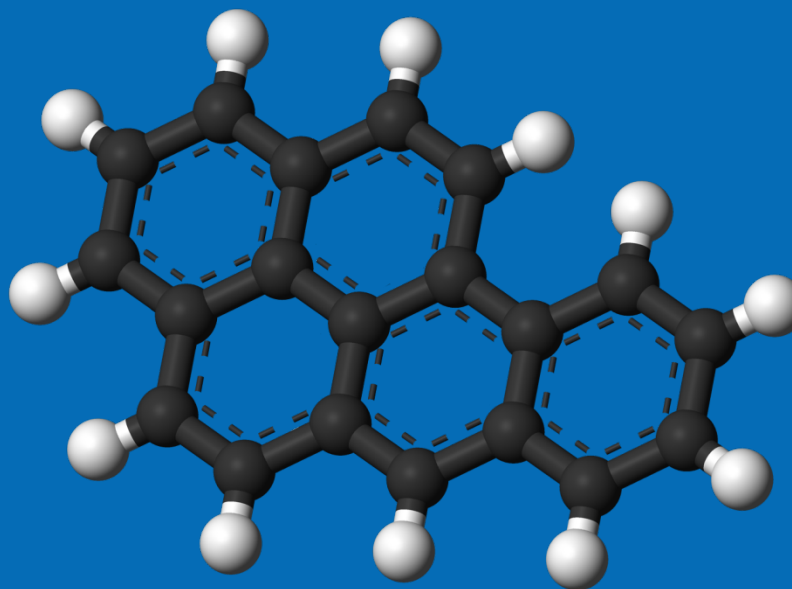


IRIS Draft Toxicological Review for Benzo[a]pyrene (BaP)

Kathleen Newhouse, Assessment Manager



General Information

Five-ring polycyclic aromatic hydrocarbon

- Relatively insoluble in water
- Low volatility

Ubiquitous in the environment primarily as a result of incomplete combustion emissions

- Natural sources include forest fires and volcanoes
- Anthropogenic sources include stoves/furnaces burning fossil fuels (especially wood and coal), motor vehicle exhaust, and various industrial combustion processes

Exposure

Major sources of occupational exposure involve

- Production of aluminum, coke, graphite, and silicon carbide
- Coal tar distillation

Major sources of non-occupational exposure

- Tobacco products
- Diet (e.g. barbequed or charred meats)

Agency Interest in BaP

Hazardous substance under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)

