

NAPHTHALENE ASSAYS & IMPLICATIONS

The Model & Meaning Of Naphthalene's Reassessment As A Potent Carcinogen

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**This presentation presents the observations of the author and does not necessarily reflect the views
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OUTLINE

- What Started All The Fuss?
- What is naphthalene?
- Is Its Cancer Designation Significant?

IMPACTS! IMPACTS!

- What's the “state of the science”?
- Coming to an informed predicate for better risk assessment & risk management

WHAT STARTED ALL THE FUSS?

New Data - EPA Targets Naphthalene

- Two Important NTP Bioassays Started All The Fuss!
 - NTP 2-yr inhalation bioassays - cancer in rodents!
 - Mouse (1992) - cytotoxicity w lung neoplasia
 - Rat (2000) - cytotoxicity w nasal neoplasia (rare!)
 - “reasonably anticipated to be a human carcinogen”
- EPA-IRIS fast-tracked naphthalene’s re-examination
 - Risk assessment model predicts **2 ppt** as E-6 *de minimus* risk!
 - DOD & industry each question review’s process and substance
 - Other agencies engage
 - Issues reach OMB - DOD explains its concerns
 - Document release postponed
- “Inside EPA” exposé - series of 5 articles (Jul/Aug05)

WHAT IS NAPHTHALENE?

Moth Balls

- Profile

White solid & polyaromatic hydrocarbon of modest volatility, sublimes at room temperature - a natural constituent of fuels, lubes, asphalts.

- Industrial production & use

Petroleum cracking, coal tar distillation, feedstock for plasticizers, azo-dyes, carbaryl, creosote constituent, octane improver

- Environmental Sources

Fossil fuel exhaust, cigarette & wood smoke, asphalts & sealants, pesticide, some fruits/vegetables, shellfish, BBQ meats, breast milk

- Ingestion & metabolism & effects

- Absorbed through all routes

- Metabolized via cytochrome P450 - ~30 metabolites identified

- Toxicity: hemolytic anemia, nausea/vomiting, CNS, kidney, liver effects, coma

WHAT IS NAPHTHALENE?

Occupational & Regulatory Guidelines*

* [Non-cancer reassessment also under way]

ACGIH	10 ppm (STEL=15)
NIOSH	10 ppm (STEL=15; IDLH=250)
OSHA	10 ppm
AIHA (WEEL & ERPG)	n/a
NAC-AEGL (AEGLs)	n/a
EU (SCOEL)	“not feasible” (NTP & other bioassays)

EPA (drinking water)	0.1 – 0.7	mg/L	
EPA (non-cancer)	0.02	mg/kg/D	(RfD – lifetime)
	0.003	mg/m ³	(RfC – lifetime)
EPA (cancer – inh)	0.0000107	mg/m³	(2 ppt)**

**de minimus

IS THE CANCER DESIGNATION SIGNIFICANT?

Impact: It Might Brand Our Fuels As Carcinogens!

- CHANGE TO JP-8 FROM JP-4 (1996)
 - Safety & logistics
- THE UNIVERSAL FUEL
 - Airplanes, helicopters, tanks, trucks, space heaters, stoves, generators, dust suppression ... coolant ...
 - Kerosene + additives = commercial Jet-A & JP-8
- ANNUAL CONSUMPTION
 - USAF -> DoD -> Civ Av -> USA -> World Wide
 - 2.5 -> 5.5 -> 25 -> 30 -> 60 BILLIONS OF GALLONS
- **29CFR 1910.1000: If carcinogen content \geq 0.1%, the mixture considered carcinogenic**
 - Crude oil \geq 0.1%
 - Jet fuel 1-3%
 - Gasoline 0-5%
 - Additives & blends \leq 10%

IS THE CANCER DESIGNATION SIGNIFICANT?

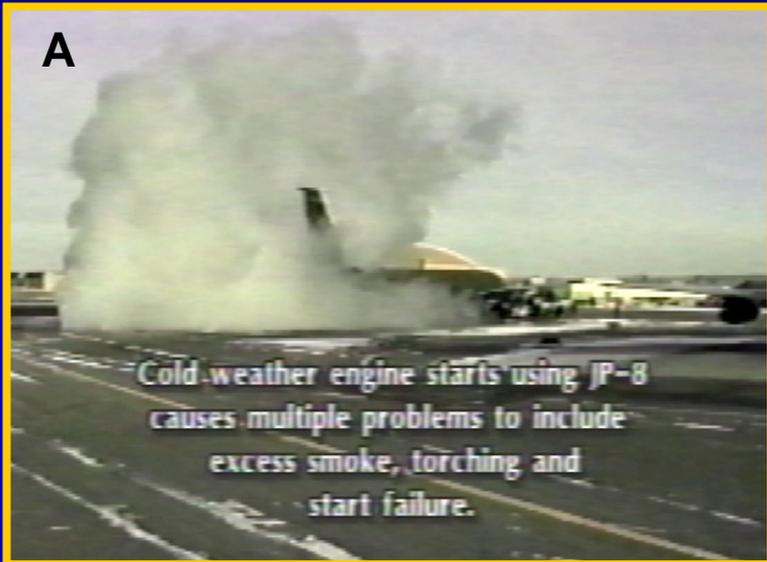
Impact: Economics of Removal

- Price impact to remove it from jet fuel?
 - Take benzene out of gasoline: 2-5 ¢/gal [per API]
 - Take naphthalene out of jet fuel: 15-50% increase [per API]

• \$1.80/gal [base price]	<u>27 ¢/gal</u>	<u>90 ¢/gal</u>
• AF uses ~ 2.5 B gals →	\$ 675 M	\$ 2250 M
• DOD uses ~ 5.5 B gals →	\$ 1485 M	\$ 4950 M
• USA uses ~30 B gals →	\$ 8100 M	\$ 27000 M
 - Any regulatory requirement would seem to meet OMB criteria for “highly significant” impact - triggering review

IS THE CANCER DESIGNATION SIGNIFICANT?

