Risk and Technology Review (RTR)

Risk Assessment Methodologies

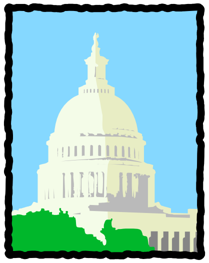
EPA Science Advisory Board

30 June 2009

This Talk

- Introduction and regulatory context – Dave Guinnup
- Review materials – Roy Smith
  - Overview of the charge
  - A quick tour of the main report and appendices
    - In paradigm order rather than linear order
    - Charge questions appear in context rather than in numerical order

Congressional Mandate



- Residual Risk CAA 112(f)
  - Assess risks that remain after implementation of the technology-based (MACT) standards within 8 years of promulgation
  - Set additional standards if MACT does not protect public health with an "ample margin of safety" based on benzene NESHAP policy
  - Set additional standards if necessary to prevent adverse environmental effects
- Technology Review CAA 112(d)(6)
  - Review standards every 8 years, taking into account developments in practices, processes, and control technologies
  - Revise as necessary
- Since the first technology review coincides with residual risk review, we combine them into one "RTR" rulemaking

RTR Process

- In December 2006, we consulted with SAB on a proposed RTR Process
- Process proceeds with 2 public comment periods
  - ANPRM → NPRM → FRM
  - Early risk assessment results are shared along with inventory to focus comments on risk drivers
  - Comments are evaluated, incorporated, risk assessments repeated with improved inputs
- Generally accomplished in bundles of source categories
- Consultation generally supported approach, suggested various ways to improve – many of these suggestions have been incorporated

Status of Regulatory Program

- EPA has issued MACT standards for 174 categories
- We have finalized residual risk standards for 16 source categories, proposed 10 more, and have received comments from an advance notice of proposed rulemaking (ANPRM) on an additional 12 categories
- 17 additional categories are to be included in an ANPRM slated for this summer

Residual Risk Decision Framework

- Goals
  - Step 1: Limit cancer MIR to no higher than about 100 in a million (MIR = cancer risk for person exposed to maximum HAP concentration(s) near a facility for 70 years)
  - Step 2: Protect the greatest number of persons possible to approximately 1 in a million lifetime cancer risk or lower
- Step 1: determine “acceptable risk” considering all health info, including uncertainty (maximum MIR ordinarily about 100 in a million)
  - Max MIR may be more or less, depending on cancer incidence, persons within various risk ranges, magnitude of noncancer hazard, uncertainties, etc.
  - Cancer incidence should not be limited to, e.g., 1 case/year, but rather weighed along with other risk info
- Step 2: set standard to provide “ample margin of safety”, considering health info and other relevant factors (costs, feasibility of control, etc.)
  - Potential for adverse environmental effects may be weighed here

Scope of Assessments

- HAP emissions covered by source category definition only
  - May be total facility, may not
  - For example, Petroleum refinery MACT 1 source category covers some, but not all refinery emissions – does not include combustion processes
- Does not include criteria pollutants
- Includes acute & chronic impacts, cancer & noncancer, human health and eco endpoints, routine and SSM releases, but not catastrophic accidental releases
- Illustrated here by 2 case studies, each at a different stage of development

Review Materials – Charge

- Introductory information
  - Reiterates regulatory background and purpose of RTR
  - Summarizes previous peer reviews
  - Provides goals for this review
- 11 Questions in 7 subject areas
  - Most begin with a general question (e.g., is this credible, are the uncertainties clear) followed by more specific questions
  - The specific questions are suggestions to focus your discussion
  - Don't feel pressured to answer them all
  - Don't feel constrained from raising other points

Review Materials – Overview

- The main report – structure
  - Section I: Introduction
    - Re-reiteration of purpose of assessments
    - Discussion of what risk managers need from assessment (and what they receive)
  - Sections II and III: Case studies
    - Petroleum refineries
    - Portland cement manufacturing
  - Section IV: Supplemental analyses of uncertainty
  - Plus two kinds of appendices...

Review Materials – Overview (cont'd)

- Appendices showing details of analyses presented in main report
  - Inhalation health assessment
    - D and H: Detailed model inputs for case studies
    - E: Refinement of acute assessments
    - F: Development of dioxin emissions estimates
  - Multipathway health
    - C: Screening method
    - I: Refined case study
  - Ecological risk
    - J: Case study for indirect effects
    - K: Case study for direct effects

Review Materials – Overview (cont'd)

- Appendices showing uncertainty analyses
  - Emissions inventory
    - A: Refinery risks before and after public comment
    - B: Short- vs. long-term emissions at Texas facilities
    - F: Dioxins emitted from Portland cement facilities
    - G: Radionuclides emitted from Portland cement facilities
    - L: Modeled and monitored benzene levels near two refineries
    - P: RTR inventory vs. modeled facility data for refineries
  - Risk estimates
    - M: Comparison of block centroids vs. nearest residence
    - N: Effect of long-term mobility on individual risk estimates
    - O: Potential importance of unassessed HAPs

Report – Introduction

- Section 1.2.1 – Basic question posed by risk managers: Do we need additional emission standards?
- Sub-questions:
  - What is the MIR for cancer?
  - What are the highest hazard indices, and for what effects?
  - Has "ample margin of safety" been achieved?
  - Is there potential for adverse environmental effects?

