

Technical Advisory Committee Background

Cleaner Air Oregon

REFORMING OREGON'S INDUSTRIAL AIR QUALITY REGULATIONS

Inviting Oregonians to help create new regulations that protect what we all care about: the health of our people, a clean environment, and the economic vitality of our communities.

July 10, 2019

CleanerAirOregon

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- Fall/Winter 2018 - A technical advisory committee with expertise in toxic air contaminant risk assessment met twice
 - Summer 2019 - Rules advisory committee provides feedback on rule writing
 - Fall 2019 - Fiscal advisory committee will meet and provide feedback on fiscal impact statement
 - Fall/Winter 2019 - Public comment period
 - To Be Scheduled - Present rules for adoption by the Environmental Quality Commission, the policy body that oversees the Oregon Department of Environmental Quality

Need for a technical advisory committee (TAC)

Oregon Legislature Senate Bill 1541, Section 7(3):

(b) Before adopting rules under this section, the commission shall establish and consider the recommendations of an advisory committee composed, at a minimum, of persons with technical expertise in toxic air contaminant risk assessment.

Technical advisory committee (TAC) formation

- Science-based committee
- 7 members with specific technical skill sets
 - 5 positions directly recruited to ensure key technical expertise
 - 2 at-large positions chosen from among applications
- Committee members with specific technical skill sets



HI TAC members

Dr. Amy Padula, UCSF



Dr. John Budroe, California (OEHHA)



Dr. John Vandenberg, US EPA (IRIS)



Dr. Kathryn Kelly, Delta Toxicology (at-large)



Dr. Neeraja Erraguntla, American Chemical Council (at-large)



Dr. Perry Hystad, Oregon State Univ.



Dr. Steven Gilbert, Univ. of Washington



HI TAC meetings

- Overarching question for TAC:
 - If you had to evaluate a list of chemicals for noncancer effects, and identify which ones have developmental or other severe health effects, how would you do this?
- If desired, TAC could interact with DEQ and OHA staff
- No committee consensus required

Cleaner Air Oregon – Hazard Index Rulemaking

Hazard Index Technical Advisory Committee – Meeting #2
Meeting Minutes

Dec. 4, 2018

Portland State Office Building, Conference Room 1E
800 NE Oregon Street
Portland, Oregon 97232

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800-425-8111
Fax: 503-229-4762
Contact: Sue Macklin at 503.229.4658 or sue.macklin@deq.or.gov

List of attendees

HI TAC members:
Steve Gilbert, Ph.D., Director and Founder of the Institute of Neurotoxicology and Neurological Disorders (INND), Seattle, Washington
Perry Hystad, Ph.D., College of Public Health and Human Sciences, Oregon State University, Corvallis, Oregon
John Vandenberg, Ph.D., National Center for Environmental Assessment (NCEA), U.S. EPA, Triangle Park, N.C.
John Budroe, Ph.D., Senior Toxicologist, California Office of Environmental Health Hazard Assessment, Oakland, California
Neeraja Erraguntla, Ph.D., DABT, American Chemistry Council, Washington, D.C.
Amy Pradula, Ph.D., MSc, Assistant Professor of Clinical Obstetrics, Gynecology & Reproductive Sciences, University of California San Francisco, San Francisco, California
Kathryn Kelly, Ph.D., President, Delta Toxicology, Inc., Crystal Bay, Nevada

Other participants:
Ali Mirzakhali, Oregon Department of Environmental Quality (DEQ)
Keith Johnson, DEQ
Sue Macklin, DEQ
Gabriela Goldfarb, Oregon Health Authority (OHA)
Susanna Wegner, OHA
David Farmer, OHA
Deb Nuselman, Facilitator, Keams and West

Audience members:
Todd Hudson, OHA
Ali Hamade, OHA
Joe Westersund, DEQ
Emil Hindey, DEQ
Sarah Armitage, DEQ
J.R. Gelsa, DEQ
Jeffrey Stoum, DEQ
Dale Felix, Hillsboro Air and Water
Ms. Abbie Lauffog, Oregon Business Institute
Taylor Lucy, Oregon Forest and Industries Council
Mike Fresse, The Roman Group
Nadege Dubulsson, Multnomah County Health Department
Jason Hill, member of the public.

DEQ
State of Oregon
Department of
Environmental
Quality

DEQ is a leader in restoring, maintaining and enhancing the quality of Oregon's air, land and water.

