Proposed EPA Changes in the Toxicological Assessment of Benzo(a)pyrene and the Potential Impact on Corrective Actions at Railroad Sites

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Agenda

- EPA's Proposed BaP Toxicity Values
- Implications for Site Clean-up Levels
- EPA's Proposed Approach for PAH Mixtures
- Impacts on BaP-Toxic Equivalent Concentrations
- Implications for Railroad Sites
- Available Mitigation Tools
- Reality Check
- EPA's Timeline
- Railroad Community Involvement

Proposed Toxicity Values Benzo(a)pyrene (BaP)

Toxicity Value Type	Current Value in IRIS	Proposed Value (Sept 2014)
Oral Reference Dose (noncancer endpoint)	None	0.0003 mg/kg-day
Reference Concentration (noncancer endpoint)	None	0.000002 mg/m^3
Oral Slope Factor *	7.3 $(mg/kg\text{-}day)^{-1}$	1 $(mg/kg\text{-}day)^{-1}$
Inhalation Unit Risk *	None in IRIS [0.001 $(\mu g/m^3)^{-1}$] **	0.0006 $(\mu g/m^3)^{-1}$ ***
Dermal Slope Factor	None	6 $(mg/day)^{-1}$ **

* Used for all potentially carcinogenic PAHs
** CalEPA value used by EPA to derive RSLs
*** More strict than that proposed in 2013

EPA's Current Mixture Approach for Carcinogenic PAHs

- BaP toxicity applied to all carcinogenic PAHs (cPAHs) by applying BaP- Relative Potency Factors (RPFs) (EPA 1993)
- Calculate BaP- Toxic Equivalents (BaP-TE)

EPA's Current List of cPAHs	RPF
Benzo(a)pyrene	1.0
Benz(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
Benzo(k)fluoranthene	0.01
Chrysene	0.001
Dibenz(a,h)anthracene	1.0
Indeno(1,2,3-c,d)pyrene	0.1

Implications for Site Clean-up Levels, Benzo[a]pyrene Toxic Equivalents

EPA's Regional Screening Level (RSL)	Existing BaP RSL*	RSL based on Proposed BaP Toxicity Values*	Difference
Residential Soil RSL	0.015 mg/kg	**0.003 mg/kg**	5 x lower
Industrial Soil RSL	0.29 mg/kg	**0.013 mg/kg**	22 x lower
Residential Ambient Air RSL	0.00092 µg/m^3	0.0017 µg/m^3	2 x higher
Industrial Ambient Air RSL	0.011 µg/m^3	0.0088 µg/m^3	1.3 x lower
Tap Water RSL	0.0034 µg/L	0.025 µg/L	7 x higher

- Derived at a 1x10^{-6} target excess lifetime cancer risk level
- mg/kg equivalent to parts per million

Implications for Site Clean-up Levels, Benzo(a)pyrene-TE (continued)

- Target risk of $1x10^{-6}$ often used for unrestricted site use (residential)
  - BaP-TE = 3 parts per *billion*
- Target risk of $1x10^{-5}$ often used for restricted site use (industrial/commercial)
  - BaP-TE = 130 parts per *billion*
- Typical levels of BaP-TE in urban soils using EPA's current list of cPAHs & Relative Potency Factor approach
  - BaP-TE = ~3,000 parts per *billion*

EPA's Proposed Mixture Approach (2010)

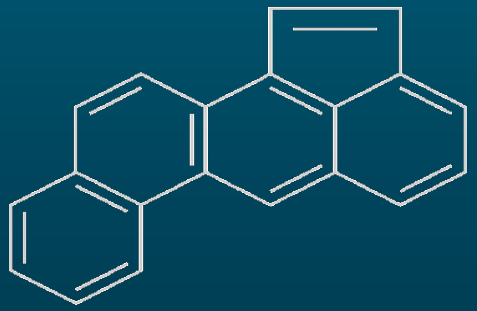
- Longer List of cPAHs
- Revised Relative Potency Factors for current cPAHs
- New Relative Potency Factors for new PAHs

EPA's Proposed Relative Potency Factors (RPFs) for Priority Pollutant PAHs

PAH	Current RPF	Proposed RPF	Change
Benzo(a)pyrene	1	1	none
Dibenz(a,h)anthracene	1	10	10x
Benzo(b)fluoranthene	0.1	0.8	8x
Benz(a)anthracene	0.1	0.2	2x
Chrysene	0.001	0.1	100x
Fluoranthene	none	0.08	New
Indeno(1,2,3-cd)pyrene	0.1	0.07	0.7x
Benzo(k)flouranthene	0.01	0.03	3x
Benzo(g,h,i)perylene	none	0.009	new

EPA's Proposed Relative Potency Approach

Benz[j]aceanthrylene



Non-Standard PAHs (n=16)

PAH	Average RPF
Anthanthrene	0.4
Benz[b,c]aceanthrylene, 11H-	0.05
Benzo[c]fluorene	20
Benz[e]aceanthrylene	0.8
Benz[j]aceanthrylene	60
Benzo[j]fluoranthene	0.3
Benz[l]aceanthrylene	5
Cyclopenta[c,d]pyrene	0.4
Cyclopenta[d,e,f]chrysene, 4H-	0.3
Dibenz[a,c]anthracene	4
Dibenzo[a,e]fluoranthene	0.9
Dibenzo[a,e]pyrene	0.4
Dibenzo[a,h]pyrene	0.9
Dibenzo[a,i]pyrene	0.6
Dibenzo[a,l]pyrene	30
Naphtho[2,3-e]pyrene	0.3

