions that enlist the public in data collection to create knowledge to community-led projects intended to identify potential EJ issues and community concerns.

For HHRA planning and scoping, participatory science may be able to fill information gaps and provide useful data that informs analysis. For example, projects may collect monitoring data in overburdened communities. For data generated by the public to have a meaningful impact, quality assurance during data gathering is critical. The EPA has developed a *Handbook for Citizen Science Quality Assurance and Documentation* (U.S. EPA, 2019b) to help guide data collection efforts and emphasize the high standards required for data to be used in regulatory decisions. See https://www.epa.gov/participatory-science/quality-assurance-handbook-and-toolkit-participatory-science-projects for the handbook and related materials.

Participatory science may also facilitate meaningful community involvement in the HHRA process. As described in the EPA's *Vision for Participatory Science* (U.S. EPA, 2022e), it can create a stronger, more inclusive, and collaborative network of individuals dedicated to environmental problem solving. It can also contribute to effective risk communication by improving public understanding of environmental issues and actions to address them.

Note: Other terms sometimes used to refer to participatory science include citizen science, community science, volunteer monitoring, or public participation in scientific research.

5.3.1.3 Risk Communication

Risk communication is intended to provide the public with the information it needs to make informed, independent judgments about risks to health, safety, and the environment. The EPA has extensive resources on effective risk communication, including frameworks, tools, and case studies.[58]

To identify potentially affected members of the public, the Presidential/Congressional Commission on Risk Assessment and Risk Management suggests using the following questions:[59]

- Who might be affected by the risk management decision?
- 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?
- Who might reasonably feel they should be included?

Analysts and risk managers can consult the *Achieving Health and Environmental Protection Through EPA's Meaningful Engagement Policy* (U.S. EPA, 2024d) for general guidance when designing a meaningful engagement and public participation process. To ensure that the public can participate

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[58] See the EPA's Risk Communication page at https://www.epa.gov/risk-communication.

[59] See the EPA's Presidential Commission on Risk Assessment and Risk Management website: http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=55006&CFID=55036505&CFTOKEN=43224210.

meaningfully in the HHRA process, the approach for soliciting information needs to be specific, involve interactive dialogue that is designed to elicit specific responses, and include accommodations for population groups facing additional barriers to participation, such as those in rural areas, with limited English proficiency, or a disability. Elements of such a dialogue may include specific questions about the types of data or models that are needed to adequately reflect EJ concerns.[60]

5.3.2 Planning and Scoping

Planning and scoping is the stage in which the risk assessor defines the process for conducting the risk assessment and identifies its general scope. This activity contributes to the development of a sound risk assessment that will eventually accomplish its intended purpose. It also assists those interested in the risk assessment process in understanding the broader context and how the anticipated results will satisfy the intended purpose. A broad range of technical experts (e.g., toxicologists, epidemiologists, statisticians, economists, and other social scientists) working as a team may be involved in this stage.

The *HHRA Framework* identifies several aspects of planning and scoping. Of note for EJ considerations are the context, purpose, and scope of the risk assessment; and planning scientific peer (and other) review. As described throughout this chapter, informing EJ considerations requires greater emphasis on the human receptor characteristics in many of these steps, which is a shift from a more conventional focus on stressor characteristics.

5.3.2.1 Defining the Context, Purpose, and Scope of the Risk Assessment

EPA human health risk assessments conducted for rulemaking are intended to inform and support risk management decisions and the development of regulatory actions, focusing on the changes in health risk that are anticipated. When planning a risk assessment for any purpose, analysts should clearly identify the decision(s) that will be supported by the analysis, specify the boundaries for the assessment (i.e., the scope), and detail what will not be addressed in the risk assessment.

Context of the Risk Assessment

A key first step in a HHRA is documenting the context for the analysis. This includes the regulatory and statutory context as well as the physical and cultural context for the investigation. To provide regulatory and statutory context that considers EJ issues, analysts need to identify any complementary requirements between the triggering statutory authority and E.O.s 12898 and 14096 that focus on identifying and addressing potentially disproportionate and adverse health effects and risks. For example, a new regulation of coal combustion residuals (CCR) and how they are managed will have an impact on the community surrounding the waste site, as well as along the roadways traveled by large vehicles moving CCR waste.

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[60] When EPA actions or decisions may affect Tribes, the EPA Tribal consultation policy provides clear guidelines for when, how, and the types of actions or decisions for which consultations with Tribal governments should occur (U.S. EPA, 2023f).

In addition to the specific policy context, other contexts may also be relevant and important to consider. For example, background exposure to chemicals from multiple sources that might affect responses, or an enhanced background risk for a relevant adverse health outcome due to other factors that may complicate measurements, are important for assessing differences in risk. In addition, communities with EJ concerns may experience differential risks due to higher vulnerability (e.g., due to lifestage or pre-existing health conditions) or other factors influencing exposures (e.g., behavioral patterns or proximity to sources of exposure).[61] Together, these existing conditions help frame and clarify the context of the HHRA.

Purpose of the Risk Assessment

Clearly articulating the overall purpose of an assessment is an iterative process and may involve extensive interaction between the assessment team and affected members of the public to establish a common understanding and ensure that relevant community concerns are considered. In addition, in this step analysts may conduct a review of data needs and limitations to ensure that the results may adequately inform decision-makers and members of the public (NRC, 2009).

The assessment's purpose and scale (e.g., regional or national) will have significant implications for the assessment's scope, level of detail, and approach. Key considerations at this stage include:

- What specific policy or regulatory decision is to be informed by the risk assessment? When is the decision anticipated? What are the risk management options being considered?
- What legal or statutory requirements affect risk management options and the level or type of analysis? (U.S. EPA, 2014b)

To ensure that a HHRA generates useful information, risk managers and analysts should develop concise statements of risk management and analytic objectives that incorporate EJ concerns. See Text Box 5.2 for an example. As risk managers and analysts develop these objectives, it is important to frame them such that the data generated by the HHRA can be used to respond to the main EJ analytic questions from Section 3.1. Analytic objectives for incorporating EJ concerns should concisely identify the evidence to be collected; the direction and structure of the planned consideration of EJ concerns; the analytic 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).

Scope of the Risk Assessment

Scoping establishes the boundaries of the HHRA (e.g., what population groups, health effects, chemicals, and exposure pathways will be included in the assessment). These boundaries should align with and support the stated purpose of the risk assessment.

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[61] As an example, primary National Ambient Air Quality Standards (NAAQS) are required to protect public health, including the health of sensitive or at-risk population groups, with an adequate margin of safety. The Integrated Science Assessment (ISA) and its supplement cite extensive evidence indicating that ''both the general population as well as specific populations and lifestages are at risk for $PM_{2.5}$-related health effects'' (U.S. EPA, 2022d; U.S. EPA, 2019c). Factors that may contribute to increased risk of $PM_{2.5}$-related health effects include lifestage (e.g., children and older adults), pre-existing diseases (e.g., cardiovascular disease and respiratory disease), race/ethnicity, and socioeconomic status.

Text Box 5.2 Considering EJ Concerns for the 2015 Coal Combustion Residuals Generated by Electric Utilities Final Rule (U.S. EPA, 2015d) - Examples of Risk Management and Analytic Objectives

Regulatory Context: The Resource Conservation and Recovery Act (RCRA) gives the EPA authority to regulate non-hazardous wastes. RCRA solid waste regulations ban open dumping of waste and set minimum federal criteria for the operation of solid waste landfills and impoundments. The EPA established requirements for disposal of coal combustion residuals (CCRs or coal ash) at landfills and surface impoundments in the 2015 CCR Final Rule. The regulation includes structural integrity requirements to reduce catastrophic failure risk; groundwater monitoring and corrective action; location restrictions; liner design and operating criteria; closure and post-closure requirements; and record keeping and notification, including public websites documenting monitoring and corrective action planning. These requirements reduce releases of arsenic and other contaminants to water and air, help ensure actions taken by power plants to comply with the rule are transparent, and that the communities impacted by the disposal of CCRs have the information they need to understand risks.

Risk Management Objective: Evaluate the effect of the 2015 CCR rule on the potential for increased risk to human health and the environment.

Example Questions:

- What hazards from corrective action, operations and closure and post-closure requirements, including accidental releases of CCR, could pose hazards resulting in differential risks to population groups and communities of concern?
- How does the rule affect the likelihood of such hazards compared to pre-2015 regulations?
- Are there potential CCR management hotspots of concern?

Analytic Objectives: (1) Evaluate whether baseline demographic characteristics of population groups potentially affected by the rule differ from the broader population; (2) Evaluate whether other factors that affect the potential for differential risk are present under the rule; and (3) Evaluate whether the potential for exposure to communities of concern is exacerbated or mitigated by the 2015 CCR rule.

Example Questions:

- Do communities near facilities subject to the rule have higher percentages of population groups of concern relative to national, state, or regional populations?
- Are the communities potentially affected by the 2015 CCR rule also affected by other sources of pollution (e.g., industrial facilities, landfills, leaking underground storage tanks)?
- Do other factors contribute to increased vulnerability (e.g., vulnerable lifestages, nursing mothers) among population groups of concern?
- Does the 2015 CCR rule reduce or improve the ability for potentially impacted communities to participate in the decision-making process?
- Does the regulation reduce existing (baseline) disparities in risk?

At this step, most EPA assessments focus on identifying and considering information available in areas such as the sources of contaminants, stressors, and associated effects; exposure routes and pathways; and vulnerable populations or lifestages. Incorporation of public concerns is also important at this stage (and should be built upon throughout the assessment process).

Depending on the nature of the assessment, consulting with affected communities can provide valuable information when identifying exposure routes, duration, pathways, and other information for constructing exposure scenarios (U.S. EPA, 2014b). This information may help reduce the need for default assumptions in the assessment. The EPA has developed extensive guidance on community and public involvement for this purpose and continues to update its guidance specifically for EJ-related contexts (U.S. EPA, 2024d; 2015b; 2013b). See Section 2.3 for a general discussion of meaningful engagement.

In the scoping stage of a HHRA that supports a regulatory action, analysts should consider several questions that can aid in identifying EJ concerns:

- **Which population groups, as characterized by geographic location, ethnicity or race, gender, occupation, age, baseline health status or other factors, should be part of the assessment?** In some instances, the presence of risk- or effect-modifiers may mean that some types of individuals or communities are at greater risk for experiencing adverse effects, and there can be interactions among these modifiers. In identifying population groups for the assessment of differential risks, analysts should consider the extent to which risk- or effect-modifiers, by themselves or in combination, may explain differences that vary by demographic or socioeconomic characteristics. If analysts decide to assess population groups defined by risk- or effect modifiers, the rationale for this decision and the associated methods needs to be transparently documented.

- **What health endpoints are to be addressed by the assessment?** Defining health endpoints clearly in the planning and scoping phase focuses the risk assessment and increases the transparency of the process. When selecting health endpoints, analysts should consider whether specific health endpoints may be significant in population groups of concern. In making this selection, it is important to evaluate whether baseline health endpoints for a given exposure differ across population groups and to consider what intrinsic and extrinsic factors might contribute to variation. 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 relevant health endpoints at the beginning of the HHRA. Some information found in toxicity assessments may only define the potential for an adverse health outcome for specific stressors. Information from sources such as EJScreen as well as community insights may also identify areas of further research as the HHRA progresses.

- **What exposure routes and pathways are relevant? Do specific exposure pathways potentially lead to specific effects? What exposure scenarios should be modeled?** Analysts 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 and duration of historical, current, and future exposure.

Unique exposure pathways based on lifestages, cultural practices, and other relevant categories may also be considered.[62] Different pathways of exposure (e.g., inhalation, dermal, ingestion) may produce different effects with varying levels of severity. See Appendix B.

At the completion of the scoping step, analysts will have a well-defined context for the analysis, a set of key analytic priorities to evaluate key policy questions, and a set of boundaries for the HHRA that reflect how the analysis will address its analytic priorities. All of these elements can be incorporated into the problem formulation phase to produce a detailed plan for the assessment.

5.3.2.2 Scientific Peer Review or Other Reviews

During the planning and scoping phase of a HHRA, analysts should also consider the need for and timing of peer review. Peer review is a documented process conducted to ensure that activities are technically supportable, competently performed, properly documented, and consistent with established quality criteria (U.S. EPA, 2014b).[63] When a HHRA that incorporates EJ concerns is subject to scientific peer review, subject matter experts may include community representatives with technical expertise and scientists with community and EJ experience. Peer review usually involves a one-time or limited number of interactions by the independent peer reviewers with the authors of the work product.

An assessment also may benefit from other types of input, such as peer involvement and public comment. Planning and scoping for the assessment includes discussion of whether and what types of reviews will be included in light of the context and constraints for the assessment, including schedule and resources (U.S. EPA, 2014b). In addition, risk assessors may rely on existing peer-reviewed literature to consider topics such as cumulative risk or differences in effects across communities.

5.3.3 Problem Formulation

Problem formulation builds on the planning and scoping phase to identify major factors to consider in the HHRA and informs its technical approach. Two important products from problem formulation are:

- A conceptual model to describe the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed lifestage(s) and population(s), and health endpoint(s) that will be addressed in the risk assessment.
- An analysis plan based on the conceptual model to describe the approach for conducting the risk assessment, including its design, methods, key inputs, intended outputs, and assessments of uncertainty and variability that might specifically affect communities with EJ concerns.

Like the planning and scoping phase, problem formulation is often an interactive, nonlinear process, and substantial re-evaluation is anticipated in the development of resulting products.

In considering EJ, problem formulation focuses on identifying whether population groups of concern experience elevated risks relative to the broader population or other appropriate comparison population group (see Section 6.5.2), both in the baseline and in response to policy changes. Specifically, this

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[62] An important consideration is to develop exposure scenarios for Tribal and Indigenous populations that draw from historical (pre-European settlement) time frames and account for the many irreversible changes that have occurred in the United States that have fundamentally altered the practice of traditional Tribal lifeways (see U.S. EPA, 2019a).
[63] Guidelines for the peer review process are available in the EPA's *Peer Review Handbook*: http://www.epa.gov/osa/peer-review-handbook-4th-edition-2015.

involves: (1) clarifying the relevant source and characteristics of the stressors; (2) identifying factors that may influence exposures that contribute to those risks; and (3) characterizing vulnerabilities of the population groups of concern that may exacerbate exposure or risk.

Text Box 5.3 provides examples of EJ-related questions that may be raised during problem formulation. For additional sample problem formulation questions, see U.S. EPA (2014b).

5.3.3.1 EJ Considerations when Developing the Conceptual Model

Conceptual models consist of (1) a set of risk hypotheses that describe predicted relationships among stressor(s), exposure(s), and health endpoints and/or responses, along with the rationale for their selection; and (2) a diagram that illustrates the relationships presented in the risk hypotheses.[64]

Generally, the conceptual model addresses the following with respect to EJ concerns:

- How and to what degree identified risk factors contribute to differences in exposure and/or risk;
- The strength and direction of relationships between these risk factors and exposure and/or risk;
- Identification of data needs by characterizing these relationships as low, medium, and high uncertainty; and
- Scope of the assessment as to EJ concerns given current scientific understanding.

Characterizing the Stressor and its Sources

The properties and sources of the stressor(s), and how these may drive differential risks, are important to consider in the context of EJ. This includes the source(s) of regulatory concern – e.g., what is the likelihood that the sources of the stressor(s) are located in areas where population groups of concern live or experience exposure? But it can also include, where relevant and appropriate, identifying the distribution of additional sources of the stressor(s) that are not the focus of the regulatory action because they may contribute to differential risks. For example, a stressor may be present in environmental media due to background concentrations (e.g., resulting from historical or past industrial activity, or natural occurrence) in areas with population groups of concern.

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[64] The *HHRA Framework* (U.S. EPA, 2014b) provides descriptions, resources, and examples of conceptual models.

Text Box 5.3 Examples of EJ-Related 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 located in geographic areas with greater proportions of population groups of concern?
- Are other sources of the stressor more prevalent in these geographic areas?
- 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 these geographic areas?
- Does each stressor have multiple sources that should be evaluated?

Differential Exposures to a Stressor

- Do population groups of concern have higher body burdens of the contaminant (e.g., higher blood concentrations)?
- 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 noticeably higher rates among population groups of concern (e.g., use of personal care or cleaning products that contain harmful chemicals)?
- Are there cultural practices or other activities that are unique to these population groups (e.g., fish consumption for sustenance or cultural reasons)?
- What is the frequency and duration of occurrence of the unique cultural practice or atypical activity?
- Is proximity to the emitting source an important factor in assessing differential exposure?
- What geographic scale is important to highlight differential exposures between population groups for the pollutant in question?

Population Characteristics

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

Identifying Exposure Pathways

It is important to clearly articulate how population groups may be exposed to one or more stressors. That is, it is key to describe the exposure pathways experienced by population groups and to identify unique exposure pathways relevant to assessing EJ concerns.[65] Burger and Gochfeld (2011) suggest that the first step in improving the risk methodology is to recognize and account for unique exposure sources (e.g., hand-to-mouth behavior of small children; use of personal care or cleaning products that contain harmful chemicals; fish consumption for subsistence or cultural reasons) and the corresponding exposure pathways. Examples of questions helpful for extracting information about unique exposure pathways are presented in Text Box 5.3.[66]

New pathways can be identified during or after planning as new data become available. For example, biomonitoring data acquired during the assessment may provide evidence of unexpected health differences, resulting in additional analyses of exposure pathways that may cause these differences. It also may be useful to seek new information about certain exposure pathways to ensure a comprehensive evaluation of the range of exposures in the population groups of concern.

In more data limited settings, it may be helpful to use national databases and screening tools to identify the potential for differential exposure for specific population groups of concern. Screening-level assessments can also be used to exclude exposure pathways of minor importance from further consideration or to determine where additional data and information is needed to evaluate key pathways (U.S. EPA, 2019a). See Appendix B for additional discussion.

Identifying Differences in Exposures that May Lead to Differential Risks

Differences in exposures can be an important indicator of differential risks across population groups of concern. For example, if the regulated sources are co-located with other sources of the same stressor, this may contribute to significant differences in patterns of exposure to the stressor.

Evaluated patterns of exposure can be location-specific or population group-specific, depending on the scale of the assessment and the types of data available. Differences in cultural practices, use of specific consumer products, and behaviors can lead to differences in exposures. Considering other characteristics, such as lifestage, gender, or income, can further clarify which population groups may face higher exposures. For example, children living in older housing, lower income households, and individuals identifying as Non-Hispanic Black have higher blood lead levels in the United States (U.S. EPA, 2024g). In addition, due to exposure via personal care products, Black women are more highly exposed to endocrine disrupting chemicals than White women (Helm et al., 2018).

Identifying Population Characteristics that May Lead to Differential Risks

Population characteristics refer to those attributes shared by individuals within a population group that influence not only the likelihood of exposure to a stressor but may also affect the risk of adverse health outcomes from this exposure. These characteristics range from those with direct health 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, transportation), age of housing, occupation, income, and educational status. Group differences in body burdens of the

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[65] Examples of such pathways include exposure to heavy metals from the use of non-traditional medicines, mercury from high fish consumption, pesticides tracked into homes from places of work, and inorganic mercury from cosmetics.

[66] The *Exposure Factors Handbook* (U.S. EPA, 2011a) also contains exposure factor data stratified by race and ethnicity. The *Guidelines for Human Exposure Assessment* (U.S. EPA, 2019a) contains additional information on exposure assessment for population groups of concern, including Tribal and Indigenous populations.

contaminant (e.g., blood concentrations) and co-exposures to multiple stressors that may affect the body's ability to detoxify a particular contaminant (e.g., metabolism) can be factors to consider.

Characterizing the distribution of relevant demographic or socioeconomic characteristics for the affected population helps identify factors that may affect communities' ability to withstand or recover from exposure to a stressor. Appendix B provides examples of integrating these characteristics into a dose-response assessment.

5.3.3.2 Analysis Plan

The analysis plan provides details on technical aspects of the risk assessment and how the hypotheses about the relationships described in the conceptual model will be assessed. While the conceptual model may identify a larger set of pathways and relationships, the analysis plan focuses on the pathways and relationships that will be pursued in the risk assessment. The plan includes the rationale for selecting or omitting pathways, the relationships between stressors and outcomes, and acknowledgements of data gaps and uncertainties (see Text Box 5.4.)

The analysis plan also may consider how the level of confidence (or precision) needed for the management decision compares with that expected from available analytic approaches. This informs how data are used, the preferred analytic approach, and the extent to which new data are needed and may be obtained.

