

# The Science of Scientific Assessments: Science for Decision Makers


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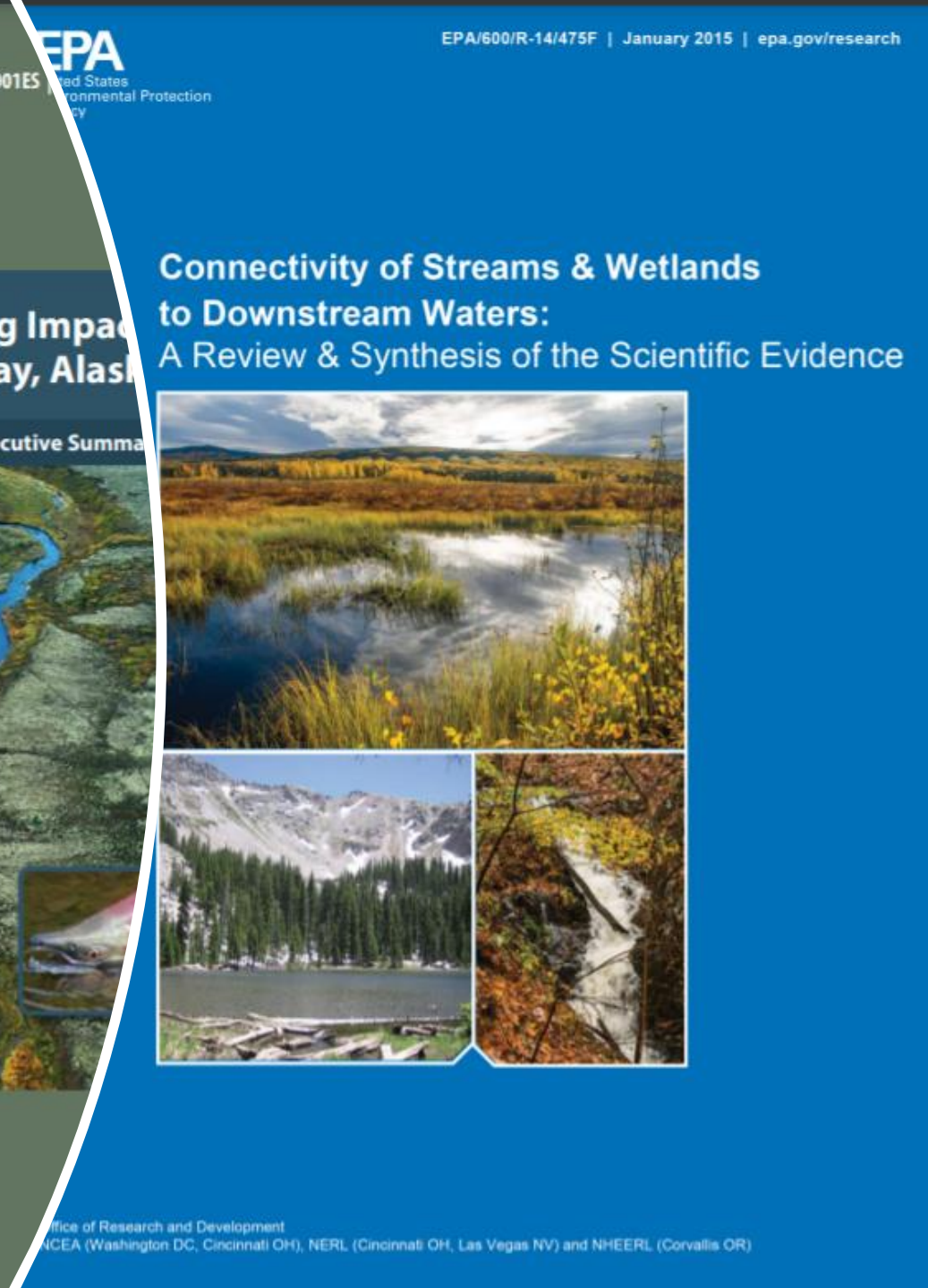
*Disclaimer: The views expressed in this presentation are those of the author and do not necessarily reflect the views or policies of the US EPA.*

# Presentation Goals

- Assessments @EPA
  - The Users
  - The Developers
- Assessments in Decision Making
  - What is it?
  - Why use it?
  - How to make it?
- Innovations in Assessment Science
  - Systematic Review
  - Evidence Tables

# EPA's mission and what we do

- **Our Mission**
  - The mission of EPA is to protect human health and the environment.
- **Our purpose is to ensure that:**
  - all Americans **are protected from significant risks to human health and the environment** where they live, learn and work;
  - national efforts to reduce environmental risk are **based on the best available scientific information**;
  - federal laws protecting human health and the environment are enforced fairly and effectively;
  - environmental protection is an integral consideration in U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade, and these **factors are similarly considered in establishing environmental policy**;
  - all parts of society -- communities, individuals, businesses, and state, local and tribal governments -- have **access to accurate information sufficient to effectively participate** in managing human health and environmental risks;
  - environmental protection contributes to making our communities and ecosystems diverse, sustainable and economically productive; and
  - the United States plays a leadership role in working with other nations to protect the global environment.

