Cumulative Risk and Risk Based Concentrations

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Cumulative risk

- Risks and hazards from multiple pollutants
- Risks and hazards from multiple facilities within an area
- Risk and hazards from background/ambient air

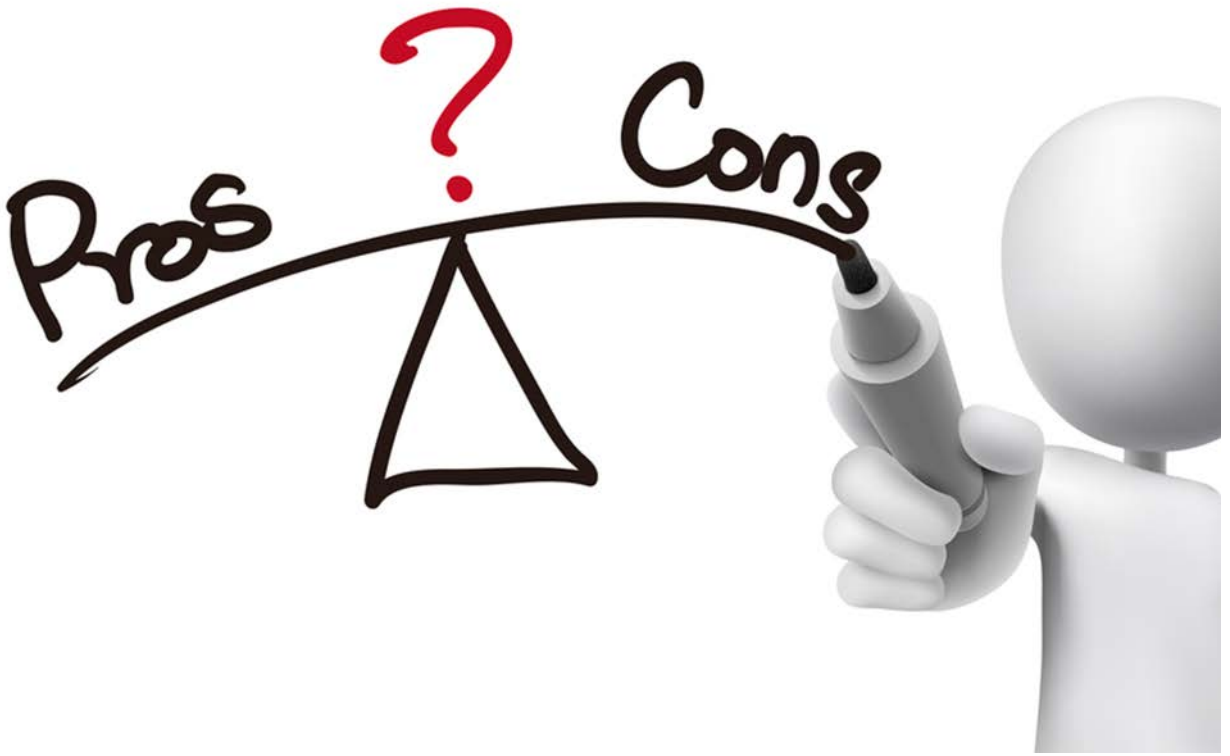
Risk based concentrations

- Methods for setting risk based concentrations
- Default toxicity values
- Criteria for using primary literature to develop RBCs
- Cross-media exposure pathways

Multiple Pollutants from a Single Facility?