The analysis plan may be divided into specific components: (a) the assessment design and rationale for selecting specific pathways to include in the risk assessment; (b) a description of the data, information, methods, and models to be used to assess exposures, effects, and risk (including associated uncertainty and variability), as well as intended outputs (e.g., risk metrics); (c) quality assurance and quality control measures; and (d) the associated data gaps and limitations. The analysis plan may also describe scientific review and specify actions for community involvement (U.S. EPA, 2014b).

A central challenge for HHRA planning is identifying the data, tools, and models needed to inform EJ considerations. 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.)

Text Box 5.4 Example: Considering Factors Related to EJ Concerns in Planning Integrated Science Assessments

The Clean Air Act requires periodic review of the science upon which national ambient air quality standards (NAAQS) are based. The EPA performs an Integrated Science Assessment (ISA) as the scientific foundation for these NAAQS reviews by evaluating and synthesizing the latest science, including the kind and extent of identifiable effects on public health. At the beginning of an ISA, the public is invited to submit research studies in identified subject areas via a “call for information.”

At its early stages, an ISA is also guided by an Integrated Review Plan (IRP) that identifies the key science issues relevant to review of the criteria for setting the NAAQS. Among other things, an IRP generally enumerates how the ISA will evaluate factors that may affect and inform the risk assessment, including those relevant to EJ concerns. The IRP is produced as a public information document and management tool and therefore may be modified to reflect information developed during the review and in response to advice and comments received during peer and public review.

The Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (PM) provides an example:

“The PM ISA will evaluate an array of factors that may contribute to increased risk of PM related health effects for various lifestages or populations. These factors reflect the multiple avenues through which a lifestage or population may be at increased risk of an air pollutant related health effect, specifically: intrinsic factors (e.g., biological factors such as age or genetic variants), extrinsic factors (nonbiological factors such as diet, low [socioeconomic status]), and/or factors affecting dose or exposure (e.g., sex, age, outdoor activity or work, low [socioeconomic status], physical activity). It is also important to recognize the interconnectedness among these factors that may also confer increased risk, an example being pre-existing diseases or conditions and socioeconomic status…

…Further, to the extent that evidence is available, the at-risk chapter of the PM ISA will discuss what evidence is available regarding interrelationships among risk factors in a particular lifestage or population as described in the preceding section that may add to the understanding of the public health impact of exposure to PM.” (U.S. EPA, 2016c).

See Section 3.4.9, At-Risk Lifestages and Populations and Public Health Impact, for more information: https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf.

Identifying Data

A key planning element for identifying data relevant to EJ concerns is consulting with the public, including communities that may have access to data useful for improving the characterization of exposure and risk. Relevant data can be location-specific or population group-specific, or, ideally, both. It 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 information on consumption or contact rates, routes, and duration of exposure, behavior data for estimating contact rates, concurrent exposures to other stressors that are of toxicological relevance, biomonitoring, or emissions. There are many sources of exposure data. Some exposures can be evaluated using bio-monitoring data on chemical hazards such as the National

Health and Nutrition Examination Survey (NHANES), although NHANES provides exposure data for limited geographic areas.[67]

Health risk data could include toxicological data as well as incidence data specific to population groups with EJ concerns, and historical population-specific disease or illness rates.[68] More generally, multiple data sources may be considered for an HHRA to inform EJ concerns, including chemical-specific epidemiological evidence and potentially the broader literature on intrinsic and extrinsic factors that influence vulnerability. State, Tribal, and local governments may also have relevant monitoring data for use in HHRA. Appendix B provides more detailed information on using bio-monitoring data and an example of estimating exposure using ambient concentration data.

Identifying Models and Tools

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(s) (e.g., effective dose), risks for a specific health endpoint(s), locational vulnerability to health effects, and other key factors. A challenge for developing a HHRA that can inform EJ considerations is ensuring that input parameters for models are representative of population groups of concern. Traditional defaults used as inputs for HHRA may not adequately reflect the demographic or socioeconomic characteristics of these population groups. While data may be insufficient to resolve this issue, it can be useful to discuss the extent to which and reasons why defaults may not be representative.

Identifying Data Quality Limitations and Data Gaps

Consideration of EJ concerns may be aided by rapidly developing data and tools; thus, it is important that the HHRA planning process include a clear discussion of data available to characterize uncertainty and variability, data quality, and lack of data that may affect methodology development and/or results.

In some cases, lack of data may prompt a decision to limit the scope of planned analysis within a HHRA. It is recommended that such decisions be clearly documented, and where possible affected communities be consulted because they can often provide input into how to proceed when there is a lack of data. In some instances, clear documentation of lack of data may lead to changes to the regulatory design to facilitate better monitoring in vulnerable communities.[69]

To further promote the integrity, objectivity, and quality of data used in planning risk assessments, analysts should review the OMB and EPA data quality guidelines (OMB, 2019; U.S. EPA, 2012a; U.S.

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[67] Some limitations of data available through NHANES can be addressed by location-specific surveys (such as the New York City Health and Nutrition Examination Survey), 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 to conduct these surveys.

[68] Analysts are advised to assess historical population-specific disease or illness rates to understand whether these data are built on potentially flawed assumptions or population selection that could exacerbate or negatively affect the accuracy of the HHRA results. For example, some population groups are less likely to seek medical care due to lack of health insurance or access to care.

[69] For example, public comments during the nitrogen oxide (NO_x) NAAQS rulemaking process resulted in siting additional monitors in vulnerable communities (U.S. EPA, 2010a). Likewise, outreach to communities living near refineries during a risk and technology review resulted in fenceline monitoring of benzene emissions to provide access to data on what is being released into nearby communities (U.S. EPA, 2015c).

EPA, 2002b).[70] Text Box 3.1 describes the factors the EPA uses to evaluate the quality and reliability of scientific and technical information used in support of its actions.

5.4 Multiple Exposures and Cumulative Effects

The science supporting assessments of the cumulative effects of exposure to multiple stressors on human health and well-being is evolving, and the data and analytic tools needed to develop richer and more informative analyses may become available as research continues. Given the importance of cumulative effects in the context of environmental justice, we briefly summarize cumulative risk and cumulative impact assessment (CIA) approaches below. In the meantime, even when utilization of a more formal approach to assessment is not feasible, analysts are advised to consider the potential implications of exposure to multiple stressors, both environmental and non-environmental, when planning and scoping for a HHRA.

5.4.1 Cumulative Risk Assessment

HHRA often focuses on characterizing risk from a single stressor or contaminant. Recognizing the potential harm associated with multiple stressors from one or more pollution sources or exposure pathways, the EPA has described a framework for assessing the cumulative risk of adverse effects associated with multiple stressors (U.S. EPA, 2003a). *Cumulative risk assessment* (CRA) is an analysis, characterization, and possible quantification of the combined risks to health and/or the environment from aggregate exposure to multiple agents and/or stressors. Specific elements and implementation of CRA may differ according to programmatic needs. Because of data and methodology limitations, applications of CRA at the EPA have mainly focused on chemical mixtures and/or single chemicals from multiple sources.[71]

Conducting a CRA is possible when there is adequate information to identify the relevant risk relationships among multiple environmental and non-environmental stressors, as well as the means to identify those most important to characterizing relevant health endpoints. This approach is consistent with the existing paradigm underlying risk assessment generally, which relies upon scientifically rigorous methods for assessing hazard and exposure and the resulting adverse outcomes. See Appendix A for links to other U.S. EPA guidance on the conduct of CRA.

As with HHRA, understanding the purpose of CRA is fundamental to its design. Clarity on the management decision context, and what information is necessary to support it, as well as data quality, are the first steps in determining if a CRA may be suitable, and if so, determining an assessment design. This step is described as fit-for-purpose and is common to all assessment processes. See prior sections of this chapter and U.S. EPA (2014b) for more information.

In planning a CRA, attention may be given to epidemiology studies that can indicate multiple chemical exposures and other factors such as non-environmental stressors that may modify or increase the risk of an adverse outcome from the target contaminant. It may be useful to use epidemiological data to

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[70] For information, visit the EPA's Information Quality Guidelines website (http://www.epa.gov/quality/epa-information-quality-guidelines) and the EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process* (http://www.epa.gov/sites/production/files/documents/guidance_systematic_planning_dqo_process.pdf).

[71] 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 the 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).

focus on diseases or health conditions with a higher prevalence within or across population groups of concern. Studies that employ stratification can provide insight into how co-exposure to additional environmental or non-environmental stressors may affect the risk of an adverse health outcome for a given population group of concern.

Incorporating non-environmental stressors in CRA can be complicated by uncertainties in exposure evaluation, potential health consequences, potential modification of effects by other stressors (e.g., chemical exposures) and variation in individual (or community scaled) vulnerabilities. When the suspected stressor estimates of risk are difficult to quantify, a qualitative or semi-quantitative characterization of suspected relationships (e.g., an empirical correlation between the stressor and adverse outcomes or the existence of a notably large number of potential stressors) can improve understanding of the range of potential stressors contributing to adverse health outcomes. See U.S. EPA (2003a) for more information on considering uncertainty and variability in CRA.

5.4.2 Cumulative Impact Assessment

Cumulative impact assessment is the process of accounting for cumulative impacts in the context of problem identification and decision-making. The term *cumulative impacts* refers to the totality of exposures to combinations of environmental and non-environmental stressors and their effects on health, well-being, and quality of life outcome throughout a person’s lifetime (U.S. EPA, 2022c).

There are linkages between CRA and CIA, both may address both environmental and non-environmental stressors, but these analyses are not the same and may serve different decision contexts; more than one approach may also be used in combination. Each approach may employ a variety of methods to provide information to decision-makers about health effects associated with exposures to multiple environmental and non-environmental stressors. Methods employed are not exclusive to an assessment approach. Determinations about which approaches and analytic methods to use depend on factors such as statutory requirements, the scope of an assessment, types of data needed and available, and applicability for the evaluation and needs of the decision-maker (U.S. EPA, 2024d). For example, total burden in CIA encompasses direct health effects, but also considers a wide set of outcomes that fall outside the purview of CRA, some of which may not be conducive to quantification (NRC, 2009). CIA may be able to “use information supported by relationships among stressors, exposures, effects, and/or health, well-being, and quality of life outcomes for which cause-and-effect linkages may not be well understood” (U.S. EPA, 2022c).

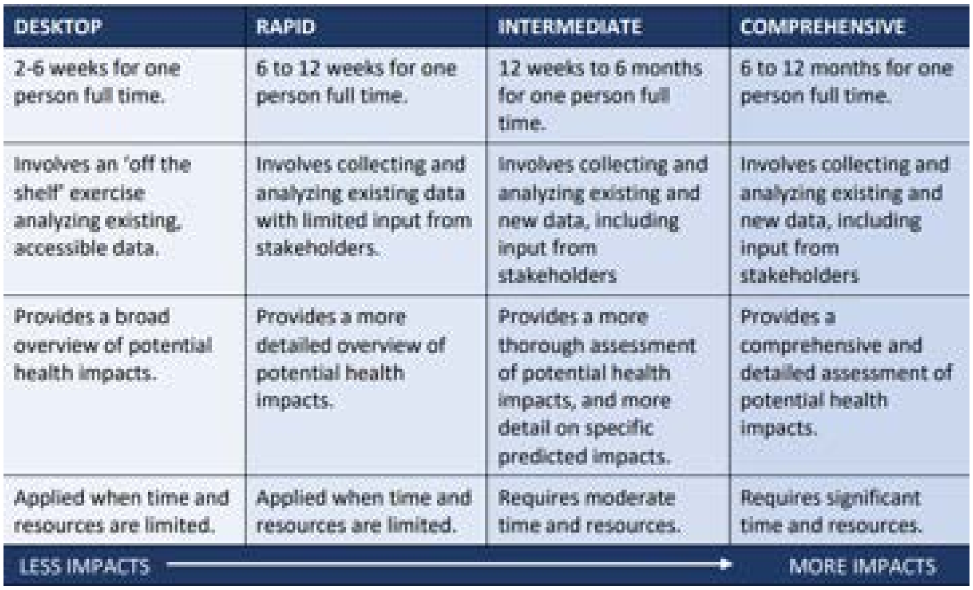
The EPA does not currently have guidance on the use of CIA in the context of rulemaking. However, the EPA has released a report on recommendations for CIA research (U.S. EPA, 2022c) and an interim cumulative impacts framework document (U.S. EPA, 2024h). The EPA has also used a community-engaged approach to assessing cumulative impacts called Health Impact Assessment (HIA) in other decision contexts (See Text Box 5.5).

Text Box 5.5 Health Impact Assessment

Health impact assessment (HIA) is “a systematic process that uses an array of data sources and analytic methods and considers input from [affected individuals, communities, and other members of the public] to determine the potential effects of a proposed policy, plan, program, or project on the health of a population and the distribution of those effects within the population” (NRC, 2011a). Given the broad purview of this approach, HIAs may consider a wider spectrum of health determinants than a typical HHRA, such as housing quality, access to services, and social cohesion, as well as exposure to contaminants or the effects of climate change.

The HIA process typically emphasizes meaningful public engagement that focuses on empowering vulnerable and affected populations to participate in decisions that have the potential to affect their daily lives. Effective input from the public can provide local knowledge of existing conditions; identify areas of concern and issues of interest that are not readily apparent to those outside the community; offer contextual/cultural perceptions and experiences; and assist in identifying and refining the HIA scope and recommendations.

HIA is most often applied in the context of a specific local community. However, while the EPA has not used HIA in support of national regulatory actions, it could serve as a complement to HHRA in the national context, for instance to evaluate cumulative effects and EJ concerns related to hot spots. The figure below illustrates how an HIA can be tailored to available time and resources.



DESKTOP	RAPID	INTERMEDIATE	COMPREHENSIVE
2-6 weeks for one person full time.	6 to 12 weeks for one person full time.	12 weeks to 6 months for one person full time.	6 to 12 months for one person full time.
Involves an ‘off the shelf’ exercise analyzing existing, accessible data.	Involves collecting and analyzing existing data with limited input from stakeholders.	Involves collecting and analyzing existing and new data, including input from stakeholders	Involves collecting and analyzing existing and new data, including input from stakeholders
Provides a broad overview of potential health impacts.	Provides a more detailed overview of potential health impacts.	Provides a more thorough assessment of potential health impacts, and more detail on specific predicted impacts.	Provides a comprehensive and detailed assessment of potential health impacts.
Applied when time and resources are limited.	Applied when time and resources are limited.	Requires moderate time and resources.	Requires significant time and resources.

Case studies to explore how HIA can be used to engage the public and incorporate EJ concerns and public health considerations into local environmental decision-making are available at: https://www.epa.gov/healthresearch/epa-health-impact-assessment-case-studies. The EPA also has compiled an inventory of HIA resources at: https://www.epa.gov/healthresearch/health-impact-assessment-hia-resource-and-tool-compilation and synthesized the state of practice at: https://www.epa.gov/healthresearch/hia-review-synthesis-report.

Chapter 6: Conducting Regulatory Analyses to Assess Environmental Justice Concerns

This chapter discusses how to conduct an EJ analysis for a rulemaking.[72] In particular, it discusses methods that may be useful for answering the three analytic questions from Section 3.1 of this document, which are repeated here:

- **Baseline:** Are there existing EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern?
- **Regulatory options:** For the regulatory option(s) under consideration, are there potential EJ concerns associated with environmental stressors that are affected by the regulatory action for population groups of concern?
- **Mitigation or exacerbation of effects:** For the regulatory option(s) under consideration, are EJ concerns exacerbated, mitigated, or unchanged compared to the baseline?

These questions provide the framework for analyzing the effects of a regulatory action on population groups of concern. The extent to which an analysis can address all three questions will vary due to data limitations, time and resource constraints, and other technical challenges. These challenges will vary by media and regulatory context, including the availability of information generated from human health risk and exposure assessments, or other components of the regulatory analysis. Regardless of the approach taken, the highest quality and most relevant data should be applied in a manner consistent with the OMB and EPA data quality guidelines (OMB, 2019; U.S. EPA, 2012a; U.S. EPA, 2002b) and the *Peer Review Handbook* (U.S. EPA, 2015e).

In determining whether EJ concerns may arise in the context of a specific regulatory action, some level of analysis is needed, be it qualitative, quantitative, or some combination of both. For many regulatory actions, including actions that strengthen environmental protection, it is not possible to rule out EJ concerns without some level of assessment.

Generally, the EPA prefers quantitative assessments that complement other types of quantitative regulatory analyses (e.g., benefit-cost analysis, risk assessment) conducted for regulatory actions. Section 3.3 recommends some level of quantitative analysis, when feasible, to address the three questions above for regulatory actions where effects or benefits will also be quantified. When information on exposures, health and environmental outcomes, and other relevant effects by population groups is available, analysts may be able to quantify exposure in the baseline and likely changes in exposure for each regulatory option. In cases where such data are unavailable, it may still be possible to evaluate risk or exposure using other quantitative metrics (e.g., density of regulated facilities as a function of race, ethnicity, or income).

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[72] While the focus in this chapter is on population groups mentioned in E.O.s 12898 and 14096, the methods discussed may be applied to any population group of concern.

When environmental and health effects or benefits cannot be quantified or disaggregated by race, ethnicity, income, or other relevant demographic or socioeconomic factors, analysts should present available quantitative and/or qualitative information that sheds light on the concerns and experiences of communities or population groups relevant to the EJ analysis. Qualitative assessment is particularly appropriate when high quality and relevant quantitative data are not available.

This chapter is organized as follows: Section 6.1 discusses how a preliminary analysis can be used to evaluate the feasibility of an in-depth analysis of EJ concerns. Section 6.2 discusses the conceptual approach to evaluating and comparing the baseline and regulatory options in an in-depth analysis of EJ concerns. Section 6.3 reviews the data and information needed to assess EJ concerns. Section 6.4 summarizes methods for assessing the three analytic questions for population groups of concern. Section 6.5 discusses analytic issues, including comparison population groups and geographic issues when the source of emissions is identifiable and health effects are fairly localized and spatially distinguishable. Sections 6.6 discusses characterizing and communicating results. Section 6.7 discusses the evaluation of costs and non-health effects. For examples, see the companion document summarizing several EJ analyses conducted for rulemakings (U.S. EPA, 2024i).

6.1 Preliminary Analysis of EJ Concerns

As discussed in Section 3.2, conducting a preliminary analysis early in the rulemaking process can offer initial insights that may merit additional investigation regarding whether there are EJ concerns in the baseline and/or a regulatory action is anticipated to raise EJ concerns.

While there is no single prescribed method for conducting a preliminary analysis, analysts should review the quality and availability of data, the availability of defensible methods to analyze the data, and the peer-reviewed literature and public input that may be used to evaluate EJ concerns. In cases where it has already been determined that a more in-depth EJ analysis is needed, these steps can be directly incorporated into the early stages of that analysis. Such information may include:

- Proximity of regulated sources near population groups of concern;
- Number and types of sources that may be impacting these populations;
- Types of stressor(s) that may be affecting these populations in the baseline, including from non-regulated sources;
- Any unique exposure pathways associated with the stressor(s) being regulated;
- Evidence of differential current or historical exposure to or risk from the stressor(s) being regulated for population groups of concern;
- Evidence of the prevalence of factors or conditions that may modify the effect of the regulated stressor(s) for population groups of concern;
- Public or community concern(s) about the effects of the potential regulatory action on specific population groups or communities of concern; and
- History of EJ concerns associated with the stressor(s) or sources(s) being regulated.

A variety of tools and methods are available to support a preliminary analysis.[73] For instance, EJScreen (U.S. EPA, 2024c) allows analysts to quickly examine a variety of demographic and socioeconomic variables and environmental indicators at the block group resolution for the United States (including Puerto Rico).[74] Demographic and socioeconomic data are drawn from the American Community Survey five-year summary file.

While EJScreen provides a way to identify areas in the United States where population groups or communities of concern or environmental indicators are currently at or above a specific relative percentile, analysts are advised to summarize the demographic and socioeconomic characteristics and relevant environmental indicators for all communities near affected sources in level terms (e.g., percent of the population that is low-income), not just for communities with indicator values above a specific percentile threshold. In addition, it is recommended that analysts avoid using indices that combine information across multiple variables or indicators, which are hard to interpret, and instead present the results for each relevant variable separately.[75] It is also important to keep in mind that while EJScreen and other screening tools can shed light on pre-existing differences for the environmental indicators included in the tools, they typically only provide a snapshot at one point in time and may not include other important sources of exposure relevant to the regulatory action.