1

HI TAC majority opinion: Consider reproductive effects as developmental effects

Toxic air contaminants expected to have **developmental or reproductive** human health effects

Issues with development of embryo or fetus (e.g. birth defects, abnormal development, death of embryo or fetus)

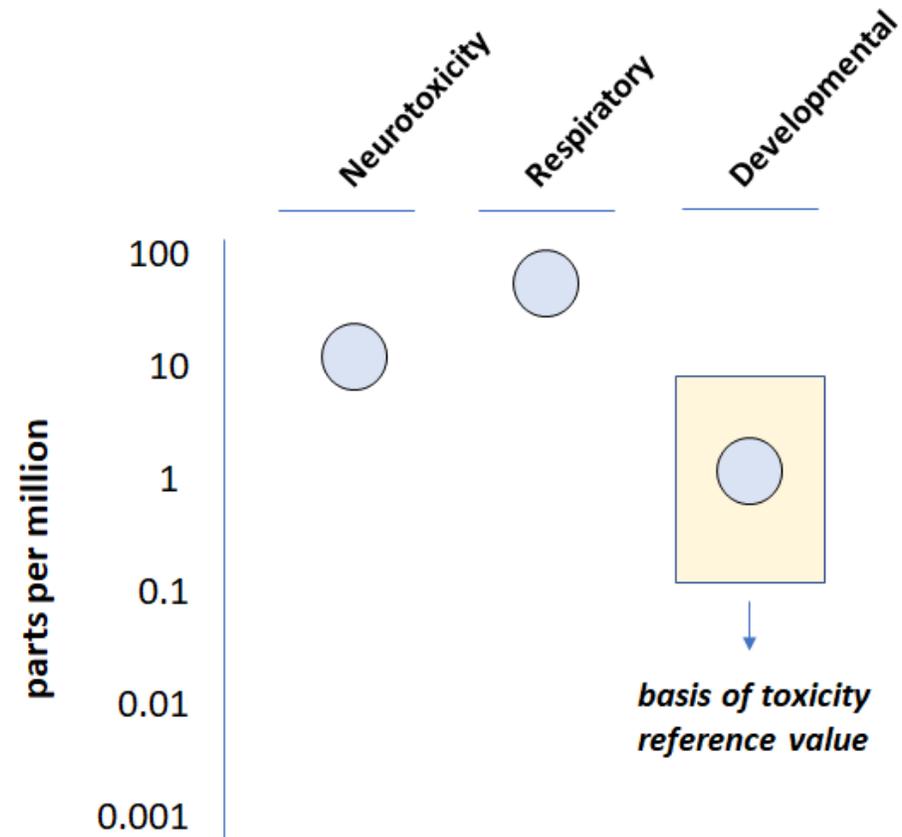
Issues with all aspects of fertility (e.g. reproductive cycle, pregnancy outcomes, sperm or eggs production and transport)



HI TAC majority opinion: Use hazard to identify toxic air contaminants with developmental or reproductive effects

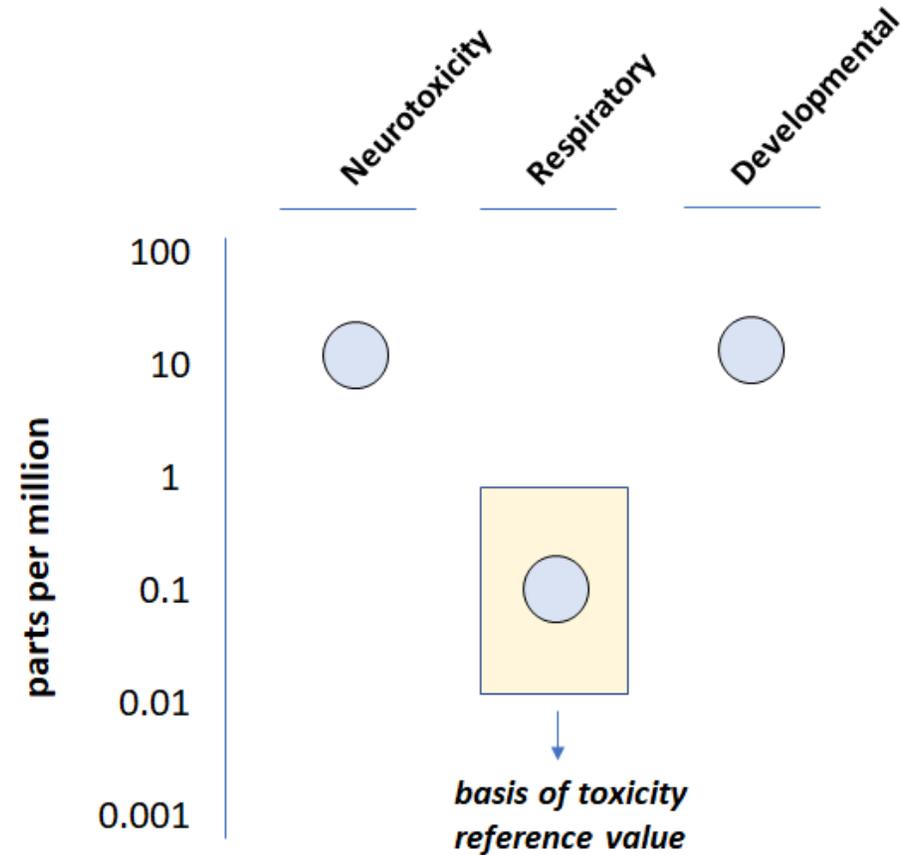
Consider a toxic air contaminant to have developmental or reproductive effects even if it also causes other health effects at lower doses