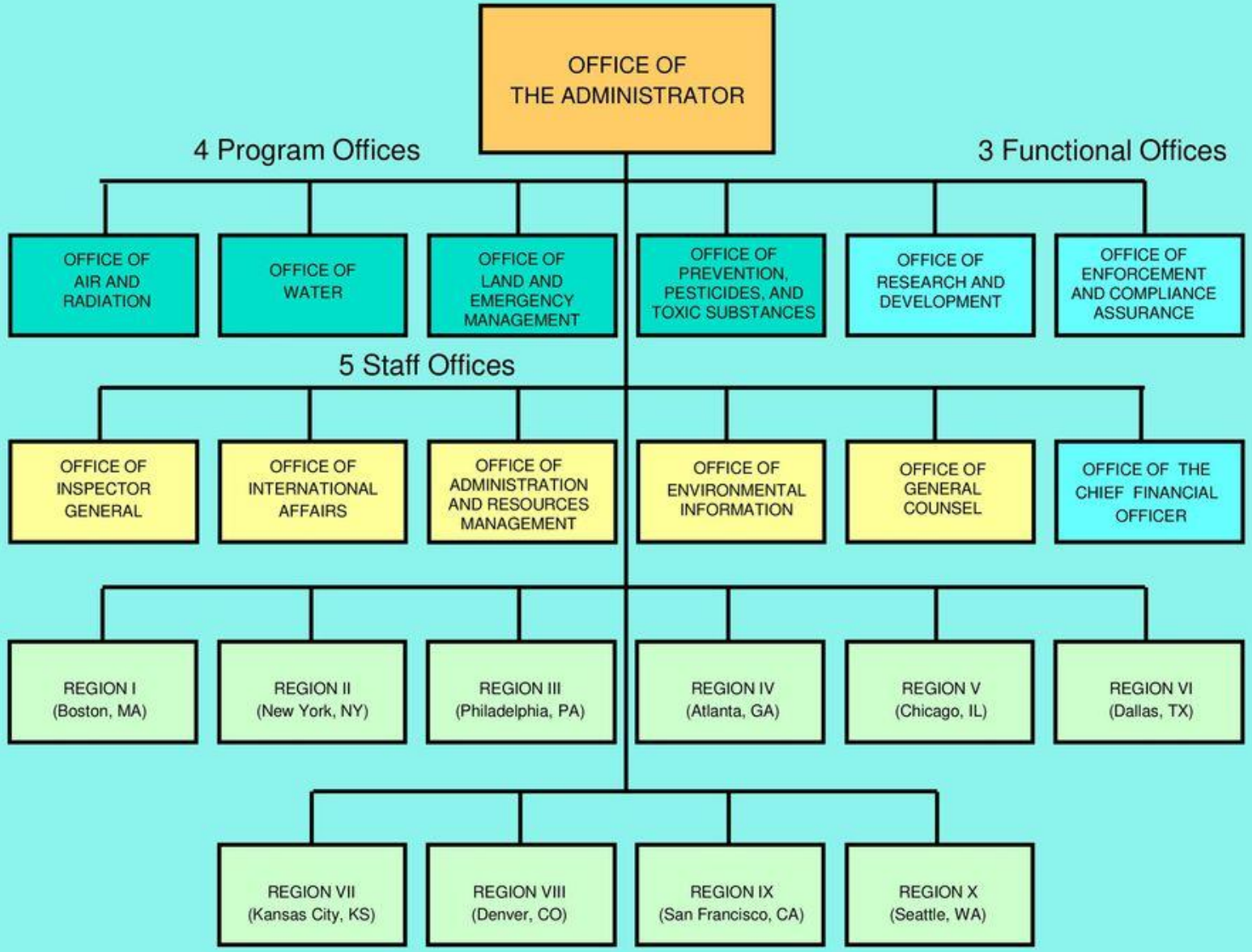
# UNDERSTANDING THE LANDSCAPE

POLITICS

PROCESS

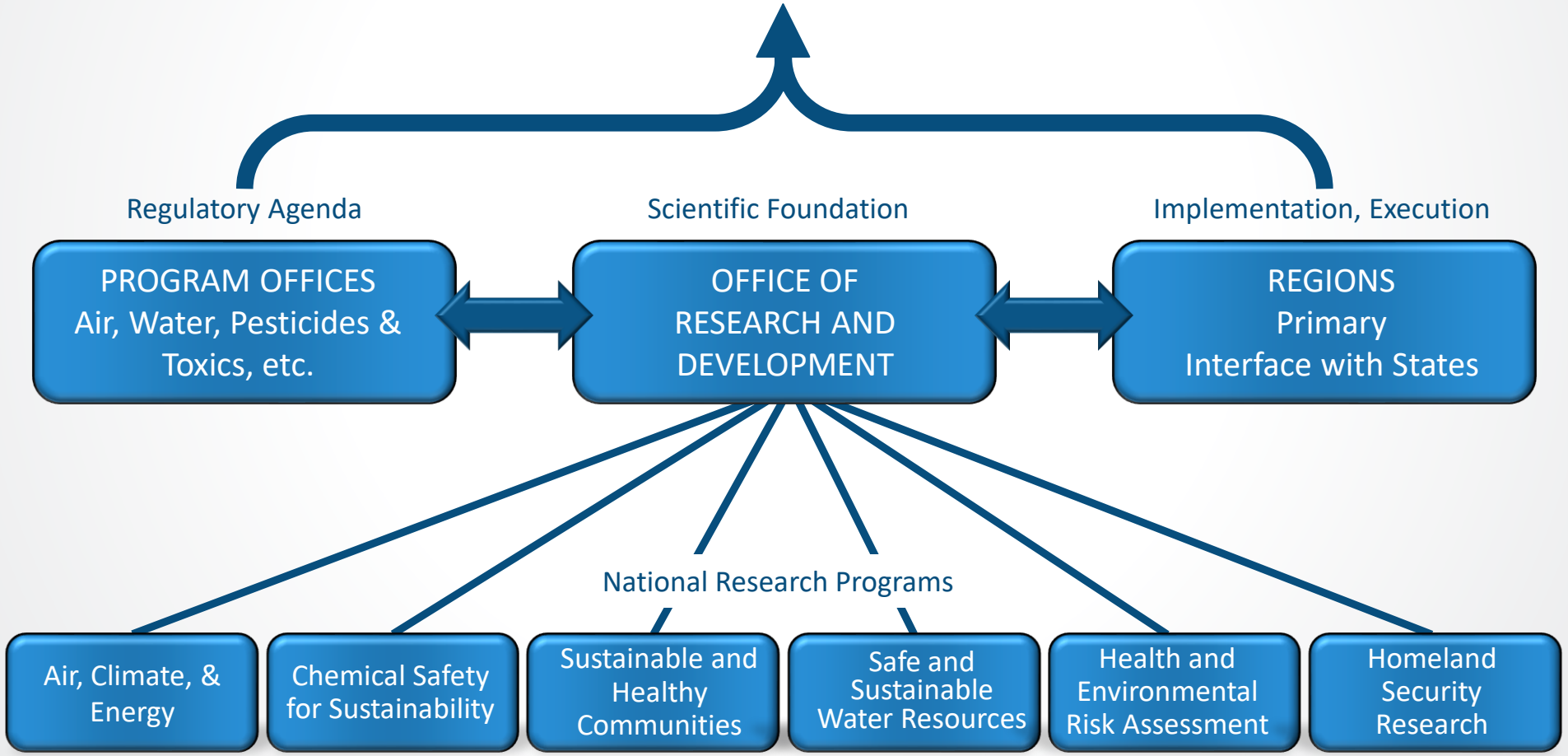
POLICY

SCIENCE


OFFICE OF THE ADMINISTRATOR
4 Program Offices
3 Functional Offices
OFFICE OF AIR AND RADIATION
OFFICE OF WATER
OFFICE OF LAND AND EMERGENCY MANAGEMENT
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
OFFICE OF RESEARCH AND DEVELOPMENT
OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE
5 Staff Offices
OFFICE OF INSPECTOR GENERAL
OFFICE OF INTERNATIONAL AFFAIRS
OFFICE OF ADMINISTRATION AND RESOURCES MANAGEMENT
OFFICE OF ENVIRONMENTAL INFORMATION
OFFICE OF GENERAL COUNSEL
OFFICE OF THE CHIEF FINANCIAL OFFICER
REGION I (Boston, MA)
REGION II (New York, NY)
REGION III (Philadelphia, PA)
REGION IV (Atlanta, GA)
REGION V (Chicago, IL)
REGION VI (Dallas, TX)
REGION VII (Kansas City, KS)
REGION VIII (Denver, CO)
REGION IX (San Francisco, CA)
REGION X (Seattle, WA)

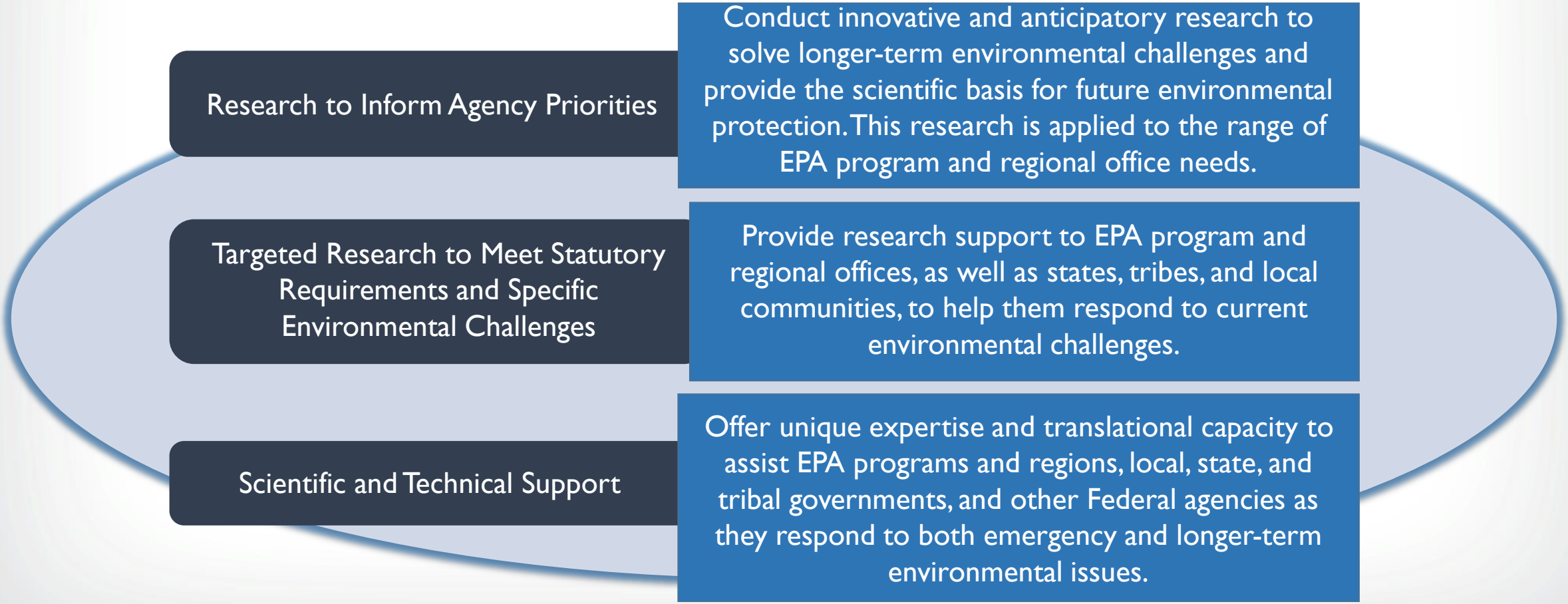
# Agency Mission and Structure

*Protect human health and safeguard the environment – air, water, land – upon which life depends*