More generally, when evaluating whether a screening tool is sufficient or appropriate for conducting a preliminary analysis of EJ concerns in the federal rulemaking context, analysts should consider the purpose for which the tool was originally designed. Certain tools are designed to evaluate environmental conditions within a certain region or state and, as such, may not contain nationally representative data. Other tools may be designed to help prioritize funding, permitting, or compliance and enforcement actions and therefore may define population groups or other key variables in specific ways, or they may incorporate policy decisions directly into the tool by weighting certain indicators or characteristics over others.

A preliminary analysis can also act as an input into determining whether it is feasible to conduct an in-depth assessment. Feasibility is informed by a technical evaluation of available data and methods, including:[76]

- Scientific literature that discusses the effects of the stressor(s) being regulated on population groups of concern;
- Information received via public comments, technical reports, press releases, or other documentation discussing the environmental and health effects of the stressor(s) being regulated for population groups of concern, including information on other relevant environmental or non-environmental stressors;

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[73] Envirofacts contains information on the location, reported emissions, and compliance history of sources regulated by the U.S. EPA under various statutes (https://enviro.epa.gov/). EasyRSEI allows analysts to examine the types and amounts of toxic chemicals reported annually by facilities to the Toxics Release Inventory (https://edap.epa.gov/public/extensions/EasyRSEI/EasyRSEI.html).

[74] See the EPA's EJScreen website: www.epa.gov/ejscreen. Other agencies also have EJ screening tools that may prove useful. For instance, the Department of Health and Human Services has developed an index-based tool at the census tract level to evaluate the cumulative impacts of environmental burden on human health. See https://onemap.cdc.gov/portal/apps/sites/#/eji-explorer.

[75] For instance, while EJScreen tabulates and reports an aggregate race/ethnicity category, labeled as "people of color", analysts are encouraged to report results separately for each relevant race and ethnicity category (see Section 2.2.1).

[76] Recall that appropriateness is informed by relevant policy, budgetary, and statutory considerations (Section 3.2).

- Availability of spatially disaggregated data for population groups that may live, work, or play in close proximity to the stressor(s) being regulated, or may otherwise be affected by the stressor(s); or
- Availability of methods for conducting in-depth analysis (e.g., proximity-based approach, risk- or exposure-assessment, and mixed methods approach, as discussed below).

If the preliminary analysis reveals that the scientific literature and data are unavailable or of insufficient quality to pursue an in-depth analysis that characterizes how exposure, risk, or health effects are distributed across population groups, analyst are expected to explain why additional analysis is not possible. In particular, analysts are encouraged to discuss relevant evidence, key limitations, and sources of uncertainty highlighted in the published literature (U.S. EPA, 2024f). Some impacts that cannot be quantified may still represent important effects that should be considered in the analysis.

6.2 Characterizing the Baseline and Regulatory Options for In-Depth EJ Analysis

As described in Section 3.2, the five main steps of an in-depth EJ analysis are: (1) identify the sources being regulated; (2) describe the environmental stressor; (3) characterize affected populations: (4) compare the affected and comparison groups; and (5) conduct sensitivity analysis. These steps can be applied to characterize baseline conditions, evaluate the effects of the regulatory options, and make comparisons between the two to evaluate the three analytic questions posed in Section 3.1, when data and methods allow.

The OMB (2023b) defines the *baseline* as "an analytically reasonable forecast of the way the world would look absent the regulatory action being assessed, including any expected changes to current conditions over time." It includes the characteristics of current populations and how they are affected by pollutant(s) prior to the regulatory action under consideration. As the OMB definition implies, however, the baseline is not a static concept. In particular, the OMB notes that analysts 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 to project future baseline conditions. How future regulations or policies affect the baseline specification is complex and requires consideration of many factors. As noted in the EPA's *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2024f), ideally all potential influences on baseline conditions would be estimated, but it is generally not practicable to do so.[77] Anticipated changes in baseline demographic composition may also be relevant in an EJ context. Per the recommendations in Section 3.3, the baseline for the EJ analysis, including the geographic scope, year of analysis, and health and other effects, should be consistent with how it is specified in other parts of the regulatory analysis.

Because exposure to other environmental and non-environmental stressors can increase an individual's responsiveness to negative health effects, it is also important to understand how already-present risks may interact with the pollutant being regulated (see Chapter 4). Risk and exposure assessments conducted in support of the regulatory action can offer a valuable source of information in this regard (see Chapter 5 and Appendix B). While explicit modeling of these interactions is often not feasible, analysts can evaluate the extent to which there are multiple polluting sources or elevated risks

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[77] See Section 5.5 of U.S. EPA (2024f) for more detail.

for other key stressors within affected communities, including historic and current social or health conditions, that affect specific population groups or communities. See Text Box 6.1 for an example.

When data and methods allow, an EJ analysis can also examine the distribution of effects for each regulatory option – different configurations of the regulatory action being considered. This analysis is based on a prediction of the state of the world under the regulatory options. For the analysis of EJ concerns, analysts are encouraged to examine how the exposure, risk of health or environmental effects, or other outcomes of the regulatory action are distributed across population groupsfor the regulatory options being considered, where practicable.[78]

The EJ analysis can then evaluate the change in the exposure or risk of relevant environmental and health effects for each regulatory option compared to the baseline. In addition to identifying whether the regulatory action is expected to exacerbate, mitigate, or leave baseline EJ concerns unchanged, the analysis should shed light on the extent and distribution of these changes.

With these three sets of information – effects in the baseline, effects under the regulatory options, and a comparison of the two –analysts can characterize the distribution of environmental and health effects associated with a regulatory action, thus answering all three analytic questions from Section 3.1.

Specifically,

- An assessment of the *baseline* can inform whether pre-existing differences in environmental and health effects are associated with the stressor(s) under consideration.

This analysis depicts how the stressor(s) and associated effect(s) are distributed across population groups prior to any regulatory action. For instance, if emissions or effects are more concentrated in one population group (e.g., low-income households), the decision-maker may want to take this into consideration when making decisions about the regulatory action; mechanisms or choices associated with implementation, for example, may allow the EPA to address pre-existing differences.

- An assessment of the *regulatory options* being considered can inform how the stressor(s) and its environmental and health effects are distributed.

It is important to note that analysis of the regulatory options is based on predictions, which may not always be sufficiently disaggregated across population groups to enable a rigorous EJ analysis. Ideally, analysts can provide an indication of how the stressor is distributed across population groups for the options being considered, either quantitatively or qualitatively. There may be some options for which the distribution of the stressor and its effects across population groups is more equitable than others.

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[78] The regulatory options in the EJ analysis should be the same as in the other parts of the regulatory analyses (e.g., benefit-cost analysis) to facilitate comparisons and ensure consistency. Typically, multiple scenarios or options are considered in a regulatory analysis (OMB, 2023b).

Text Box 6.1 Examples of the Role of Non-Environmental Stressors in EJ Analysis

The Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (U.S. EPA, 2024m) includes the following discussion of non-environmental stressors:

"EPA has expanded the populations evaluated in this exposure EJ assessment … to evaluate potential exposure disparities more comprehensively, regardless of any pre-existing biases. Several populations added to this final action have been included in other rulemaking [regulatory impact assessments] RIAs evaluating PM2.5 emission changes (e.g., employment status, health insurance status, and linguistic isolation). Additionally, this RIA assesses exposure in communities with a legacy of discriminatory land use designations and siting decisions (i.e., historically redlined areas, using the Home Owners' Loan Corporation (HOLC) gradings A-D, with grade D areas being defined as redlined). EPA believes all population groups added to this exposure assessment provide additional insight into community-level vulnerability."

The Multi-Pollutant Emissions Standards for Model Years 2027 and Later Light-Duty and Medium-Duty Vehicles (U.S. EPA, 2024n) also discusses the role of non-environmental stressors:

"As described [previously], people who live or attend school near major roadways are more likely to be people of color and/or have a low [socioeconomic status] SES. Additionally, people with low SES often live in neighborhoods with multiple stressors and health risk factors, including reduced health insurance coverage rates, higher smoking and drug use rates, limited access to fresh food, visible neighborhood violence, and elevated rates of obesity and some diseases such as asthma, diabetes, and ischemic heart disease. Although questions remain, several studies find stronger associations between air pollution and health in locations with such chronic neighborhood stress, suggesting that populations in these areas may be more susceptible to the effects of air pollution."

- An assessment of the *changes* in exposure or risk across population groups – when the regulatory options are compared to the baseline – can help inform to what extent the regulatory action will address identified EJ concerns.

It is helpful for analysts to provide information on how effects under each regulatory option compare to the baseline to show the extent to which an option improves or degrades environmental quality and health risk across population groups of concern.

Note that a constant reduction in risk or exposure across population groups will likely not mitigate EJ concerns if there are differences in baseline environmental quality or health risk across population groups or communities (Maguire and Sheriff, 2011). Conceptually, an EJ concern is only completely mitigated when there is no difference in the distribution of effects across population groups for the regulatory options being considered – i.e., everyone is experiencing the same environmental quality or health risk post-regulation.

6.3 Data and Information to Assess EJ Concerns

In general, the type of analysis that can be conducted depends on the availability and quality of data. In some cases, spatially resolved, individual-level data may be most appropriate and relevant for an analysis of EJ concerns. In other cases, distance from a regulated source may be the best available metric. At times, the best available information may be qualitative, including local knowledge from affected communities and Tribes (e.g., Indigenous Knowledge, also referred to as Traditional Ecological Knowledge). In all cases, analysts should use the highest quality and most relevant data and information, as discussed below. Text Box 6.2 illustrates how data quality may affect the level of analysis in an air quality context.

When data are missing or incomplete it is recommended that analysts document what specific types of data are unavailable or of insufficient quality, including but not limited to cases where the data are available but not of the desired granularity (spatially or temporally) and/or available for only subsets of the population.

Recognizing the importance of data quality, data needed to conduct an EJ analysis may include:

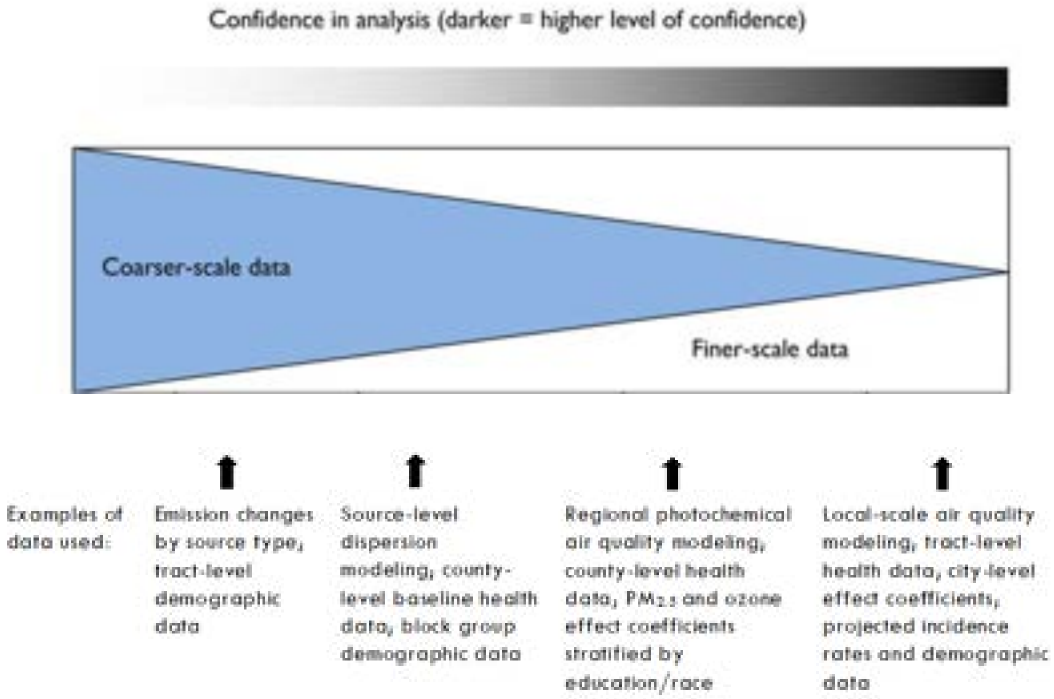
- Demographic and socioeconomic characteristics (e.g., race, ethnicity, income);
- Location of pollution sources (e.g., latitude/longitude coordinates, zip code, county);
- Historical, current, and projected emissions or concentrations of stressor(s) relevant to the regulatory action;
- Prevalence of specific exposure pathways that may increase risk for some population groups;
- Health effects (e.g., hospital and emergency admissions, race and ethnicity-stratified mortality rates, race and ethnicity-stratified asthma or other morbidity rates);
- Other environmental or non-environmental stressors that may be risk- or effect modifiers (e.g., indoor air concentrations, vulnerability to effects of climate change);
- Risk coefficients stratified by population groups of concern (e.g., race, ethnicity, income); and
- Distribution of economic costs, when relevant (see Section 6.7.1).

We briefly describe three types of information frequently used as inputs into an EJ analysis: demographic and socioeconomic data, emission data for regulated sources, and data on pre-existing health conditions or other intrinsic or extrinsic factors that may increase an individual’s vulnerability when exposed to releases from regulated sources.

The U.S. Census Bureau is the recommended source for demographic and socioeconomic data in an EJ analysis. It produces several national-level data products that report these types of data at relatively fine spatial scales (e.g., census tract, block group), including the decennial Census, the American Community Survey (ACS), and the American Housing Survey (AHS).

The decennial Census is administered every ten years with the aim of including the total U.S. population (including U.S. territories). As such, overall margins of error are minimal. Data on race, ethnicity, age, sex, and owner/renter status and other characteristics are available at the census tract level. For privacy reasons, statistical noise is deliberately introduced into publicly released Census results. This has led to larger measurement errors for low-population geographies (Kenny et al., 2024). Due to these privacy measures and other issues, there is evidence that the Census systematically undercounts mixed-race populations, Native American individuals, and undocumented immigrants (Warren, 2022; Kenny et al., 2021; Connolly and Jacobs, 2020).

Text Box 6.2 Data Quality and Spatial Resolution in the Context of Air Regulations



Analysts’ ability to address how a regulatory action changes the distribution of risk across population groups depends on the quality and spatial resolution of the data available. Finer-scale air quality, health, and demographic data allow one to assess the distribution of effects across population groups 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 is more limited.

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

An example in data-rich environments: Using finely resolved air quality data, analysts can identify at a highly disaggregated level (e.g., 1 km) population groups that experience the highest exposure to air pollution. Analysts can also identify population groups that exhibit the highest baseline incidence or prevalence rates for air pollution health effects. Using geospatial tools, analysts can spatially combine the two data sources. Using race-specific or standard risk coefficients analysts can then estimate health effects for each population group.

Compared to the decennial Census, the ACS contains information on a wider range of demographic and socioeconomic characteristics, such as income, education, disability status, and employment, at a greater level of spatial disaggregation – the block group level. Further, the ACS relies on annual population sampling and therefore reflects more timely information, especially for rapidly changing geographic areas. The five-year ACS is preferable to the one-year ACS because the five-year estimates contain information on all areas (including those with fewer than 65,000 individuals) and has estimates of population statistics with lower margins of error. Using more reliable estimates may be important when investigating specific locations or areas with low population.

Even five-year ACS estimates for low population areas are likely based on smaller samples and have larger margins of error and reduced accuracy.[79] Strategies to improve estimates in areas with low population include combining data across geographic units or population groups. The U.S. Census Bureau suppresses estimates with unacceptable levels of statistical reliability, but analysts still need to carefully consider data quality, especially in rural areas.[80]

The American Housing Survey is a longitudinal, nationally representative biennial survey at the housing-unit level that contains information on the quality and cost of housing and resident characteristics, including demographics. The survey includes owner- and renter-occupied and vacant housing units but excludes group quarters, businesses, hotels, and motels.[81] While national data are collected in each year in which the AHS is conducted, housing units in major metropolitan areas and those receiving assistance from specific federal programs are oversampled. Weights are applied to each housing unit in the national survey to minimize sampling error.[82] Statistical techniques, such as the introduction of noise, are used in the AHS to protect privacy and confidentiality concerns.[83]

The demographic and socioeconomic data described above are based on where people live. However, exposure can also occur when individuals are in other locations (e.g., work, school). For this reason, analysts may want to consider using non-residential demographic and socioeconomic data, such as spatially resolved data on workers (see Text Box 6.3) and school-aged children.[84] [85] [86]

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[79] Note that the ACS and AHS both use 90% confidence intervals for margins of error.

[80] For more information on compensating for low population in rural areas, see Section 2 of *Understanding and Using American Community Survey Data: What Users of Data for Rural Areas Need to Know* (U.S. Census Bureau, 2020a) at: www.census.gov/programs-surveys/acs/library/handbooks/rural.html.

[81] It may be possible to incorporate geospatial data on populations omitted from or underrepresented in Census data. For example, the Homeland Infrastructure Foundation-Level Data contains geospatial prison boundaries on local, state and federal correctional facilities, and on nursing and assisted care facilities in the United States.

[82] The U.S. Census Bureau releases information on sample design, weighting and accuracy of the survey in each year the AHS is administered. See https://www.census.gov/programs-surveys/ahs/tech-documentation/def-errors-changes.2021.html#list-tab-427877428. For information on measurement and sampling error, see https://www.census.gov/content/dam/Census/programs-surveys/ahs/publications/h12195-1.pdf

[83] For more information on statistical techniques used in the AHS to protect privacy and confidentiality, see https://www.census.gov/content/dam/Census/programs-surveys/ahs/tech-documentation/2015-later/Disclosure%20Avoidance%202015%20and%20Beyond.pdf

[84] Another possible source of data on worker characteristics is the U.S. Census Transportation Planning Products. These data offer aggregate (but separate) counts of workers employed by two-digit industrial classification and earnings level, two-digit industrial classification and occupation, race/ethnicity, poverty status, sex, and education level at the Public Use Microdata Area (PUMA) and, in some cases, county level. See Elliott and Smiley (2019) for an example.

[85] For example, Yoo et al. (2023) use the Longitudinal Employer-Households Dynamics Origin-Destination Employment Statistics to examine disparities in workplace exposure to air pollution by race and ethnicity.

[86] The Education Demographic and Geographic Estimates (EDGE) combines national-level data from the National Center for Education Statistics and the ACS to create socioeconomic and housing indicators for school-aged children and their parents. It includes spatial information such as school district boundaries, point locations for schools, and rural/urban school classification. The Bureau of Indian Education (BIE) also produces geospatial data for all schools and education centers overseen by the BIE.

Text Box 6.3 Data for Characterizing Worker Characteristics

Publicly available data linking worker characteristics to specific sources are not generally available. Nor is this information available at a fine spatial resolution and disaggregated industry classification. The table below highlights several sources of data on worker characteristics analysts may consider, along with their main advantages and disadvantages.

Data product	Advantages	Disadvantages
American Community Survey microdata (U.S. Census Bureau)	• Six-digit industry classification • Worker occupation information • Includes household income, race, ethnicity, sex • Spatial resolution may be finer in urban areas	• Spatial resolution may contain multiple counties outside urban areas • Small sample sizes at intersection of spatial unit and industry classification
Longitudinal Employer-Household Dynamics Origin-Destination Employment Statistics, Workplace Area Characteristics) (U.S. Census Bureau)	• Very fine spatial resolution (block) • Aggregate (but separate) annual counts of workers employed by earnings level, two-digit industrial classification, sex, race, ethnicity, and education level	• Industrial classification may not be sufficiently granular in highly concentrated industrial areas. • No worker occupation information • Statistical modelling necessary to make claims about worker characteristics or earnings at two-digit industrial classification
Quarterly Workforce Indicators (U.S. Census Bureau)	• Four-digit industry classification • Quarterly census of private employment covering 95% of private sector jobs • Includes race, ethnicity, sex, and age • County spatial resolution	• No information on occupation/job type • No information on worker income • Data suppression common at intersection of spatial unit, industry classification, and worker characteristic of interest
EEO-1 Statistics (Equal Employment Opportunity Commission)	• National census of private employers with >50 or >100 workers • Includes race, ethnicity, and sex • Statistics for 10 distinct job types • County spatial resolution	• Three-digit industry classification • No information on worker income • Data suppression somewhat common within spatial unit, industry classification, and worker characteristic of interest

The EPA can collect worker information from regulated sources under some statutory authorities. For example, under section 4 of Toxic Substances Control Act, the EPA may issue test orders to develop information about occupational exposure to a specific chemical substance, chemical mixture, or categories of chemical substances/mixtures. A carefully crafted test order may be able to collect exposure information at a facility differentiated by job type and length of service as well as worker characteristics. Industry associations and trade groups also sometimes publish reports that provide an overview of worker characteristics within a particular industry based on proprietary surveys of their members. Access to more granular U.S. Census and Equal Employment Opportunity Commission data is also a promising avenue to pursue to allow analysts to leverage more granular information on worker characteristics (Ash and Boyce, 2018; Walker, 2013).

