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Using Human Health Risk Assessments in Regulatory Decision Making

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Outline

- What is an HHRA?
  - Uses of term
  - Lessons learned over time
- Different types of HHRA and their purpose
- Case Studies
  - State Air Toxics
  - Combustion Risk Assessment
  - NESHAP RTR

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What is an HHRA?

- Human Health Risk Assessment ("HHRA") describes a fairly wide variety of regulatory topics such as:
  - State-specific risk evaluations related to air toxics emissions identified as part of new construction CAA permitting
  - Combustion risk assessments related to incineration or use of hazardous waste as fuel
  - MACT RTR (residual risk) evaluations for HAP emissions
- Key to HHRA development is clearly defining and right sizing its use for technical studies, and in decision making

Types of HHRAs

- State air toxics – part of state/local agency permit application review criteria
- NESHAP Risk and Technology Review (RTR) – part of EPA's periodic review criteria for regulated (MACT) source groups
- Site remediation – periodic checks of contaminant levels to quantify adequacy of cleanup

Types of HHRAs (cont.)

- Combustion – HHRA often used to support issuance of RCRA hazardous waste permit (or renewal) for hazardous waste combustion (HWC) facility
- Combustion (non-waste) permitting – can be used to support air permitting; similar to HWC combustion risk assessment, but scope of analysis is normally very narrow (i.e., mercury evaluation only)

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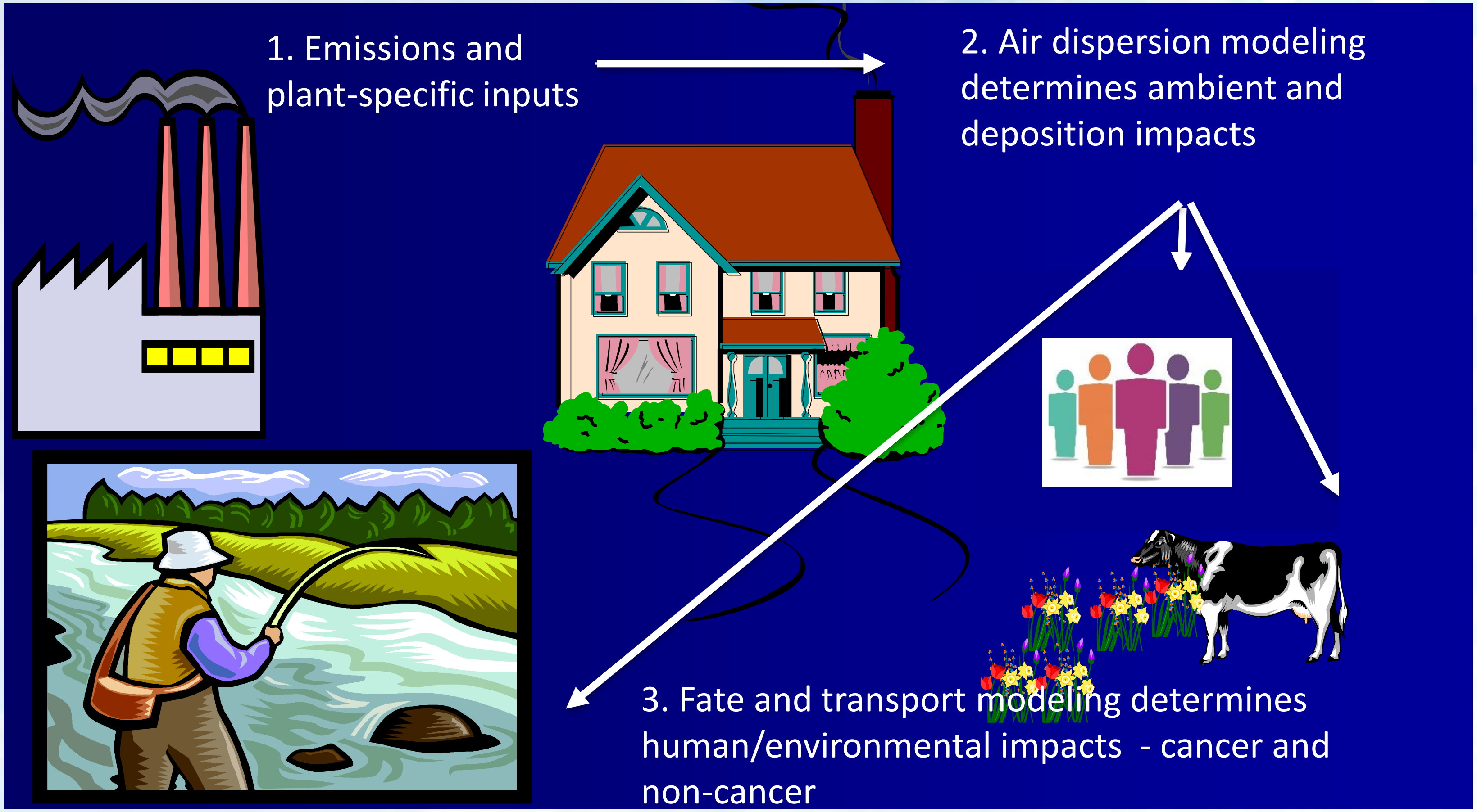
Risk Assessment Process Overview