# EPA Research

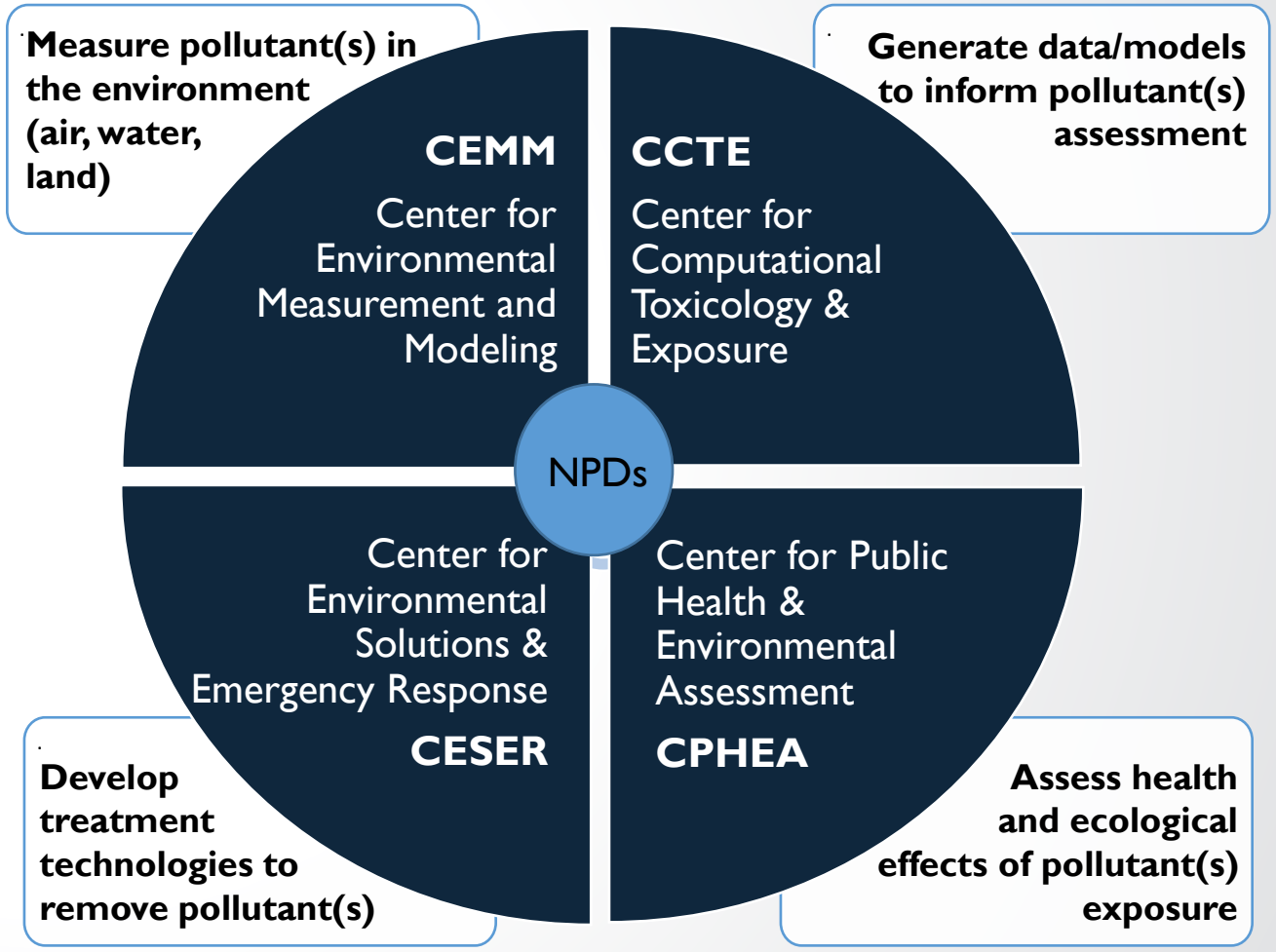
ORD provides the scientific foundation for EPA to execute its mandate to protect human health and the environment.



# Office of Research and Development

## National Research Programs

Air, Climate, & Energy
Chemical Safety for Sustainability
Homeland Security
Health & Environmental Risk Assessment
Safe & Sustainable Water Resources
Sustainable & Healthy Communities



## EPA Vision

To promote a clean, healthy and well-protected environment supporting a sustainable society and economy.

## ORD Vision

We are the world's leader in environmental science, technology and research, developing breakthrough solutions that enable EPA, federal agencies, states, tribes, and communities to protect human health and the environment, now and in the future.

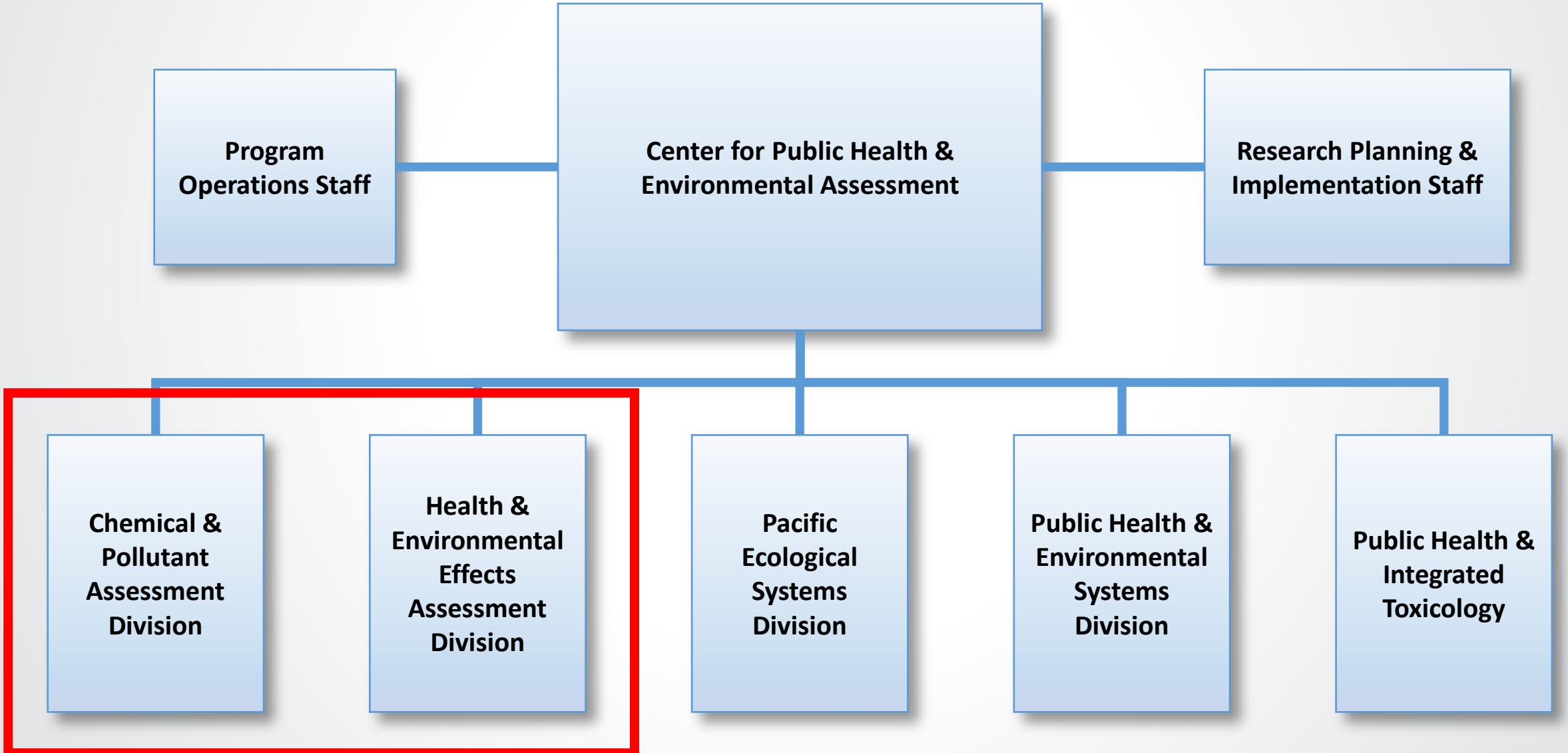

## CPHEA Vision

We are world science leaders delivering innovative and integrative research providing the foundation for evidence-based decisions and actions to protect our environment, public health, and well-being.