Information provided by RTR assessments

- MIR for cancer
- Annualized and lifetime cancer incidence
- Distribution of cancer risk across population
- Maximum chronic HQs
- Maximum chronic TOSHIs and target organs
- Maximum acute HQs
- Distribution of TOSHIs across population
- Which HAPs drive risk
- Ecological benchmark exposures and receptors at risk

Information provided by RTR assessments (cont'd)

- Charge Q7: Do these characterizations objectively and completely incorporate the goals and principles of EPA's *Risk Characterization Handbook* to the extent scientifically feasible?
  - In particular do they provide a complete and transparent discussion of uncertainties and limitations?
  - If not, how can the risk characterizations be improved?
  - Can you suggest where we might focus any additional efforts and resources in order to have the biggest impact on refining risk characterizations for these RTR assessments, ultimately leading to better regulatory decision-making?

Case Studies – Chronic Inhalation Assessment Methods

- Developed and used for previous regulatory assessments; many elements already reviewed
- Emissions inventory data
  - Reviewed and revised internally
  - Reviewed by public and revised again
  - Special emissions estimates for Portland cement facilities
    - Dioxin (Appendix F)
    - Radionuclides (Appendix G)

Case Studies – Chronic Inhalation Assessment Methods (cont'd)

- Charge Q1: Is this approach [for radionuclides] rigorous enough to consider placing it in the RTR assessment, which has regulatory implications?
  - If not, given the lack of reliable emissions data for radionuclides, how can we improve the approach?
  - If the quality of emissions data remains an irreducible stumbling block, can you suggest ways to obtain better emissions data?
- Charge Q1: Does the approach used to estimate dioxin and furan emissions from Portland cement facilities represent the best available methodology in support of a risk analysis?
  - Can you suggest improvements?

Case Studies – Chronic Inhalation Assessment Methods (cont'd)

- Dispersion and exposure modeling using HEM3
  - Dispersion by AERMOD
  - Exposure surrogate – modeled ambient concentration at block centroid
  - Short- and long-term behaviors not modeled
  - Detailed inputs and defaults in report & appendices
- Dose-response information – prioritized
  - Cancer: IRIS, Cal EPA
  - Noncancer: IRIS, ATSDR, Cal EPA
- Cancer risk and noncancer HQ calculated as usual, for each Census block
  - Cancer risk summed across HAPs
  - Chronic noncancer risk summed across HAPs by target organ

Case Studies – Chronic Inhalation Assessment Methods (cont'd)

- Charge Q3: Is our process of selecting and prioritizing chronic dose-response values appropriate for RTR risk assessments?
  - Should we consider additional sources, or a different prioritization process?
- Charge Q4: Does our process of estimating inhalation exposures adequately support regulatory [i.e., RTR] rulemaking?
  - Is our rationale for omitting daily behavior convincing, or does the omission compromise the value of our assessments?
  - Should this, or some other, adjustment for long-term migration be incorporated into our risk assessments?

Case Studies – Acute Inhalation Assessment Methods

- Short-term emissions unavailable, so default assumptions used for acute screening:
  - Peak 1-h rate equals 10X average rate
  - Peak 1-h emissions occur simultaneously at all emission points
  - Offsite location with highest modeled 1-h concentration chosen for exposure point (i.e., assumes simultaneous 10X emissions and worst-case meteorology)
  - Receptor is present at this point for 1 hr
  - Where acute risks do not screen out, these inputs are refined as data permit

Case Studies – Acute Inhalation Assessment Methods (cont'd)

- Dose-response information – <u>not</u> prioritized
  - Emergency guidelines: AEGLs, ERPGs
  - No-effect levels: Cal EPA RELs
- HQs calculated for each HAP and each benchmark
  - HQs are not combined across HAPs
- Where HQ>1
  - Examine maps and aerial photos of each facility, refine exposure points
  - Refinement process is described in detail in Appendix E

Case Studies – Acute Inhalation Assessment Methods

- Charge Q3: Given the gaps and inconsistencies among available acute benchmarks, do the case studies characterize acute risks adequately?
  - Should we include ATSDR MRLs in our assessments, and if so, how can we solve the temporal mismatch?
  - Is the use of emergency guidelines in our assessments adequately described and interpreted?
  - Are there other acute health metrics EPA should consider using for these assessments?
  - Do you have suggestions for improvements in any of these areas?

Case Studies – Acute Inhalation Assessment Methods

- Charge Q5: Does the 10X acute screening assumption for petroleum refineries appear to be appropriately protective?
  - If not, is it under- or over-protective?
  - Given that this analysis applies only to sources in the Houston area, can we apply the 10X assumption to HAPs in other geographic areas, for other source categories, and for other HAPs, or should we consider some other approach for some other HAPs, *e.g.,* metals?
  - Is there some other way we might address high emission events such as startup or shutdown of processes?
  - Are the refinements to the acute screening assessment objectively employed and scientifically defensible?
  - Should we sum acute hazard quotients by target organ in the same way we do for chronic hazard quotients, *i.e.,* a target organ specific hazard index (TOSHI) approach, or are our reasons for not doing so adequate?