On the emissions side, the EPA collects source-level data in some contexts, which can be used as an input into fate and transport modeling to project concentrations (see Section 6.4.2).[87] Analysts may also consider nationally representative data from other sources, such as rule-specific data collection requests to affected sources, datasets available from other Federal agencies, or proprietary datasets. When nationally representative data are not available, state, local, or Tribal data may support an illustrative analysis or case study approach. Modeled data – for instance, remote sensing data that have been combined with a process-based or machine learning model to estimate concentrations – may also generate spatially- and temporally-resolved information.[88] When using geospatial information on pollution sources, analysts need to be mindful of the limitations associated with how the data are represented, such as if multi-dimensional sources are represented as points rather than polygons or how non-point source pollution is characterized.

Absent the ability to explicitly model differences in vulnerability across population groups, it is also important to gather data on pre-existing conditions or non-chemical stressors that the literature have shown may contribute to differentiated health risks when individuals are exposed to the pollutant being regulated.[89] Note, however, that data on disease prevalence or consumption patterns differentiated by demographic or socioeconomic characteristics may be incomplete, only available at a more aggregate spatial scale, or subject to substantial measurement error.

Both the EPA and the OMB have data quality guidelines that should be followed when evaluating whether data and information are of sufficient quality for use in regulatory analyses of EJ concerns (see OMB, 2019; U.S. EPA, 2012a; U.S. EPA, 2002b). When evaluating data quality, it is recommended that analysts consider whether the methods used to generate or collect the data have been independently validated and whether the data have been used in peer reviewed studies (U.S. EPA, 2003b). Text Box 3.1 describes the five factors the EPA uses to evaluate the quality and reliability of scientific and technical information used in support of its actions.

Finally, an EJ analysis should clearly describe all important data sources and references. Unless the data are confidential business information or some other form of private data, they should be made publicly available. Providing documentation and access to the data used in an analysis is crucial to the credibility and reproducibility of the analysis.

6.4 Analytic Methods

A variety of scientifically defensible methods can be used to assess EJ concerns associated with regulatory actions. The choice of analytic method is most often driven by data availability. Analysts may also rely on a combination of these methods when analyzing a regulatory action. The conclusions that can be drawn from the analysis will vary depending on the method used.

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[87] For instance, the National Emissions Inventory is released every three years based on air emissions data provided by state, local, and Tribal governments and supplemented by data developed by the EPA. See https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei for more information.

[88] For instance, these types of approaches have been used to estimate ambient air concentration levels (Di et al., 2019, 2016) and streamflows across the U.S. (Feng et al., 2022).

[89] For example, the U.S Census Bureau administers the National Health Interview Survey. The survey collects demographic and socioeconomic variables from a nationally representative set of households, as well as information on pre-existing conditions such data on asthma, diabetes, disabilities, mental health status, health insurance access, and food security. For more information, see https://www.census.gov/programs-surveys/nhis.html.

Considerable uncertainty may exist about key relationships and health outcomes, such as how a reduction in emissions or other types of releases from a given source translates into ambient environmental quality and how it, in turn, translates into the human health effects of interest. This is particularly problematic if uncertainties differ across population groups. For instance, if an overexposed population group is more responsive to exposure (i.e., individuals in the group experience greater adverse health effects per unit of exposure), then using exposure alone as a proxy will underestimate the health risk posed by a stressor to that group. On the other hand, if proximity to a pollutant source does not correlate with exposure, it could overstate potential differences in health risk. Analysts should select the method that is most appropriate for the available data, recognizing time and resource constraints. The sections below discuss three methods that are often used for assessing EJ concerns: proximity-based analysis, use of exposure and risk modeling tools, and qualitative approaches. Note that these are not the only possible methods that can be used to assess EJ concerns. For each of the three approaches discussed, we highlight key advantages and limitations.

Regardless of the analytic approach used, the EJ analysis should be presented in a transparent way and include the following:

- Information about the specific population groups and individuals 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, including the role of other relevant environmental and non-environmental stressors;
- Relevant geographic scale;
- Descriptions of the main methods of analysis used;
- Descriptions of key data or modeling assumptions;
- Summary statistics for the baseline and each regulatory option (both the mean and distribution) by population group;
- An easy-to-understand description of what the summary statistics show;
- Conclusions based on the information available;
- Sensitivity analysis to examine the robustness of results across options presented; and
- Data quality, key sources of uncertainty, and limitations that affect conclusions regarding potential differential effects.

Analysts should follow best practices appropriate to the questions under consideration (see Text Box 3.2). If it is not feasible to follow a particular best practice, analysts should explain why this is the case.

6.4.1 Proximity-Based Analysis

Proximity to a source of pollution is commonly used when a direct measure of risk or exposure is not available and the activities or emissions associated with the stressor of concern are likely localized

(Maantay et al., 2022; Banzhaf et al., 2019a; Cameron et al., 2012; Wolverton, 2009; Baden and Coursey, 2002).[90] Generally speaking, a proximity-based approach compares the demographic and socioeconomic characteristics of population groups affected by the sources of pollution to the demographic and socioeconomic characteristics of population groups unaffected by these sources. Note that this approach typically cannot differentiate between sources based on the magnitude of emissions, concentrations, exposure, or risk of health effects.

It is important to note that a proximity-based approach is not recommended when risk of exposure to a specific stressor is not correlated with the location of its source. For example, exposure to pollutants found in drinking water systems can be more dependent on distribution system characteristics than proximity to a pollutant source or the treatment plant. Likewise, exposure to specific chemicals may occur at home or in the workplace, such as through use of cleaning or personal care products or because of lack of access to personal protective equipment.

For practical reasons, the boundary of an affected area is usually based on a Census-defined geographic area (e.g., census tract or block group) or a distance-based buffer (e.g., a specified radius around a site). It is critical to use accurate spatial information when mapping the location of sources of pollution. Analysts must also decide what distance from the facility most accurately reflects the community's exposure to a stressor; no single distance is appropriate for all analyses. The buffer distance around sources of pollution can be chosen to approximate actual risk and exposure, although distance should be the same around each source. In some cases, it may be possible to use a dispersion model to select a buffer that approximates the effect of atmospheric conditions (for instance, wind direction and weather patterns) on exposure; these types of models are more data intensive.[91]

Using a proximity-based approach to evaluate the implications of a regulatory action to improve surface water quality deserves special mention, as proximity is along a river network or water feature affected by the regulation. In these cases, analysts should select a distance upstream or downstream that is likely related to the stressor(s). Pollutant transport and dilution models can also provide insight on the relevant distance. Some pollutants may degrade after a relatively short distance traveling in water, while others (e.g., bromide) maintain their physical properties for hundreds of kilometers. In addition to choosing the up or downstream distance, it is appropriate to incorporate a buffer around the water segment to define the affected population. Depending on the regulation's effects, the buffer could be relatively narrow (e.g., 1, 3, or 5 miles) or wide (e.g., up to 25 miles). Multiple buffers around affected water segments may also be appropriate to reflect uncertainty as well as distinct exposure pathways, such as via drinking water or subsistence fishing.

Regardless of how the size or extent of the affected area is selected, a proximity-based approach typically assumes that the effects of the stressor(s) occur only within the designated boundary (i.e., people located outside the boundary do not suffer ill effects) and that all individuals residing within the

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[90] Even when risk or exposure modeling is available, proximity-based analysis with a relatively small distance buffer (e.g., one or three miles) may offer insights into who is impacted by potential harms from changes in economic activity (e.g., noise, odors, traffic, leaks).

[91] It may also be 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. For an overview of proximity-based analysis, including a discussion of various spatial analysis techniques used in the literature, see Chakraborty et al (2011), Chakraborty and Maantay (2011), and Mohai and Saha (2007).

boundary are equally exposed.[92] As such, a proximity-based analysis is not able to determine which populations within the boundary may face higher risks or adverse health effects. The results of a proximity-based analysis may also vary with the geographic unit of analysis (e.g., Mascarenhas et al., 2021; Mohai and Saha, 2007; Ringquist, 2005). For this reason, analysts should explore alternative geographic units or distances when defining proximity to a source and describe the choices and assumptions that are used in selecting specific buffers. When conducting a proximity-based analysis, the results can also vary with the method used for assigning populations from Census-designated geographic units (e.g., a tract or block group) to a specific distance buffer (see Text Box 6.4).

The two groups – individuals located near and far from the source, as determined by the selected buffer – can be compared based on simple statistical or regression estimation techniques. Statistical tests on summary data can be used to identify whether, on average, statistically discernible differences exist in the characteristics of the two groups. Regression techniques, such as a binary logit, can formalize this comparison, where the dependent variable takes on the value of 1 for areas where one or more sources are located, and 0 indicates areas with no sources of the stressor. The independent variables are demographic or socioeconomic variables, such as share of the population that is low-income in that area. A statistically significant coefficient on an independent variable indicates a measurable difference in the demographic or socioeconomic variable across geographic areas with and without stressor sources. Note, however, that the coefficient estimates from such a regression cannot be interpreted as identifying the causal effects of race, income, or other characteristics on source location.[93] See Section 6.6.3 for a discussion of statistical significance.

Advantages of Proximity-Based Analysis

- Provides a quantitative analysis of the characteristics of communities in nearby locations;
- Can be a statistically rigorous approach if supported by data;
- Accounts for where individuals reside, providing a proxy for exposure when other more detailed information is unavailable; and
- Can be used to identify potential hot spots.

Disadvantages of Proximity-Based Analysis

- Requires accurate information on locations of sources;
- Less useful when risk of exposure to the stressor is not correlated with source location;
- Cannot distinguish between sources based on the level of exposure, risk, or health effects for the population within the boundary; and
- Exposure is often defined as a binary indicator instead of a continuous measure.

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[92] Chakraborty and Maantay (2011) address how to account for areas with more than one pollutant source, which are typically treated the same as those with only one source. Each pollutant source is treated as identical with regard to its effect on the nearby community. In reality, sources may vary widely in size, age, and production techniques resulting in differing amounts of emissions.

[93] See Banzhaf et al. (2019b) for an overview and empirical evidence of the possible causal mechanisms between pollution and demographics.

6.4.2 Exposure and Risk Modeling

Exposure and risk modeling generally falls under the domain of HHRA, where a set of common methods and tools are typically employed to inform risk-based regulatory decisions, as described in Chapter 5 and Appendix B. These tools can be useful, by themselves or in combination with other tools and data, for evaluating EJ concerns.

When data are available, analysts may choose to combine either a direct measure of or proxy for exposure with fate and transport modeling to examine distributional effects at a disaggregated level. For instance, the EPA's Air Toxics Screening Assessment tool uses fate and transport modeling to estimate hazardous air pollutants concentrations and respiratory and cancer risks from point, non-point, and mobile sources at the census tract level. The Risk-Screening Environmental Indicators (RSEI) model combines a fate and transport model and information on chemical toxicity to estimate the dispersion of toxic chemicals reported by specific facilities to the Toxics Release Inventory (TRI). Many EPA offices also maintain fate and transport models specific to a particular regulatory context. Information from these types of modeling exercises can be combined with demographic and socioeconomic data to generate baseline and regulatory distributions of pollutants by population groups of concern. (See Appendix B for examples.)

Likewise, direct measures of surface water quality or modeled water quality data can be combined with hydrological modeling to estimate pollutant concentrations in waterways. This allows analysts to consider exposure to pollutants such as lead and mercury via fish consumption. Drinking water quality sampling results or violations of the Safe Drinking Water Act can also be used along with water system service area boundaries to estimate exposure to pollutants through drinking water and assess distributional effects across population groups.[94]

In cases where disaggregated information is available on differences in exposure across population groups and there is a credible and scientifically defensible approach for translating exposures into a response (e.g., evidence from the literature or HHRA on how a given level of exposure manifests as a change in the risk of a specific health effect), it may be possible to characterize differences in health effects due to the regulatory action. See U.S. EPA (2024f), U.S. EPA (2019a), and U.S. EPA (2014b) for specific guidance on risk assessment, exposure assessment, and quantifying benefits, respectively. In some cases, it also may be possible to combine exposure data with information on differential responses across population groups.

Advantages of Exposure and Risk Modeling Methods

- Represent the most detailed and rigorous type of analysis; and
- Provide the most direct source of information on exposures or other outcomes.

Disadvantages of Exposure and Risk Modeling Methods

- Require detailed data at a fine geographic scale;

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[94] When evaluating exposure to specific drinking water pollutants, it is important to know who is served by a specific water system. However, drinking water service areas rarely correspond to Census-defined or other standardized geographic designations. See https://www.epa.gov/ground-water-and-drinking-water/community-water-system-service-area-boundaries.

- Are more complex to implement; and
- Provide results in a form that may be more challenging to communicate to the public.

6.4.3 Combining Qualitative and Quantitative Approaches

While the EPA often uses quantitative data and analysis to support the regulatory process, available data are often not sufficiently disaggregated to allow quantification of distributional effects in the baseline and across regulatory options. Other times, only partial information may be available.[95] In either case, the use of qualitative information or methods may be an appropriate supplement to quantitative approaches. Qualitative methods may be particularly useful for offering insight into people's values, behaviors, motivations, cultures, and local lived experiences, or when providing context for the cumulative effects of exposure to multiple stressors on human health and well-being, which are often omitted from quantitative assessment. Qualitative approaches may also be useful at the preliminary stages of analysis.

Qualitative approaches systematically collect data via a series of open-ended questions and then evaluate them to identify emerging patterns or themes (Tashakkori et al., 2020). Sample size is typically small but allows for practitioners to dive more deeply into specific questions of interest. Qualitative approaches share one or more of the following characteristics:

- Employ a variety of empirical materials, such as case study, narrative or personal experience, introspection, life story, interview, observational, historical, interactive, and visual text;
- Gather empirical materials using some form of observation or interviewing method;
- May be iterative, with initial results informing later choices; and
- May rely on primary or secondary data sources, or a combination of the two.

Qualitative data can also be evaluated using a variety of approaches that range from identifying interconnections within narrative data to more formal coding and statistical analysis of emerging themes (referred to as content analysis).

Qualitative and quantitative approaches can also be used in combination (referred to as mixed methods). They can be used iteratively or sequentially to inform a subsequent analytic stage (e.g., qualitative information may be collected via focus group to inform subsequent quantitative analysis of a larger sample). Qualitative and quantitative approaches can also be used concurrently to shed light on different aspects of the same phenomenon or to identify areas where themes or patterns converge or diverge across the two data sets. It is also possible to combine qualitative and quantitative data into a single analysis (Taherdoost, 2022).

Analysts should use their best judgment when evaluating the appropriate use of quantitative and qualitative approaches for the analysis of EJ concerns. Similar to quantitative data, qualitative data can be evaluated for both internal validity (e.g., are the findings credible?) and external validity (e.g., are the

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[95] U.S. EPA (2024f) discusses how to consider qualitative information in benefit-cost analysis (Chapters 7 and 11).

findings transferable?), and are subject to EPA guidance on the quality of scientific and technical information used in support of Agency decisions (See Text Box 3.1).[96]

Note that approaches that directly engage local communities or Tribes can be long, time-intensive processes and are subject to Paperwork Reduction Act requirements and Tribal consultation policies. Special thought should also be given to addressing barriers to meaningful engagement when using qualitative approaches, including those related to disability, language access, and lack of technical assistance, tools and resources (See Sections 2.3 and 5.3.1.2, and Text Box 5.1).

Advantages of Qualitative Approaches

- Useful supplement when data are unavailable or incomplete for conducting a quantitative analysis; and
- Allow analysts to incorporate hard-to-quantify information, such as cultural factors, pre-existing vulnerabilities, public narratives, and community lived experiences.

Disadvantages of Qualitative Approaches

- Can be difficult to summarize results succinctly;
- Results can be uncertain, and the degree of uncertainty can be difficult to characterize; and
- Can be difficult to compare to quantitative information, (e.g., from a benefit-cost analysis or risk assessment).

6.5 Analytic Considerations

Regardless of the analytic approach taken, analysts make a number of key decisions that can have a substantial effect on the results of the analysis, including: the geographic and temporal scope of the analysis; how to specify the comparison population group; how to spatially identify and aggregate effects across affected and unaffected populations; whether to conduct analysis from a community and/or facility perspective; and how to evaluate underlying variability, including the potential for hotspots.

An important general strategy in analyzing EJ concerns is the use of sensitivity analysis. Due to the uncertainties associated with the analytic decisions discussed below, sensitivity analysis around key assumptions is often critical for clearly communicating results to the public.

6.5.1 Geographic and Temporal Scope

The geographic scope of analysis for an EPA regulatory action is often the entire United States since requirements typically apply nationwide. However, in some cases the effects of a regulatory action are expected to be concentrated in specific regions or states. In such cases, it may make sense to analyze and present differences in health and environmental outcomes across population groups at both a national and a sub-national level. Because the geographic scope can affect the results of the analysis

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[96] See Tesch (2013) for a discussion of different types of qualitative analyses. Tashakkori et al. (2020), Seawright (2016), and Lieberman (2005) provide approaches and best practices for combining qualitative and quantitative research. Mohai and Saha (2015) also provide a literature review of mixed method and qualitative studies in the EJ context.

(Baden et al., 2007), analysts should make certain that the scope is relevant for the regulatory action under consideration. In addition, it is important to keep in mind that differences in health and environmental outcomes in one region or state may not necessarily hold in other regions or states.

It may be important to evaluate regulatory action effects on both shorter and longer time horizons. For instance, while a regulatory action may result in near-term reductions in emissions, changes in health and other risks may occur on a longer timeframe. In some cases, effects may even be felt intergenerationally (e.g., climate change) and the analysis may accordingly extend beyond the current generation to include a robust discussion of far-future health effects and costs. In general, the period of time over which the analysis is conducted should also be consistent with other parts of the regulatory analysis.

The scope of the analysis should generally match the scope used in other parts of the regulatory analysis (e.g., benefit-cost analysis). However, in some situations, using a different time horizon or spatial scale may be appropriate when considering EJ. For example, phasing in of regulatory requirements or relocation of polluting activities in response to the regulatory action may result in EJ concerns due to effects that occur on a time horizon or spatial scale that differs from other effects considered in the regulatory analysis. If such situations arise, analysts should clearly articulate the reasons for considering an alternative time horizon.

Another aspect of characterizing temporal scope is adequately anticipating the long run dynamic effects of a regulatory action (Cain et al., 2024). The literature uses spatial sorting models to examine how regulations may affect residential location choice but typically focuses on a specific city or region (e.g., Redding and Rossi-Hansberg, 2017; Kuminoff et al., 2015).[97] [98] Spatial sorting can occur when improved environmental quality is capitalized into housing values, attracting higher-income households and shifting renters and lower-income households to less expensive neighborhoods with lower environmental quality (Melstrom and Mohammadi, 2022). On the other hand, some residents may be more likely to move into high-risk zones due to differences in housing prices (Bakkensen and Ma, 2020). Given the challenges of modeling these types of effects on a national scale, it is recommended that analysts qualitatively discuss possible household responses based on the available literature, while acknowledging the limitations of the analysis.

6.5.2 Comparison Population Group

To evaluate differences in effects for population groups of concern, results need to be presented relative to another group, typically referred to as a comparison population group. How the comparison population group is selected has important implications for evaluating differences in health, risk, or exposure effects across population groups of concern. It is possible to define the comparison population group as individuals with similar socioeconomic characteristics in areas of the state, region, or nation unaffected by the regulatory action (i.e., within-group comparison) or as individuals with different socioeconomic characteristics within the affected areas (i.e., across-group comparison).

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[97] One exception is Fan et al. (2018). They link spatial sorting and economy-wide models of the United States to explore where people migrate in response to increased risk of extreme temperatures, while accounting for wage and housing price feedbacks.

[98] Likewise, while hedonic price methods may be useful for demonstrating how changes in environmental quality factor into housing prices, predicting the effect of such price changes on household migration by race or income may be infeasible.

