Creating Health Benchmarks
EGLE/Air Quality Division
Toxics Unit

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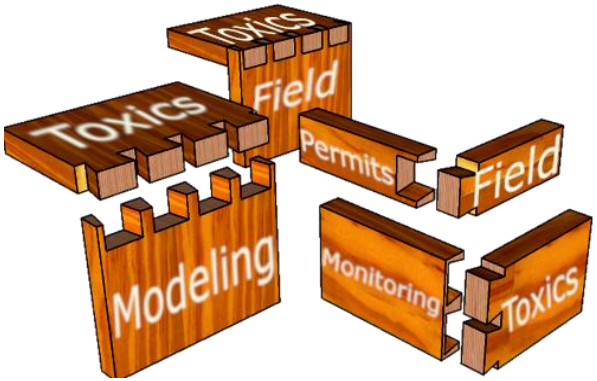
Introduction to the Toxics Unit

Air Quality Division (AQD):

- Ensures Michigan's air remains clean by regulating sources of air pollutants to minimize adverse impacts on human health and the environment.

Toxics Unit:

- Develop health-based screening levels for toxic air contaminants (TACs)
- Health based screening levels are used in air permitting
- TAC emissions cannot be more than the screening levels



Toxic Air Contaminants

- A toxic air contaminant (TAC) is any air contaminant with no National Ambient Air Quality Standard and may become harmful to public health or the environment when present in the outdoor air in sufficient quantities and duration.
- There are 39 exceptions in Part I of the Air Pollution Control Rules.

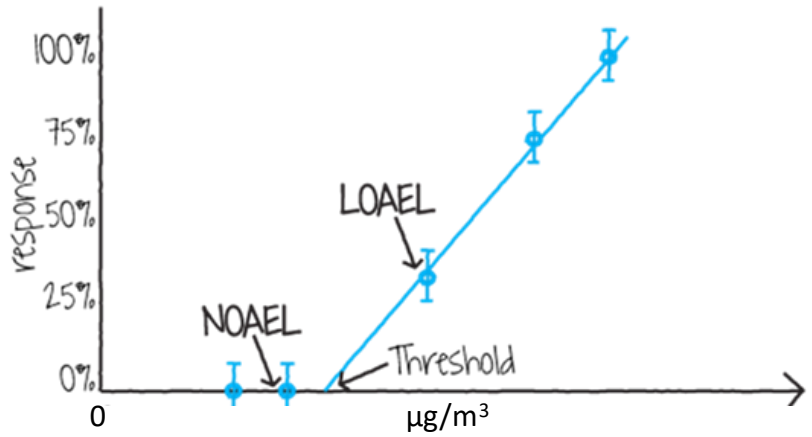
What are Screening Levels?

- Health-based Screening Levels (SLs) provide a level of protection to the public from inhalation (only) exposure in µg/m³.

- Two types:
  - Initial Threshold Screening Levels (ITSLs)
  - Initial Risk Screening Levels (IRSLs)

Initial Threshold Screening Level (ITSL)

- Threshold Response
  - Injury must exceed the body's capacity to repair itself.



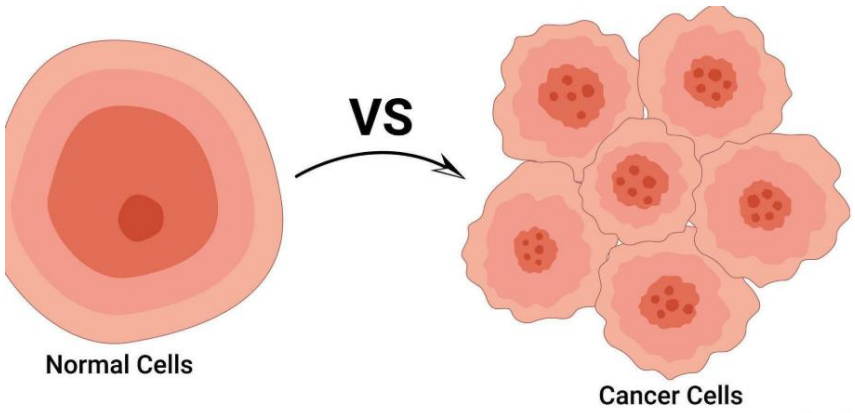
- Threshold level
  - a limit or boundary that must be reached for a particular event, reaction, or response to take place.

