

Integrated Science Assessment Development Process

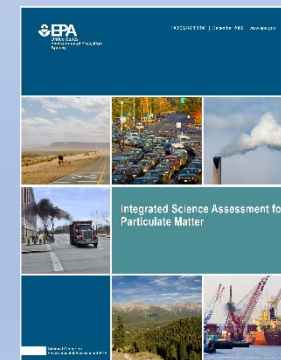
ILA COTE, PhD

Health Effects Institute Annual Meeting 2018

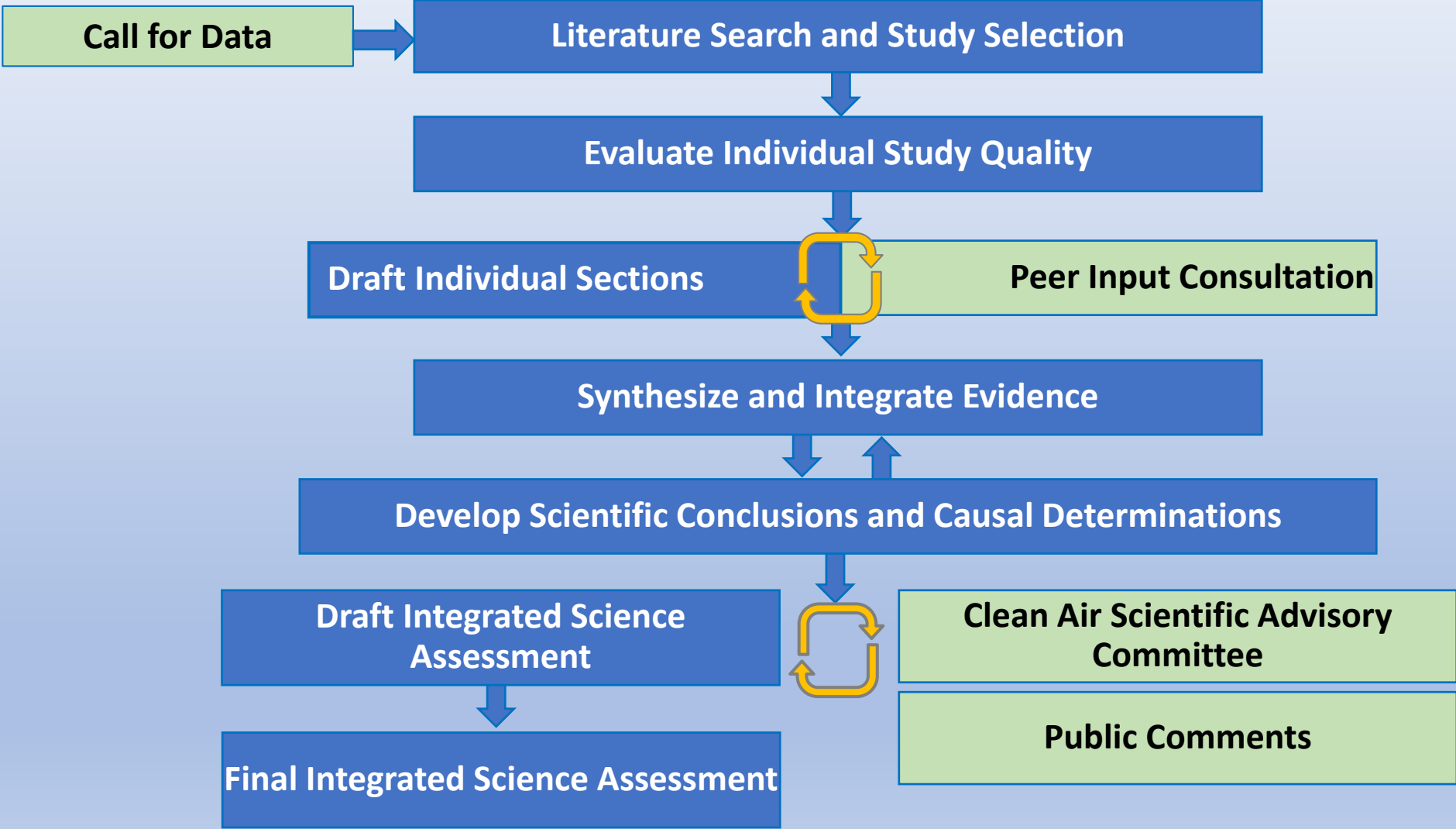


The Integrated Science Assessments Shaped by the Law

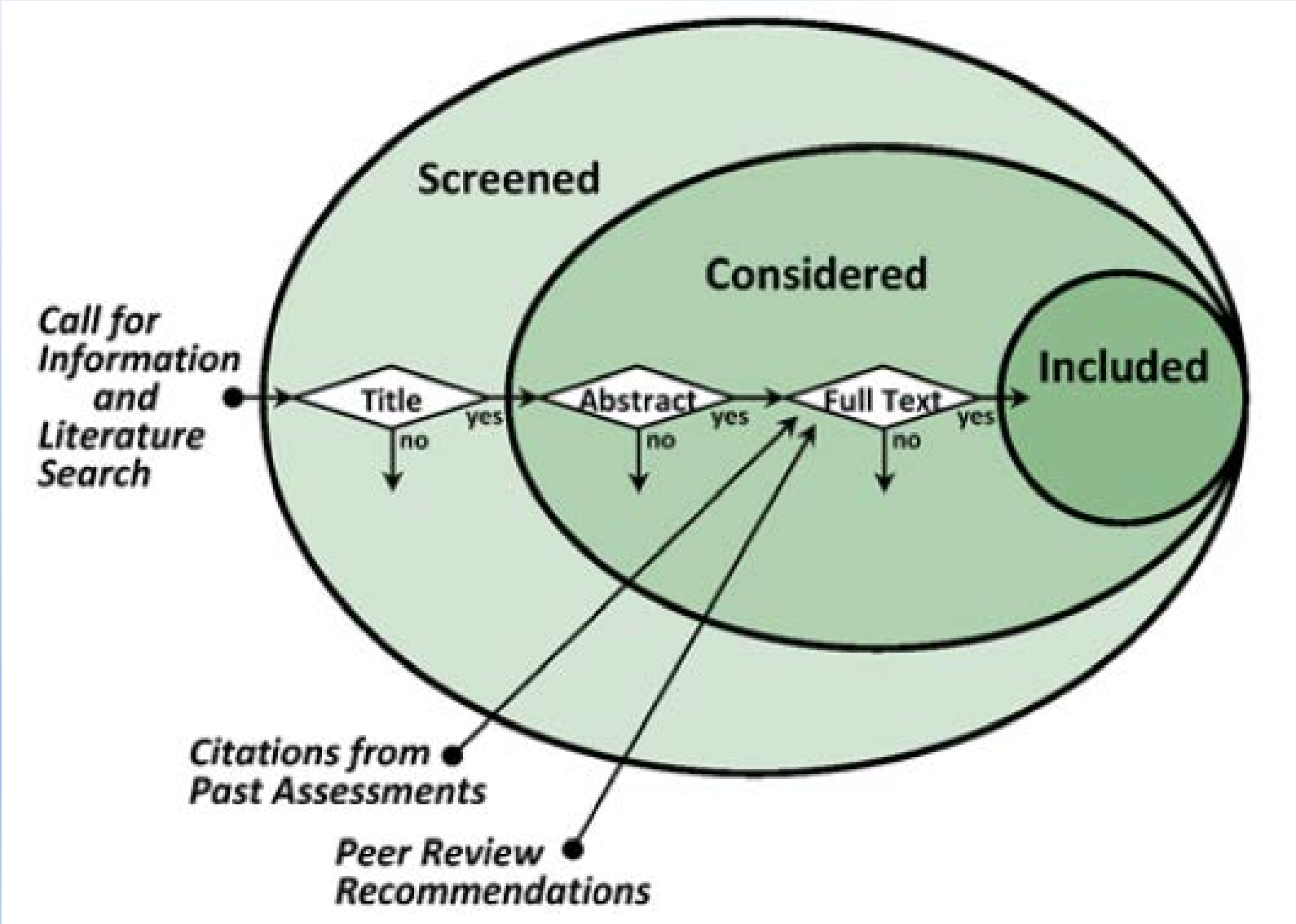
- Clear Air Act Section 108: “shall accurately reflect **the latest scientific knowledge useful** in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant...
- Clear Air Act Section 307(d)(3) ...proposed rulemaking ...is accompanied by... a **“summary” of factual data and methods** used...