Analysts should aim to define the comparison population group for an across-group comparison as similar as possible to the population group of concern, but without the socioeconomic characteristics defining the group of concern. For example, analysts could compare the proportion of low-income households within areas affected by the regulatory action to the proportion of non-low-income households within the same affected areas. If analysts have fate-and-transport information on emissions, they can compare the average concentrations faced by low-income households within the affected areas to those faced by non-low-income households living in the same areas. Thus, the results from an across-group comparison indicate how the likelihood of risk or exposure within the affected areas varies with demographic and socioeconomic characteristics.

A within-group comparison compares the likelihood of risk or exposure for a specific demographic or socioeconomic group in affected areas to the likelihood of risk or exposure for that same demographic or socioeconomic group elsewhere. Again, analysts should aim for the comparison group to be as similar as possible to the population group of concern but without the risk or exposure of interest. For example, analysts can compare the proportion of low-income households within areas affected by the regulatory action to the proportion of low-income households in unaffected areas. Similarly, if analysts have information on the fate and transport of emissions, they can compare the average concentrations faced by low-income households within the affected areas to those faced by low-income households living in areas unaffected by the regulatory action.

If a regulatory action is expected to differentially affect populations within a given area (e.g., communities living near regulated facilities or in a specific region), then a combination of within- and across-group comparisons can demonstrate whether there are differences between specific population groups of concern and the general population. Across-group comparisons are also informative in instances where it is difficult to identify a comparison population group because a large share of the U.S. population will be affected by the regulatory action. In these instances, it may not be appropriate to use a comparison population group that includes the population of concern (such as the entire U.S. population), as this will reduce the differences between them by construction.

It is unlikely that the same comparison population group will be appropriate in every instance. Analysts should carefully document the criteria used to select the comparison population group for a particular regulatory action, why it provides a useful counterfactual to the population group of concern, how the two groups differ, and whether and why those differences might be important to the interpretation of results within the EJ analysis.

In some contexts, it may make sense to define the comparison population group at a sub-national level to reflect differences in socioeconomic composition across geographic regions. For instance, because larger populations are concentrated in urban areas, the results of the analysis are often dominated by effects in these areas. If a regulatory action primarily affects rural areas,[99] inclusion of urban areas in the comparison population group may obscure underlying differences.

Using a sub-national comparison population group may also be more defensible when there is a great deal of heterogeneity in industrial development and economic growth and/or inherent differences in demographic and socioeconomic composition across geographic regions (e.g., relatively more

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[99] See the Federal Committee on Statistical Methodology’s discussion of the different definitions the federal government uses to classify rural populations, as well as the advantages and disadvantages associated with the different definitions: https://nces.ed.gov/fcsm/edt/rural_definitions.html

Hispanics reside in the Southwest) (e.g., Bowen, 2001). In these instances, analysts may consider comparing the populations of concern near an affected source to populations living just outside of the affected area. By selecting a comparison group that is geographically proximal and of a relatively similar size to the affected population, analysts can better control for other confounding factors. See Text Box 6.4 for examples.

Note, however, that placing restrictions on the comparison population group may “reduce the power of statistical tests by reducing sample sizes” (Ringquist, 2005) or bias results against finding differences in adverse human health and environmental effects because such restrictions reduce variation in demographic or socioeconomic variables of interest. In selecting a comparison population group, analysts should therefore evaluate how different comparison population groups affect the way information is conveyed. When appropriate and practicable, analysts should conduct sensitivity analysis using alternate definitions of the comparison population group to provide a more complete depiction of potential effects.

6.5.3 Spatial Identification and Aggregating Effects

The spatial distribution of health and welfare outcomes is a relevant consideration for some regulatory actions, such as those that reduce emissions from point sources that have fairly localized effects or when there is a differential distribution of associated health or environmental effects. In other cases, the regulatory action’s effects may be more widespread, and spatial distribution is less relevant (e.g., when exposure to a chemical substance depends on its purchase, use, transport, or disposal).

When exposures, risks, or human health effects are spatially distributed, analysts need to determine how to spatially identify affected and unaffected populations. The nature of the stressor(s) should guide analysts’ choices of the geographic area of analysis. Some air pollutants, for example, may be emitted out of tall stacks and travel long distances, affecting individuals hundreds of miles away from the sources and thereby 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 effects from point sources – including possible traffic, odors, and noise implications from changes in production – may call for more spatially resolved data than those that affect regional air quality.

Complications can arise when the spatial resolution of the analysis is either too refined or too coarse. For example, small geographic areas of analysis (e.g., less than one mile from the source location) may not be sufficiently outside of an emitting source’s fenceline to capture potential effects on nearby populations. A geographic unit of analysis that is too large may begin to resemble state or national averages and can be more difficult to interpret due to the influences of many, multiple sources of risk and exposure.

Text Box 6.4 Selecting a Comparison Population Group – Recent Examples

For the final Phasedown of Hydrofluorocarbons rule (U.S. EPA, 2021a), analysts examined the socioeconomic characteristics of communities living within a specific distance of a production facility subject to the rule both in aggregate and for each individual facility. The comparison population group for the facility-by-facility analysis was selected to reflect whether a facility is in a rural or urban area (i.e., overall or rural average) and presented at both the state and national levels.

For the final Control of Air Pollution from Heavy Duty Engine and Vehicle rule (U.S. EPA, 2022f), analysts used a proximity-based approach to examine the proportion of the population living within different distances of major truck freight routes by race, ethnicity, and income. The analysis then compared the characteristics of those living within 1,000 meters to those living beyond 1,000 meters. Results were further delineated based on U.S. Department of Agriculture rural-urban continuum designations and by region.

For the final Mercury and Air Toxics Standards rule (U.S. EPA, 2011c), analysts examined mortality risk associated with fine particulate matter (PM) by race, income, and poverty level for people living in high-risk counties (i.e., in the counties identified as experiencing the top five percent of risks from exposure). The comparison population group was defined as people living in counties not facing a high mortality risk.

For the final Lead Emissions from Aircraft Engines Endangerment finding (U.S. EPA, 2023g), analysts examined the characteristics of residents within 1 kilometer of airport runways in the U.S. (where piston-engine aircraft may use leaded aviation fuel). Resident characteristics included race, ethnicity, poverty level, and children under age five. The comparison group was defined as residents that live within 1 to 5 kilometers of those locations.

Another challenge that arises when using geospatial data is when data are spatially autocorrelated – that is, locations in closer proximity are more highly correlated with the variable of interest than those further away. When this occurs, then the assumption that error terms are independently distributed is violated (Chakraborty and Maantay, 2011), which can violate the assumptions of some statistical techniques.[100] When considering whether and by what method to address spatial autocorrelation (Mennis and Heckert, 2017; Chakraborty, 2011), it is important to consider the goal of the analysis (e.g., statistical association, prediction, significance testing of an estimated effect, or distinguishing correlation from causation).[101]

The quality and type of data available also affect the spatial resolution of the analysis (see Section 6.3). For instance, in rural areas Census-based geographies can be large, introducing a higher level of uncertainty regarding where specific populations groups live within that boundary. Thus, more than one geographic area of analysis to examine the robustness of results may be useful since effects are

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[100] For more discussion on methods to address spatial autocorrelation, see Chapter 8 in Haining (2003). For examples of regression techniques that have been employed to address spatial autocorrelation, see Kuminoff et al. (2010).

[101] Bayesian regression techniques may be appropriate in some circumstances, for instance when combining data across multiple data sets where there are complex interdependencies across space and time, and it is difficult to quantify uncertainty using traditional approaches. See Chun et al. (2012) and Carlin and Xia (1999) for examples of how these approaches have been applied in the EJ context.

unlikely to be neatly contained within geographic boundaries and results may be sensitive to the choice of the geographic area of analysis (Baden et al., 2007; Mohai and Bryant, 1992).

Census-based geographic delineations and definitions often align with topographical or infrastructure features such as rivers, highways, and railroads. As a result, they may exclude a portion of the affected population that experiences the same adverse effects from a stressor, even if they are on the other side of the physical feature. While Census-based definitions are easily accessible and offer many options regarding geographic scale, use of a spatial-defined distance can potentially allow for a more flexible approach. Using geospatial tools, analysts can define spatial buffers around emissions sources that are more uniform in size and easier to customize to reflect the appropriate scale and characteristics of the emissions being analyzed (e.g., fate and transport).

Buffers can be created and combined with Census data in many ways, including selecting the Census units (e.g., tracts or block groups) that intersect the buffer circle, selecting tracts with centroids within the buffer circle, spatially intersecting the buffer circle with the tract polygon, and transferring the attributes from tracts to the buffer area using area- or population-weighting (see Text Box 6.5). Mohai and Saha (2007, 2006) show that using distance from a facility instead of a buffer-based approach may provide a more complete comparison of effects (see also Mascarenhas et al., 2021; Mohai and Saha, 2015).

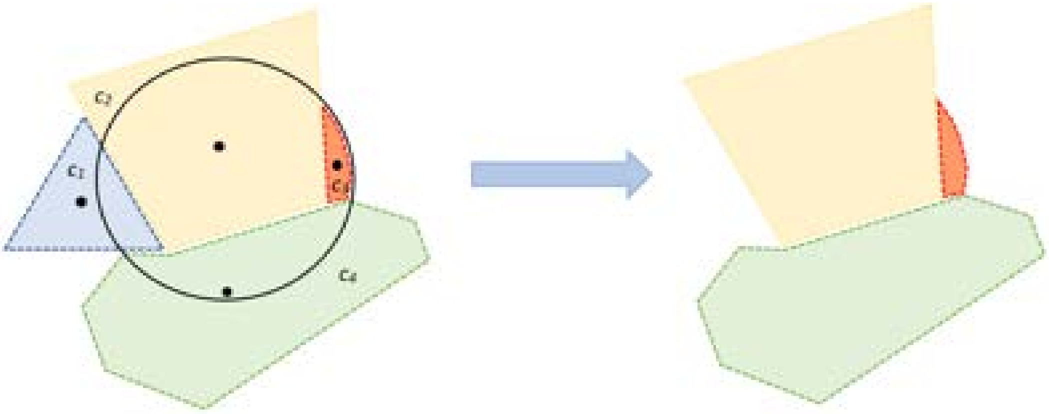
Analysts should be aware of the potential for the “modifiable areal unit problem” when aggregating geospatial data. The modifiable areal unit problem refers to the fact that results can be sensitive to the level of spatial aggregation used in the analysis, such as how the results may differ if the data are aggregated to the census tract versus county level (see Shadbegian and Wolverton, 2015; Baden et al., 2007; Mohai and Bryant, 1992). Additionally, analysts should exercise caution when extrapolating the results to more spatially resolved units. For example, relationships estimated using county level data may mask neighborhood level associations between pollution exposure and demographic and socioeconomic characteristics (see Banzhaf et al., 2019a).

When selecting a unit of analysis, it is also important to weigh any potential tradeoffs between completeness (fully capturing the populations at risk) and variability in risk (for instance, possibly masking information about those most at risk by including populations that are much less affected). Analysts are encouraged to discuss the approach used to create buffers and aggregate geospatial data, as what is most appropriate will vary with the stressor(s) affected and data used in the analysis, and to provide a transparent justification of their choice. In some cases, it may be helpful to consider multiple buffers to evaluate the effects of a regulatory action, for instance, because of uncertainty regarding fate and transport of a specific environmental stressor or because the regulatory action affects environmental stressors that travel different distances.

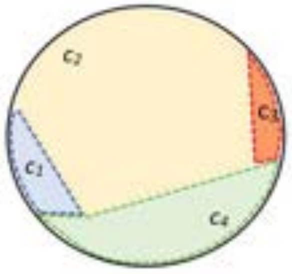
Text Box 6.5 Centroid-Based vs. Areal Apportionment Methods

Demographic and socioeconomic data are typically available at an aggregate level within the boundaries of a Census geographic unit (e.g., tract or block group). Analysts must then decide how to map the available data to circular buffers around an emissions source. There are two main approaches.

The centroid-based method assigns the population from a Census geographic unit to the circular buffer when the centroid of the unit lies within it. In the figure below, the centroid method excludes the population in Census unit c_1 because its centroid lies outside the circular buffer but includes the entire populations of Census units c_2, c_3, and c_4.



An alternative method is areal apportionment, which assigns populations to a circular buffer based on the extent to which a Census geographic unit overlaps with that buffer. In the example from above, this approach includes only the portions of c_1 – c_4 that overlap with the circular buffer. It apportions the population living within c_1 – c_4 to the circular buffer by assuming they are uniformly distributed within each Census geographic unit.



For a given spatial resolution, areal apportionment can yield more accurate estimates than the centroid-based approach. When the centroid-based approach is applied to Census geographic units with large spatial extents (e.g., rural areas), analysts may find that the centroids of some units are not located within the circular buffer. This leads to the exclusion of geographic areas from the analysis and can skew results. Note, however, that the centroid-based method is less computationally intensive and therefore may have the advantage when Census geographic units are small.

6.5.4 Facility vs Community-Based Perspectives

Exposure to other environmental and non-environmental stressors can increase the vulnerability of individuals or population groups to negative health effects from exposure to a specific environmental hazard. While explicit modeling of these interactions is often not feasible, analysts can shed light on this issue by evaluating and presenting results using not only a facility, but also a community-based perspective.

An analysis with a facility-based perspective primarily considers who may be exposed to sources regulated by the specific action under consideration. For example, such an analysis would examine proximity, emissions, concentrations, or risk associated with each regulated source in conjunction with the demographic and socioeconomic characteristics of those most likely to be exposed.

However, communities may be affected by multiple sources of pollution relevant to characterizing risk for a specific regulatory action. An analysis that takes a community-based perspective considers proximity, emissions, concentrations, or risk to a given community from multiple nearby sources of pollution to which individuals are exposed, accounting for the possibility that certain communities face increased vulnerability due to a greater number of nearby pollution sources.

Examples of analyses that take a community-based approach include:

- The total number of polluting facilities within a specific distance from the regulated source.[102]
- Measures of other sources of exposure to the same environmental stressor being regulated (e.g., age of home and proximity to a major highway are positively associated with the likelihood of homes having lead in paint, service lines, and soil).
- Measures of exposure or risk to a broader array of contaminants in communities near the regulated source (e.g., cancer risks from exposure to air toxics). [103]
- Explicitly accounting for non-regulated or other routes of exposure when modeling risk faced by the affected communities.[104]

6.5.5 Evaluating Underlying Variability and Identifying Potential Hot Spots

In addition to presenting aggregate results for population groups of concern affected by the regulatory action, it is important to understand the extent to which there are heterogeneous effects, both within specific population groups as well as across communities, given that communities often vary widely in the risks they face from the affected sources as well as from other environmental and non-environmental stressors. When data allow, analysts should characterize the distribution of risks, exposures, or outcomes within each population group of concern, not just average effects, with particular attention paid to the characteristics of populations at higher risk of exposure. When relying on proximity-based analysis, differentiating results by key facility characteristics that may be correlated with risk (e.g., plant age, capacity, production levels, accident history, types of chemicals stored on site) can be useful.

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[102] For example, see the EJ analyses in U.S. EPA (2024j) and U.S. EPA (2022g).
[103] For cancer risks associated with air toxics, see https://www.epa.gov/AirToxScreen.
[104] See the EJ analysis in U.S. EPA (2022h), in which cancer risk is modeled using hazardous air pollutant concentrations from both regulated and non-regulated sources within a specific distance of regulated sources.

It is also important to evaluate the potential for hot spots, with particular attention paid to the communities in the upper end of the distribution of exposure or risk. Hot spots refer to geographic areas with higher levels of localized concentrations of emissions from one or more sources within a larger geographic area with more “normal” environmental quality. Hot spots may result from baseline conditions, such as exposure to other pre-existing stressors within the community. For example, the siting of polluting facilities near populations of concern may be reflective of historic discriminatory land use policy and practices (Estien et al., 2024; Gonzalez et al., 2023). Studies have demonstrated that population groups of concern experience higher concentrations of air toxics due to proximity to nearby industrial facilities (Bouvier, 2014; Zwickl et al., 2014; Ash et al., 2013; Pastor et al., 2002). Extractive industries are also associated with localized environmental concerns such as contamination of groundwater in rural areas and Tribal lands from abandoned uranium mines, resulting in high incidences of kidney cancer and other adverse health effects (Ingram et al., 2020; Lewis et al., 2017; Corlin et al., 2016). See Text Box 6.6 for a specific example.

It is also possible that hot spots may be created, exacerbated, or mitigated following a regulatory action. Relevant issues to consider may include proximity to multiple sources of pollution, specific exposure pathways, and other drivers of increased vulnerability. Qualitative or other sources of data may also help to identify specific population groups or communities where a more detailed analysis is warranted.

A preliminary analysis early in the analytic process may help identify the potential for hot spots. In addition, information received via public comments can yield insights into the potential for a regulation to create or exacerbate hot spots.[105] More sophisticated modeling or econometric approaches may also facilitate systematic identification of potential hotspots (e.g., fate and transport modeling, hydrologic modeling, hedonic analysis). If a relatively small number of potential hot spots are identified, case studies or in-depth qualitative analysis may be useful.[106]

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[105] For instance, the public has expressed concern that cap-and-trade policies designed to reduce carbon dioxide emissions may lead to increases in criteria air pollutants in already overburdened neighborhoods, further exacerbating existing health issues. In the context of the California trading program, research has not reached consensus on the degree to which the policy has exacerbated existing emissions in communities of color or low-income communities (e.g., Mansur and Sheriff, 2021; Hernandez-Cortes and Meng, 2020; Cushing et al., 2018; Grainger and Ruangmas, 2017; Fowlie et al., 2012).

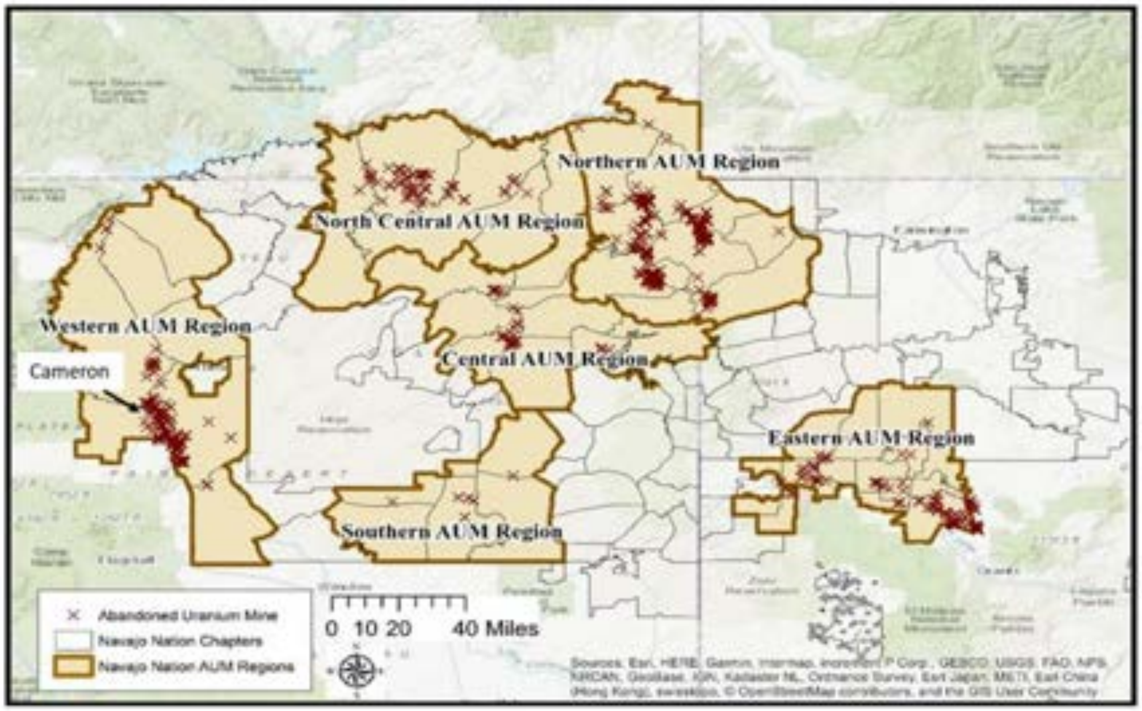
[106] See Arcury et al. (2021), Rocha et al. (2017), Mohai and Saha (2015), Schwartz et al. (2015), and Grineski (2009) for examples of qualitative discussions of hot spots.