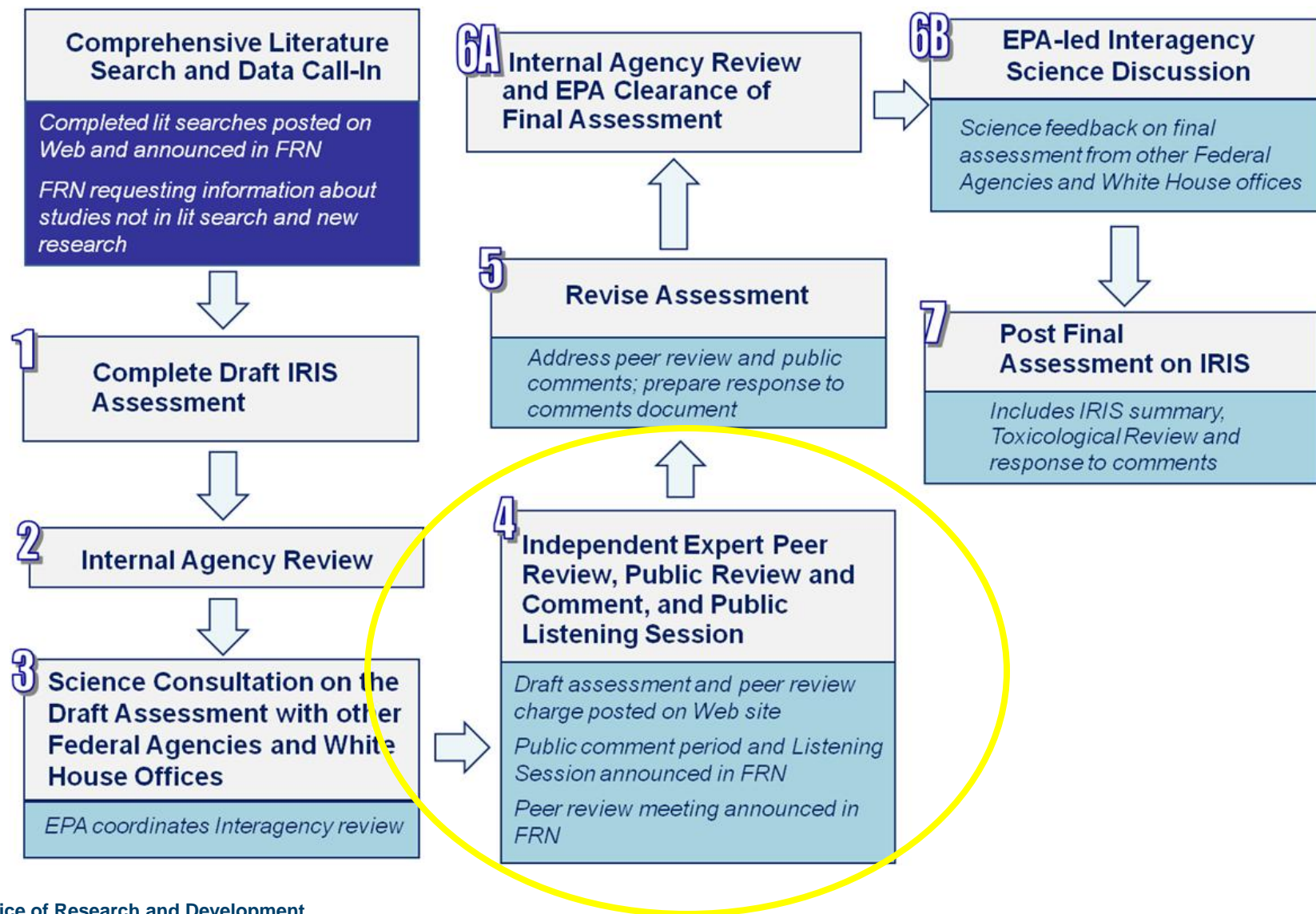
- Found at 524 hazardous waste sites on the National Priorities List (NPL)

Drinking water contaminant under the Safe Drinking Water Act (SDWA)

- Maximum Contaminant Level Goal (MCLG) of zero and enforceable Maximum Contaminant Level (MCL) of 0.0002 mg/L have been established