Case Study 1
State Air Toxics - Missouri

- Construction permitting project with HAP PTE > Screening Model Action Levels (SMALs) requires site-specific ambient impact analysis
- Modeled air concentrations are compared to Risk Assessment Levels (RALs)

10 CSR 10-6.060 Appendix J

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Case Study 1
State Air Toxics - RALs

- Ambient air concentrations that are not expected to produce adverse cancer and non-cancer health effects during a defined period of exposure
- Basis is animal toxicity studies, human clinical studies, and human epidemiology studies accounting for exposure to sensitive populations
  - e.g. elderly, pregnant women, children, and those with respiratory illnesses like asthma
- Health-based levels developed, maintained, and reviewed by Missouri APCP
- Similar to National Ambient Air Quality Standards
  - If max modeled concentrations exceed RAL, ambient impacts must be further reduced until potential air toxic concentrations are below RALs

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Case Study 1
State Air Toxics - List of SMALs and RALs

Missouri Department of Natural Resources

Air Pollution Control Program
Table of Hazardous Air Pollutants, Screening Model Action Levels, and Risk Assessment Levels

Chemical	CAS #	SMAL (tons/yr)	8-HR RAL (µg/m^3)	24-HR RAL (µg/m^3)	Annual RAL (µg/m^3)	10× Annual RAL (µg/m^3)	Group ID	VOC	PM	Synonyms
ACETALDEHYDE	75-07-0	9		2	0.5	5		Y	N	ACETIC ALDEHYDE, ALDEHYDE, ETHANAL, ETHYL ALDEHYDE
ACETAMIDE	60-35-5	1						Y	N	ACETIC ACID AMIDE, ETHANAMIDE
ACETONITRILE	75-05-8	4	933.33					Y	N	METHYL CYANIDE, ETHANENITRILE, CYANOMETHANE
ACETOPHENONE	98-86-2	1						Y	N	ACETYLBENZENE, METHYL PHENYL KETONE AND HYPNONE
ACETYLAMINOFLUORINE, [2-]	53-96-3	0.005					V	Y	Y	N-2-FLUORENYL ACETAMIDE, N-FLUOREN-2-YL ACETAMIDE, 2-ACETAMIDOFLUORENE
ACROLEIN	107-02-8	0.04		6.9	0.02			Y	N	ACRYLALDEHYDE, ACRYLIC ALDEHYDE, ALLYL ALDEHYDE, PROPENAL
ACRYLAMIDE	79-06-1	0.02	0.0533					Y	N	PROPENAMIDE, ACRYLIC AMIDE, ACRYLAMIDE MONOMER, ETHYLENECARBOXAMIDE
ACRYLIC ACID	79-10-7	0.6	80					Y	N	PROPENOIC ACID, ETHYLENE CARBOXYLIC ACID, VINYLFORMIC ACID
ACRYLONITRILE	107-13-1	0.3		0.4	0.01	0.1		Y	N	VINYL CYANCIDE, CYANOETHYLENE, PROPENE NITRILE, AN
ALLYL CHLORIDE	107-05-1	1	0.533					Y	N	1-CHLORO-2-PROPENE, 3-CHLOROPROPYLENE, CHLORALLYLENE, ALPHA-PROPYLENE
AMINOBIPHENYL, [4-]	92-67-1	1					V	Y	N	BIPHENYLINE, P-PHENYLANILINE, XENYLAMINE, 4-AMINODIPHENYL, 4-BIPHENYLAMINE
ANILINE	62-53-3	1		0.2	0.1	1		Y	N	AMINOBENZENE, PHENYLAMINE, ANILINE OIL, AMINOPHEN, ARYLAMINE
ANISIDINE, [ORTHO-]	90-04-0	1						Y	N	O-METHOXYANILINE
ANTHRACENE	120-12-7	0.01					V	Y	N	ANTHRACIN, GREEN OIL, PARANAPHTHALENE, TETRAOLIVE N2G

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Case Study 1
State Air Toxics

- Typical Process
  - Identify project HAP emission rates above SMALs
  - Determine receptors (locations to calculate concentrations)
  - Determine source/stack parameters
  - Conduct air modeling using EPA models (AERSCREEN or AERMOD) to determine HAP concentration (8-hr, 24-hr, annual average)
  - Compare modeled concentration to RAL
  - If above RAL, make changes
    - Evaluate RAL for possible update
    - Changes in emission rate via control equipment
    - Changes in source parameters

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Case Study 1
State Air Toxics (cont)