NOAEL = No Observable Adverse Effect Level

LOAEL = Lowest Observable Adverse Effect Level

Initial Risk Screening Level

- An **Initial Risk Screening Level (IRSL)** is developed for carcinogens.
  - No threshold is thought to exist.
  - Genotoxic insult (DNA) to a single cell is theoretically sufficient to allow cell growth into a malignant tumor.



How do we derive these Screening Levels?

- AQD's Rules (R336.1231 and R336.1232) of values determined by other federal and state agencies.
  - Inhalation values can be adopted based on risk assessments from other credible agencies (e.g. IRIS, ATSDR, TCEQ, etc.)

  or

  - Can be calculated from an Occupational Exposure Levels. For example, from ACGIH or MAK with exposure adjustments that reflect the general population.

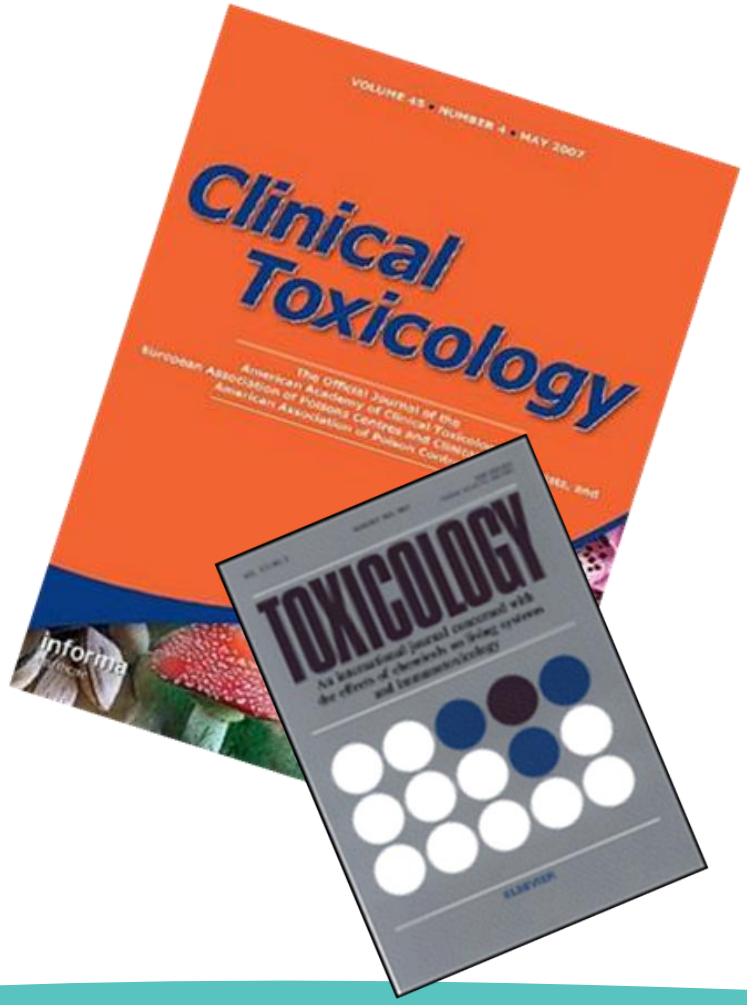
EPA IRIS: Environmental Protection Agency's Integrated Risk Information System
ATSDR: Agency for Toxic Substances and Disease Registry
TCEQ: Texas Commission on Environmental Quality
ACGIH: American Conference of Governmental and Industrial Hygenists

Criteria Based on Standard Risk Assessment Practices

- Steps in Risk Assessment
  - Hazard Identification
  - Dose-Response Assessment
  - Exposure Assessment
  - Risk Characterization

