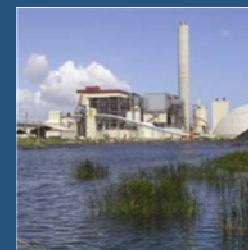
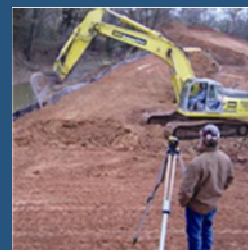


Toxicology & Risk Assessment in the News: Recent EPA Proposals with Broad Implications



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Polycyclic Aromatic Hydrocarbons (PAHs) Proposal

- EPA proposed a new approach for evaluating relative potency factors (RPF) of PAHs

RPF - numerical estimate of the order of magnitude potency of individual PAHs (or scaling) in comparison to an index PAH, benzo(a)pyrene (BaP)

- Literature from the 1950s through 2009 was reviewed
 - List of 74 PAHs
 - Dose-response data for 51 of the 74 PAHs
 - RPFs derived for 27 PAHs identifying 24 as potentially carcinogenic
- Public comment period ended April 2010
- Final assessments projected to be complete Q1 of FY11

Comparison of Current and Draft Proposed Additional RPF PAH values			
Chemical	PAH RPF Current Approach (USEPA, 1993)	Proposed RPF (Average) For Review and Comment	USEPA Method of Analysis Available?
Benzo(a)pyrene	1	1	8270C/ SIM
Anthanthrene		0.4	None
Anthracene		0	8270C/ SIM
Benz(a)anthracene	0.1	0.2	8270C/ SIM
Benz(b,c)aceanthrylene, 11 H-		0.05	None
Benzo(b)fluoranthene	0.1	0.8	8270C/ SIM
Benzo(c)fluorene		20	None
Benz(e)aceanthrylene		0.8	None
Benzo(g,h,i)perylene		0.009	8270C/ SIM

Benz(j)aceanthrylene		60	None
Benzo(j)fluoranthene		0.3	None
Benzo(k)fluoranthene	0.1	0.03	8270C/ SIM
Benz(l)aceanthrylene		5	None
Chrysene	0.001	0.1	8270C/ SIM
Cyclopenta(c,d)pyrene		0.4	None
Cyclopenta(d,e,f)chrysene, 4H-		0.3	None
Dibenzo(a,e)fluoranthene		0.9	None
Dibenz(a,e)pyrene		0.4	None
Dibenzo(a,h)anthracene	1	10	8270C/ SIM
Dibenzo(a,h)pyrene		0.9	None
Dibenzo(a,i)pyrene		0.6	None
Dibenzo(a,l)pyrene		30	None
Fluoranthene		0.08	8270C/ SIM
Indeno(1,2,3-cd)pyrene	0.1	0.07	8270C/ SIM
Naphtho(2,3-e)pyrene		0.3	None
Phenanthrene		0	8270C/ SIM
Pyrene		0	8270C/ SIM

Implications of Changes in PAH RPFs

- Adoption of this extended list of PAHs poses many challenges
 - Relevance: Not been determined
 - Analysis: Not commonly included in analytical programs
 - Reference Standards: Not commercially available for instrument calibration
 - Analytical Technology: Changes required to measure relevant concentrations of analyte 60x BaP potency
 - Risk-Based Corrective Action: Addition of PAHs with potencies 60x BaP will affect ability to meet risk-based screening levels
 - Current EPA RSLs
 - » 0.015 mg/kg for residential soil
 - » 0.21 mg/kg for industrial soil
 - Background studies of urban soils estimate a UCL of 3 mg/kg (BaP TEQ)

Arsenic Proposal

- EPA is proposing a new oral cancer slope factor (CSF) for arsenic that is 17-fold higher than the current value
 - Assessment of non-cancer health effects to be released later
 - No current plans to update inhalation toxicity assessment
- Same Taiwanese study used to develop the original CSF
 - Difference is that tumors in different sites, specifically lung and bladder were used to estimate potency rather than skin
 - Continued debate over whether there is a threshold for arsenic carcinogenicity
- Public comment period ended March 2010
- Final assessment projected to be complete Q4 FY10

Comparison of Current and New Proposed Arsenic Values

Dose-Response Value for Arsenic	Current IRIS	Draft Proposed (USEPA, 2010)
Oral Cancer Slope Factor (mg/kg-day) ⁻¹	1.5	25.7