- Consider cumulative effects of emissions that affect the same organ system (non-cancer affects)
- Consider risks from multiple pollutants from single piece of equipment (1 in 1 million risk)
- Consider risk from multiple pollutants, allow a higher risk level (ranges from 3.8 to 100 in 1 million)
- Do not consider multiple pollutants

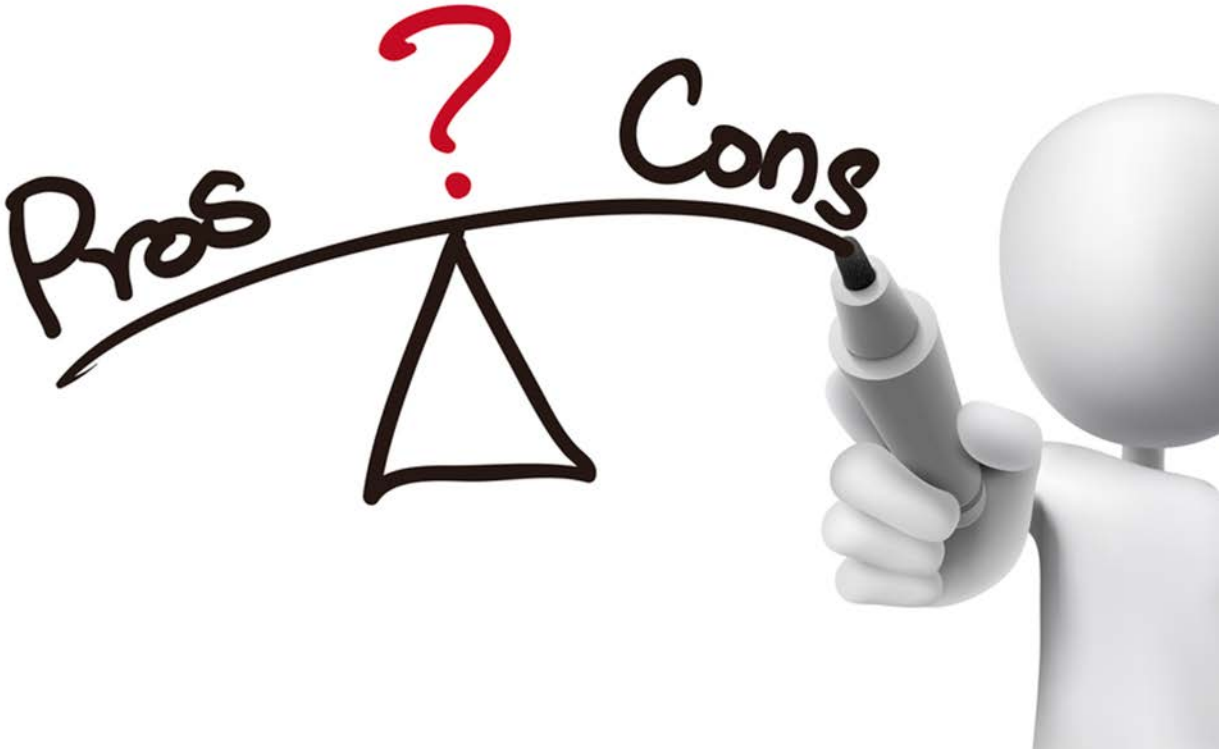
Pros and Cons of Assessing Cumulative Risks Related to Multiple Pollutants?



Cumulative risk from multiple sources within an area?

- Not included (RI)
- Included
  - WA: Estimate background by modeling nearby sources within a 1.5-km radius
  - NY: Integrated into calculation of maximum off-site air concentrations, which are then compared to risk-based levels

Pros and Cons of Assessing Multiple Pollutants from Multiple Sources within an Area?