Case Studies – Multipathway Screening

- New methodology intended to reduce unneeded refined multipathway assessments
- Goal – Quickly & efficiently determine if multipathway risks for 14 PB-HAPs are below levels of concern
  - Development of dioxin inventory described in Appendix C
  - Develop a “reasonable maximum” exposure scenario
  - Run model iteratively to back-calculate emission rates for 1e-6 risk or HQ=1.
- Used in both case studies for Cd, Hg, dioxin, and POM
  - Detailed inputs, defaults, and methods described in Appendix C

Case Studies – Multipathway Screening (cont'd)

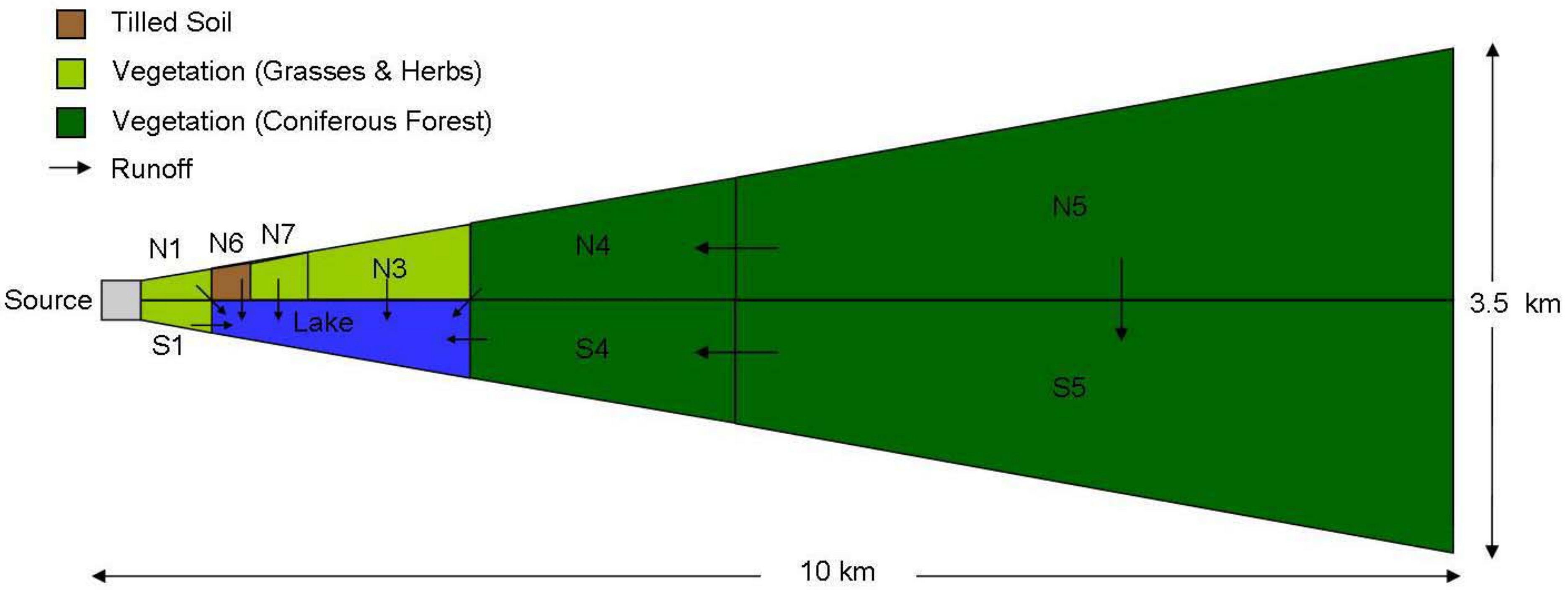


*Figure not drawn to scale.

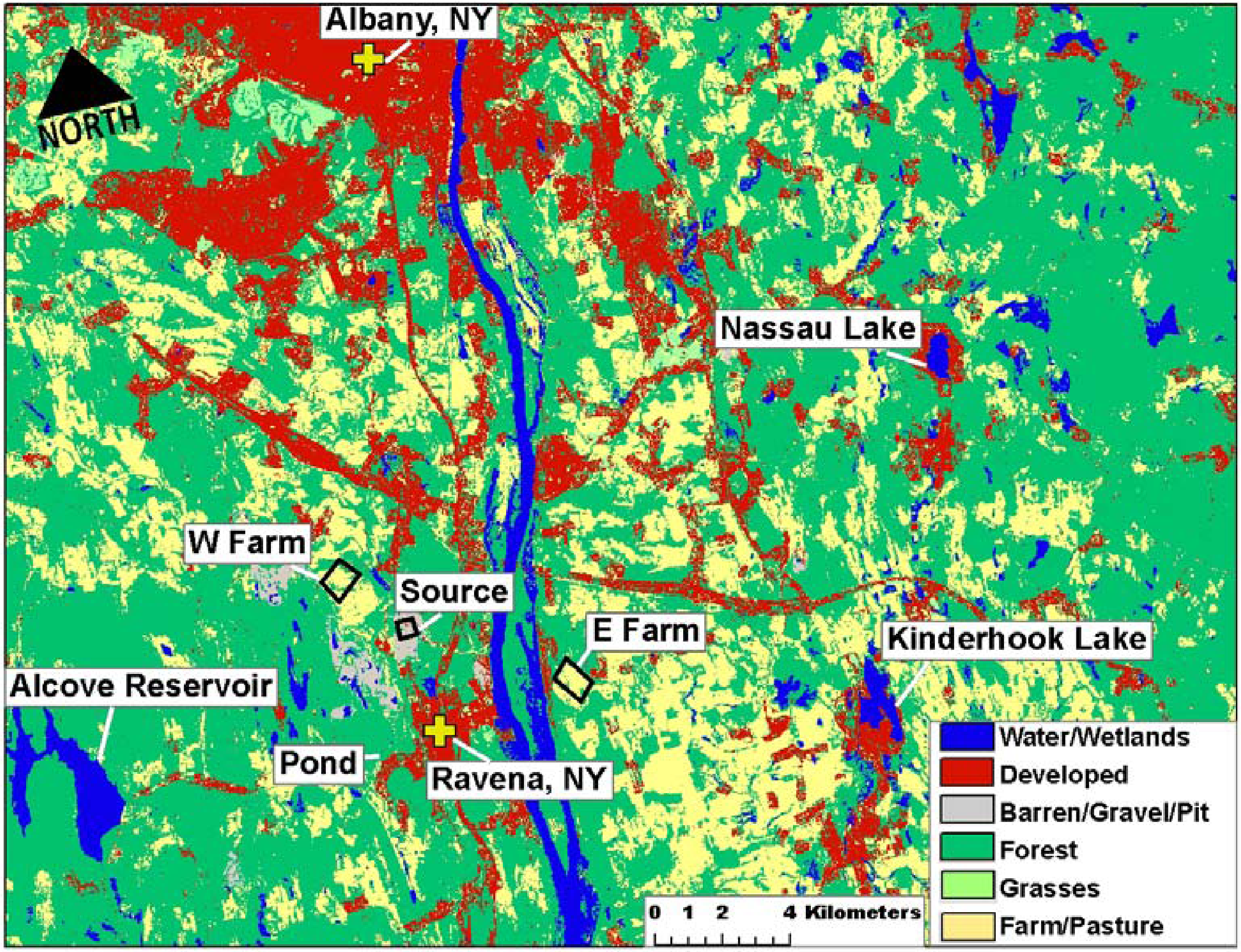
Case Studies – Multipathway Screening (cont'd)