Text Box 6.6 Hot Spots Example: Abandoned Uranium Mines on Navajo Nation Land

In the western United States, many abandoned hardrock mines are located near or on Tribal lands. Over 600,000 Native Americans live within 10 kilometers of an abandoned mine (Lewis et al., 2017). Of particular concern are the over 4,000 abandoned uranium mines, 75% of which are within 80 kilometers of an Indian reservation. Over 500 abandoned uranium mines are located on or near the Navajo Nation in the Four Corners region alone.

Documented adverse health outcomes for Navajo Nation members exposed to uranium mine waste during the mining era (1940s - 1980s) include congenital anomalies at birth (Shields et al., 1992) and later life kidney disease (Lewis et al., 2017). Navajo men who were underground uranium miners had high excess risks of lung cancer (Gilliland et al., 2000). One report found that Navajo residents were more than seven times more likely to die from gallbladder cancer, more than four times more likely to die from stomach cancer, more than two times more likely to die from kidney cancer, and almost two times more likely to die from liver cancer compared to non-Hispanic White people (Navajo Epidemiology Center, 2023).

In addition, these mines' legacy contamination of Tribal groundwater poses a drinking water concern to residents, given limited public water infrastructure in the region and widespread reliance on private wells. Studies testing drinking water in the Navajo Nation have detected uranium above the national regulatory limit (Ingram et al., 2020; Corlin et al., 2016).



Map of the Navajo Nation with abandoned mine sites represented by Xs and the Navajo Agencies and Chapters outlined within the map (OpenStreetMap on Garmin May 13, 2019). Retrieved from: https://wiki.openstreetmap.org/w/index.php?title=OSM_Map_On_Garmin&oldid=1851574

6.6 Characterizing Analytic Results

Once an EJ analysis has been conducted, analysts face choices about how to characterize and communicate the results. Analysts need to present summary metrics for relevant population groups of concern and the comparison population group and characterize the differences between them. This section discusses the way in which information from the analysis can be summarized and presented, including the choice of summary metrics, ways of displaying the results in tables, maps or other visual displays, and the distinction between statistical and policy significance when interpreting results.

6.6.1 Choice of Summary Metrics

Simple summary measures can be used to characterize the distribution of health and environmental effects in the baseline and for regulatory options relative to appropriate comparison population groups. Metrics commonly used to summarize information on effects across population groups of concern relative to a comparison population group include:

- Levels, stratified by demographic or socioeconomic characteristic (e.g., average $PM_{2.5}$ concentrations for Black residents within three miles of regulated sources compared to average $PM_{2.5}$ concentrations nationally).
- Percents, stratified by demographic or socioeconomic characteristic (e.g., percent low-income within three miles of regulated sources compared to percent low-income nationally).
- Differences in means (e.g., the difference in mean cancer risk for low-income vs. for non-low-income residents affected by the regulatory action).
- Percentile rankings (e.g., how affected areas rank, in percentile terms, relative to the national, regional, or state average).
- Relative ratios (e.g., the ratio of average risk or exposure for one group to the average risk or exposure for another group within the same geographic area).[107]
- Inequality indexes, such as the Gini coefficient (Muller et al., 2018), measure the extent to which an outcome (e.g., emissions or exposure) is distributed unequally across society or communities.[108] Lorenz curves are closely related to Gini coefficients and can be used to visualize inequality across the distribution of pollution exposures (Andarge et al., 2024).

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[107] A relative ratio of one indicates that the specific group has the same risk or exposure as the comparison group. The higher the ratio is above one, the higher the risk or exposure relative to the comparison group. If the ratio falls below one, this indicates that the specific group has a lower risk or exposure than the comparison group.

[108] Alternatives to the Gini coefficient include the Atkinson index (Levy et al., 2006) and the Kolm-Pollak equally distributed equivalent measures (Sheriff and Maguire, 2020). There are important interpretational differences between inequality measures as applied to income or wealth (a good) vs. pollution exposure (a bad). For example, the Atkinson index places greatest weight on the worst off when applied to income, but with respect to environmental harms it more prominently weights those with the lowest pollution burden. Separately, inequality indexes may obscure potentially important information about absolute levels of exposure.

Analysts should consider characterizing results of the EJ analysis using more than one type of summary metric to provide a richer picture of potential effects. For instance, relative ratios can facilitate comparisons across groups or locations because all ratios are in common units. However, without presenting information on the absolute levels of risk or exposure, it is not possible to determine if either group is at risk of experiencing a potential health effect. Analysts should also present information that communicates underlying heterogeneity in the data, such as the degree of spread in the data relative to the mean (i.e., standard deviation).

Counts of the number of sources or geographic areas where the percent of a specific population group living nearby exceeds a particular threshold (e.g., the state/national average or a specific percentile) are not recommended. Counts are hard to interpret because they do not account for differences in population size or density across geographic areas. It is more informative to display metrics that characterize the full population or risk distribution to understand the extent to which affected communities differ from the comparison group.

To the extent that the underlying data allow, analysts should disaggregate the summary information so that the public can discern how risk, exposure, and/or health effects vary for different types of individuals within a population group. For instance, exposure or health effects can be presented for income quantiles, in addition to presenting this information for those above or below a particular income threshold. Likewise, analysts might describe the average demographic or socioeconomic characteristics of workers differentiated by the affected industry and/or geographic areas relative to a comparable but unaffected population of workers.

In many cases, the distribution of environmental exposure or risk across individuals or communities follows a non-normal distribution with a long right tail. In other words, while many individuals may be exposed to low or moderate levels of environmental stressors, a handful of them may face differentially high risk. In these cases, demonstrating that the average of the affected group is similar to the national average is not very informative. Rather, it would be useful to characterize the full distribution as well as the exposure or risk for individuals or communities that are in the high-end of exposure, such as those in the 95th or 99th percentile (Gochfeld and Burger, 2011). Information on risk, exposure, and/or health effects can be presented for the average-exposed individual as well as a maximally-exposed individual in each population group. If specific communities are substantially affected, analysts can present summary statistics for those specific communities in addition to presenting aggregate summary statistics for all communities affected by the regulatory action. (Also see Section 6.5.5.)

6.6.2 Displaying Results Visually

Tables, maps, and other visual displays help communicate a large amount of information in an organized way to facilitate comparisons, convey results, and support discussion. Careful thought should go into how information is presented, particularly when there are:

- Multiple comparison groups (e.g., state, U.S., rural areas);
- Different types of effects (e.g., pollutants, health effects, or other environmental metrics);
- Multiple categories of regulated facilities or types of sources;
- Many individual sources;

- Clustering of sources in specific geographic areas;
- Multiple scenarios (e.g., baseline, multiple regulatory options); or
- Sensitivity analysis around key analytic assumptions (e.g., buffer distance).

Analysts need to clearly explain how to interpret the information presented in tables, maps, or figures to properly contextualize results and guard against erroneous conclusions (e.g., a large percentage change from a small baseline value may not be a large change in absolute terms).

Often more than one table is needed to present results. In addition, bolding or shading specific cells can ease navigation of a dense table of results. Table 6.1 illustrates how results for multiple types of sources and several distance buffers can be presented within a single table. This example also uses shading to indicate values above the national average.

Table 6.1 Example Summary Table for Proximity-Based Analysis Results

Sociodemographic Category	Population within 1 Mile of Sites with Legacy CCR SIs	Population within 3 Miles of Sites with Legacy CCR SIs	Population within 1 Mile of Sites with CCRMUs	Population within 3 Miles of Sites with CCRMUs	U.S. Population
Race					
Asian	10.36%	4.66%	2.37%	2.82%	5.64%
Black or African American	13.47%	17.03%	8.37%	13.73%	12.53%
Native Hawaiian/Pacific Islander	.03%	.08%	.06%	.07%	.18%
Native American or Alaskan Native	.79%	.93%	.86%	.78%	.82%
Other	16.65%	15.82%	20.63%	18.94%	12.82%
White	58.47%	61.47%	67.71%	63.67%	68.01%
Ethnicity					
Hispanic (any race)	26.27%	22.0%	32.61%	27.02%	19.24%
People of color					
People of Color	52.42%	46.31%	46.70%	46.59%	41.14%
Poverty Level					
Households below the poverty level	16.21%	16.11%	14.94%	14.9%	12.71%
Other Sociodemographic Indicators					
Linguistically isolated households	9.23%	5.42%	9.38%	6.05%	4.84%
Less than a high school diploma	17.60%	14.02%	17.11%	15.57%	11.24%
Person with disability	15.53%	15.61%	14.66%	15.23%	12.70%

Source: Table 6-9. Estimated Percent of Key Sociodemographic Indicators Near Legacy CCR Surface Impoundment (SI) and CCR Management Unit (MU) Sites (U.S. EPA, 2024k).

Visually displaying information in maps or figures can also help demonstrate how sources, risks, and exposures are geographically distributed across population groups, including baseline conditions and spatial clustering of sources (see Figure 6.1 for an example). Choropleth maps, which use color or shading to represent the range of a variable's values, can be used to visualize the levels of environmental, demographic and socioeconomic variables across space.

Note that it can be difficult to visually discern differences between baseline and regulatory options in maps or figures unless differences are large.[109] However, differences not discernible on a map may still be important. Additionally, it is important to consider how visual indicators can be used to characterize data uncertainty, how geographic boundaries relevant to the analytic context (e.g., watershed, state, or Tribal lands) are identified on a map, and how to select appropriate intervals for visually representing the distribution of the data. For this reason, visual displays are only suggestive of potential effects and should be accompanied by tables or other graphics that allow the reader to access the underlying statistical information.

Figure 6.1 Example Map of Relative Cancer Risks from Air Toxics within 1 Mile of Regulated Sources

Source: U.S. EPA (2022g).

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[109] For an overview of general mapping best practices to communicate EJ concerns, such as selecting a projection, avoiding unintentional misrepresentation, and choosing a color scale to represent values, see Stieb et al. (2019).

6.6.3 Statistical Significance and Other Considerations

Tests of statistical significance can be used to examine whether the difference between the mean values of two groups is due to factors other than chance.[110] This can be done for a pairwise comparison, which does not control for other factors, or via a regression approach, which allows analysts to assess the relationship between two variables while controlling for other factors.

It may also be useful to examine parts of the distribution further from the mean (e.g., quantile approaches) or to use approaches that can account for outliers, skewness or heteroscedasticity (varying levels of spread) in the data. Note that the ability to test statistical significance is predicated on having a sufficiently large sample size and, for parametric approaches, an assumed distribution (e.g., normality).[111]

It is important to understand that a statistical difference does not necessarily indicate that the difference is meaningful from a policy perspective. For instance, analysts may find that low-income households are more likely to be located near a pollution source than wealthier households, and that this effect is statistically significant (i.e., the effect is statistically distinguishable from zero and not due to sampling error).[112] However, the difference in likelihood between these types of households could still be quite small in magnitude. Analysts need to examine what the difference implies (e.g., how different poverty is across geographic areas), and summarize those differences in a manner appropriate for policy relevance.

When using multi-variate regression analysis, analysts need to be aware that many demographic and socioeconomic characteristics are highly correlated with each other, making it difficult to interpret the meaning of a coefficient on any given variable. In cases where standard errors may be correlated across groups of observations, analysts can cluster standard errors to account for correlation (Abadie et al., 2023; Cameron and Miller, 2015). These clusters can be at the geographic unit level, such as by county, and/or at the temporal level, such as by year. Finally, analysts can consider other factors aside from demographic and socioeconomic characteristics that may have influenced the location of sources (e.g., labor and land costs, land use restrictions, proximity to highways, railroads, or ports). Regression techniques can partially control for these factors; the use of statistical tests on summary data cannot. See Kim and Chun (2018) and Gilbert and Chakraborty (2011) for examples of how researchers have approached these issues.

It is also important for analysts to be aware of and discuss the biases and limitations introduced when proximity or distance is used instead of risk and exposure modeling (see Mohai and Saha, 2015; Chakraborty and Maantay, 2011). Given the analytic challenges associated with proximity-based

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[110] Tests of statistical significance could include a t-test or a chi-square test. Statistical significance is often reported in terms of a p-value. A low p-value (e.g., <0.05) indicates that the likelihood that changes in the predictor variable are not related to changes in the response variable is very low (i.e., the relationship between the predictor and response variable is statistically distinguishable from zero).

[111] See U.S. EPA (2006) for more information on different types of correlation coefficients, comparisons of means across populations including nonparametric tests, treatment of outliers, tests of distributional assumptions, and further discussion of statistical significance. The EPA also maintains a website on different analytic approaches and methods for conducting a statistical data assessment. See https://www.epa.gov/caddis/caddis-volume-4-data-analysis for more information.

[112] When using U.S. Census Bureau ACS data, analysts can use the Census' Statistical Testing Tool to conduct statistical analyses. See https://www.census.gov/programs-surveys/acs/guidance/statistical-testing-tool.html for more information and to download the tool. Also see Chapter 7 in U.S. Census Bureau (2020b).

analysis, it may only be possible to draw limited conclusions regarding differences across populations groups (see Section 6.4.1).

Finally, it is important to address and characterize uncertainty. Point estimates alone do not provide information about whether estimates are robust to alternate assumptions, nor can they convey the full range of potential outcomes. When statistical analysis is used, information such as confidence intervals and variance should be presented. Sensitivity analysis can also play a role in understanding the robustness of outcomes to key assumptions. Where the analysis is sensitive to the choice of model or method used, this uncertainty should also be described.[113] Uncertainty can also be discussed by highlighting limitations in the literature, identifying caveats associated with results, or highlighting gaps in the data.

6.7 Assessing the Distribution of Costs and Other Effects

This section addresses when it may be appropriate to evaluate how economic costs or challenges are distributed across population groups, how compliance and enforcement may vary across regulatory options under consideration, and the evaluation of non-health effects. We specifically refer to costs as defined in U.S. EPA (2024f).[114]

6.7.1 Distribution of Economic Costs

This *EJ Technical Guidance* mainly focuses on approaches to assess the potential for differential exposure, risk, or health effects associated with regulatory actions on population groups of concern. However, certain directives (e.g., E.O. 13175, E.O. 14008, and OMB Circular A-4) identify the distribution of economic costs or challenges as an important consideration in developing policy alternatives and for regulatory analysis. The economics literature also typically considers both costs and benefits when evaluating distributional consequences of an environmental policy to understand its net effects. Fullerton (2011) discusses six possible types of distributional effects that may result from an environmental policy: costs to consumers via changes in relative product prices; costs to producers or factors of production via changes in the relative returns to capital and labor; the distribution of scarcity rents (i.e., excess benefits due to restricted nature of a good, such as pollution permits); the distribution of environmental quality improvements; temporary costs of adjustment and transition (e.g., for capital and labor); and the capitalization of environmental improvements into asset prices (e.g., land or housing values).

In the context of EJ, the distribution of health or environment effects alone might convey an incomplete – and potentially biased – picture of the overall burden faced by population groups of concern. For instance, if costs are unevenly distributed such that low-income households bear a larger relative share, it is possible that they may experience net costs even after accounting for environmental improvements. That said, the consideration of economic costs in an EJ context may be challenging, given a lack of data and methods in many instances.

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[113] Model uncertainty may also be addressed through techniques such as model averaging. See Steel (2020) for an overview of model averaging applications in economics, for example. Chapter 5 of the *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2024f) also contains a more detailed discussion of statistical and model uncertainty.

[114] *Private costs* are the costs that the purchaser of a good or service pays the seller. *Social cost* is the total burden a regulation imposes on the economy. The bearers of social costs can be either specific individuals or society at large.

Whether to undertake an analysis of economic costs as it pertains to EJ is a case-by-case determination. It will depend on the relevance of the information for the regulatory decision at hand, the likelihood that economic costs of the regulatory action will be concentrated among particular types of households, and the availability of data and methods to conduct the analysis.[115] Analysts should coordinate with economists from the Office of Policy when evaluating the potential relevance of economic costs for EJ and the degree to which they can be discussed or analyzed.

In many cases, analysis of economic costs from an EJ perspective will not substantially alter the assessment of distributional effects for population groups of concern. For instance, often the costs of regulatory action are passed onto consumers as changes in prices or wages that are spread fairly evenly across many households. When these price changes are small, the effect on an individual household also will likely be relatively small. In this case, further analysis is unlikely to yield additional insights.

However, in some circumstances further exploration of the distribution of economic costs may offer substantial insight because costs are expected to differentially affect specific population groups. For example, further analysis may be warranted when costs to comply with the regulatory action represent a noticeably higher proportion of income for some population groups; when some population groups are less able to adapt to or substitute away from goods or services with now higher prices; when changes in environmental quality or health and costs are likely to accrue to the same set of individuals; when costs are concentrated on some types of households (e.g., renters) or in specific geographic areas; when there are identifiable plant closures in or relocation of facilities away from or into communities in which population groups of concern reside and work; or when behavioral changes in response to the costs of the regulatory action leave population groups of concern less protected than other groups.

While the Agency continues to investigate ways to improve incorporation of economic costs into an analysis of EJ concerns, it recognizes that, even in cases where the information is relevant, data or methods may not exist for full examination of the distributional implications of costs. For example, the EPA may expect pollution control costs to be passed on to electricity consumers in the form of higher prices that differentially affect budget-constrained households in particular regions more than others. To evaluate the effects of the regulatory action properly, analysts need to understand how costs are passed through to customers (which may differ by state); how these changes are broken down between residential and commercial customers; what assistance is available for low-income consumers; how consumption patterns differ by race, ethnicity, and income; and how these consumption patterns may change in response to electricity price changes. Likewise, if environmental improvements associated with the regulatory action are unevenly distributed, demand for housing in some neighborhoods may affect rental prices for housing. This, in turn, may result in households moving to other locations that have a different risk and exposure profile.

In addition to methodological limitations, incomplete data may limit the ability of analysts to fully characterize the distribution of costs across population groups of concern. Specifically, available data may only shed light on baseline distributions, without anticipating the distribution of costs in cases where the regulatory action is expected to result in indirect behavioral changes through changes in

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[115] Note that there may be other effects of a regulatory action (e.g., employment) beyond direct compliance and social costs but understanding how all effects vary across population groups may not be feasible. For example, data on the distribution of changes in employment across low-income households may be difficult to assess.

price.[116] Due to method and data limitations, it might not be possible to predict the total effect of a regulatory action on different population groups. In these instances, the issue can be qualitatively discussed and the limitations and assumptions associated with characterizing costs explained.

When analyzing the distribution of costs, other considerations include the time frame and use of partial versus general equilibrium approaches for the analysis. For instance, most consumers may experience similar price changes due to a regulatory action, but in the short run budget-constrained households have more difficulty accommodating higher prices. In contrast, higher automobile prices due to a regulatory action will initially affect higher income households who purchase new cars more frequently; over a longer period of time, these higher prices may also affect lower-income households due to changes in the prices for used cars. More extensive analysis could consider the use of dynamic general equilibrium analysis to examine first and second-order costs and their implications for changes in wages and prices across households over time. However, such analyses are typically resource- and time-intensive, usually only utilized in cases where sectors are expected to experience significant effects as the result of a regulatory action, and generally focused on medium- to long-run effects (U.S. EPA, 2024f).

6.7.2 Considering Compliance and Enforcement

Evidence suggests that compliance with environmental regulations can vary widely across sources in ways that exacerbate pre-existing disparities (e.g., Fedinick et al., 2019; Allaire et al., 2018; McDonald and Jones, 2018; Balazs et al., 2012;). Analysts may want to consider whether regulated sources have a history of significant non-compliance or enforcement actions taken against them under various statutes or how capacity for monitoring and enforcement may differ across communities, including those on Tribal lands. Past compliance issues may indicate pre-existing EJ concerns that warrant further investigation.[117]

Analysts are encouraged to consider differences in compliance and ease of enforcement across regulatory options in the EJ analysis. When there are pre-existing differences in risk or exposure, options consistent with applicable law that improve monitoring coverage or encourage compliance can reduce exposure in communities with EJ concerns (e.g., enhanced reporting requirements for higher risk sources). Collecting, processing, and making publicly available real-time monitoring or remotely sensed data may also be effective for enhancing public awareness and participation (U.S. EPA, 2021d).[118]

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[116] Data on household consumption patterns are available from the Consumer Expenditure Survey. The baseline distribution of electricity and energy prices by household type is available from the Energy Information Administration. In addition, industry-specific data on household consumption patterns may be available for specific products or services related to the regulatory action. When such disaggregated data are available, they are less likely to differentiate by race and ethnicity, though they may be available by income.

[117] There is also a literature that explores whether the intensity of enforcement activities for environmental regulations varies with demographics such as race and income (Konisky et al., 2021; Shadbegian and Gray, 2012).

