Introduction and Role of the Protocol in the IRIS Systematic Review Process

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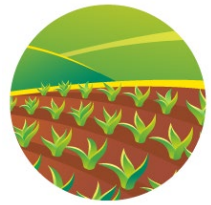
- **Created in 1985 to foster consistency in the evaluation of chemical toxicity across the Agency.**
- **IRIS assessments contribute to decisions across EPA and other health agencies.**
- **Toxicity values**
  - Noncancer: Reference Doses (RfDs) and Reference Concentrations (RfCs).
  - Cancer: Oral Slope Factors (OSFs) and Inhalation Unit Risks (IURs).
- **IRIS assessments have no direct regulatory impact until they are combined with**
  - Extent of exposure to people, cost of cleanup, available technology, etc.
  - Regulatory options.
  - Both of these are the purview of EPA's program offices.

IRIS Provides Scientific Foundation for Agency Decision Making

IRIS

- Clean Air Act (CAA)
- Safe Drinking Water Act (SDWA)
- Food Quality Protection Act (FQPA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Resource Conservation and Recovery Act (RCRA)
- Toxic Substances Control Act (TSCA)

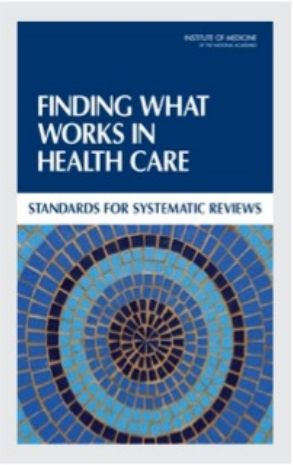


Broad Input to Support

- Agency Strategic Goals
- Children's Health
- Environmental Justice

Systematic Review

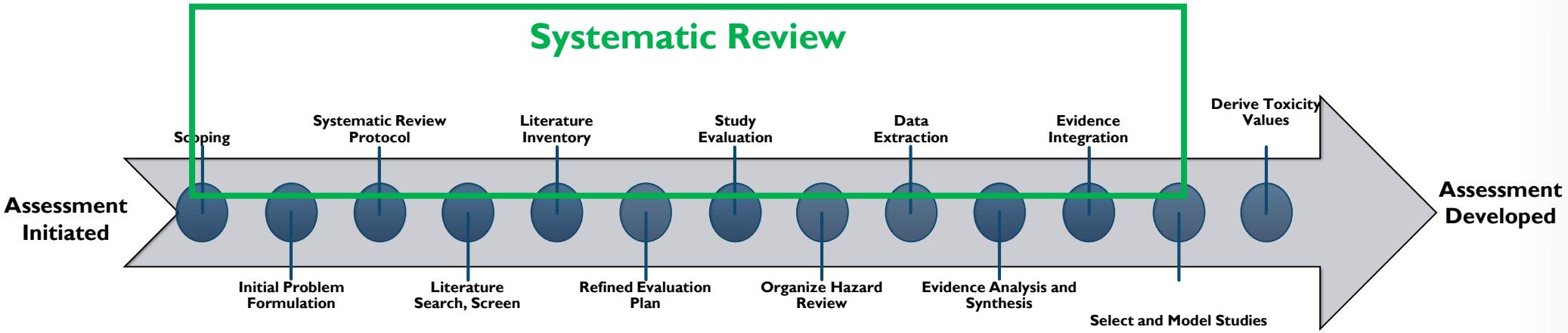
A structured and documented process for transparent literature review



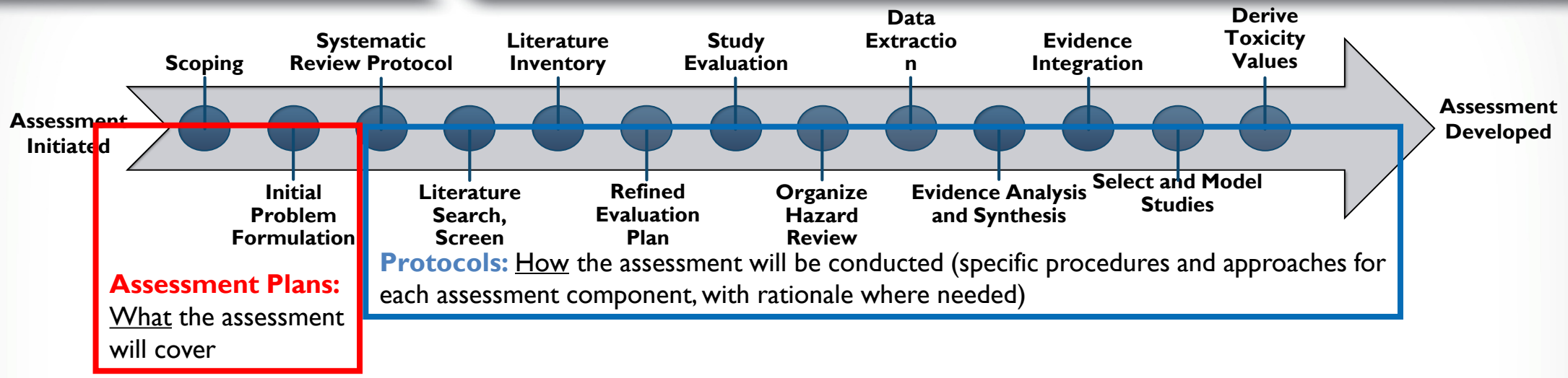
"As defined by IOM [Institute of Medicine][1], systematic review 'is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies."