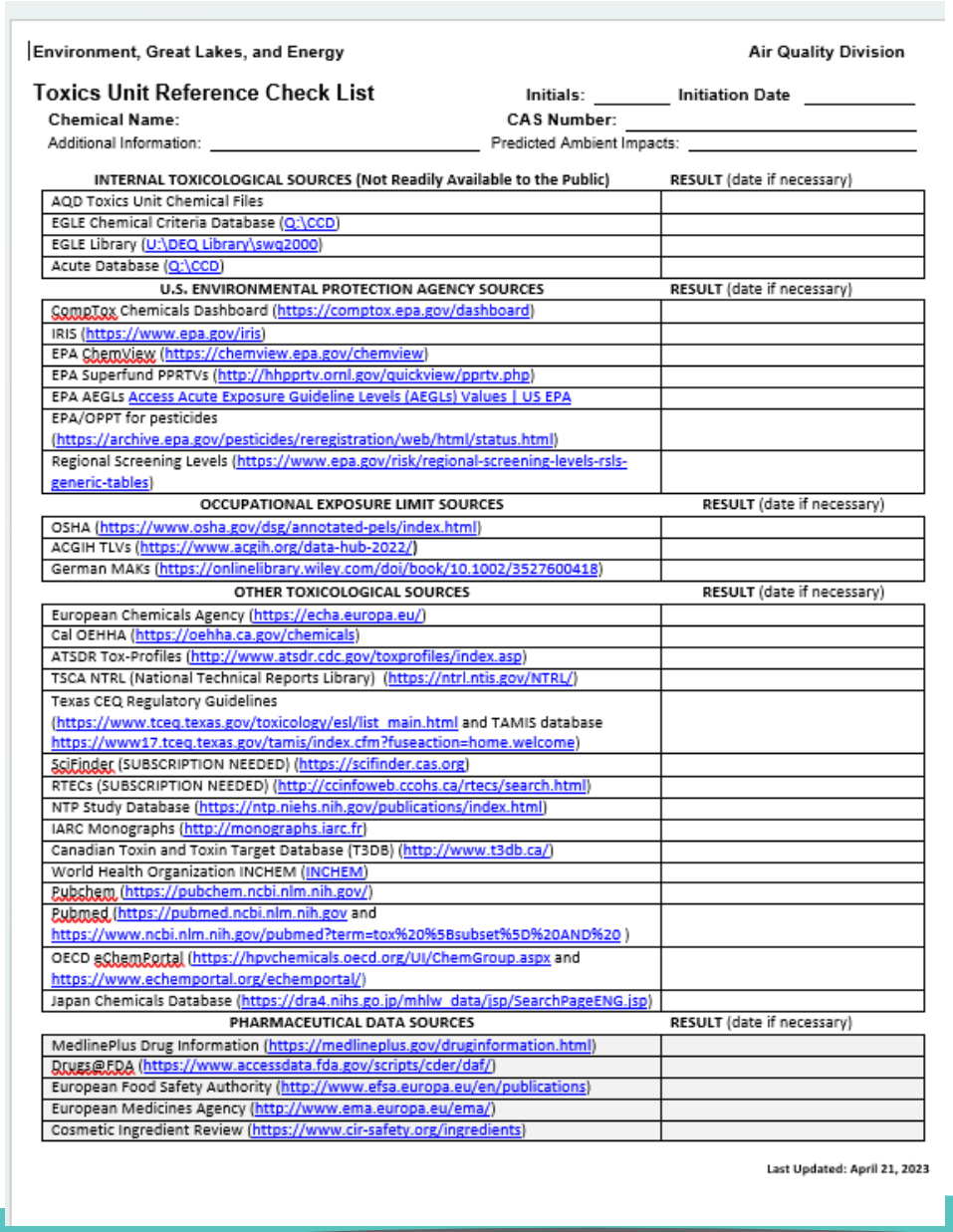
Hazard Identification

- Evaluate weight of the evidence for adverse effects in humans based on all available data on toxicity and mode of action.
- Determine if an agent may pose a health risk to humans and under what circumstances



Hazard Identification

- Literature search



Environment, Great Lakes, and Energy — Air Quality Division

Toxics Unit Reference Check List

Initials: _____ Initiation Date _____

Chemical Name: **CAS Number:** _____

Additional Information: _____ Predicted Ambient Impacts: _____

INTERNAL TOXICOLOGICAL SOURCES (Not Readily Available to the Public)	RESULT (date if necessary)
AQD Toxics Unit Chemical Files	
EGLE Chemical Criteria Database (Q:\CCD)	
EGLE Library (U:\DEQ Library\swq2000)	
Acute Database (Q:\CCD)	

U.S. ENVIRONMENTAL PROTECTION AGENCY SOURCES	RESULT (date if necessary)
CompTox Chemicals Dashboard (https://comptox.epa.gov/dashboard)	
IRIS (https://www.epa.gov/iris)	
EPA ChemView (https://chemview.epa.gov/chemview)	
EPA Superfund PPRTVs (http://hhpprtv.ornl.gov/quickview/pprtv.php)	
EPA AEGLs Access Acute Exposure Guideline Levels (AEGLs) Values | US EPA	
EPA/OPPT for pesticides (https://archive.epa.gov/pesticides/reregistration/web/html/status.html)	
Regional Screening Levels (https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables)	