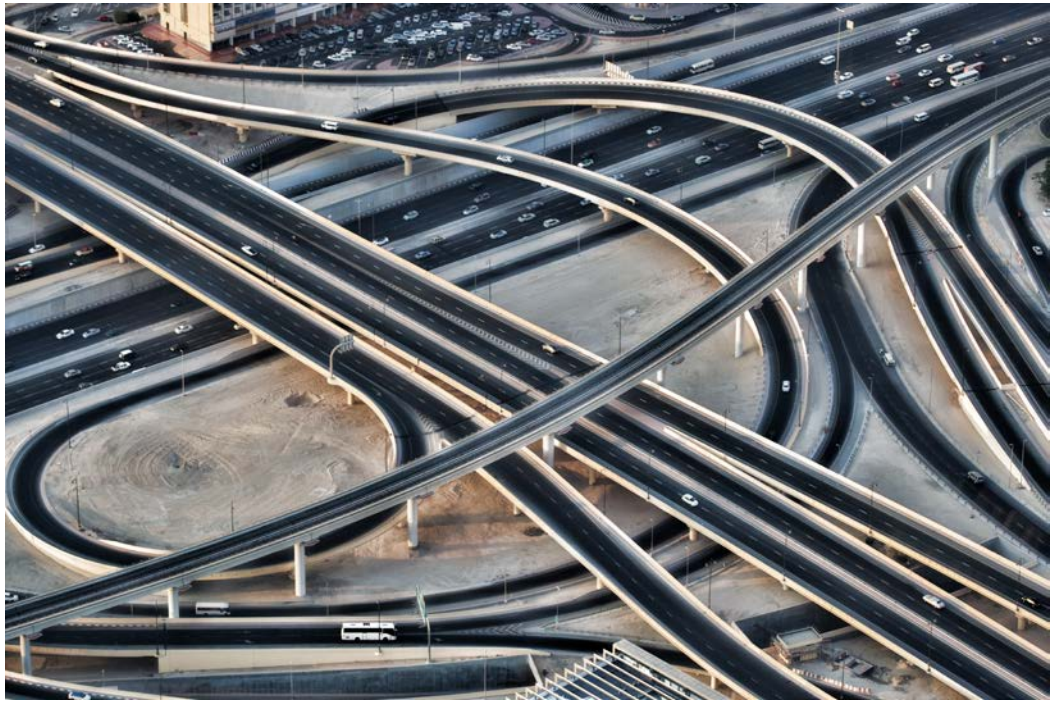
Background/Ambient Concentrations in the Assessment of Risk?

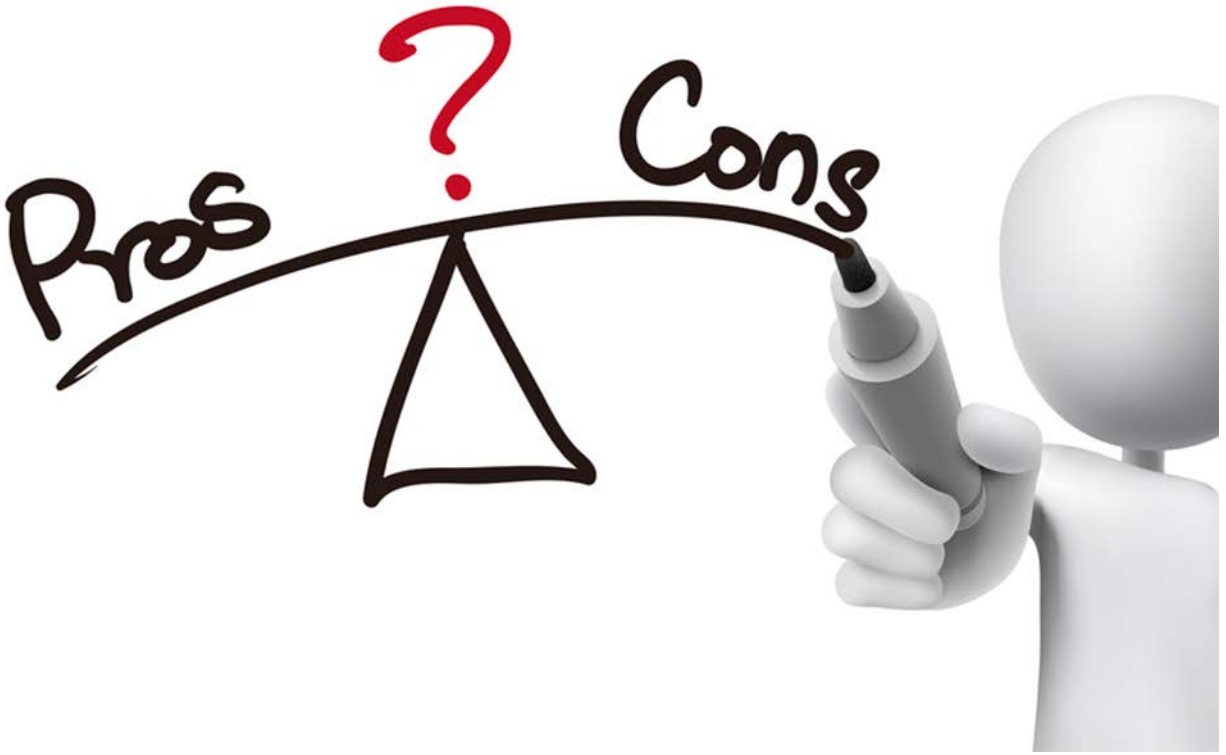
- Not included (RI)
- Included (WA)
  - *WA: background assessment is required by rule, but how it affects subsequent decision-making is not spelled out*
- How is the background/ambient calculated?
  - *WA: Three acceptable methods are:*
    - *Model sources within 1.5 km*
    - *Air monitoring results*
    - *Concentration from NATA at relevant census-tract level*