HI TAC majority opinion: Use hazard to identify toxic air contaminants with developmental or reproductive effects



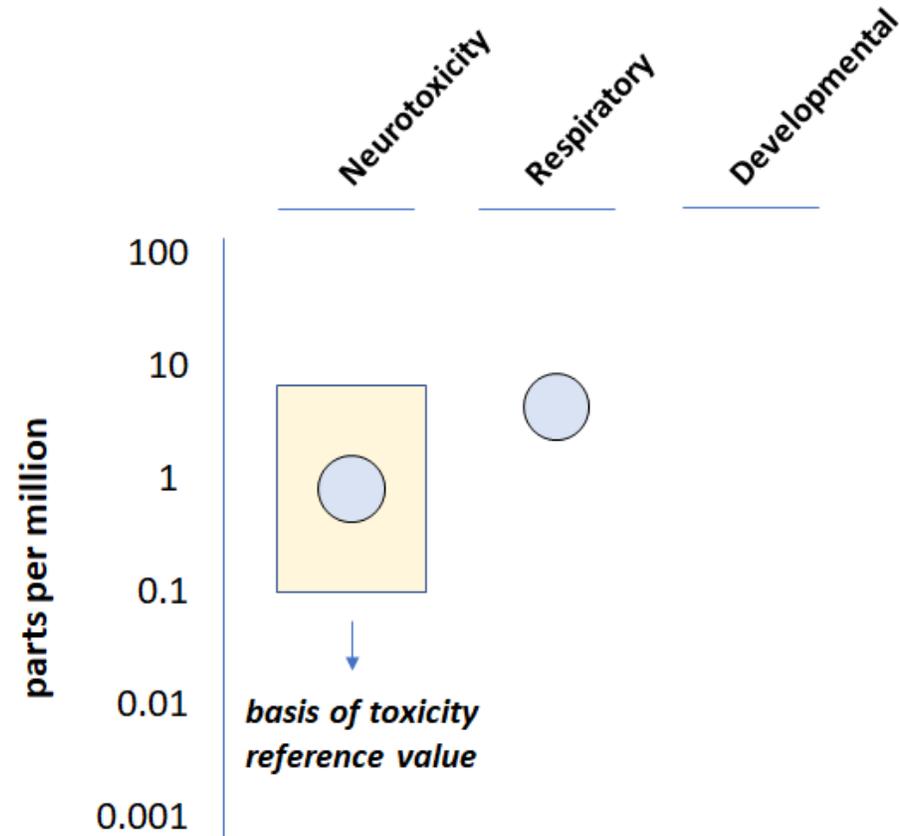
Levels of Significant Exposure to Chemical A

HI TAC majority opinion: Use hazard to identify toxic air contaminants with developmental or reproductive effects



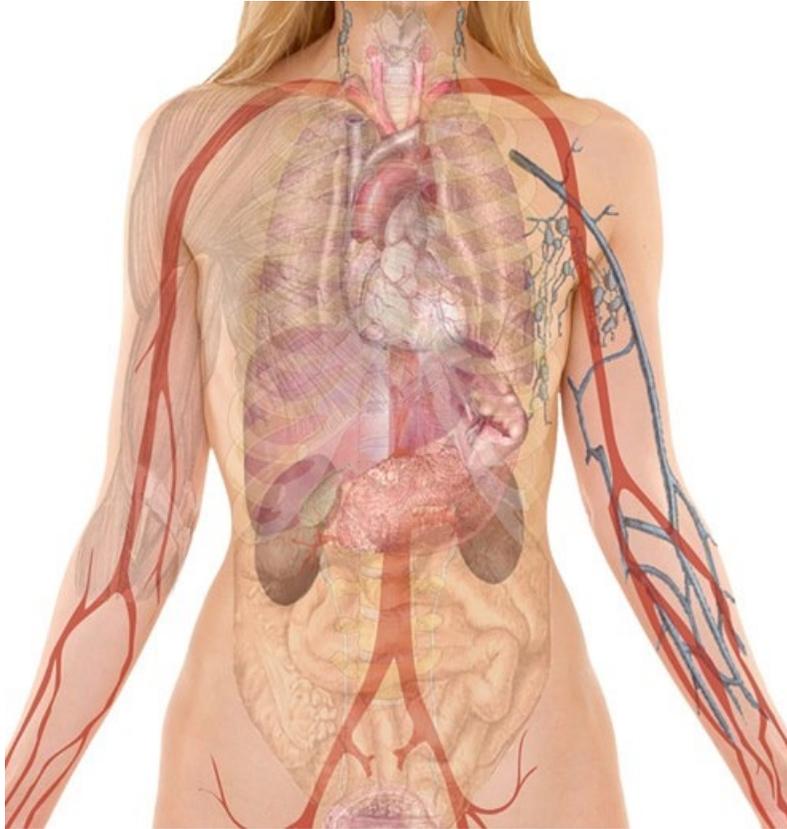
Levels of Significant Exposure to Chemical B