## CPHEA Mission

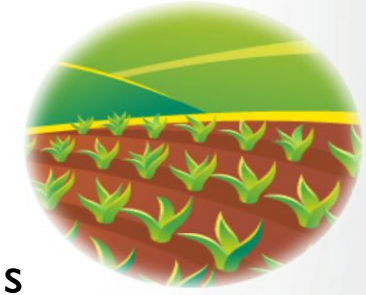
To provide the science needed to understand the complex interrelationship between people and nature in support of assessments and policy to protect human health and ecological integrity.

# Primary Assessment Divisions



# Addressing Agency Priorities and Mandates

- Clean Air Act (CAA)
- Safe Drinking Water Act (SDWA) and Clean Water Act (CWA)
- Toxic Substances Control Act (TSCA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Superfund Amendments and Reauthorization Act (SARA)
- Resource Conservation and Recovery Act (RCRA)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)



**Broad Input to Support**

- Agency and ORD Strategic Goals
- Children's Health
- Environmental Justice
- Climate Change

# Primary Assessment Divisions
## Chemical & Pollution Assessment Division
## Health & Environmental Effects Assessment Division

Develop scientific assessments on the effects of chemicals and nonchemical stressors on human health and the environment and provide scientific technical support to inform EPA Region and Program Offices.


- Integrated Science Assessments (ISA)
  - Ozone
  - Particulate Matter
  - Carbon Monoxide
  - Lead
  - Nitrogen Dioxide & Sulfur Dioxide
- Integrated Risk Information System (IRIS)
  - Formaldehyde
  - PFAS
  - Asbestos
- Environmental Assessments
  - Biofuels Report to Congress
  - Pebble Mine, Bristol Bay AK
  - Waters of the United States
  - Mountain Top Mining
  - Hydraulic Fracturing
  - Report on the Environment

# Primary Assessment Divisions
# Chemical & Pollution Assessment Division
# Health & Environmental Effects Assessment Division

**Integrated Risk Information Systems (IRIS)**

IRIS assessments provide the following toxicity values for health effects resulting from chronic exposure to chemicals

Reference Concentration (RfC)

Reference Dose (RfD)

Cancer Descriptions


**Integrated Science Assessment (ISA)**

Evaluate and synthesize the health and welfare effects of the 6 criteria air pollutants (Pb, $O_3$, PM, NOx, SOx, CO)

Provide the scientific foundation for OAR recommendations on NAAQS rulemaking

**Environmental Assessment**

1) Connectivity of Streams and Wetlands to Downstream Waters- CWA Jurisdictional Determination of Waters of the US
2) Bristol Bay Assessment- CWA 404(c) Proposed Determination
3) Triennial Biofuels Report to Congress- CAA Environmental Impact of Biofuel Production

# Primary Assessment Divisions
# Chemical & Pollution Assessment Division
# Health & Environmental Effects Assessment Division

Integrated Risk Information Systems (IRIS)

1) **Hazard Identification**
2) **Dose Response Assessment**
3) Exposure Assessment
4) Risk Characterization


Integrated Science Assessment (ISA)

1) **Science Assessment**
2) Risk & Exposure Assessment
3) Policy Assessment
4) Rule Making

Environmental Assessment

1) **Science Assessment**
2) Programmatic Decision
3) Rule Making

# Primary Assessment Divisions
# Chemical & Pollution Assessment Division
# Health & Environmental Effects Assessment Division

We produce scientific information that can/may have clear and substantial impact on important public policies or private sector decisions


**Influential Scientific Information (ISI)**

1) Significant precedent, model, or methodology
2) Economic impact of $100 million or more
3) Adverse impact to a sector, productivity, competition, jobs, the environment, public health, states, tribes, local communities

***Highly Influential Scientific Assessments (HISA)***

1) Could have a potential impact of more than $500 million in any year
2) Is novel, controversial, precedent setting, or significant interagency interests

Office of Research and Development

# EPA's Integrated Risk Information System

*IRIS Assessment Plans, Protocols, and 7-Step IRIS Process*

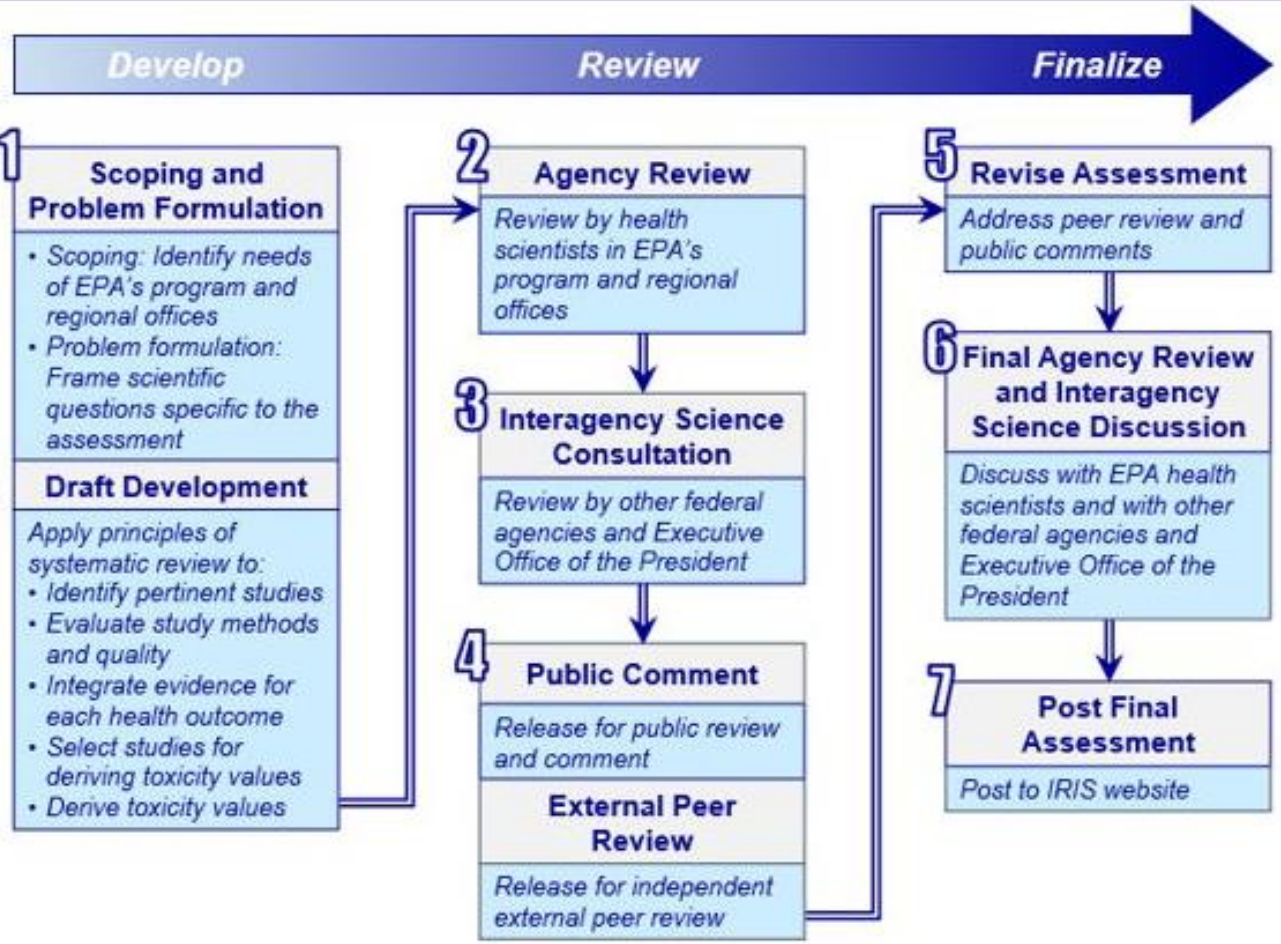
## IRIS Assessment Development Process

**Early Step 1 - Release IRIS Assessment Plans:**

- What the assessment covers released for public comment and discussion at a public meeting

**Mid-Step 1 – Release Systematic Review Protocols:**

- How the assessment will be conducted released for public comment



# Assessment Development

- Scoping & Problem Formulation
- Literature Search & Screen
- Information Quality & Extraction
- Analysis, Synthesis & Interpretation
- Science Assessment

Identify need for evidence relating to a question of concern in policy or environmental management practices. Describe the evidence needs and specific research questions. Come to agreement on priority issues and how to spend limited resources.