- Charge Q4: Is our use of the TRIM model to develop *de minimis* emission rates appropriate as a screening tool?
  - Are the application of the model and the assumptions used clearly articulated?

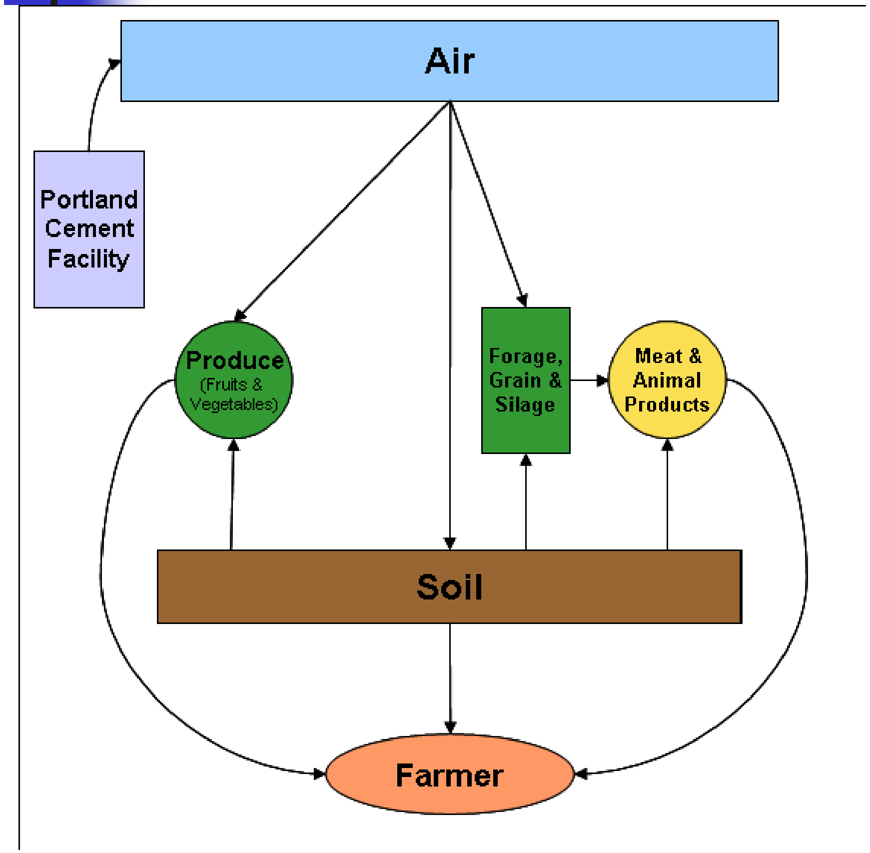
Portland Cement – Refined Multipathway Assessment

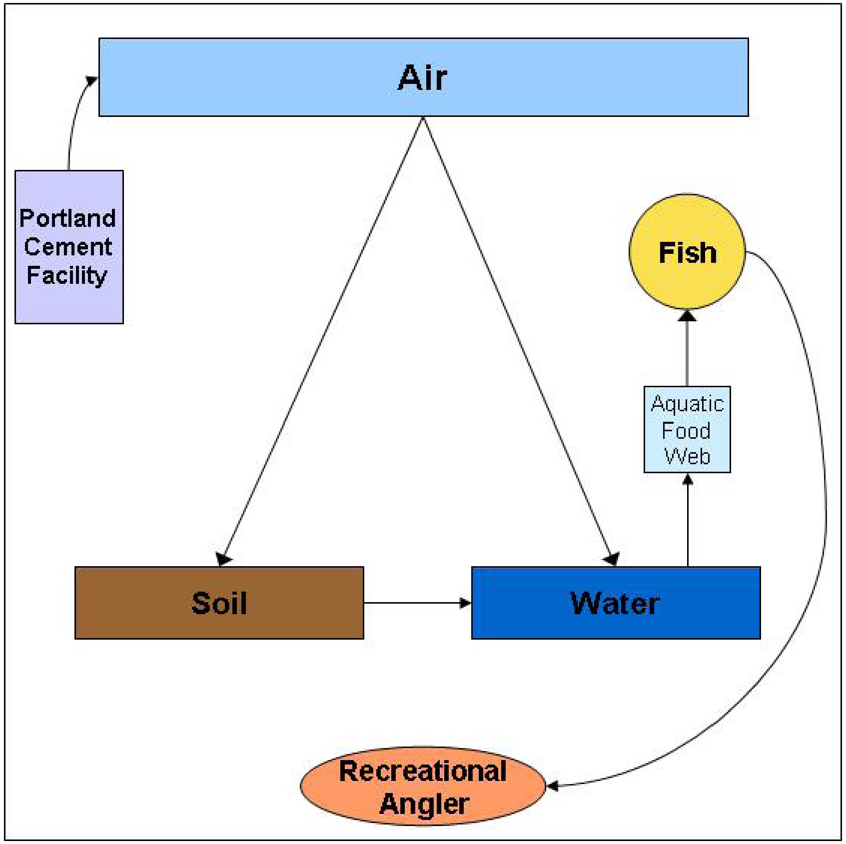
- All facilities failed screen for dioxins; Hg also included in refined case study of a single facility
- Dispersion model results entered into EPA's TRIM.fate model, estimating levels in:
  - Soil
  - Surface water
  - Sediment
  - Fish
  - Farm products
- Subsistence farming and recreational fishing scenarios applied to these exposure concentrations
- Details provided in Appendix I.