HI TAC majority opinion: Use hazard to identify toxic air contaminants with developmental or reproductive effects



Levels of Significant Exposure to Chemical C

HI TAC majority opinion: No science-based process available to determine which chemicals have “other severe human health effects”



+ wide range of individual responses to chemical exposures

Identifying which toxic air contaminants are expected to have developmental, reproductive, or other health effects

- Spreadsheet
 - Authoritative sources
- Established a process and criteria for agency toxicologists to review and verify spreadsheet
 - Reviewed and refined by TAC

Chemical Name	CAS No.	Health Effect	Source	Notes
Acetone	67-64-2	Reproductive	Authoritative	
Acrylonitrile	100-52-7	Reproductive	Authoritative	
Acrylonitrile	100-52-7	Developmental	Authoritative	
Acrylonitrile	100-52-7	Other	Authoritative	
Acrylonitrile	100-52-7	Reproductive	Authoritative	
Acrylonitrile	100-52-7	Developmental	Authoritative	
Acrylonitrile	100-52-7	Other	Authoritative	
Acrylonitrile	100-52-7	Reproductive	Authoritative	
Acrylonitrile	100-52-7	Developmental	Authoritative	
Acrylonitrile	100-52-7	Other	Authoritative	

Target Organ Spreadsheet

Inclusion criteria for developmental and reproductive toxic air contaminants:

"a" - A reproductive or developmental effect is the basis for the TRV.
OR
"b" - A reproductive or developmental effect is identified by the authoritative source for the TRV, but is not the basis of the TRV.
OR
"c" - A reproductive or developmental effect is identified by another authoritative source.

In the cases where reproduction or developmental effects are flagged as "b" or "c", the criteria below were used:

- at least one inhalation studies in animals or humans that show significant effects on reproductive or developmental endpoints that could be the basis for a LOAEL
 - Consistent with EPA guidance, developmental effects should be considered regardless of maternal toxicity.
 - Occupational studies that are confounded by the presence of other simultaneous co-exposures are not sufficient as the sole evidence for reproductive and developmental effects. Results from occupational studies should be considered if such confounders are adequately controlled for.
 - Do not include studies for which authoritative sources note a lack of statistical significance (i.e., a significant pairwise test or trend test)
 - If other chemicals in the chemical class have reproductive or developmental effects that haven't been evaluated in the chemical in question (unless an authoritative source makes a clear statement that the chemical with more data is unlikely to be predictive, e.g. due to differences in metabolism).

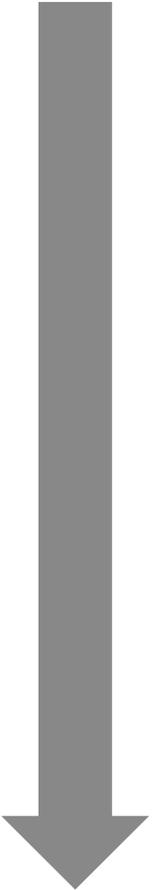
OR

"d" - reproductive or developmental effects are documented through other routes of exposure. In the absence of sufficient inhalation studies for reproductive and developmental endpoints, studies using other routes of exposure (oral or injection) can be used to demonstrate significant reproductive and/or developmental toxicity, as detailed below:

- Oral reproductive and developmental studies should be evaluated using the same criteria described above for inhalation studies.
- Oral effects should not be considered if the authoritative source specifically states that it is inappropriate to extrapolate across routes of exposure for that chemical.

Inclusion Criteria

Chemical numbers



600 chemicals

must be reported to DEQ if emitted from a facility within CAO program

261 chemicals

have toxicity reference values based on cancer and/or non-cancer effects

184 chemicals

have toxicity reference values for non-cancer effects

141 chemicals

expected to have developmental or reproductive effects

Questions