# Assessment Development

- Scoping & Problem Formulation
- Literature Search & Screen
- Information Quality & Extraction
- Analysis, Synthesis & Interpretation
- Science Assessment

Detail search strategy, search terms, inclusion criteria, critical appraisal criteria, and synthesis methods. Conduct literature search and screening as described in the protocol.

# Assessment Development

Scoping &
Problem Formulation

Literature Search & Screen

Information Quality &
Extraction

Analysis, Synthesis & Interpretation

Science Assessment

Extract evidence from papers. Assess quality of included evidence for risk of bias.

# Assessment Development

Scoping &
Problem Formulation

Literature Search & Screen

Information Quality &
Extraction

Analysis, Synthesis & Interpretation

Science Assessment

Conduct synthesis to obtain qualitative and quantitative conclusions.

# Assessment Development

Scoping &
Problem Formulation

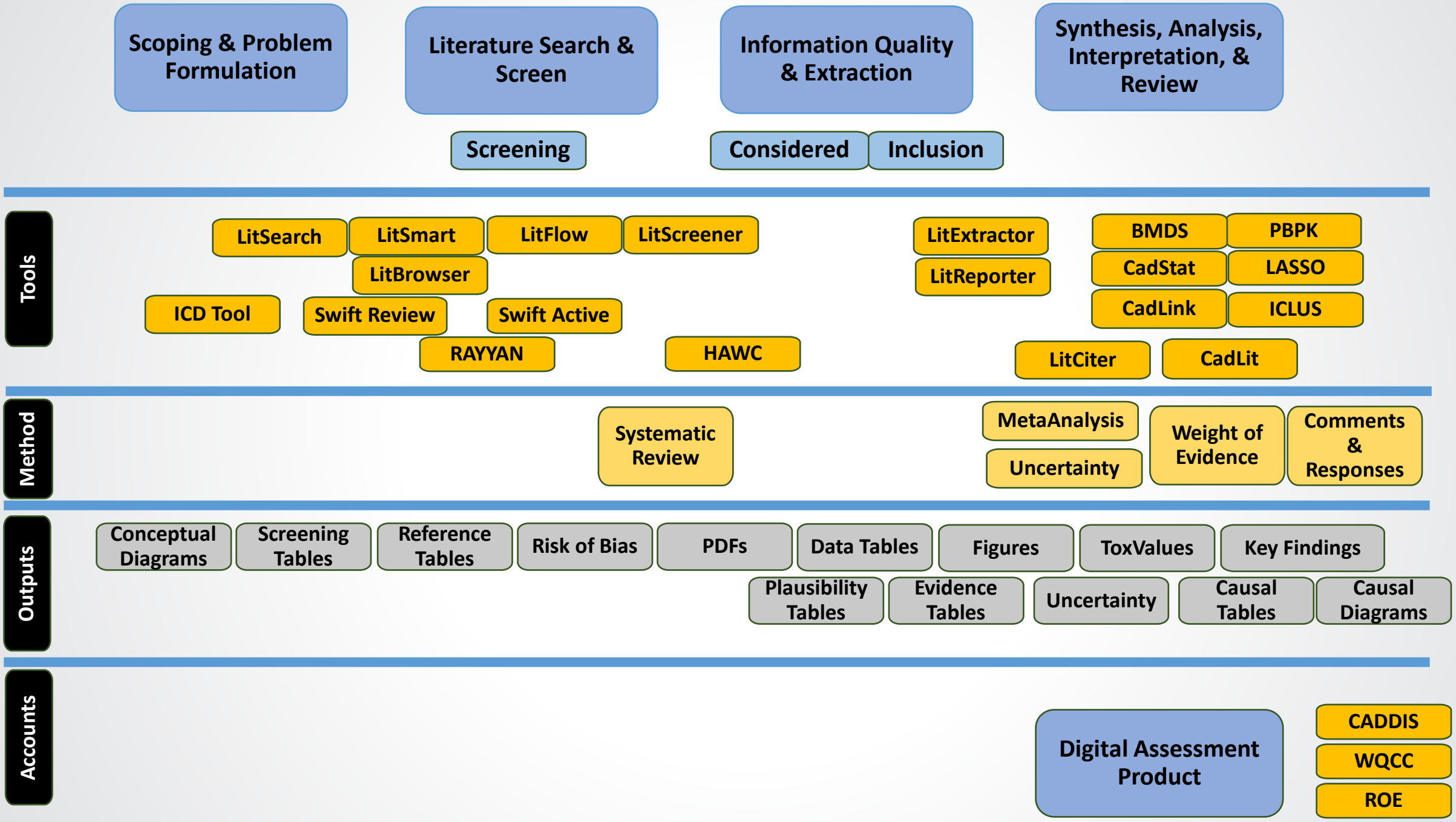
Literature Search & Screen

Information Quality &
Extraction

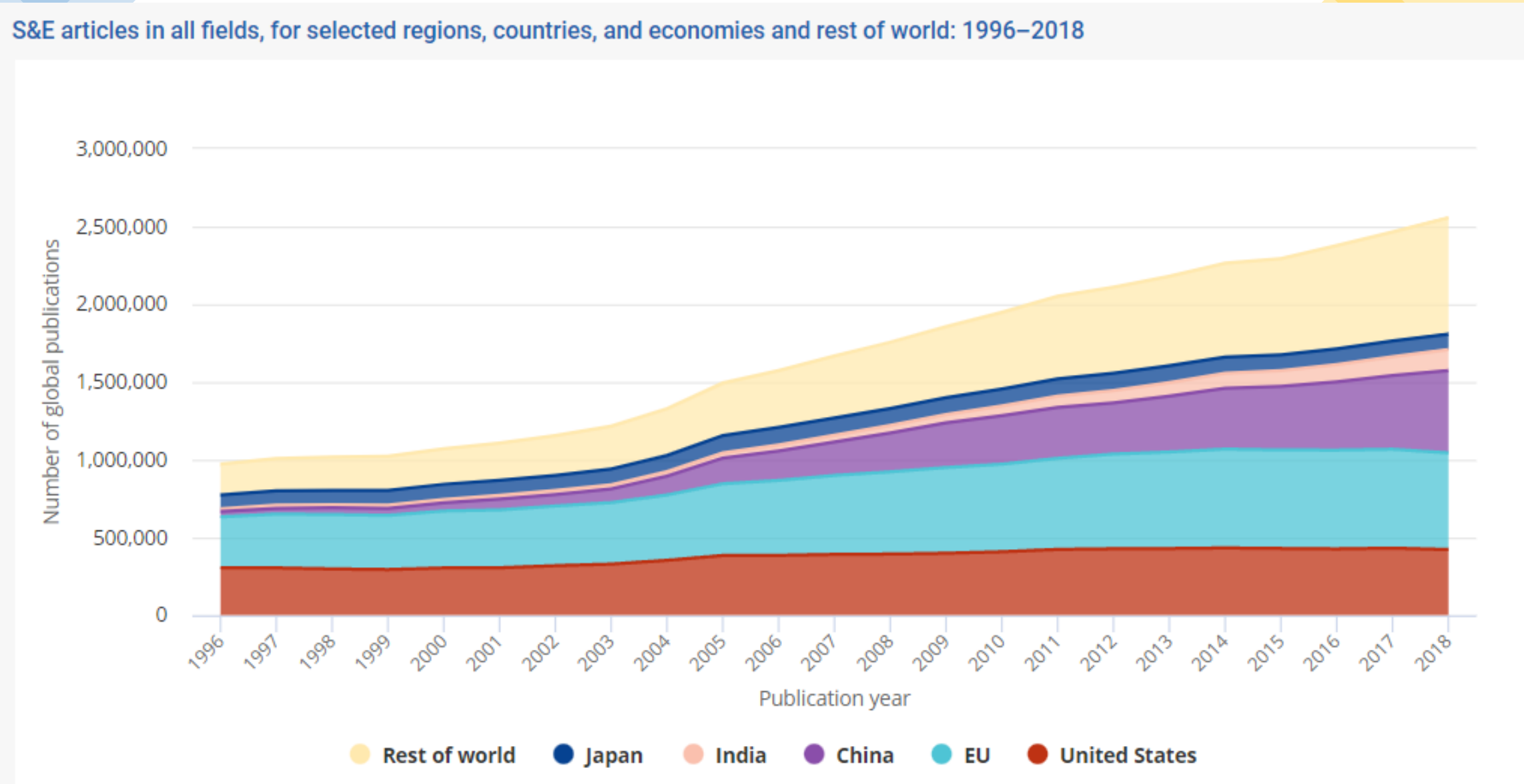
Analysis, Synthesis & Interpretation

Science Assessment

Develop tools, visualizations, executive summary reports, fact sheets, or other products that help stakeholders use evidence.


