Addressing Unassessed Chemicals in California

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Unassessed Chemicals: Nature of the Problem

- Establishing health guidance values (e.g., RELs, Unit Risk Factors) by traditional approaches can be time- and resource-intensive.
- OEHHA and other entities have only established health guidance values for a fraction of chemicals.
- Chemicals without health guidance values commonly appear in:
  - Environmental monitoring or sampling of air, water, soil, and food.
    - Community air monitoring
    - Other environmental sampling (e.g., synthetic turf)
  - Emissions inventories (e.g., Hot Spots)
  - Use reporting (e.g., fracking chemical disclosures)

Possible Solution: "Provisional" Health Guidance Values

- A mechanism to provide information in a more expedited manner on potential for health risks from exposure to toxic chemicals
- May be quantitative (a number) or qualitative (a category)
- Likely to carry greater uncertainty than traditional procedures
  - Level of confidence should match the decision context
  - Level of uncertainty may be unacceptable in some contexts

Approaches to Providing Provisional Health Guidance

- Use work from other entities when it exists
  - *Adopt* others' existing health guidance values, such as recent values from US EPA's IRIS program
  - *Adapt* others' existing health guidance values, to make more consistent with established California methodologies (e.g., change uncertainty factors)
- Use alternative approaches when there are no values from existing authorities
  - Expedited health guidance values (in-house)
    - Readily available studies that can establish point-of-departure
  - "Read-across" using potential analogues
    - Structural, metabolic/toxicokinetic, toxicity (bioactivity)
  - Other approaches

Considerations in Adopting/Adapting Values from Other Entities

- Consistent with California's health risk assessment guidance
  - Purpose: Risk assessment and protection of sensitive populations (versus assessments to support occupational standards)
  - Methodology (e.g., uncertainty factors; dose-response assessment)
  - Route of exposure
- Comprehensive
  - e.g., all potential endpoints assessed
- Peer-reviewed
- Publicly reviewed and available
- Recent

Alternative Approaches

- Expedited health guidance values (in-house)
  - Small reliable data set
  - Straightforward dose-response
- "Read-Across"
  - Method of filling a data gap whereby a chemical with existing data is used to make a prediction for a "similar" chemical (G Patlewicz, US EPA).
  - Example workflow: Decision context → Analogue identification → Data gap analysis → Analogue evaluation → Read-across → Uncertainty assessment
  - Can be adapted to different levels of confidence, completeness, and speed
- Other approaches (e.g., Thresholds of Toxicological Concern (US FDA))

Next Steps

- Ongoing work at OEHHA
  - Follow-up to April 2019 Symposium: *Understanding and Applying Read-Across for Human Health Risk Assessment*
  - Evaluation of existing read-across platforms
  - Development of methods using *in vitro* studies and *in silico* molecular docking data, in collaboration with academic partners.
- Bring more robust discussion to SRP in areas:
  - Evaluating existing non-California health guidance values
  - Applying alternative approaches