OCCUPATIONAL EXPOSURE LIMIT SOURCES	RESULT (date if necessary)
OSHA (https://www.osha.gov/dsg/annotated-pels/index.html)	
ACGIH TLVs (https://www.acgih.org/data-hub-2022/)	
German MAKs (https://onlinelibrary.wiley.com/doi/book/10.1002/3527600418)	

OTHER TOXICOLOGICAL SOURCES	RESULT (date if necessary)
European Chemicals Agency (https://echa.europa.eu/)	
Cal OEHHA (https://oehha.ca.gov/chemicals)	
ATSDR Tox-Profiles (http://www.atsdr.cdc.gov/toxprofiles/index.asp)	
TSCA NTRL (National Technical Reports Library) (https://ntrl.ntis.gov/NTRL/)	
Texas CEQ Regulatory Guidelines (https://www.tceq.texas.gov/toxicology/esl/list_main.html and TAMIS database https://www17.tceq.texas.gov/tamis/index.cfm?fuseaction=home.welcome)	
SciFinder (SUBSCRIPTION NEEDED) (https://scifinder.cas.org)	
RTECs (SUBSCRIPTION NEEDED) (http://ccinfoweb.ccohs.ca/rtecs/search.html)	
NTP Study Database (https://ntp.niehs.nih.gov/publications/index.html)	
IARC Monographs (http://monographs.iarc.fr)	
Canadian Toxin and Toxin Target Database (T3DB) (http://www.t3db.ca/)	
World Health Organization INCHEM (INCHEM)	
Pubchem (https://pubchem.ncbi.nlm.nih.gov/)	
Pubmed (https://pubmed.ncbi.nlm.nih.gov and https://www.ncbi.nlm.nih.gov/pubmed?term=tox%20%5Bsubset%5D%20AND%20)	
OECD eChemPortal (https://hpvchemicals.oecd.org/UI/ChemGroup.aspx and https://www.echemportal.org/echemportal/)	
Japan Chemicals Database (https://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp)	

PHARMACEUTICAL DATA SOURCES	RESULT (date if necessary)
MedlinePlus Drug Information (https://medlineplus.gov/druginformation.html)	
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/daf/)	
European Food Safety Authority (http://www.efsa.europa.eu/en/publications)	
European Medicines Agency (http://www.ema.europa.eu/ema/)	
Cosmetic Ingredient Review (https://www.cir-safety.org/ingredients)	

Last Updated: April 21, 2023

Hazard Identification: What Are We Looking For?