[118] For example, the oil and gas sector climate review rule (U.S. EPA, 2023h) allows certified third parties to report methane leaks from oil and gas sources using advanced detection technologies, which the EPA makes publicly available. Likewise, the 2015 Petroleum Refinery Sector Risk and Technology Review and New Source Performance Standards created a dashboard for benzene concentrations from refinery fenceline monitoring. See Textbox 2.2 and: https://awsedap.epa.gov/public/extensions/Fenceline_Monitoring/Fenceline_Monitoring.html?sheet=MonitoringDashboard

6.7.3 Other Effects and Considerations

While this technical guidance mainly focuses on tools that analysts may use to evaluate differences in health effects across population groups of concern, the distribution of non-health effects associated with environmental stressors affected by the regulatory action may also be important to consider. For instance, certain population groups may place a higher value on a cultural resource (e.g., spiritual or sacred sites). If a regulatory option affects those resources, then the groups with a higher value will experience a different effect than groups that do not place a value on the cultural resource. Likewise, some regulatory options may differentially affect access to specific recreational activities for some population groups.

Quantifying changes in non-health effects may be challenging. Often, data on the distribution of baseline conditions for non-health effects are not easily available or are difficult to quantify, and/or are not suitable for analyzing the effects of a regulatory action. For instance, data on some ecosystem services (e.g., cultural uses of specific ecosystems) in the United States are quite limited in availability compared to baseline health data, such as mortality incidence. Likewise, data and models to assess how various regulatory options affect non-health related endpoints may not be available.

When the distribution of non-health effects is difficult to quantify, a case study approach may more easily accommodates qualitative sources of information or allow for enhanced meaningful engagement to gain better understanding of how these endpoints may be affected by the regulatory action (see Section 5.3.1.2). For example, analysts may note any non-health effects associated with specific cultural practices for population groups of concern, discuss how they are distributed across population groups in the baseline, and describe how they may be affected by the regulatory action under consideration when feasible.

Chapter 7: Research Priorities to Fill Key Data and Methodological Gaps

High quality, scientific peer-reviewed data, methods, tools, and findings are necessary to support the conclusions drawn from prospective analyses of EJ concerns, including information about population group characteristics, environmental exposures and contaminants, routes of exposure, health outcomes, and current and past experiences and concerns within communities. Keeping up with current data and state-of-the-art methodologies to inform analyses of EJ concerns is of critical importance to the EPA.[119]

For the purposes of identifying research priorities related to the intersection of EJ and regulatory actions, *data gaps* include cases where data (including environmental and demographic or socioeconomic data) are missing all together or limited in scope. For example, the spatial or temporal resolution of the data may be insufficient, data may be unavailable or inaccessible due to privacy issues, or no data have been collected to date. *Methodological gaps* occur when the current peer-reviewed literature does not point to an established method or existing published methods are insufficient to evaluate a specific question. The EPA program offices conducting EJ analyses are interested in addressing data and methodological gaps to improve their analyses and advance equitable outcomes. The intensity of effort and amount of time needed to address important research gaps depend upon factors such as the complexity of the issue being studied and the extent to which conventional or new research techniques are required. Note that the specific nature of some data and method gaps will also vary across programs and regulatory contexts.

Developing research plans and strategies to address the breadth of EJ issues is an iterative process requiring multiple levels of public engagement. This section provides a summary of data and methodological gaps identified through brainstorming sessions (i.e., virtual focus groups) with EPA program office management and staff who write or inform the development of regulatory actions and through input from the SAB, the public, and Tribes on research needs and priorities relevant to the analysis of EJ concerns for regulatory actions (See Text Box 7.1). Together, recommendations from these groups will help the EPA understand and identify research priorities related to data, methods, tools, and information for assessing EJ concerns in regulatory analysis.[120]

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[119] For more information on EPA efforts to use rigorous and relevant data and methods to support policy and decision making as part of the Agency's implementation of the Foundations for Evidence-Based Policymaking Act of 2018, refer to the EPA's Evaluation and Evidence-Building Policy: https://www.epa.gov/evaluate/evidence-act.

[120] In developing research plans and strategies responsive to the data and methods gaps identified by the public, Tribes, and the SAB for the conduct of EJ analysis for rulemakings, the broad set of science, data, and research gaps identified by the Environmental Justice Subcommittee of the National Science and Technology Council to help advance the EJ goals is also relevant (NSTC, 2024).

Text Box 7.1 Main Categories of Identified Data and Methodological Needs

1. Building consistency in terminology and definitions
2. Enhancing consideration of EJ in human health risk assessments
3. Cross-cutting analytic issues
4. Meaningful engagement and risk communication
5. Incorporating EJ into regulatory analysis

7.1 Building Consistency in Terminology and Definitions

While the EPA has operationalized consistent, agency-wide definitions for many key EJ-related terms, EPA program office participants expressed a need for guidance on how to interpret terminology when research areas or peer-reviewed studies use differing definitions. Participants also identified common terminology and definitions for risk communication as an important need. Precise terminology and definitions underpin the EPA's risk analyses and provides an important basis for ensuring that clear and consistent terminology is used in incorporating EJ concerns into regulatory analysis.

7.2 Enhancing Consideration of EJ in Human Health Risk Assessment

The following sections describe identified research priorities relevant to different aspects of HHRA: planning and scoping and problem formulation, effects assessment, exposure assessment, and risk characterization.

7.2.1 Planning and Scoping and Problem Formulation

Problem formulation is a process for generating and evaluating preliminary hypotheses about why health effects may be associated with specific stressors. Program office participants highlighted a need for research to evaluate the impact of adopting various assumptions and definitions when considering EJ at these early planning stages. For example, it would be valuable to understand the implications of using different income thresholds to identify low-income populations on variability in establishing reference populations for the risk assessment.

7.2.2 Effects Assessment

Effects assessment includes both hazard identification and dose-response assessment. *Hazard identification* is the process of identifying the type of hazard to human health (e.g., cancer, birth defects) posed by the exposure of interest. In an EJ context, one can ask, "What adverse health outcomes may be caused by the pollutant(s) and how might this response vary by population group?" *Dose-response assessment* addresses the relationship between the exposure or dose of a contaminant and the occurrence of specific health effects. In an EJ context, analysts can ask, "What adverse health outcomes exist at different exposures, and do they vary by type or incidence in population groups of concern?"

Identified data and methodological needs for effects assessment focus on better understanding the causal relationships between demographic and socioeconomic characteristics or other relevant factors and adverse health outcomes associated with environmental stressors, and how these might vary across population groups. Program office participants and members of the public also identified the need to develop methods that integrate community characteristics, social conditions, and cultural influences with environmental stressors into risk assessments. For example, current data indicate that communities with EJ concerns may be exposed to a greater number and quantity of environmental stressors based on their proximity to waste sites, landfills, congested roadways, and manufacturing facilities. Such communities may experience co-exposure to multiple contaminants that may contribute to variability in individual responses. Program office participants also identified a need to incorporate lifestages and pre-existing conditions, including allostatic load (cumulative stress effects) and changes to DNA structure that can result from exposure to environmental stressors, into risk assessment.

Risk assessment uses a variety of dose-response models and tools to estimate the dose or concentration relationships for adverse health outcomes. Program office participants highlighted the need to ensure that dose-response modeling accounts for differences in vulnerability associated with specific population groups, especially for infants and children. An important first step would be to produce a comprehensive review of each relevant dose-response function that includes an analysis of baseline risk variation across different population groups. This information would enable risk analysts to consider the range of population-specific risk distributions along the dose-response curve.

7.2.3 Exposure Assessment

EPA program office participants noted a need to better understand actual exposures rather than relying on standard models of fixed behavior. A critical area for research is improving cumulative risk assessment and cumulative impact assessment methods for evaluating exposure to multiple environmental and non-environmental stressors. Analysts also identified the need to delineate more clearly between measures of cumulative impacts, measures of exposure, and/or indicators of risk to communities experiencing multiple and layered stressors. In addition, program office participants and Tribes emphasized continuing to develop ways in which community input regarding its values and traditions can inform a cumulative assessment.

Tribes, the SAB, and program office participants highlighted the need for higher quality land use and environmental exposure data, especially:

- Exposures people face when they are outside the home (e.g., the workplace, especially for outdoor workers; commuting; schools; recreational activities; or senior centers) via activity diary datasets or household surveys;
- More spatially resolved and comprehensive water pollution and drinking water quality data, including from private wells;
- Real-time monitoring data, including measurements of routine emissions and emergency events that impact air and water quality, especially in non- or under-monitored areas, such as on Tribal lands; and
- Longer-term chronic, intergenerational, and legacy exposures.

7.2.4 Risk Characterization

The final step in risk assessment is characterizing risk. Risk characterization strives to provide a clear discussion of the overall findings, key areas of uncertainty, overall data quality, and data limitations that may affect methodology development and the overall conclusion. EPA program office participants and members of the public identified several data and methodological needs in this area:

- How baseline risk varies by demographic or socioeconomic group and lifestage;
- How activity patterns change over time as individuals age or move to inform future-year projections for exposure and risk;
- Better incorporation of epidemiological data when assessing the health risks of pesticides; and
- Demographic and socioeconomic data for workers in specific locations (including access to personal protective equipment), small business owners, and owners of regulated facilities.

7.3 Cross-Cutting Analytic Needs

Beyond characterizing the risk paradigm, EPA program office participants, Tribes, and members of the public identified several other cross-cutting analytic needs that have bearing on EJ-related analyses. They emphasized the importance of filling data gaps on topics including biomonitoring data, drinking water service boundaries, and fish and game consumption data. Program office participants, Tribes, and the SAB also highlighted the need for more spatially and temporally resolved human health (including on intrinsic and extrinsic factors) and environmental sampling (e.g., water and soil) data.

The following are cross-cutting considerations that have bearing on filling data gaps, especially for more spatially resolved data:

- While race, ethnicity, and income characteristics are often used to characterize communities of concern, program office participants asked for research into ways to characterize vulnerable communities more broadly, both in the context of potential effects from climate change and from other environmental stressors, at a spatially disaggregated scale.
- Thoughtfully standardized approaches to data collection and analytic methods for more spatially resolved data may require coordination across EPA program offices and with other federal agencies, external researchers and practitioners, and other relevant stakeholders to limit duplication and ensure that the data serve the needs of as many users as possible.
- There may also be benefits to clear and consistent definitions of key spatial features and their representation in the spatial datasets used to assess EJ concerns. For example, differences arise when representing ports as points (i.e., a location on a map represented as a zero-dimensional point) vs. polygons (i.e., an area on a map represented as a two-dimensional shape, such as a site footprint).
- Another identified data need for conducting risk evaluations and EJ analyses is improved understanding of how population demographics change over time. One aspect is how the U.S. population will geographically shift over time, including migration patterns due to climate change, and how this will impact health outcomes at both the national and regional level. A second aspect is how population and/or exposure dynamics change across various time frames and lifestages (e.g., due to aging).

- EPA program office participants raised the question of how to balance the need for improved spatial resolution to adequately consider variability in exposure and health effects (e.g., biomarker data) with maintaining anonymity and protecting individuals from accidental disclosure of personally identifiable information.

- Generating more spatially resolved estimates requires running models with higher-resolution data, which can result in computational challenges (e.g., requires significant computer memory, data storage, expertise, or computation time) that are sometimes costly to address.

- It would be useful to establish mechanisms for data standardization and transparency and provide guidance on alternative data sources or methodologies when comprehensive data are not available. Additionally, members of the public asked that the EPA create a centralized data repository for comprehensive and standardized data.

- As emerging methods for combining remotely sensed data with process-based models become more widely available, there is a need to better understand their data quality implications when incorporating them into EJ analysis.

7.4 Meaningful Engagement and Risk Communication

As emphasized in Chapters 2 and 5, meaningful engagement and community outreach throughout the policy process are integral to the consideration of EJ concerns. EPA program office participants and Tribes pointed to the need for research on appropriate ways to collect and use community-generated information in the EPA's regulatory analyses, including data collected by community groups, Indigenous Knowledge (also referred to as Traditional Ecological Knowledge), and other information that reflects the lived experiences of communities. These data are typically community-generated and more qualitative in nature. Members of the public also emphasized the importance of developing guidance on how to incorporate Indigenous Knowledge into analysis in collaboration with Indigenous and Tribal communities.

Program office participants also expressed a desire for more assistance on effective public engagement and communication about EJ concerns throughout the rulemaking process (e.g., how to best communicate about individual regulatory actions as part of a larger and more dynamic set of policy goals and how to measure the effectiveness of communication approaches on a continuous basis). Both Tribes and the SAB identified the need for better communication of the risks and effects associated with pollution exposure and non-environmental stressors to population groups of concern.

7.5 Incorporating EJ into Regulatory Analysis

Data and methodological needs for incorporating EJ concerns into regulatory analysis are discussed in this section.

7.5.1 Data Gaps for Evaluating EJ Concerns

Often, data most relevant to EJ analysis are not sufficiently disaggregated by race, ethnicity, income, or other demographic or socioeconomic characteristics of interest or available at a more spatially granular level, which is necessary to better understand the distributional effects of a particular regulatory action. EPA program office participants and Tribes identified several specific data gaps:

- Finer resolution air quality data and alternative ways to collect them;
- Spatially granular household information on access to income-based government programs that may offset some distributional effects (e.g., Supplemental Nutrition Assistance Program assistance, utilities assistance);
- Delineation of water and other utility service areas that may affect the type or amount of assistance received (e.g., healthy homes inspections and modifications, such as radon remediation);
- How product use varies with demographic and socioeconomic characteristics; and
- Data on subsistence fishers, where they live, and their fish consumption behavior.

Collaboration with other federal agencies and other stakeholders to facilitate the sharing and access to data sources was also identified as a need. Currently, access to data collected by other federal agencies, Tribes, states, or local governments, universities, and non-government organizations varies.

7.5.2 Methodological Gaps for Evaluating EJ Concerns in the Baseline and for Regulatory Options

Program office participants and members of the public indicated a need to continue to improve characterization of relevant pre-existing conditions into the baseline for EJ analysis. Program office participants also pointed to a lack of methodological tools to account for behavioral responses to a regulatory action when analyzing their distributional effects. This research gap is likely broader than just analyses of EJ concerns but can be particularly important for understanding who is ultimately affected by the regulatory action. For example, program office participants identified the need to better understand the adaptive behavior of lower-income households (e.g., purchase of air filters or bottled water) and improved approaches for evaluating affected worker and employment effects. Program office participants also identified improved modeling of the incidence of price changes faced by households that vary with respect to key demographic and socioeconomic characteristics as a need for evaluating the effects of a regulatory action.

To better evaluate the effects a regulatory action, program office participants expressed a need for dose-response curves that vary by demographic and socioeconomic characteristics; information on how to consider exposures during critical lifestages, such as childhood; and the link between genetic factors or behaviors that could give rise to greater vulnerability. Another frequently noted methodological gap was how to incorporate non-environmental stressors into the analysis and consideration of the cumulative effects of exposure to multiple stressors on human health and well-being.

EPA program office participants and members of the public also noted a need for research into methods to capture EJ concerns in specific regulatory contexts. For example, it is not always clear how to analyze EJ concerns for global pollutants; mobile sources; or ubiquitous chemicals where it is difficult to characterize exposures due to their wide commercial use, persistence, and accumulation of these chemicals over time. In addition, program office participants identified the need for improved approaches for analyzing the EJ implications of regulations that indirectly affect health by affecting which chemicals are used in manufacturing and production or how information is provided.

Program office participants also identified as a methodological gap how to leverage qualitative analysis in assessing environmental justice in regulatory analysis. Mixed methods approaches and qualitative case studies can be time- and resource-intensive and often focus on narrow applications in a specific setting or place. Additional research is needed to understand how these methods may be leveraged for regional and national scale applications.

7.5.4 Other Analytic Considerations

Program office participants expressed a need for more spatially granular Census data to better align with the spatial resolution of certain environmental sampling data. Given the aggregate nature of the publicly available U.S. Census data (e.g., the ACS), analyses do not report information on how demographic and socioeconomic characteristics vary within a given administrative unit (e.g., within a block group).

Program office participants also identified the need to investigate downstream chemical effects relevant to evaluating EJ concerns and potential risk mitigation options. Finally, program office participants noted the importance of better understanding the implications of low probability, but high consequence, events (e.g., accidental releases).

7.6 Other General Needs

EPA program office participants and members of the public identified the need for enhanced cross-agency coordination and information sharing. Specifically, they expressed interest in sharing best practices across EPA offices through a methods or resource library to address common EJ analytic questions, such as:

- Stratification of effects by demographic and socioeconomic characteristics;
- Best practices for proximity-based and other types of quantitative analysis;
- Expanded use of additional surrogate or proxy variables for identifying populations of interest (e.g., pre-existing health conditions, critical service gaps);
- Understanding population-level risk; and
- Measuring and modeling cumulative impacts/exposure/risk to communities.

Program office participants also expressed a need for in-house technical support and/or training for addressing specific EJ methodological gaps in their work.

7.7 Next Steps

The EPA is a science-based agency. As such, it is committed to the pursuit of research related to advancing EJ analysis for regulatory actions to better meet the needs of Agency analysts, decision-makers, and the public in support of scientifically sound regulatory decisions that protect the health of all communities.

Each EPA program office engages in research to address specific needs and concerns, including those related to EJ concerns. In addition, the Office of Policy works jointly with program offices to craft, review and promulgate regulations that protect human health and the environment and ensure they comply with key statutes and Executive Orders. It also helps to promote analytic consistency and rigor across the Agency’s regulatory portfolio and conducts research to develop improved methods for measuring the effects of regulation, including those related to EJ concerns.

The EPA’s Office of Environmental Justice and External Civil Rights was launched in October 2022 to:

- Support communities by providing grants and technical assistance;
- Ensure equity, EJ, and civil rights are incorporated into EPA’s policies and programs;
- Ensure compliance and enforcement of federal civil rights laws; and
- Provide conflict prevention and resolution on environmental issues.

The Office of Environmental Justice and External Civil Rights serves as a resource for EPA program offices to strengthen consideration of environmental justice during the rulemaking process. In addition, it develops and improves tools, such as EJScreen, and works along-side partners to assess the community-level impacts of the agency's activities and identify communities with environmental justice concerns.

The EPA’s Office of Research and Development (ORD) also actively pursues and supports environmental justice research. It developed an *EJ Research Roadmap* to highlight the role of ORD science in addressing EJ concerns (U.S. EPA, 2016d). ORD EJ research is publicly available at https://www.epa.gov/ej-research.

Building on this roadmap, the ORD also developed a series of actionable recommendations for cumulative impacts research, including: establishing the decision context for cumulative impact assessment with meaningful public engagement, addressing scientific considerations for meeting community needs with holistic and fit-for-purpose approaches with the support of different screening and decision tools, empowering local decisions and actions through participatory science, supporting science translation and delivery to meet community needs, and providing research management and support (e.g., coordinating with other EPA offices and external partners) (U.S. EPA, 2022c). The document also includes a summary of current research areas and an overview of research gaps and barriers identified by ORD (many of which are consistent with the topic areas described in this chapter) that informed research conducted under the fiscal year 2023-2026 Strategic Research Action Plans.[121]

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[121] The ORD Fiscal Year 2023-2026 Strategic Research Action Plans are available at: https://www.epa.gov/research/strategic-research-action-plans-fiscal-years-2023-2026.

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Appendix A: Select EPA Guidance and Other Documents

This appendix contains a list of EPA technical guidance and other documents that may be helpful to analysts when evaluating EJ concerns for regulatory actions. Table A1 lists relevant technical guidance, guidelines, and framework documents. Table A2 lists other EPA documents that may prove useful.