Impacts on BaP-TE Concentrations

- Magee (2011) predicted 10-20x higher for coal tar & creosote using new RPFs
- Emsbo-Mattingly et al. (2013) analyzed selected samples using an extended PAH analytical method
  - Diesel Fuel 250x higher
  - Creosote 15x higher
  - Tar/Pitch 10-100x higher
  - Coal 10x higher
  - Mineral Oil 100x higher
  - Pavement 15-100x higher

Implications of BaP Toxicity ***and*** Mixture Changes on Site Clean-Ups

- Probable clean-up level for unrestricted site use
  - BaP-TE = 3 parts per *billion*
- Probable clean-up level for restricted site use
  - BaP-TE = 130 parts per *billion*
- Typical levels of BaP-TE in urban soils using *new* PAH list & Relative Potency Factors
  - BaP-TE = ~30,000 parts per *billion* or more depending on PAH sources

Key Issues

- 2010
  - More PAHs
  - High Relative Potency Factors
- 2014
  - High Dermal Slope Factor
  - Risks now driven completely by dermal exposure

Implications for Railroad Sites: Proposed Mixture Approach & New Dermal Slope Factor

- New analytical methods may have to be used to characterize sites
- Sites in progress may need to be *re-characterized*
- Closed sites may need to be re-opened
- Issues
  - EPA has no new analytical method for PAHs
  - Standards are not available for some analytes
  - Current analytical methods result in co-elutions confounding the results

Implications for Railroad Sites: Proposed Mixture Approach & New Dermal Slope Factor (continued)

- More PAHs on EPA's list cause
  - Higher BaP-TE concentrations
  - Higher risk estimates
  - Lower clean-up levels
- Higher Relative Potency Factors and new Dermal Slope Factor cause
  - Higher risk estimates
  - Lower clean-up levels

Available Mitigation Tools

- EPA's default soil dermal absorption factor of 13% for BaP is flawed and overestimates risk
  - Site-specific dermal absorption studies may yield values of 1% or less
- Area background levels of PAHs may be higher than risk-based clean-up levels
  - Challenge is regulatory approval of sampling locations
  - Agencies disallow samples collected near roads, railroad rights-of-way, parking lots, etc.
- Most important – Lobby Science Advisory Board

Reality Check

- New PAH Relative Potency Factors (2010) are not scientifically valid
- New Dermal Slope Factor (DSF) (2014) is scientifically flawed in derivation
- DSF cannot possibly be true
  - Predicts that 10% of all human skin cancer is caused by PAHs in soil & pharmaceuticals
  - With other exposures, predicts >10%
  - Users of coal tar pharmaceuticals do not have increased risk of cancer
  - Human skin xenografts on mice do not get cancer from PAHs
  - Genetic signature of human skin cancer does not match PAH signature in rodent tumors

EPA's Timeline

• EPA PAH Mixtures Policy	Feb 2010
• Industry comments	Apr 2010
• EPA Science Advisory Board Report	Mar 2011
• EPA BaP report	Aug 2013
• Industry Comments	Nov 2013
• IRIS Quarterly Meeting	Dec 2013
• Nomination Request, SAB panel	Jan 2014
• Revised EPA BaP report	Sep 2014
• Comments, potential SAB panel	Oct 2014
• SAB panel meetings	Jan 2015? Feb 2015?

Railroad Community Actions

- 2010: Association of American Railroads (AAR) joins API-led Consortium to fund ARCADIS comments to EPA docket on Mixture Proposal
- 2013: AAR and API Consortium funds ARCADIS comments on BaP Proposal & participation at quarterly IRIS meeting
- 2014: API forming Consortium & considering proposal to inform Science Advisory Board
- 2010/2013 Consortium: American Coke and Coal Chemicals Institute, American Fuels and Petrochemical Manufacturers, American Petroleum Institute, Asphalt Institute, Association of American Railroads, Beazer East, Inc., Pavement Coatings Technology Council

Current Window of Opportunity to Affect Policy

- Focus is now on EPA Science Advisory Board (SAB) BaP Panel, not on EPA
- SAB panel should be a balanced group of 12-15 members from academia, industry, consulting, state governments, etc.
- We expect that SAB will not act until January – February 2015
- There is time to perform new analysis work before comments are due to SAB Panel
- Proposed tasks are currently under consideration by API et al.

Imagine the result

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Coal Tar (CT) Pharmaceutical Studies

- EPA's bibliography totally ignored CT pharm users
- Commenters sent bibliography to EPA
- EPA (2013) cited 3 of 12+ studies and ignored weight of evidence
- EPA did not ask for FDA's opinion during Interagency Commenting
- Most recent study - Roelofzen et al. (2010)
  - 13,200 psoriasis and eczema patients
  - 8,062 received coal tar treatments
  - No increase in risk of: Skin cancer, all cancer, internal cancer, cancer of specific sites

Human Skin Xenograft Studies

- Five studies of human skin grafted to mice demonstrate that human skin behaves differently from mouse
  - Human skin grafts susceptible to UV-induced tumors
  - Human skin grafts not susceptible to PAH-induced tumors
  - Mouse skin surrounding the human grafts develop tumors from PAH
- EPA (2013) ignored human skin xenograft studies arguing that skin grafts don't behave normally (based on 1 paper)
- Ignores 12+ papers that demonstrate the utility of human skin grafts