1. Human Studies
   - Epidemiological Studies
   - Case Histories
   - Accidental Exposures
4. Mode of Action Studies

2. Animal Studies

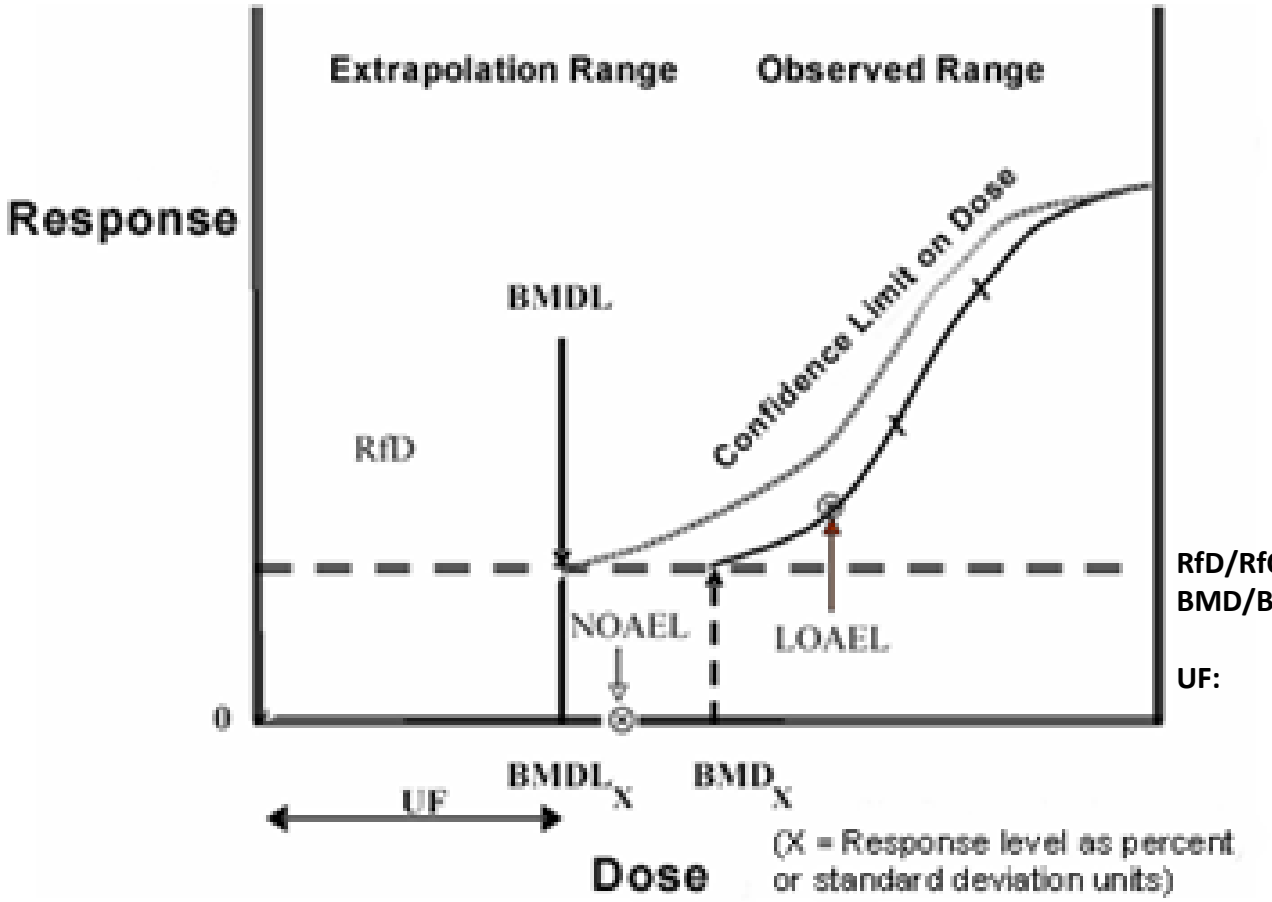
   Guidelines
   - right species,
   - number of animals,
   - good dose-response,
   - nature and extent of the endpoints considered,
   - well-documented

3. In Vitro Studies

Hazard Identification/Dose Response

- Identify a Key Study:
  - Provides the most relevant, reliable, and complete data
- Identify a Critical Effect:
  - First adverse effect as dose increases.
- Identify a Point of Departure
  - No observable adverse effect level (NOAEL)
  - Lowest observable adverse effect level (LOAEL)
  - Benchmark Dose:
    - An alternative method of defining the lower end of the dose response curve.

Dose/Response Curve



RfD/RfC: Reference Dose/Concentration
BMD/BMDL: Benchmark Dose/Benchmark Dose Lower Confidence Limit
UF: Uncertainty factors.

Adjusting the Point of Departure (POD)

Example: For a 90-day inhalation study in animals, the exposure may be 5 exposures per week and 6 hours per day.

- POD_{adj}= Adjusted to continuous exposure.
- If exposure = 5d/wk and 6 hrs/day then (POD x 5/7 x 6/24)

- Therefore, if the NOAEL is 1000 ug/m3 then:
  - 1000 ug/m3 x 5/7 x 6/24

    or
  - 178 ug/m3

Uncertainty Factors

$$\text{ITSL}\left(\frac{\mu g}{m^3}\right) = \frac{POD\ (adj)}{Uncertainty\ Factors\ (UFA\ x\ UFH\ldots.)}$$

- UF_A = Interspecies variability, accounts for extrapolating from animal to human (1 to 10).
- UF_H = Intraspecies variability, accounts for range of sensitivity in human populations (1 to 10).

Other Uncertainty Factors

$$\text{ITSL}\left(\frac{\mu g}{m^3}\right) = \frac{POD\ (adj)}{Uncertainty\ Factors\ (UFA\ x\ UFH\ x\ UFL\ x\ UFS)}$$

UF_L = LOAEL to NOAEL (1 to 10)