Scoping & Problem Formulation
Literature Search & Screen
Information Quality & Extraction
Synthesis, Analysis, Interpretation, & Review
Screening
Considered
Inclusion
Tools
LitSearch
LitSmart
LitFlow
LitScreener
LitBrowser
ICD Tool
Swift Review
Swift Active
RAYYAN
HAWC
LitExtractor
LitReporter
BMDS
PBPK
CadStat
LASSO
CadLink
ICLUS
LitCiter
CadLit
Method
Systematic Review
MetaAnalysis
Uncertainty
Weight of Evidence
Comments & Responses
Outputs
Conceptual Diagrams
Screening Tables
Reference Tables
Risk of Bias
PDFs
Data Tables
Figures
ToxValues
Key Findings
Plausibility Tables
Evidence Tables
Uncertainty
Causal Tables
Causal Diagrams
Accounts
Digital Assessment Product
CADDIS
WQCC
ROE

# Assessment Challenge: Publication Wave

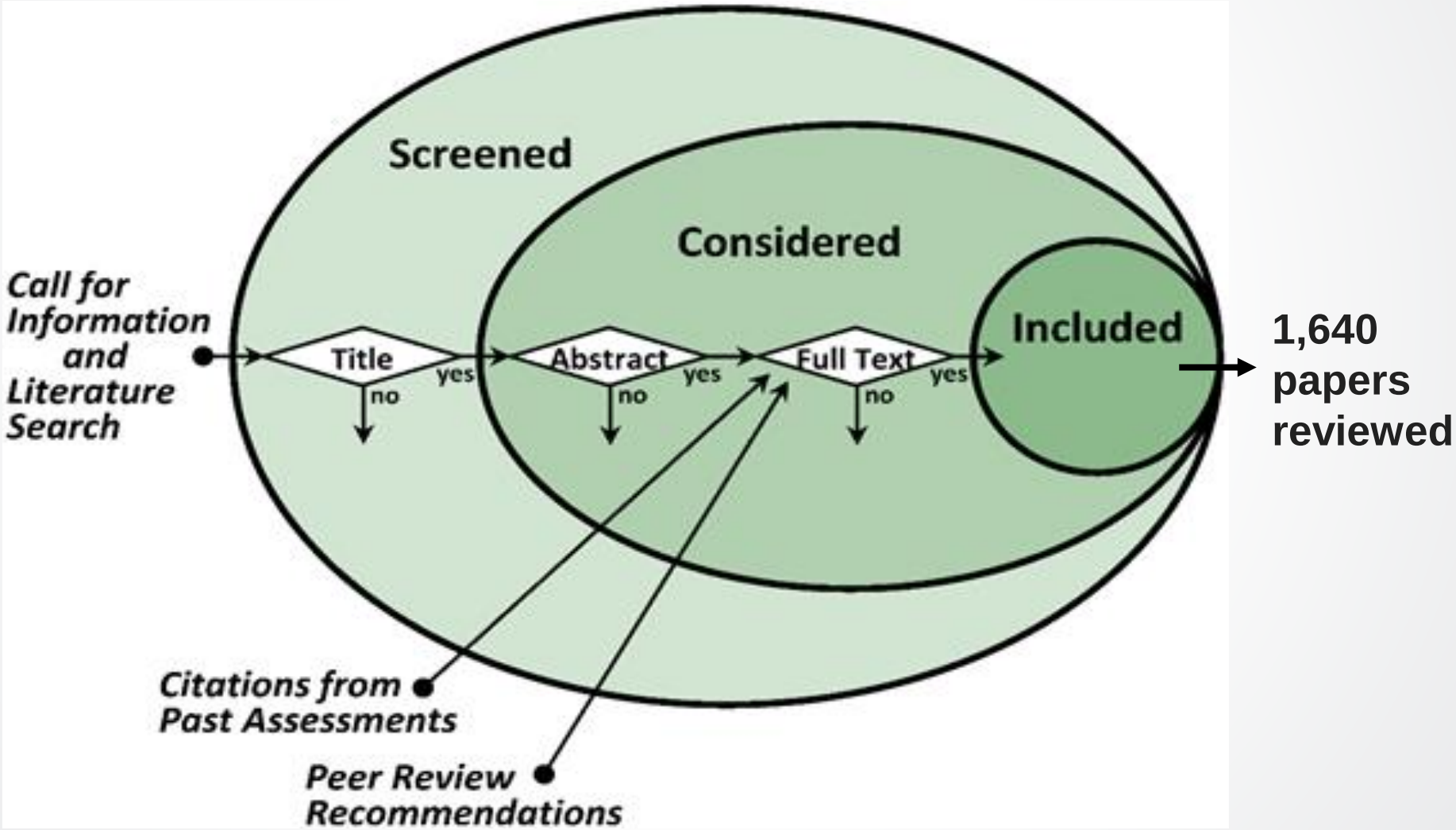



https://ncses.nsf.gov/pubs/nsb20206/publication-output-by-region-country-or-economy