Portland Cement – Refined Multi-pathway Assessment (cont'd)



Portland Cement – Refined Multi-pathway Assessment (cont'd)





Portland Cement – Refined Multi-pathway Assessment (cont'd)

- Charge Q4: Are the methodologies used in the refined multipathway assessment consistent with the best available science regarding multi-pathway pollutant transport and human exposures?
  - Are the application of the model and the assumptions used clearly articulated?
  - Are the resultant estimates of media concentrations and exposures clearly presented, explained, and interpreted?
  - Given the large uncertainties surrounding the radionuclide inhalation assessment, are we justified in omitting radionuclides from the multipathway assessment?

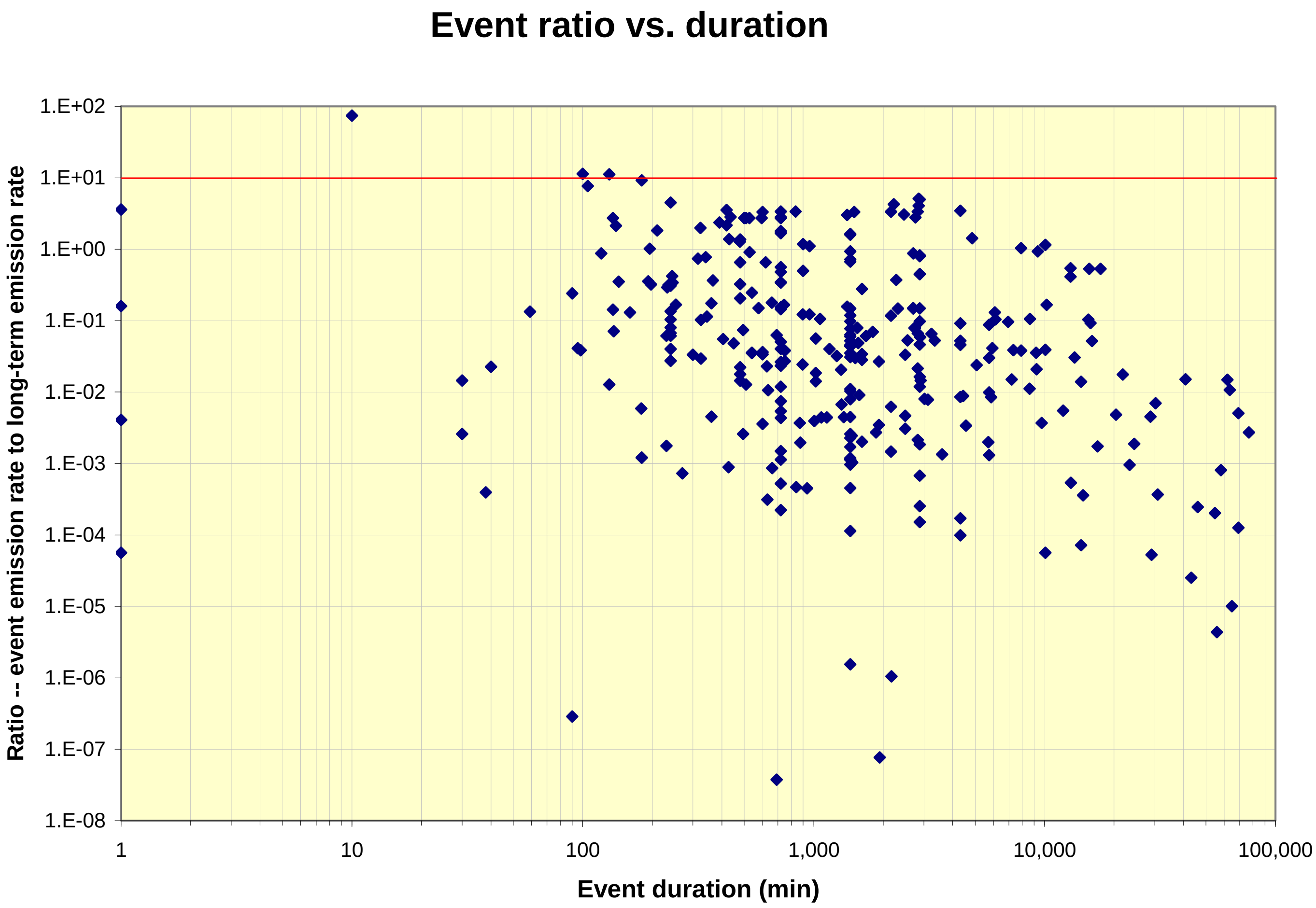
Portland Cement – Refined Ecological Assessment