Background/Ambient Concentrations in the Assessment of Risk?

- Included (NY)
  - *NY: Must be considered in estimation of maximum off-site air concentration, which is then compared to risk-based levels*
- How is the background/ambient calculated?
  - *NY: Uses current NATA information regarding background concentrations of air toxics.*

Pros and Cons of Including Background/Ambient Concentrations in the Assessment of Risk?





Setting Risk Based Concentrations

How do other programs set RBCs?

Primary research evaluation by agency	Use of hierarchy with discretion to evaluate special cases	Use of rigid hierarchy or algorithm	Use of someone else's values
EPA, ATSDR, CalEPA do this.	Most similar to what ATSAC does now.	States with very large pollutant lists (e.g. WA, RI) do this.	For example New Jersey only uses EPA values

What are the advantages/limitations of different ways to derive/select state RBCs?

Considerations:

- Flexibility and control
- Dependence on work done by other jurisdictions
- Responsiveness to latest science
- Level of certainty
- Applicability
- Clear criteria for derivation method and related communication and justification
- Resources required
- Number of pollutants for which values could be derived

Pros and Cons of Methods to Set Risk Based Concentrations

Primary research evaluation by agency	Use of hierarchy with discretion to evaluate special cases	Use of rigid hierarchy or algorithm	Use of someone else's values
EPA, ATSDR, CalEPA do this.	Most similar to what ATSAC does now.	States with very large pollutant lists (e.g. WA, RI) do this.	States with very large pollutant lists (e.g. NJ) do this.

Default Toxicity Values

Example default toxicity values

The STAR program (Louisville, KY)

- Cancer risk default value = 0.0004 µg/m^3
- Non-cancer default value = 0.04 µg/m^3

