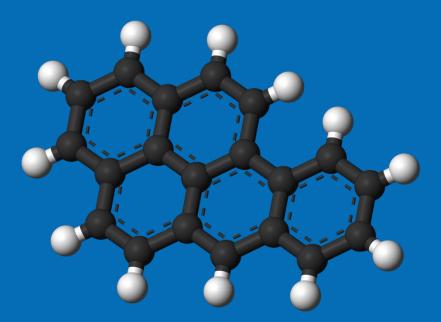


IRIS Draft Toxicological Review for Benzo[a]pyrene (BaP)

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

<u>Exposure</u>

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



Comprehensive Literature Search and Data Call-In

Completed lit searches posted on Web and announced in FRN

FRN requesting information about studies not in lit search and new research



Complete Draft IRIS Assessment



Internal Agency Review



Science Consultation on the Draft Assessment with other Federal Agencies and White House Offices

EPA coordinates Interagency review

Internal Agency Review and EPA Clearance of Final Assessment



Revise Assessment

Address peer review and public comments; prepare response to comments document



Independent Expert Peer Review, Public Review and Comment, and Public Listening Session

Draft assessment and peer review charge posted on Web site

Public comment period and Listening Session announced in FRN

Peer review meeting announced in FRN



Science feedback on final assessment from other Federal Agencies and White House offices



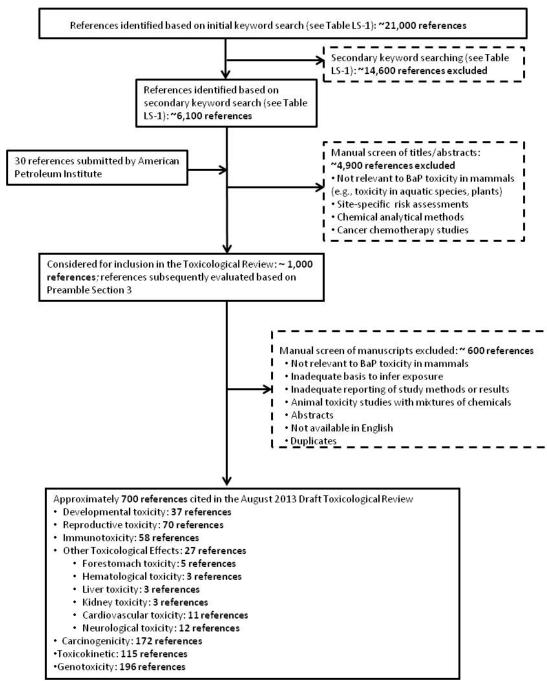
Post Final Assessment on IRIS

Includes IRIS summary, Toxicological Review and response to comments



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