IMPACT: ESOH



- A. KC-135 Cold Weather Start**
- B. Aircraft Service Operations – confined space entry & exposure**
- C. Fuel Bladder Failure**



IS THE CANCER DESIGNATION SIGNIFICANT?

Impact: ESOH Environmental Monitoring

- Where does the AF find naphthalene?
 - Search AFCEE's ERPIMS database:
 - Most AF bases detect naphthalene somewhere
 - Percent of samples w detects:
 - groundwater, 63%; soil, 33%;
 - Sediment, 2%; surface water, 2%
 - Common sites – underground storage tanks & pipelines, landfills, spills
- Can we analyze for it?
 - Most bases exceed proposed criteria for soil & water. Air?
 - Current analytical methods probably OK for soil: **820 ug/kg**
 - Current methods not sensitive enough for water: **0.04 ug/L**
 - Current methods not sensitive enough for air: **0.01 ug/m³**

IS THE CANCER DESIGNATION SIGNIFICANT?

IMPACT: AF Stewardship

- Safety & Operational Health Issues

Impacts on storage, transport, handling, use

Base-level occupational health programs affected
personnel training, engineering controls, PPE,
monitoring air levels, medical surveillance,
establishment regulated/restricted areas

Legacy issues from past exposures...

- Environmental Restoration

Cleanup of 1000 sites w fuel at issue - cancer risk not addressed
~50% AF sites w fuel contamination - common analyte at AF sites

Records Of Decision may reopen for review

- Overall cost impact unknown – assumed to be large

IS THE CANCER DESIGNATION SIGNIFICANT?

Impact: National Emissions Compliance

- EPA's *de minimus* risk estimate 2 ppt
- Naphthalene in Cal So. Coast LA air shed ~120 ppt
 - Fresno, CA – inside homes & schools 89 ppt
 - outside 41 ppt
- Airborne concentrations for most urban areas ~50-100 ppt
- Canada – overall mean for urban & rural areas 84 ppt
- European Union
 - Industrial median 822 ppt
 - Creosote industry > 37,600 ppt
 - Mothball manufacturing > 620,400 ppt
- Can any major metropolitan area meet this standard ?

STATE OF THE SCIENCE

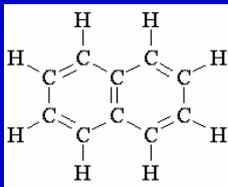
Uncertainties Remain

- EPA conclusion per NTP bioassays
 - “reasonably anticipated to be a human carcinogen”
 - However, new draft assessment forthcoming – content unknown
- Naphthalene “State of the Science” Symposium
 - An accounting of what’s known/unknown about the scientific issues attending naphthalene’s CA potential to humans at *environmentally relevant doses*.
 - Goal - better informed risk assessment, management and policy.
- DOD response
 - “Issues, identified data gaps and possible studies to address areas of uncertainty associated with human cancer risks from the inhalation of naphthalene”
- Industry response
 - Executing \$\$M multi-faceted research plan to address the key gaps that remain in naphthalene’s data base

STATE OF THE SCIENCE INDUSTRY PERSPECTIVE

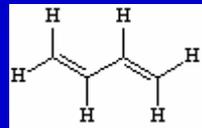
- Based on EPA's new estimates of carcinogenic risk from inhalation exposure
- **RELATIVE RISK: Air Concentrations At The One In A Million Risk Level**

Parts per Trillion



2 ppt

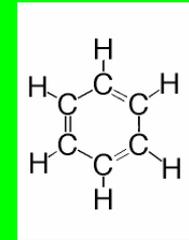
Naphthalene
2004 Draft IRIS



14 ppt

Butadiene
2002 IRIS

41 ppt



Benzene
1998 IRIS

STATE OF THE SCIENCE

Epidemiologic Perspective - Where are the bodies?

- Yamane & D'Mello (AFIOH): Jet fuel exposure vs invasive cancer in AF population
 - *Preliminary assessment*: exploit existing dataset of cancer vs occupation
 - Jet fuel exposure **not** significantly associated w invasive cancer
- Dr. B. Magee (AMEC): Incidence of nasal cancer in the American population
 - EPA's potency factor for naphthalene in rats extrapolated to man
 - Predict ~2.5M lifetime cancers in man?
 - Annualized rate ~36,000/yr
 - Actual rate ~2,000/yr
 - Nasal cavity & paranasal sinus cancer – rare in man
- Is there a disconnect between animal studies and human experience?

IS NAPHTHALENE IMPORTANT?

To DOD and to You!

- More informed data set key to a more informed evaluation – predicate for...
- **Risk Assessment – getting it right**
 - High stakes & limited data
 - Context - animal studies & human experience
- **Risk Management – doing it right**
 - Ubiquitous chemical in our every day environment
 - ESOH impacts diverse & wide spread – legacy issues
 - people; cleanup & restoration; current & past exposures
 - Balance responsibility & liability & cost

Questions?