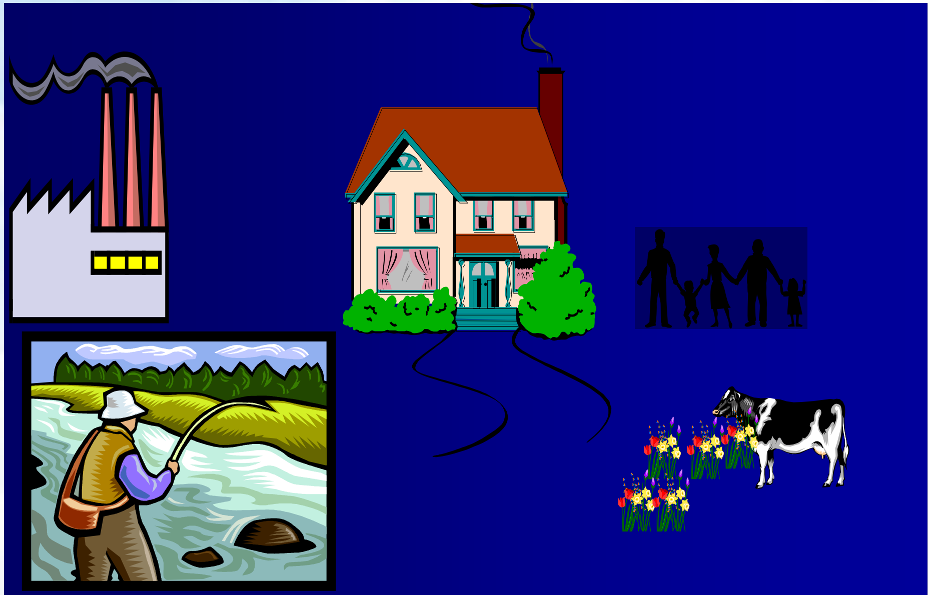
- Permitting new sources at existing plant
  - New source HAP emissions > SMALs
  - Screen modeling indicated RAL exceedances
    - Source parameter changes? Not feasible
    - Refined modeling analysis? Also have existing HAP emissions
    - Emissions controls for new sources? Lack of options for level needed
    - Limit emissions of new sources and verify through testing – only solution for this case

Case Study 2
Combustion Risk Assessment

- HHRAP Protocol submittal and agreement
  - Overall approach (guidance, assumptions)
  - Selection of receptors and exposure scenarios
  - Selection of constituents of concern and emissions data source(s)
- Run air dispersion model
- Run risk model & evaluate results
- Verify regulatory limits are protective

Case Study 2
Combustion Risk Assessment (cont)

- Locations evaluated (receptors)
  - Residents
  - Recreational/Subsistence Fishers
    - Subsistence or high-end recreational fishers levels evaluated despite documentation of no such receptors
  - Farmers/Subsistence Farmers
    - beef, dairy
  - Home Gardeners
  - Sensitive receptors
    - nursing homes, schools, nursing infant



Case Study 2
Combustion Risk Assessment (cont)

- Results measured against:
  - Carcinogenic threshold $\leq 1 \times 10^{-5}$
  - Non-carcinogen threshold HI/HQ ≤ 0.25
- Most constituents orders of magnitude below thresholds
- Few constituents are near thresholds requiring further evaluations - referred to as “risk drivers”
- Initial (screen) evaluation uses conservative defaults
  - Defaults refined to more site-specific if issues

Case Study 2
Combustion Risk Assessment (cont)

- HW incinerator – RCRA-permitted
- Atypical feed streams = Atypical COPCs
  - Up front research to define input parameters for air/risk models
- Typical risk drivers are limiting factor
  Dioxin/furans, mercury

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Case Study 2
Combustion Risk Assessment (cont)

- Cement plant using hazardous waste-derived fuel (RCRA-permitted)
- Multiple options for risk receptors
  - Up front preliminary analysis to define areas of concern
  - Negotiate receptors for analysis with agency
- Typical risk drivers are limiting factor
  - Dioxin/furans, mercury

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Case Study 3
NESHAP RTR

- Combined risk and technology
- CAA Section 112(d)(6) requires periodic (8 year) review and MACT standard revision, if necessary
  - Developments in practices, processes and control technologies taken into account
- CAA Section 112(f)(2) evaluates residual risks after MACT standards applied
- Determines if current MACT does a good job of protection, or if additional controls needed

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Case Study 3
NESHAP RTR (cont)

- HHRA used to determine risk remaining after application of industry-specific MACT standards
- Similar to combustion HHRA but unique models used for industry-wide vs. site-specific approach
- EPA has conducted 44 thus far in accordance with CAA Section 112(f)

https://www3.epa.gov/airtoxics/rrisk/rtrpg.html

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Case Study 3
NESHAP RTR Examples

- Wool Fiberglass Area Source Rule – RTR Review 2015
  - EPA evaluated actual Cr(VI) emissions from existing facilities and found current levels acceptable at 20-in-1 million.
  - One furnace emitted at a higher level. EPA evaluated hypothetical risk scenario - all furnaces emit at higher (not actual) level; 400-in-1 million risk.
  - EPA limited chromium from gas fired furnaces to prevent increased risk/provide ample margin of safety.
- Portland Cement NESHAP – RTR Review 2017
  - EPA found risks acceptable with ample margin of safety, no revisions standards proposed.

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