[1] Institute of Medicine. Finding What works in Health Care: Standards for Systematic Reviews. p.13-34. The National Academies Press. Washington, D.C. 2011

Systematic Review in IRIS Assessments



IRIS Assessment Plans and Protocols



- For new IRIS assessments, a scoping and problem formulation document (IAP) is released with a public comment period; comments received on IAP are then considered when preparing the protocol.
- Scoping and problem formulation materials for arsenic were released for NAS review in 2013 and 2015; and public comment in 2014; eight science issues public webinars were held in 2013.
- iAs protocol incorporates information from these meetings and reflects experience in implementing prior recommendations.
- Protocol is iterative – Public comment and knowledge gained during implementation may result in revisions to the protocol to focus on the best available evidence.
- Public comments received on the protocol will be considered during conducting the assessment and an updated protocol will be released when the draft assessment is released for public comment

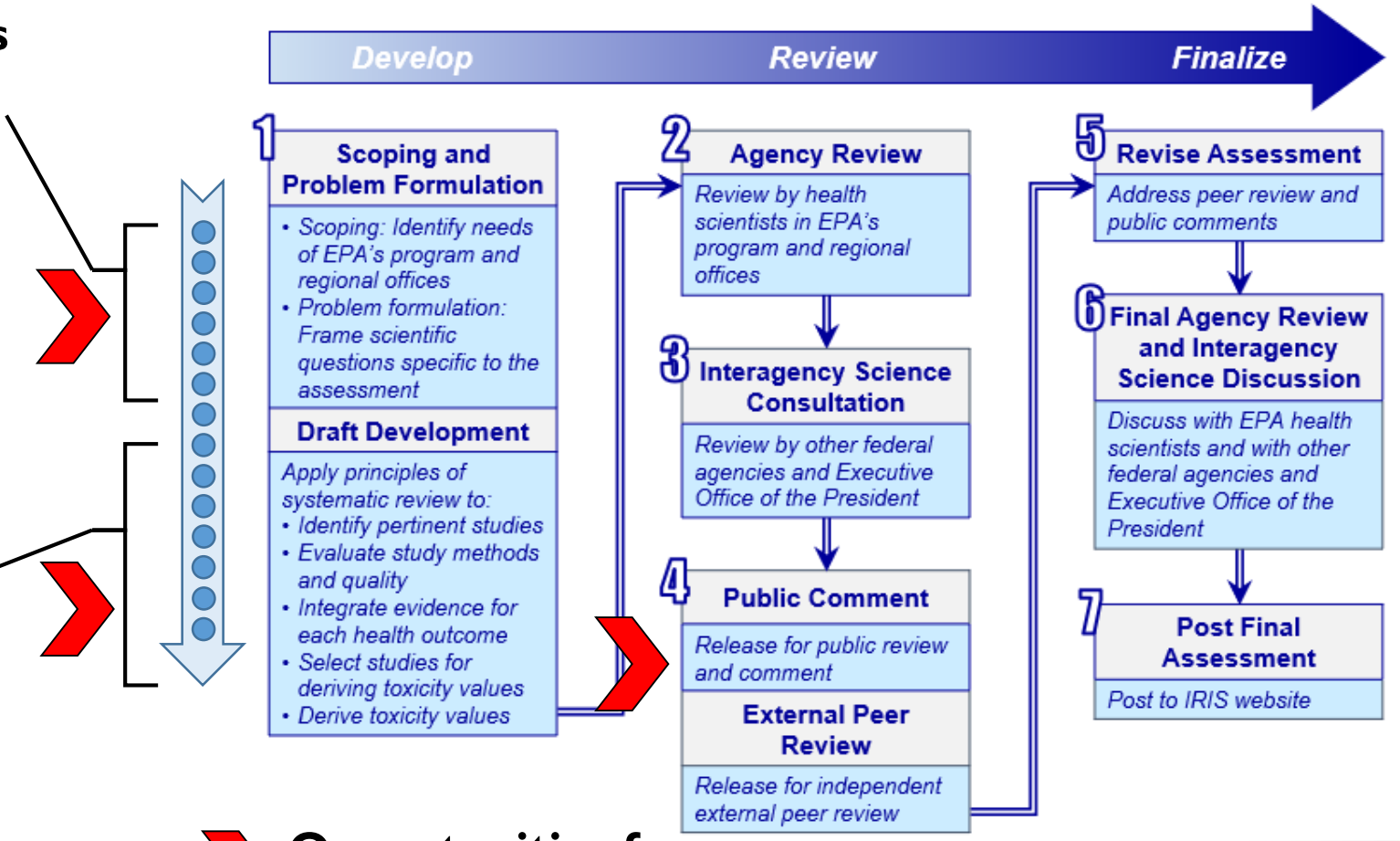
IRIS Assessment Plans, Protocols, and 7-Step IRIS Process

Early Step 1: IRIS Assessment Plans

- What the assessment covers
- 30-day public comment period + public science meeting

Mid-Step 1: Protocols

- How the assessment will be conducted
- 30-day public comment



https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process