- Based on same emissions data, and fate/transport analysis as multipathway assessment
  - Hg and dioxins also chosen for ecological risk
  - Three bird and one mammal species as sensitive receptors
  - Evaluated food web exposures to each species
- Additional analysis of potential foliar damage by direct contact with HCl vapor
- Details of both analyses in Appendix J

Portland Cement – Refined Ecological Assessment (cont'd)

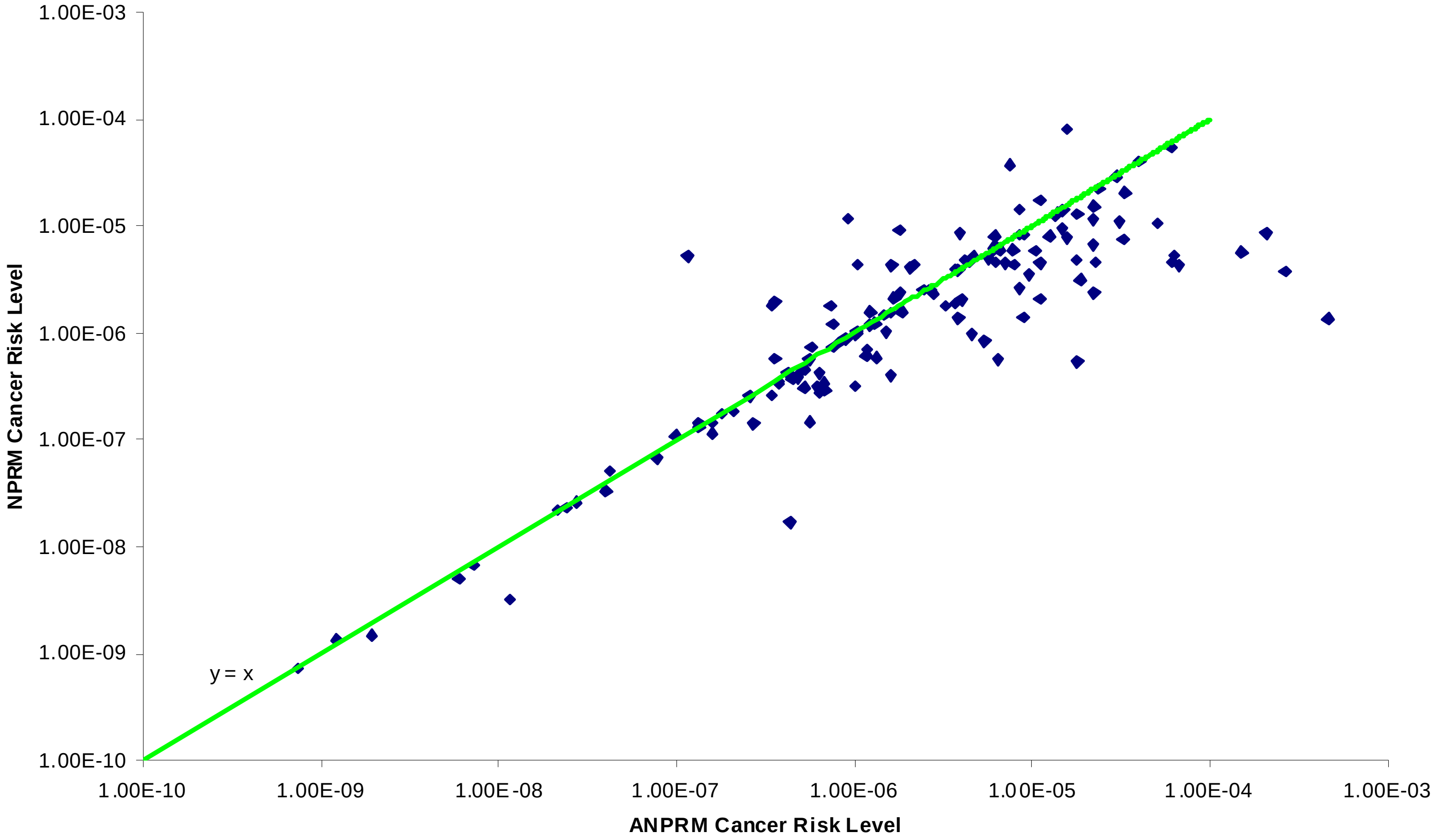
- Charge Q6: Is the ecological assessment case study scientifically defensible?
  - Does it conform to EPA risk assessment guidance (*e.g.*, *Guidelines for Ecological Risk Assessment*, *Risk Characterization Handbook, etc.*)?
  - If not, how can we improve it?
  - Are the elements of the ranking scheme adequate to identify the facilities most likely to be of concern?
  - Are there better data sources or approaches for drawing conclusions for specific locations?
  - With regard to investigating the potential for direct ecological effects at air concentrations below human health thresholds from other sources or source categories, what suggestions can be made for prioritizing additional HAPs for literature searches similar to that done for hydrogen chloride in Appendix K?