USEPA Regional Screening Levels for Arsenic	Current (USEPA, 2009)	Revised Based on Draft Proposed CSFo (USEPA, 2010)
Residential Soil (mg/kg)	0.39	0.023
Industrial Soil (mg/kg)	1.6	0.093
Residential Tapwater (ug/L)	0.045	0.0026

Implications of Changes in Arsenic Oral Cancer Slope Factor

- Risk-based screening levels in soil and water would decrease by a factor of 17
- Well below typical background levels across the U.S.
 - Average between 5 – 7 mg/kg
 - Can range up to more than 90 mg/kg
- Understanding site-specific background and bioavailability will be increasingly important to developing sound remedial solutions at arsenic sites

Dioxin Proposal (Preliminary Evaluation)

- EPA is proposing a new oral cancer slope factor (CSF) for tetrachlorodibenzo(p)dioxin (TCDD) that is \approx 8-fold higher than the current value
- Public comments due 3rd week in August
- EPA's Science Advisory Board (SAB) will convene an expert panel to review this draft report
 - First public meeting expected to be July 13-15, 2010

Comparison of Current and New Proposed Dioxin Values

Dose-Response Value for Dioxin	Current EPA RSL (USEPA, 2010a)	Draft Proposed (USEPA, 2010b)
Oral Cancer Slope Factor (mg/kg-day) ⁻¹	1.30E+05	1.00E+06

US EPA Regional Screening Levels for Arsenic	Current	Revised Based on Draft Proposed CSFo
Residential Soil (mg/kg)	4.50E-06	5.63E-07
Industrial Soil (mg/kg)	1.80E-05	2.25E-06
Residential Tap Water (ug/L)	5.20E-07	6.50E-08

Implications of Changes in Dioxin Oral Cancer Slope Factor

- Requires more detailed evaluation, but
- Risk-based screening levels in soil and water would decrease by a factor of 8

Coal Combustion Products Proposals

- Two co-proposals to address potential risks from the disposal of coal combustion products (CCP) generated from burning coal by electric utilities for public comment:
 - Regulation of CCP as hazardous waste under RCRA subtitle C
 - Reverse the Bevill exemption for CCP and define these residuals as a special waste
 - » Identification and Listing of Hazardous Waste, Subpart F – Special Wastes Subject to Subtitle C Regulations when CCP are destined for disposal in landfills or surface impoundments
 - » Bevill exemption would be maintained for CCP destined for beneficial reuse
 - Regulation of CCP as a solid waste under RCRA subtitle D
 - EPA would leave the Bevill regulatory determinations in place and regulate disposal of CCP
 - Does not address the placement of CCP in mine fills
 - Regulatory review completed 4 May 2010
 - Projected date of publication of proposed rule is June 2010

Coal Combustion Products Proposals (Cont)

- Under both proposals, EPA is proposing to establish:
 - Dam safety requirements to address the structural integrity of surface impoundments to prevent catastrophic releases
 - Within 1 year of the effective date of the regulations, all surface impoundments are required to be in compliance with groundwater monitoring requirements to continue to accept waste
 - All impoundments not in compliance with the liner requirements (subtitle D) or the land disposal restrictions (subtitle C) are required to cease accepting waste 5 years after the effective date of the regulations and close within 2 years after last placement of waste in the existing CCP impoundment
 - No liner requirements for existing landfills, but groundwater monitoring would be required
 - New landfills or expansions would require composite liner systems, leachate collection systems, and groundwater monitoring networks

Implications of CCP Proposals

- Subtitle C (Hazardous Waste)
 - CCP would be regulated from the point of generation to the point of final disposition
 - Coal power industry subjected to all of the hazardous waste generator, transporter, and treatment, storage, and disposal facility requirements of RCRA subtitle C
 - Cost to manage/dispose of CCP will increase substantially
 - EPA would have enforcement authority
- Subtitle D (Solid Waste)
 - Establish national criteria to ensure the safe disposal of CCP
 - States or citizens enforce the requirements under RCRA citizen suit authority or under independent state enforcement authority
 - Cost to manage/dispose of CCP will increase
- Beneficial Reuse??

Challenges of Protecting Human Health and the Environment

- Knowledge is often inadequate to yield high confidence in the consequences of regulatory decisions
 - Environment cannot be managed by making uncertainty go away, or by delaying all decisions until high confidence is obtained
 - Level of protection taken against a risk should be informed by weighing its likelihood and severity against the cost of action to avoid it
- Increasing trend within the current administration toward more stringent environmental regulation
 - New scientific evidence may support greater stringency or public pressure may encourage government action
 - When science is used to make policy choices, political debate is sometimes pushed back into the processes of developing the scientific advice