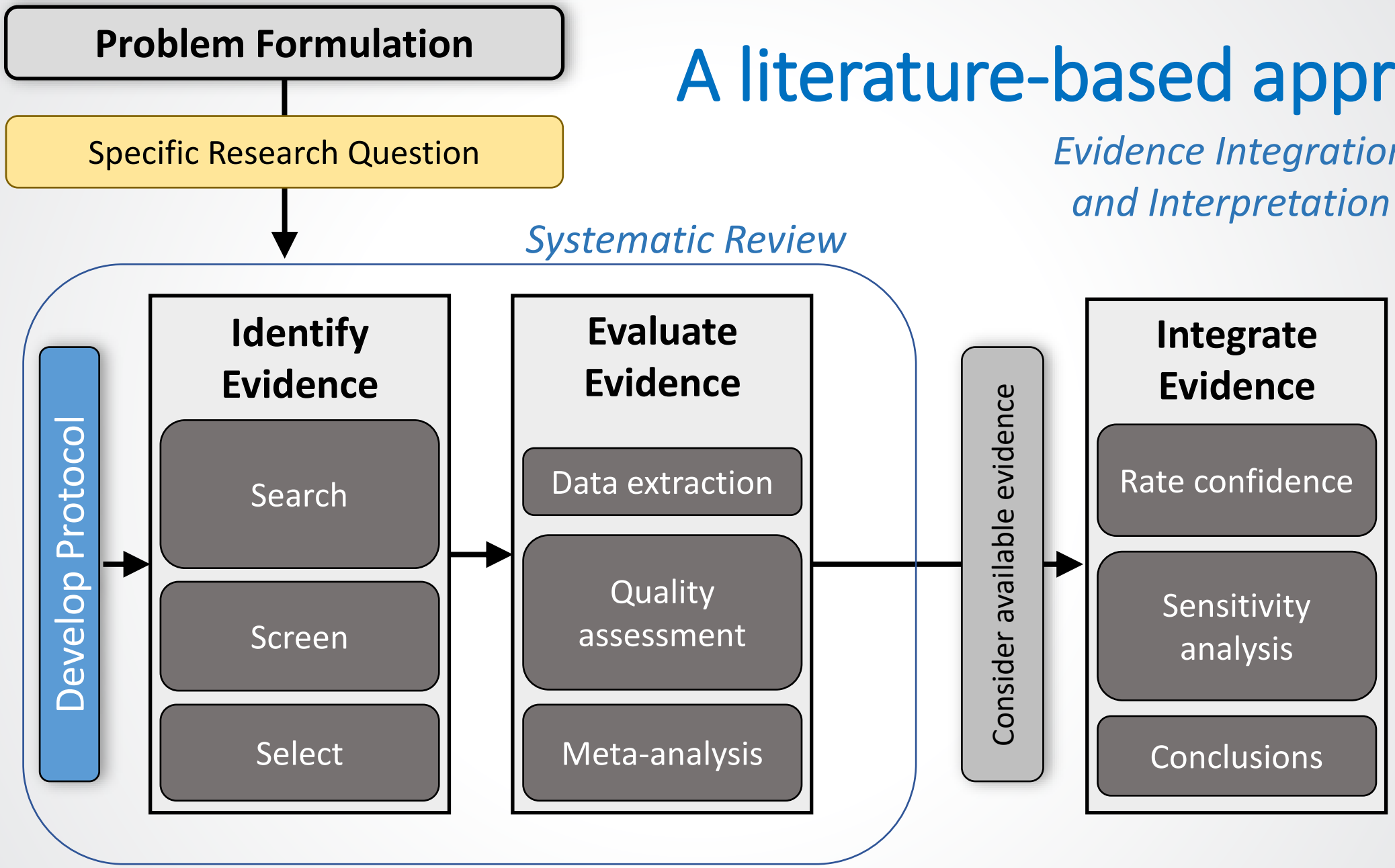
# Systematic Review

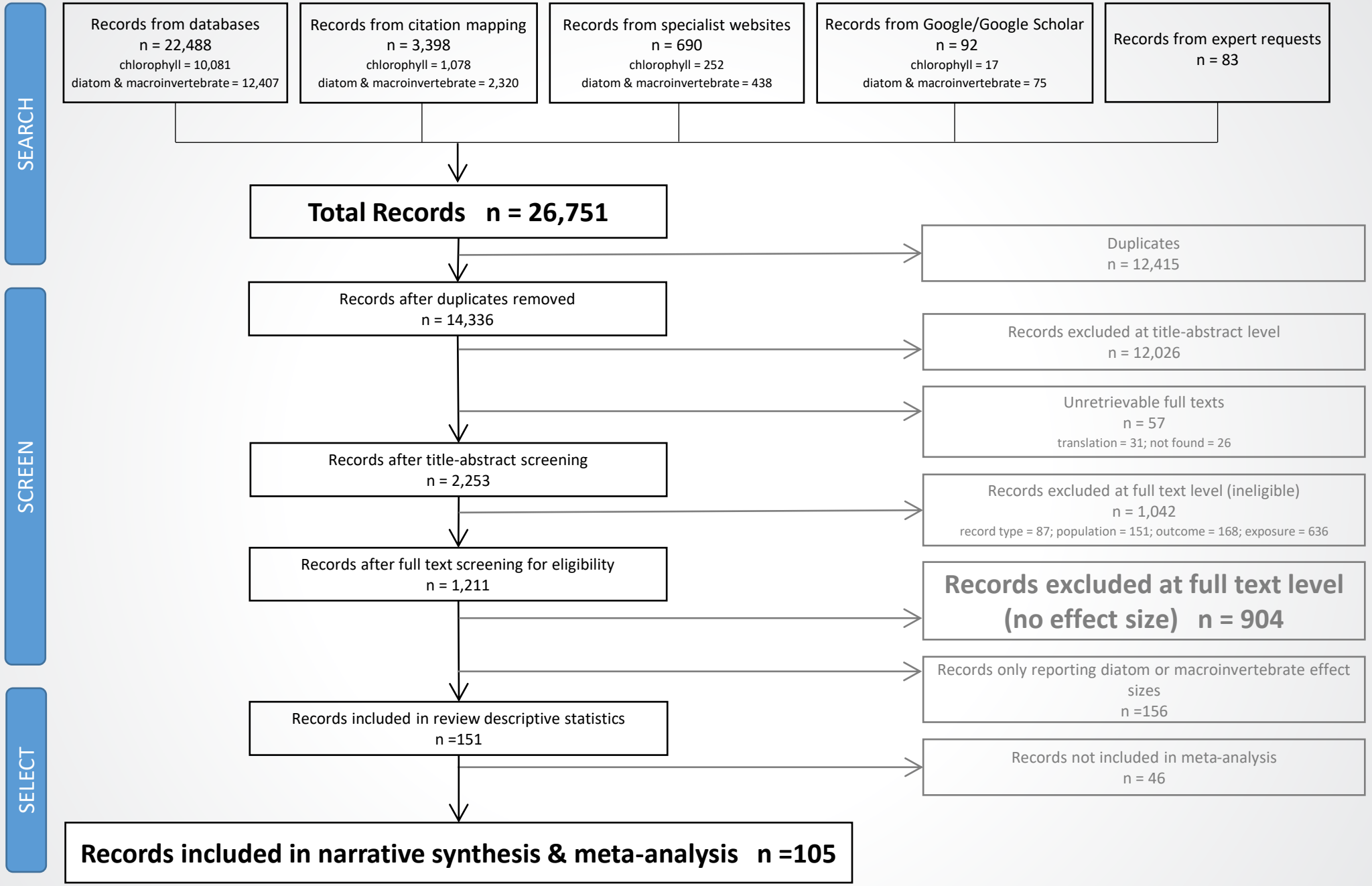
- **a review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify**, select and critically appraise relevant primary research, and to extract and analyze data from the studies that are included in the review

# Systematic Review



# A literature-based approach

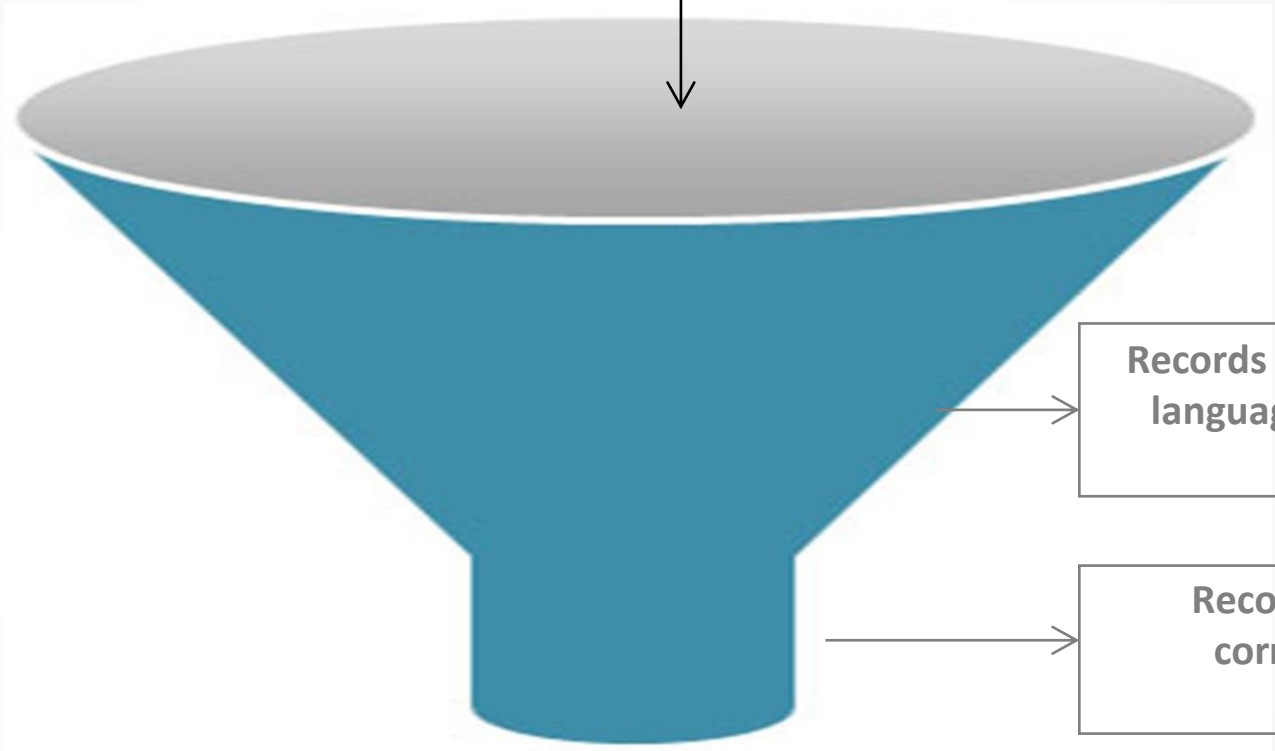



SEARCH
SCREEN
SELECT
Records from databases
n = 22,488
chlorophyll = 10,081
diatom & macroinvertebrate = 12,407
Records from citation mapping
n = 3,398
chlorophyll = 1,078
diatom & macroinvertebrate = 2,320
Records from specialist websites
n = 690
chlorophyll = 252
diatom & macroinvertebrate = 438
Records from Google/Google Scholar
n = 92
chlorophyll = 17
diatom & macroinvertebrate = 75
Records from expert requests
n = 83
Total Records n = 26,751
Duplicates
n = 12,415
Records after duplicates removed
n = 14,336
Records excluded at title-abstract level
n = 12,026
Unretrievable full texts
n = 57
translation = 31; not found = 26
Records after title-abstract screening
n = 2,253
Records excluded at full text level (ineligible)
n = 1,042
record type = 87; population = 151; outcome = 168; exposure = 636
Records after full text screening for eligibility
n = 1,211
Records excluded at full text level (no effect size) n = 904
Records only reporting diatom or macroinvertebrate effect sizes
n =156
Records included in review descriptive statistics
n =151
Records not included in meta-analysis
n = 46
Records included in narrative synthesis & meta-analysis n =105