Supplemental Uncertainty Analyses Appendix B: Short-term Emission Rates



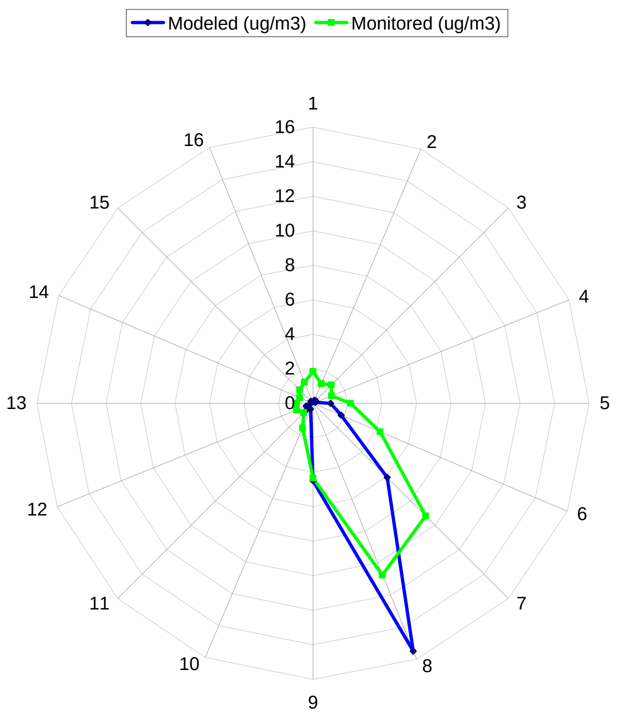
Supplemental Uncertainty Analyses Appendix A: Inventory Quality

Figure 5. NPRM Cancer Risk vs. ANPRM Cancer Risk for Petroleum Refinery Data Sets

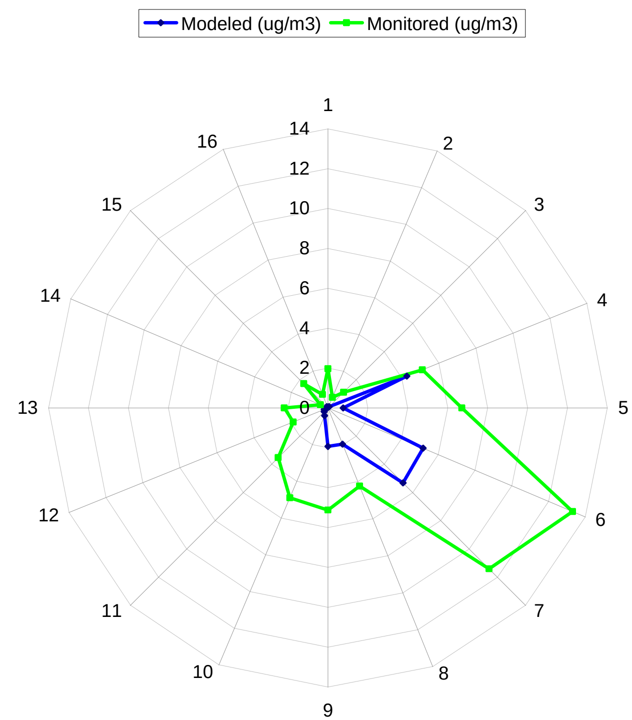


Supplemental Uncertainty Analyses Appendix L: Inventory Quality

BP Monitor, 2004:
Mean Modeled and Monitored Benzene Concentrations by Wind Sector



Marathon Monitor, 2006:
Mean Modeled and Monitored Benzene Concentrations by Wind Sector



Supplemental Uncertainty Analyses Appendix P: Inventory Quality

Table 3. Summary of Risk Estimates Projected from the RTR and REM Analyses

Parameter	REM	RTR
Number of facilities modeled	151	156
Annual HAP emissions (tons/yr)	17,800	6,820
Highest Maximum Individual Lifetime Cancer Risk (MIR, in 1 million) from any one Refinery	20 to 30 (benzene, naphthalene, POM)	30 (naphthalene, POM)
No. Facilities with MIR ≥ 100 in 1 million	0	0
No. Facilities with MIR ≥ 10 in 1 million	41	5
No. Facilities with MIR ≥ 1 in 1 million	135	77
Estimated Cancer Incidence (excess cancer cases per year)	0.1 to 0.2	0.03 to 0.05
Contribution of HAP to Cancer Incidence[A]		
benzene	63%	48%
naphthalene	17%	21%
1,3-butadiene	11%	5%
POM[B]	6%	15%

Supplemental Uncertainty Analyses: Inventory Quality

- Charge Q1: Are the analyses performed in a scientifically credible manner and are the uncertainties and limitations adequately described?
  - Do these comparisons provide useful information about the quality of the emissions data, and ultimately the risk estimates?
  - Does the alternative viewpoint provided in as Attachment L-1 to Appendix L provide a better approach for analyzing and interpreting the monitoring data?
  - Can you suggest improvements to these analyses, or others that might be more useful?
  - Should we use these results to revise our risk assessment for petroleum refineries?
  - Given that we have relatively high confidence about benzene emissions from refineries, can you suggest ways that we can develop similar analyses for other HAPs and source categories?

Supplemental Uncertainty Analyses: Sensitivity of Dispersion Model Inputs

- Time scale – effect of basing risks on a single year of meteorological data (section 4.4)
- Location of meteorological stations (section 4.5)
- Omitting atmospheric chemistry and deposition from dispersion modeling (sections 4.6 and 4.7)
- Receptor location – effect of using census block centroids as exposure points (Appendix M)

Supplemental Uncertainty Analyses

- Charge Q2: Do these analyses adequately support the practices of (1) using a single year of meteorological data, (2) using facility-supplied meteorological data, when available, (3) omitting atmospheric chemistry from modeling, (4) omitting deposition from modeling, and (5) using block centroids as surrogate exposure locations for these case studies?
  - If so, can any or all of the analyses be applied to other source categories?
  - If not, can you suggest ways we might improve them?