The ISA Development Process Overview



Literature Search and Study Selection Process



Recent Literature Searches and Study Selection

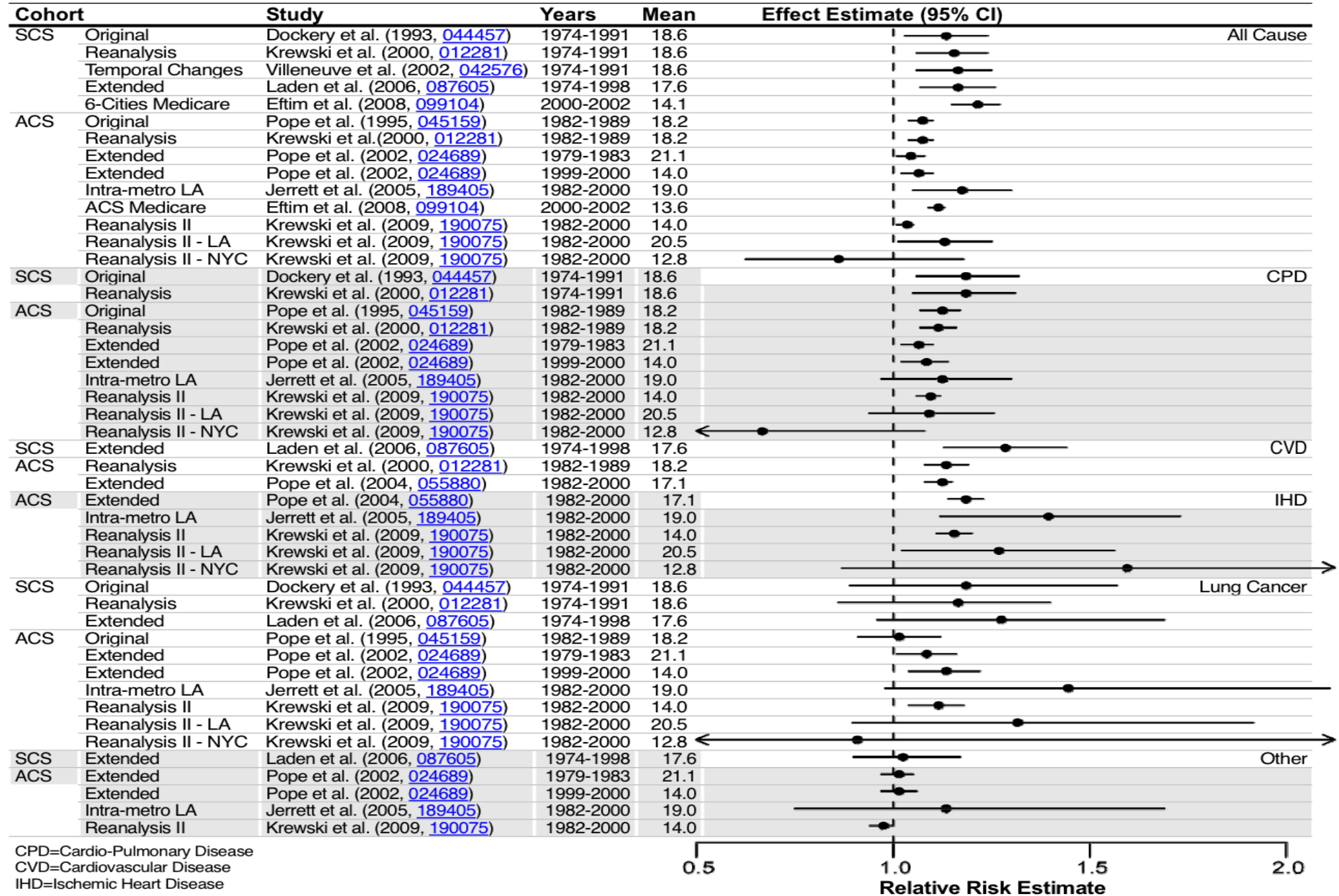
ISA	Screened	Considered	Included
PM – Health and Welfare Criteria 1 st External Review Draft	310,094	In progress	
NO _x SO _x PM – Ecological Criteria 1 st External Review Draft	~198,000	~3,200	2,603
SO _x – Health Criteria Final Report (2017)	56,502	1,526	1,017
NO _x – Health Criteria Final Report (2016)	246,817	5,466	1,682
O ₃ – Health and Welfare Criteria Final Report (2013)	Not recorded	4,044	2,276
Pb – Health and Ecological Criteria Final Report (2013)	~500,000	7,398	3,189

Snapshot of 2013 O₃ ISA

Epidemiology n ≈ 425	
Cardiovascular	94
Respiratory	237
Mortality	45
Repro/Dev	65
Experimental n ≈ 363	
Cardiovascular	50
Respiratory	275
Nervous System	34
Repro/Dev	17
Exposure n ≈ 222	
Ecology n ≈ 654	
Climate n ≈ 151	

Sorting, and related references, are document in the publicly available in EPA's [Health Effects Research Online \(HERO\) database](#)

Synthesis of Information: An Example



Formal Framework for Causal Determinations

Evidence is sufficient to conclude that there is a causal relationship...

- Rule out *chance, confounding, and other biases*
- *Consistency, coherence, biological plausibility, high-quality studies*

Evidence is sufficient to concluded that there is a likely causal relationship

- Multiple, high-quality studies show effects
- Uncertainty remains

Evidence is suggestive of, but not sufficient to infer, a causal relationship

Association found in at least one high-quality study or results are inconsistent

Inadequate to infer a causal relationship

Evidence is of insufficient quantity, quality, consistency

Not likely to be a causal relationship

Multiple studies consistently show no effect across exposure concentrations

From the Preamble to the ISA

The Courts Have also Shaped the Process

The courts have said

- **“Requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary”** (American Trucking Associations, Inc., Petitioners, v. EPA. (D.C. Cir. 2002)).
- **“An agency's failure adequately to consider a relevant and significant aspect of a problem may render its rulemaking arbitrary and capricious”** (American Farm Bureau and National Pork Producers Council v. EPA (D.C. Cir. 2009)
- The Supreme Court agrees that NAAQS must be based on “published air quality criteria that reflect the latest **scientific knowledge**” (State of Mississippi v. EPA, (D.C. Cir. 2013)).

Summary of Key Points

- Both the Clean Air Act and Courts have shaped the current process
- Formal process for identifying and evaluating all information
 - Heroic and systematic review of the literature
 - Rules for evaluating the evidence and causal determination
- Multiple interactions with the science community and stakeholders
- Very transparent



Thank you!