SEARCH

SCREEN

SELECT



Total Records n = 26,751

Records excluded b/c duplicate, language, wrong habitat, etc.
n = 25,742

Records excluded b/c no correlation coefficient
n = 904

Records included in synthesis & meta-analysis n =105

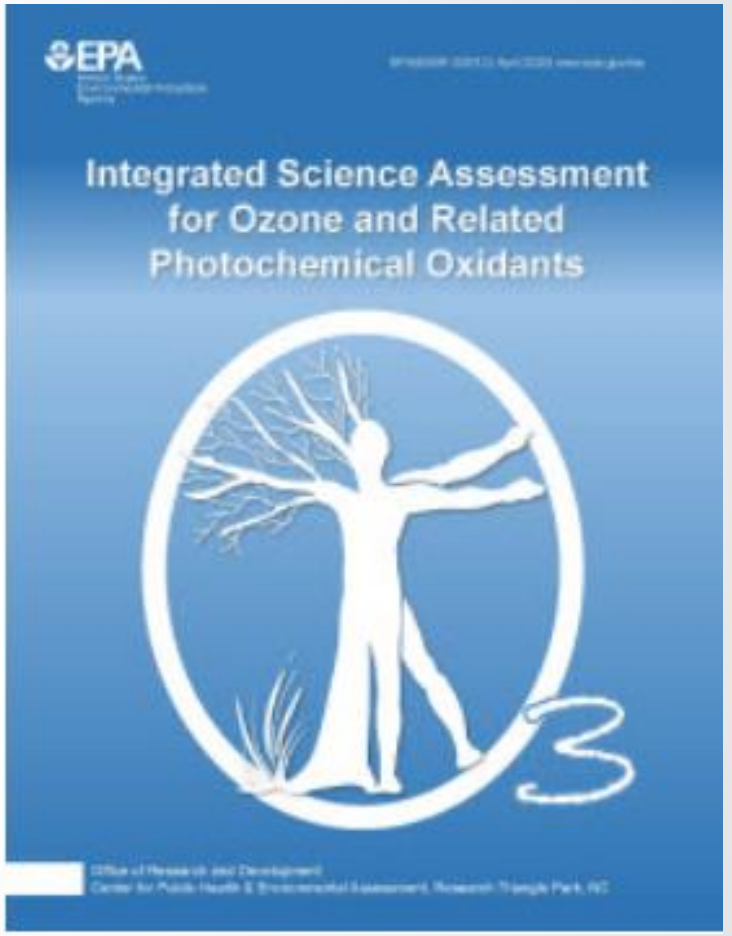
Evidence Tables

## Causality Determinations for Ecological Effects of Ozone

| Scale of Ecological Response | | | | |
|---|---|---|---|---|
| Ecosystem | | Belowground Biogeochemical Cycles | | |
| | | Water Cycling | | |
| | | Carbon Sequestration | | |
| | | Productivity | | |
| Community | | Biodiversity | Terrestrial Community Composition* | |
| | | Species Interactions | Plant-Insect Signaling + | |
| Population | Individual | Survival | Trees + | |
| | | Growth | Plants | Herbivores+ |
| | | Reproduction | Plants+ | Herbivores+ |
| | | Yield | Agricultural Crops | |
| Individual | | Visible Foliar Injury | | |

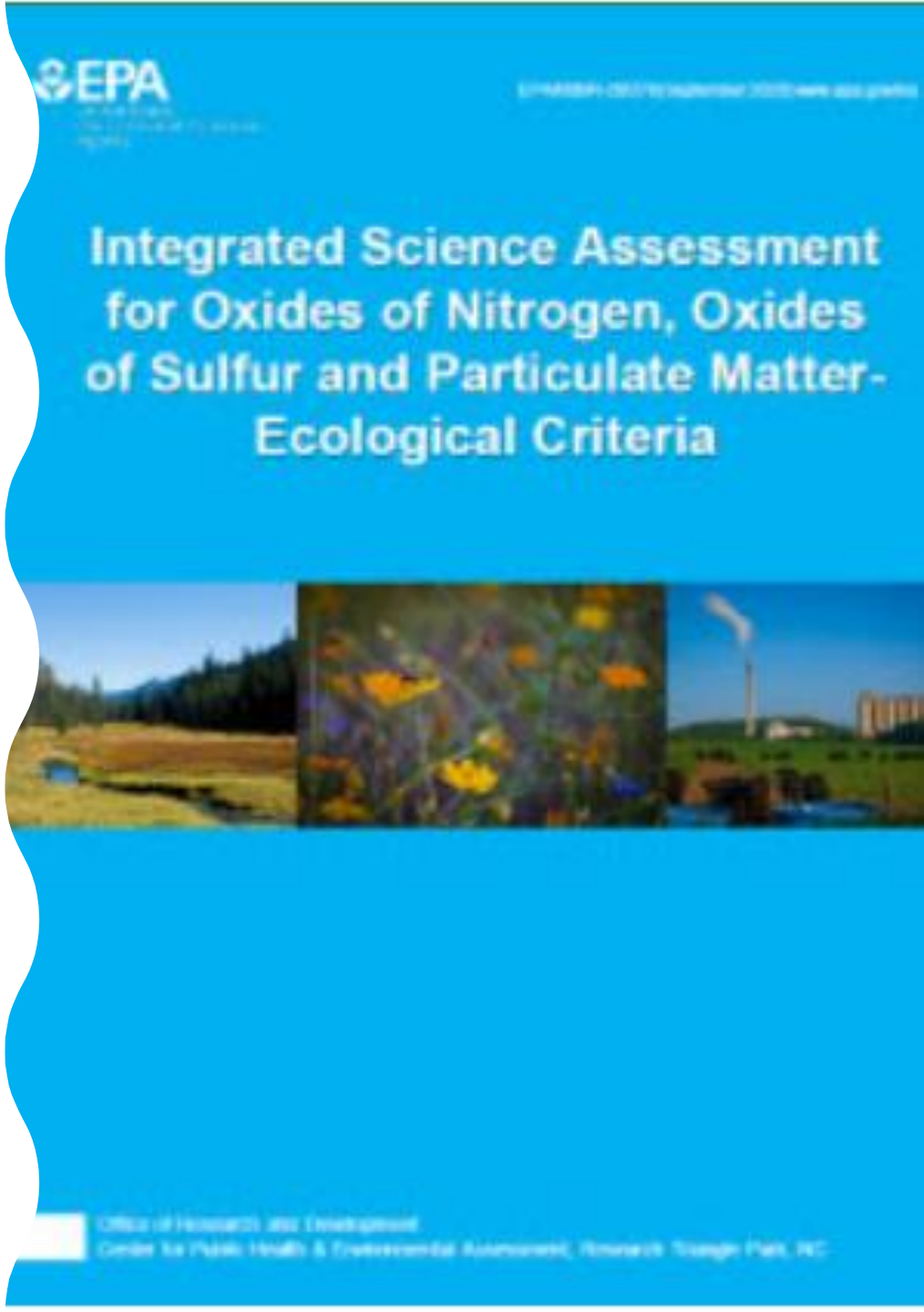
Causal  Likely Causal

New determination (+) or change in causality determination (*) from 2013 Ozone ISA



# Take Home Messages

- Assessments provide the scientific evidence that underpin EPA regulatory and policy decisions
- Assessments are developed following the principles of scientific integrity
  - Objectivity
  - Clarity
  - Reproducibility
  - Transparency
- The Science of Assessments yields the innovations to improve development efficiencies and impact of assessments



# Thank You!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