Table A.1 Relevant EPA Guidance Documents

Topic Area	Title	Publication Year	Web Link
Economics	*Guidelines for Preparing Economic Analyses*	2024f	https://www.epa.gov/sites/default/files/2017-08/documents/ee-0568-50.pdf
Human Health Risk Framework	*Framework for Human Health Risk Assessment to Inform Decision-Making*	2014b	https://www.epa.gov/sites/production/files/2014-12/documents/hhra-framework-final-2014.pdf
Human Health Risk Framework	*Framework for Assessing Health Risk of Environmental Exposures to Children*	2006	https://assessments.epa.gov/risk/document/&deid=158363
Other Health Risk Guidance	*Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water*	2012b	http://www.epa.gov/sites/production/files/2013-09/documents/mra-guideline-final.pdf
Other Health Risk Guidance	*Guidelines for Carcinogen Risk Assessment*	2005a	https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf
Other Health Risk Guidance	*Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*	2005b	https://www.epa.gov/sites/default/files/2013-09/documents/childrens_supplement_final.pdf
Other Health Risk Guidance	*Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures*	2000a	http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=4486
Other Health Risk Guidance	*Technical Support Document on Risk Assessment of Chemical Mixtures*	1990	http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=35770
Other Health Risk Guidance	*Guidelines for the Health Risk Assessment of Chemical Mixtures*	1986	http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=22567
Exposure Assessment	*Guidelines for Human Exposure Assessment*	2019a	https://www.epa.gov/risk/guidelines-human-exposure-assessment
Exposure Assessment	*Guidance for Conducting Fish Consumption Surveys*	2016a	https://www.epa.gov/sites/default/files/2016-12/documents/guidance-fish-consumption-surveys.pdf

Topic Area	Title	Publication Year	Web Link
Exposure Assessment	*Exposure Factors Handbook*	2011a[122]	https://www.epa.gov/expobox/about-exposure-factors-handbook
Risk Characterization	*Risk Characterization Handbook*	2000b	http://www.epa.gov/risk/risk-characterization-handbook
Cumulative Risk Assessment	*Considerations for Developing a Dosimetry-Based Cumulative Risk Assessment Approach for Mixtures of Environmental Contaminants (Final Report)*	2007a	http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=172725
Cumulative Risk Assessment	*Concepts, Methods, and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures, and Effects: A Resource Document (Final Report)*	2007b	https://assessments.epa.gov/risk/document/&deid=190187
Cumulative Risk Assessment	*Framework for Cumulative Risk Assessment*	2003a	http://www.epa.gov/sites/production/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf
Cumulative Risk Assessment	*Guidance on Cumulative Risk Assessment of Pesticide Chemicals that have a Common Mechanism of Toxicity*	2002a	http://www.epa.gov/sites/production/files/2015-07/documents/guidance_on_common_mechanism.pdf
Cumulative Risk Assessment	*General Principles for Performing Aggregate Exposure and Risk Assessments*	2001	http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/general-principles-performing-aggregate-exposure-and
Cumulative Risk Assessment	*Guidance on Cumulative Risk Assessment: Planning and Scoping*	1997	https://www.epa.gov/sites/default/files/2015-01/documents/cumrisk2_0.pdf

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[122] While the latest edition of the Exposure Factors Handbook was published in 2011, the EPA has updated several individual chapters more recently: Soil and Dust Ingestion in 2017; Intake of Fruits and Vegetables, Intake of Meat, Dairy Products, and Fats, Intake of Grain Products, and Building Characteristics in 2018; and Ingestion of Water and Other Select Liquids was updated in 2019.

Table A.2 Other Relevant EPA Documents

Topic Area	Title	Publication Year	Web Link
Meaningful Engagement	*Achieving Health and Environmental Protection Through EPA's Meaningful Engagement Policy*	2024d	https://www.epa.gov/environmentaljustice/epas-meaningful-engagement-policy
Meaningful Engagement	*Better Decisions Through Consultation and Collaboration*	2015b	https://www.epa.gov/sites/default/files/2015-09/documents/better_decisions.pdf
Meaningful Engagement	*Policy on Environmental Justice for Working with Federally Recognized Tribes and Indigenous People*	2014a	https://www.epa.gov/sites/production/files/2015-02/documents/ej-indigenous-policy.pdf
Meaningful Engagement	*Model Guidelines for Public Participation: An Update to the1996 NEJAC Model Plan for Public Participation*	2013b	https://www.epa.gov/environmentaljustice/model-guidelines-public-participation
Meaningful Engagement	*An Update on Ongoing and Future EPA Actions to Empower Communities and Advance the Integration of Environmental Justice in Decision-Making and Research*	2011b	https://www.epa.gov/sites/default/files/2015-02/documents/100-day-challenge-2011-10-26.pdf.
Data Quality	*Handbook for Citizen Science Quality Assurance and Documentation*	2019b	https://www.epa.gov/sites/default/files/2019-03/documents/508_csqapphandbook_3_5_19_mmedits.pdf
Data Quality	*Peer Review Handbook*	2015e	http://www.epa.gov/osa/peer-review-handbook-4th-edition-2015
Data Quality	*Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information.*	2012a	http://www.epa.gov/sites/production/files/2015-05/documents/assess3.pdf
Data Quality	*A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*	2003b	https://www.epa.gov/sites/default/files/2015-01/documents/assess2.pdf
Data Quality	*Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*	2002b	http://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf

Appendix B: Incorporating EJ Concerns into Exposure and Effects Assessments

The planning, scoping, and problem formulation phases provide a key opportunity to ensure that EJ concerns are incorporated into HHRA. This appendix provides several key EJ-specific questions to consider when planning for an exposure or dose-response assessment. It describes the implications of each question for the data gathering and analytic work that may be necessary to address them. Also included are examples of analyses from the peer-reviewed literature and/or U.S. government analyses, which may suggest approaches for analysts to consider during planning, scoping, and problem formulation.

Planning for an Exposure Assessment

Patterns of exposure to stressors across population groups of concern may vary for several reasons. Variation 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. Exposure differences 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). Exposure may reflect unique aspects of the use or application of the chemical (e.g., exposures to pesticide applicators) or it may be affected by other factors that increase vulnerability for a specific population group (e.g., greater prevalence of a pre-existing health condition such as asthma).

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 drift from pesticide applications that result in pesticides falling on “off-target” locations, which may then lead to increased exposure for certain populations that live in close proximity to the treated fields (e.g., farmers, migrant workers, children). Text Box B.1 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., volatilization), 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.

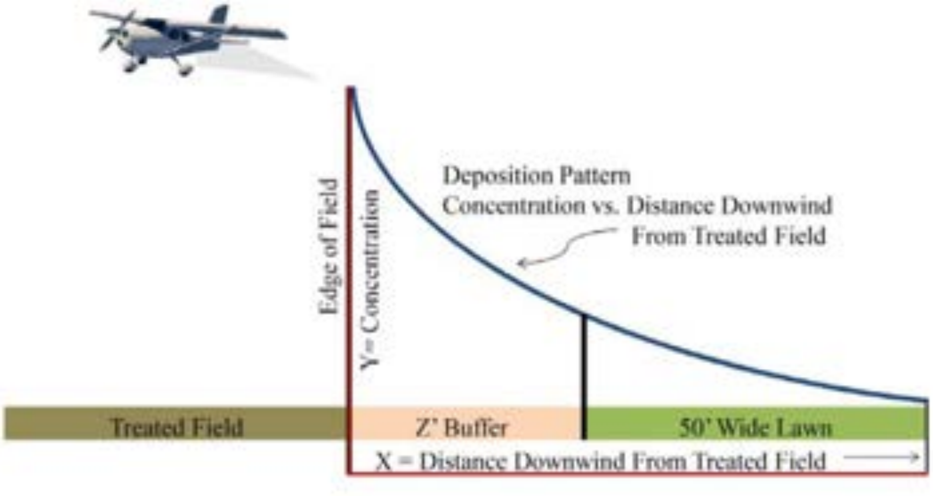
Text Box B.1 Pesticide Spray Drift Risk Assessment to Bystanders

Farmworkers 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, 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 effects 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), the 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. Analysis of spray drift evaluates risks from pesticides similar to how they are evaluated for use 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 all pertinent routes for both adults and children.

Conceptual Model for Spray Drift Modeling (U.S. EPA, 2012c)



See draft EPA guidance documents on the consideration of spray drift in pesticide risk assessment (White et al., 2013; U.S. EPA, 2013c).

2. Are exposure variabilities predominantly a spatial phenomenon (e.g., due to contaminant hot spots)? Is proximity to a 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 Chakraborty et al. (2011) and in Chapter 6 of this technical guidance.

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 and socioeconomic 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 information 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; 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 racial, ethnic, and income diversity, as well as 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.2.

Modeled data can sometimes serve as a surrogate for monitoring data when high quality data inputs are used. 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 support assessment of differences in exposure. Analysts 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 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 beginning of such an analysis. An important resource to consider is the *National Report on Human Exposure to Environmental Chemicals* (CDC, 2022). Human exposure data in this report are presented by lifestage, race, ethnicity, and income to the extent that such detailed breakouts are possible.

Text Box B.2 Understanding Environmental Inequality Using Different Policy Instruments

Using a case study approach, the EPA evaluated the viability of a multi-pollutant, risk-based pollution control strategy as an alternative to a traditional pollutant-by-pollutant approach to air quality (Fann et al., 2011). The study used spatially resolved air quality, population, and baseline health data from the Detroit metropolitan area to perform within- and across-group comparisons of exposure and risk. The objective of the study was to demonstrate how states might design air quality attainment strategies that: (1) attain tighter standards, (2) maximize human health benefits of air quality improvements, and (3) achieve a more equitable distribution of air pollution-related risk.

The assessment of EJ concerns followed four steps: (1) identify and model exposure to population groups vulnerable to $PM_{2.5}$-related mortality and morbidity effects in the baseline, based on fine scale air quality modeling and population characteristics such as education attainment, race, and poverty level; (2) design an emission control strategy that maximizes air quality improvements among these population groups, primarily by reducing emissions of directly-emitted $PM_{2.5}$; (3) compare the multi-pollutant, risk-based strategy with the traditional pollution control strategy for attainment by modeling the air quality effects of each strategy and comparing the results with the baseline scenario; and (4) calculate the change in exposure/risk inequality from the baseline 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)

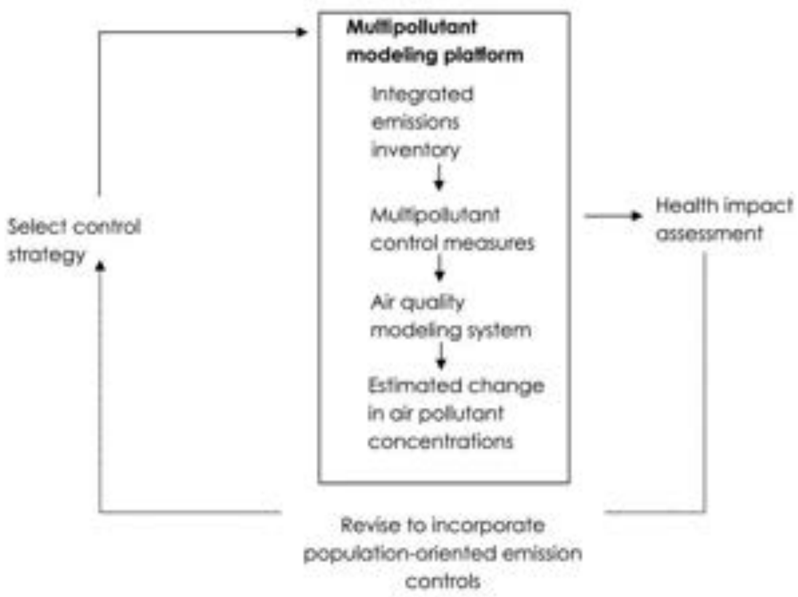


Fig. 1. Risk-based, multipollutant modeling framework.

Using similar indicators of inequality as Fann et al. (2011), Mansur and Sheriff (2021) compare the distributions of nitrogen oxide (NOx) emissions from California's Regional Clean Air Incentives Market cap-and-trade program to estimated counterfactual emissions under a prescriptive regulatory approach. Using U.S. Census data, they estimate individual exposure from facility emissions using NOx emissions as a proxy for health effects by race, ethnicity, and poverty status. They find that trading led to a more equitable distribution of emissions reductions across all groups.

Additional information about the Detroit multi-pollutant project can also be found at https://www.epa.gov/sites/default/files/2021-01/documents/detroitpres_final09.pdf.

When using exposure biomarkers to draw inferences about exposure differences for a source-specific regulatory action, analysts should carefully consider the extent to which measured levels reflect exposure, and 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. Analysts may use simple, well-established comparative methods such as ratios to examine between-population group comparisons or may apply more complex approaches such as analysis of variance or regression techniques as needed. Comparisons may focus on specific segments of the distribution or on the proportion of a population group represented within a percentile category. At times, several years of data may need to be combined to obtain sufficient sample size to conduct analysis in the tail of the distribution, subject to resource, analytic, and data constraints.

As discussed in Section 5.3.3, use of biomonitoring data has both benefits and limitations. While a large population survey (e.g., 2014-2016 Survey of the Health of Wisconsin or NHANES) may suggest the existence of exposure difference, locale- or site-specific surveys (e.g., New York City Health and Nutrition Examination Survey) can yield more detailed insights into the dimensions of the differences. For example, analysis of Survey of the Health of Wisconsin and NHANES data demonstrate that Wisconsin residents have lower PFAS levels in serum than the U.S. as a whole. More data are needed to evaluate the effects of PFAS on non-White or low-income populations (Schultz, 2023).

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

Analysts can 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 diets or greater reliance on hunting and fishing for food), behaviors (e.g., hand-to-mouth behavior of young children), or through greater use of specific products (e.g., personal care and cleaning products). Understanding potential exposures from these types of sources will allow for more accurate estimates of exposures to the stressor(s) of concern. Differences in exposures from ingestion may be due to several factors, including regional variability in dietary habits, and cultural, ethnic, or religious practices.[123] 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, 2011a). 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 and their families may have higher exposure levels (U.S. EPA, 2011a). Similarly, some cosmetics may contain lead. Analysts can 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). The EPA's *Guidelines for Human Exposure*

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[123] "Variability in exposure occurs because of location, occupation, activities within a location, socioeconomic status, consumer preferences, dietary habits and other lifestyle choices. Behaviors relative to lifestage can be particularly influential determinants for exposure, especially for infants and toddlers and for the embryo/fetus during pregnancy. Lifestage, health status, sex and genetic differences also can be important factors that determine dose. The drivers for human activities are complex and, unlike stressors, cannot be predicted using first-principle models based on physical/chemical properties. Instead, human activities are treated as stochastic properties (random variables) described by population distributions based on available (e.g., observational or modeled) data" (U.S. EPA, 2019a). See Chapter 8 in U.S. EPA (2019a) for detailed discussion of uncertainty and vulnerability in exposure assessments.

Assessment (U.S. EPA, 2019a) include information on considerations of lifestages, vulnerable groups, and population groups of concern in exposure assessment, including Tribal and Indigenous populations and other racial or ethnic groups.

Text Box B.3 illustrates how the five scoping questions for integrating EJ into an exposure assessment could be posed to evaluate dietary risks from pesticide residues.

Text Box B.3 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 evaluating 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., subsistence diets or other cultural practices)?
- 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; regular consumers of fish, shellfish, or game)?
- Is the pesticide used on, or likely to be found in, foods that are consumed in substantially higher amounts by certain population groups (e.g., lemon grass)?
- Does the pesticide have an atypical or unusual use pattern that could result in unusual exposures for certain population groups (e.g., use in non-traditional agriculture, or locally-restricted use)?
- Do the physical and/or chemical properties of the pesticide indicate a potential for long range transport (e.g., volatility, persistence), 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 to the pesticide through their diet?

Planning For an Effects Assessment

An effects assessment includes hazard identification and dose-response assessment. Planning, scoping, and problem formulation for the effects assessment of HHRA present other opportunities to incorporate EJ concerns into a risk assessment. Planning, scoping, and problem formulation play key roles in identifying population groups of concern that may exhibit a particular sensitivity to a stressor. This is also the point at which analysts can consider how demographic and socioeconomic characteristics might modify effects seen in the general population. Analysts can consider whether factors particular to a population may alter dose-response relationships for the contaminants in question.

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 an effects assessment.

Questions and Key Considerations

1. What population groups are most relevant from a risk perspective for the stressor(s) in question?

The purpose of asking this question is twofold: (1) defining the 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 characteristics of the population (i.e., care should be taken not to fit a dose-response function to a population group to which it does not apply). To answer this question, analysts may need to consider stratification by race, ethnicity, and income, or factors such as educational level, access to health care, and baseline disease prevalence.

2. Are there population-specific effect assessments for the population groups of concern?

In answering this question, analysts can investigate these factors: (1) Are there known or identified effect modifiers?; (2) For identified factors that modify hazards of interest, how are they distributed among population groups of concern?; and (3) Are effect modifiers distributed differently among various lifestages within population groups? To answer these questions, a review of relevant literature is necessary to identify potential sources of population group-specific dose-response information or data on effect modifiers (see Text Box B.4).

3. Are the spatial and temporal scales of the studies supplying the dose-response function consistent with the spatial scale needed to incorporate 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 incorporating EJ concerns. Analysts may introduce measurement error if dose-response functions from studies conducted over smaller geographic areas are applied at a more aggregate scale. For example, if the study assigned each subject in the cohort a county-level average response, the study could underestimate the true relationship between exposure and outcome at a finer spatial scale. Likewise, if the exposure in the study is acute, it cannot be applied directly to incorporate EJ concerns where the exposure of interest is chronic; rather, the exposure duration being modeled in the regulatory analysis should be considered.

Analysts may consider adjusting the geographic scale to incorporate 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 scale (e.g., at the local urban level or at the acute exposure level).

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 including age and race. Di et al. (2017) analyzed the relationship between air pollution exposure and mortality in the Medicare population, specifically working to understand concentration-response relationships by race and Medicaid eligibility. For $PM_{2.5}$, the risk of death among men, Black individuals, and people with Medicaid eligibility was notably higher than for the rest of the population.

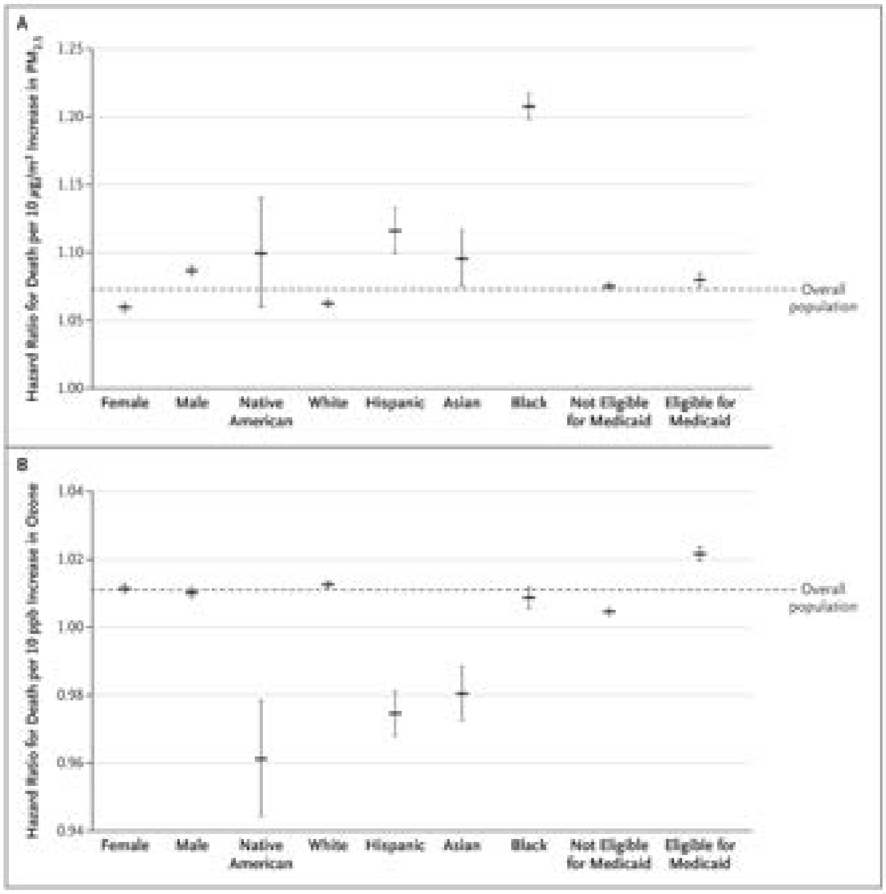

Figure. Risk of death associated with an increase of 10 μg/m^3 in $PM_{2.5}$ concentrations (top) and an increase of 10 ppb in ozone exposure (bottom)

The EJ analysis for the final PM NAAQS reconsideration (U.S. EPA, 2024m) includes a distributional analysis of the estimated relative risk of $PM_{2.5}$-related mortality using the dose-response functions stratified by race and ethnicity from Di et al. (2017). This analysis improved upon assessments performed in previous NAAQS regulatory impact assessments by combining these differentiated concentration-response functions with county-level baseline mortality rates. Using this approach, the EPA found that the same $PM_{2.5}$ exposure reduction will reduce the risk of mortality approximately three times more in Black populations than in White populations.