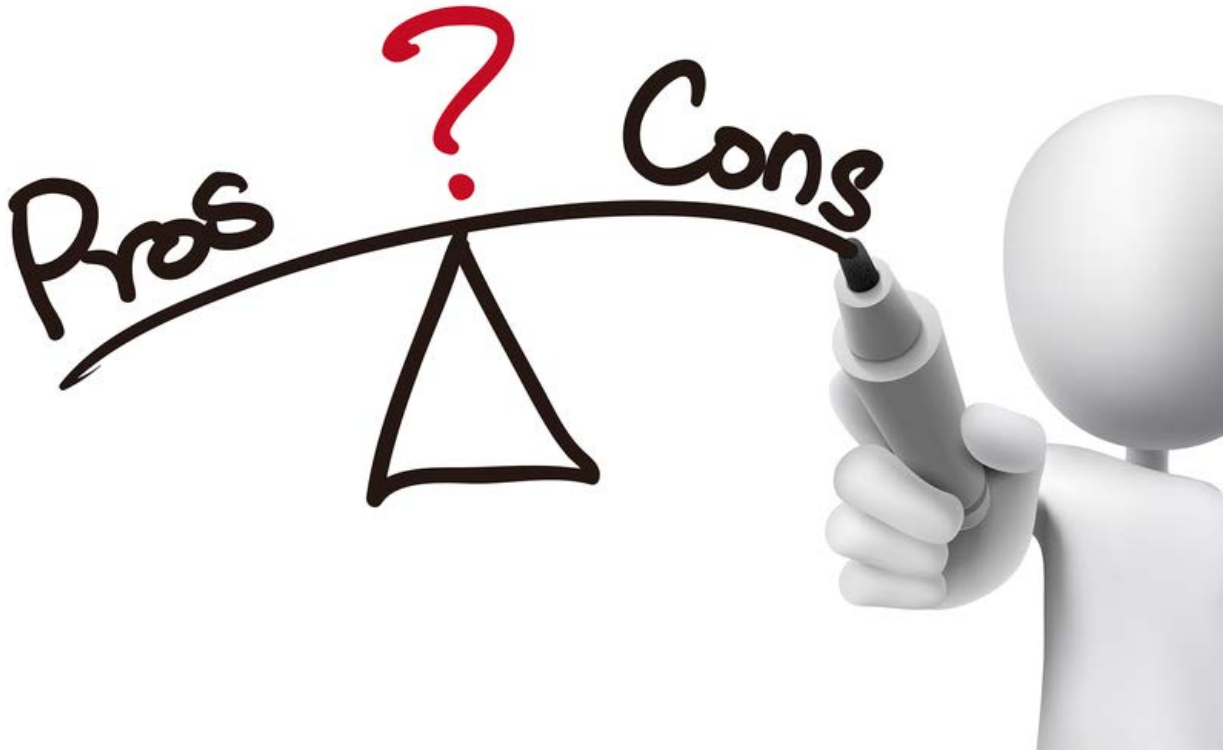
New York

- Contaminant is known not to be "high toxicity" default = 0.1 µg/m^3
- Contaminant known to be "low toxicity" default = 1 µg/m^3
- Contaminant is known to be "high toxicity" = 2 x10^{-5} µg/m^3