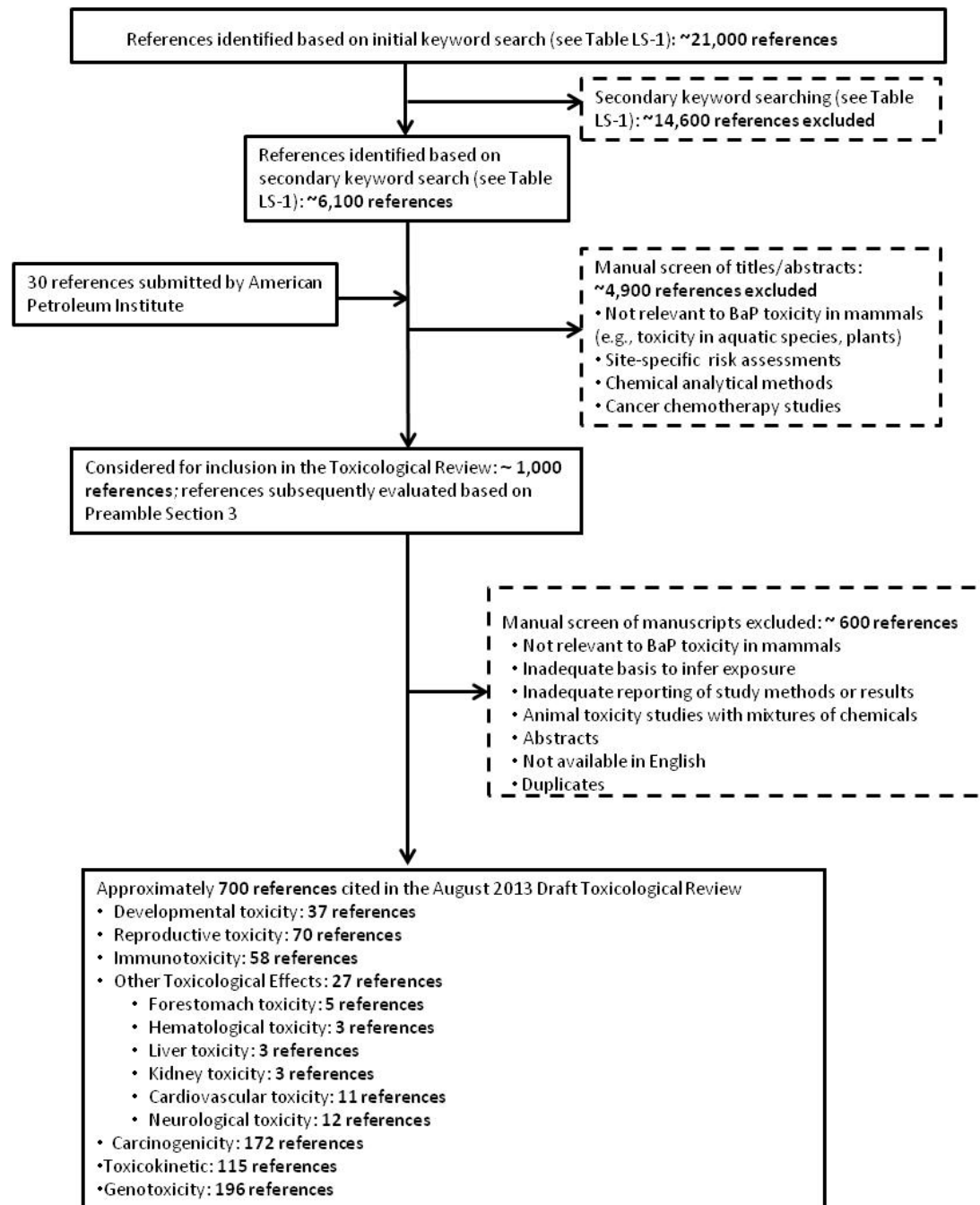
Component in a class of chemicals referred to as Polycyclic Organic Matter, defined as a Hazardous Air Pollutant in the 1990 amendments to the Clean Air Act

Index chemical for the EPA Relative Potency Factor approach for PAH mixtures



Literature Search Strategy

- The literature search identified more than 21,000 studies for BaP.
- Approximately 700 references were cited in the August 2013 Toxicological Review (Public Comment Draft).



Health Hazards Identified in the Public Comment Draft

EFFECTS OTHER THAN CANCER

- Animal studies indicate that the strongest evidence for potential hazard following BaP exposure is for **developmental** and **reproductive toxicity** and **immunotoxicity**.
- Human studies report effects that are generally analogous to the effects observed in animal toxicological studies, and provide qualitative, supportive evidence.

CANCER

- Under EPA's *Guidelines for Carcinogen Risk Assessment* (2005) BaP is “**carcinogenic to humans**” based on strong and consistent evidence in humans and animals, as well as mechanistic data.
- The weight of evidence supports **mutagenicity** as the primary mode of action for BaP-induced carcinogenicity.

Specific Issues Identified in the Public Comment Draft Charge

The new document structure

- The Preamble
- Executive Summary
- Literature Search Strategy/Study Selection

The synthesis, integration, and weight of the evidence for the identified hazards

The development of candidate values and organ/system-specific reference values

The development of cancer risk estimates for oral, inhalation, and dermal exposure

- Including the method used for interspecies scaling of the dermal slope factor

Innovative Features of the BaP Public Comment Draft

- New document structure, responsive to NRC recommendations
- First IRIS derivation of non-cancer reference values for BaP
- First assessment to calculate multiple organ/system specific reference values (facilitates subsequent risk assessments of multiple chemicals)
- First IRIS inhalation unit risk for BaP; updated oral slope factor
- Presentation of the first dermal cancer risk estimate for any chemical on IRIS
- First characterization of a chemical as “carcinogenic to humans” based in part on mechanistic data
- First systematic analysis of transcriptomics data in an IRIS assessment