Supplemental Uncertainty Analyses Appendix N: Receptor Migration

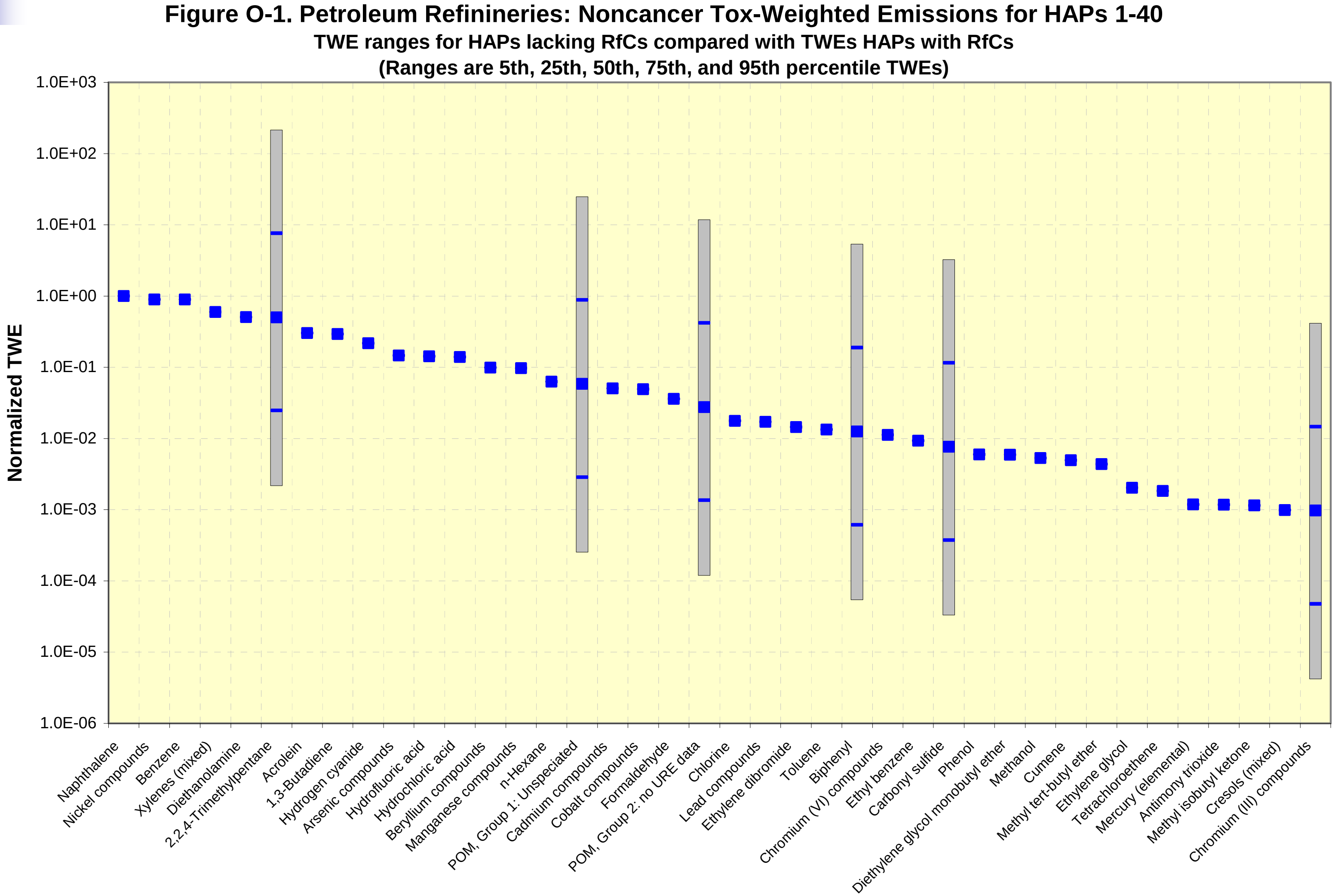
- Modeled effect of relocation and emigration behavior on individual cancer risk estimates for both case studies
  - Individual risk estimates decline
  - Size of exposed population increases
  - Cancer incidence remains the same

Cancer Risk	Portland Cement		Petroleum Refineries	
	Unadjusted	Adjusted	Unadjusted	Adjusted
> 1e-4	0	0	0	0
> 1e-5	125	43	4,378	2,556
> 1e-6	5,066	2,955	430,800	292,003

Supplemental Uncertainty Analyses Appendix N: Receptor Migration

- Charge Q4: Should this, or some other, adjustment for long-term migration be incorporated into our risk assessments?

Supplemental Uncertainty Analyses Appendix O: Unassessed HAPs



Supplemental Uncertainty Analyses Appendix O: Unassessed HAPs

- Charge Q3: Can the analysis of unassessed HAPs be improved by developing prior assumptions regarding the toxicity of these HAPs, and if so, how should this be done?
  - Are there other ways we can improve it?
  - Is this approach inherently limited to the current bounding exercise and tool for identifying research needs, or can it be further developed and incorporated into RTR assessments?
  - Can you provide advice on how we can incorporate HAPs lacking dose-response values into our risk characterizations?

Summary

- We apologize for the size of the package
- We've tried to structure the materials in a way that allows reviewers to
  - Read the report for context, then
  - Focus on appendices relevant to their areas of expertise
  - Please don't feel restricted to this, however; if you want to tackle the whole thing, we'll welcome your comments
- But, still…
  - There are nearly 800 pages
  - Most of our internal reviewers were left asking for more details and more rigor
- We deeply appreciate your interest and efforts in helping EPA develop the highest-quality RTR assessments possible