Michigan

- default Initial Threshold Screening Level (ITSL) value of 0.1 µg/m^3

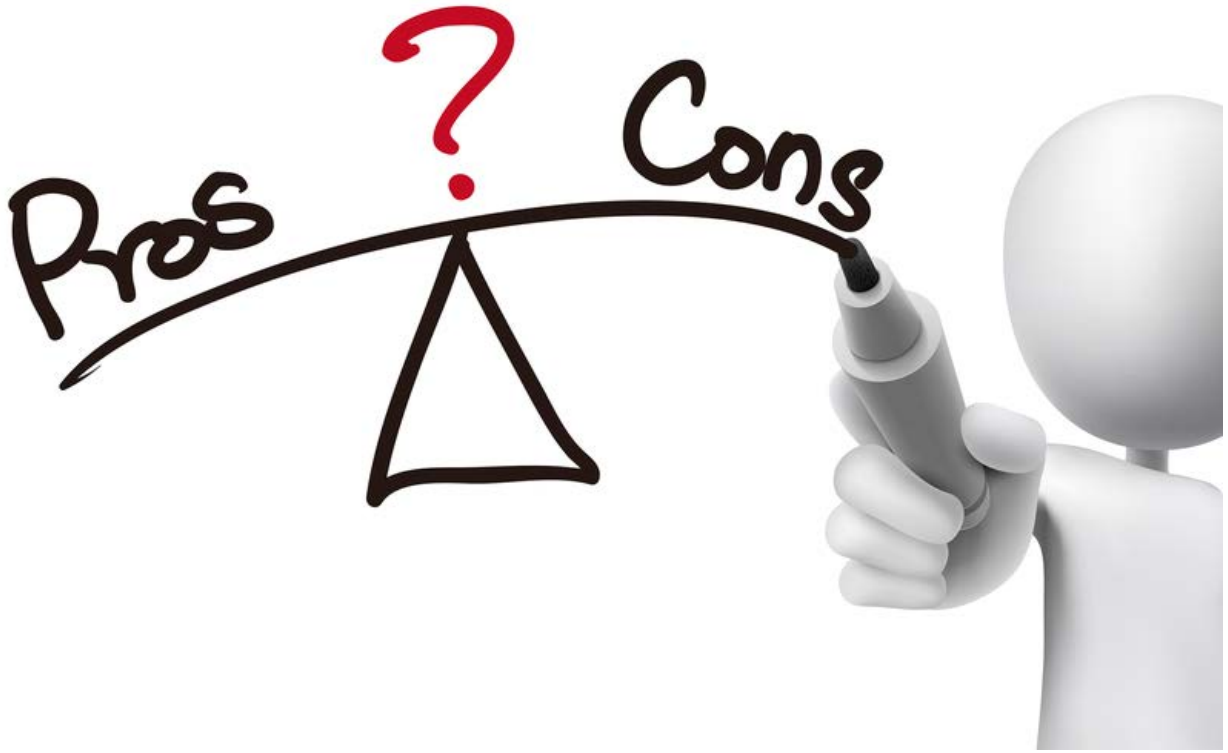
Pros and Cons of Using Default Toxicity Values?



Modification of Occupational Exposure Limits or chronic RBCs to Derive Acute Risk Based

- Many states modify occupational exposure limits to derive RBCs– especially for acute RBCs (e.g., Divide ACGIH TLV by 100)
  - New York, New Hampshire, Texas, Michigan
- Other states modify chronic RBCs to generate acute RBCs (e.g., multiply EPA RfC by 10)
  - Missouri, EPA school study

Pros and Cons of Modifying Occupational or Chronic RBCs to Generate Acute RBCs?



Example Process for selecting/developing RBCs?

1. Use established sources of toxicity values
   a) EPA IRIS or other EPA (PPRTV, etc.)
   b) ATSDR
   c) Cal OEHHA
   d) Other States Values

Example Process for selecting/developing RBCs?

2. If none available – generate from acceptable mammalian toxicological and/or epidemiological studies:
   a) Look for tox/epi studies (sources: peer-reviewed literature, WHO, REACH, FDA)
   b) Review the studies – must have following qualities:
      i. Investigates relevant and sensitive health endpoint
      ii. Exhibits dose response relationship
      iii. Exposure route and duration that is relevant to public health
      iv. Uses appropriate statistical analysis
      v. Conclusions clearly supported by data in the study

Example Process for selecting/developing RBCs?

3. If no established tox values or available tox or epi studies then use surrogate chemical:
   a) Look for appropriate surrogate (QSAR) that has an established toxicity value
   b) Look for appropriate surrogate (QSAR) that has a quality tox or epi study
4. If none of the above, use default toxicity value

Cross-media pathways: How do other programs account for this in their RBCs?

- 2 out of 6 programs evaluated use cross-media exposures as a basis for modification to RBCs themselves
  - RBCs divided by additional modification factors if likely to bioaccumulate or cause cross-media exposures
- An additional 2 programs address cross-media issues as part of site-specific risk assessments, but do not modify the actual RBCs

Advantages/limitations of adjusting RBCs for cross-media exposure pathways?

Considerations:

- Protectiveness of public health
- Criteria for application of modifying factors
- Establishment of modifying factors

Pros and Cons of adjusting RBCs for cross-media exposure pathways