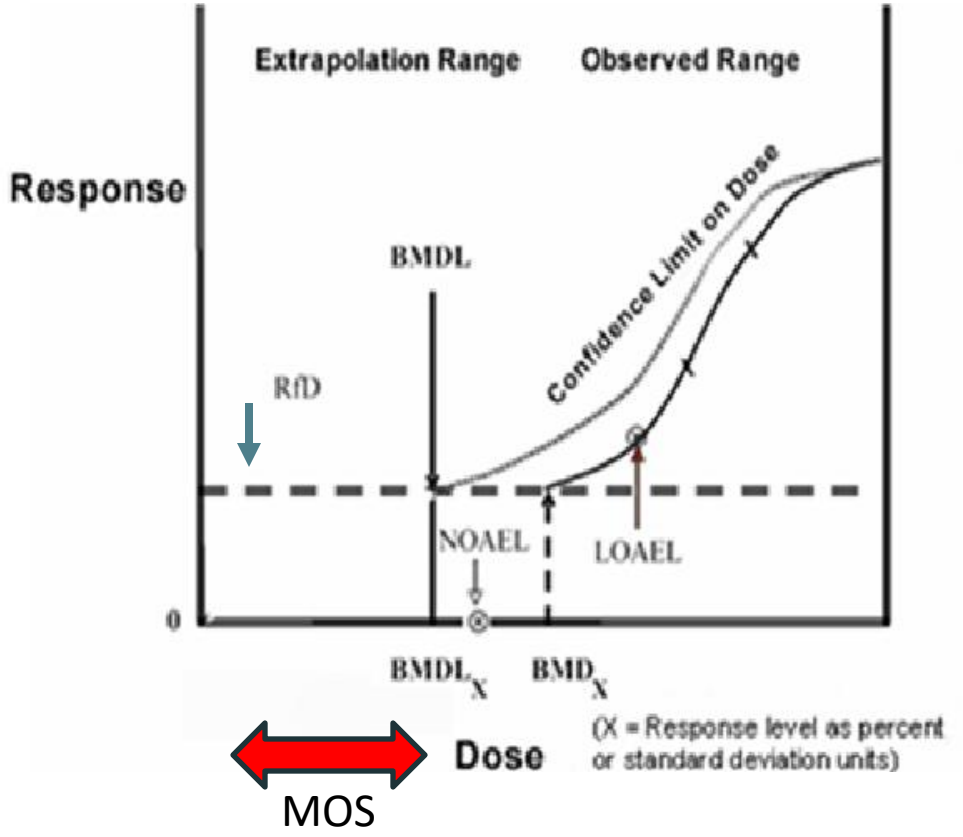
UF_S = Adjust a subchronic to chronic exposure (1-10)*

UF_D = Database (1)

* Additional Subacute to Subchronic UF of 3.5 is used, if appropriate.

Margin of Safety (MOS)

- Total amount of uncertainty accounted for to establish a reference dose (screening level)
- In this case, we can say we reduced the POD by 100x or more to come to an acceptable level. MOS = 100



Example of ITSL Determination

- ITSL = POD/UF_A X UF_H X UF_S
- ITSL = (178 ug/m3)/10 x 10 x 10 = 0.178 ug/m3
- ITSL = 0.2 ug/m3 (round to 1 significant figure)
  - UF_A = 10x for animal to human
  - UF_H = 10x for human variation
  - UF_S = 10x for subchronic to chronic

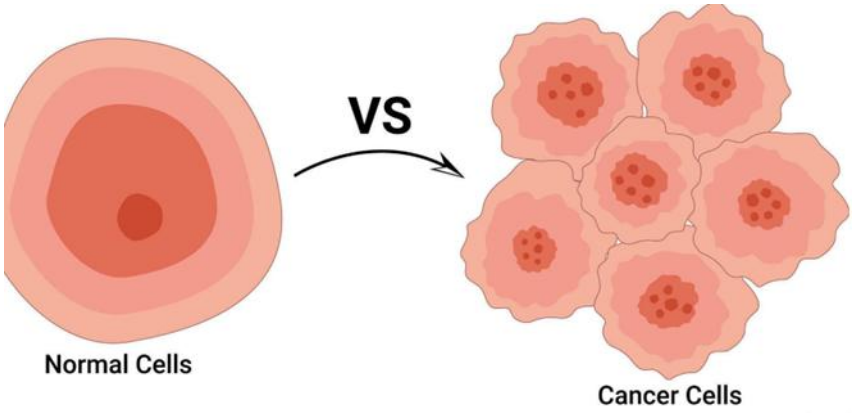
$$\text{ITSL}\left(\frac{\mu g}{m^3}\right) = \frac{POD\,(adj)}{\sum Uncertainty\ Factor\ (UF)}$$

Default Values

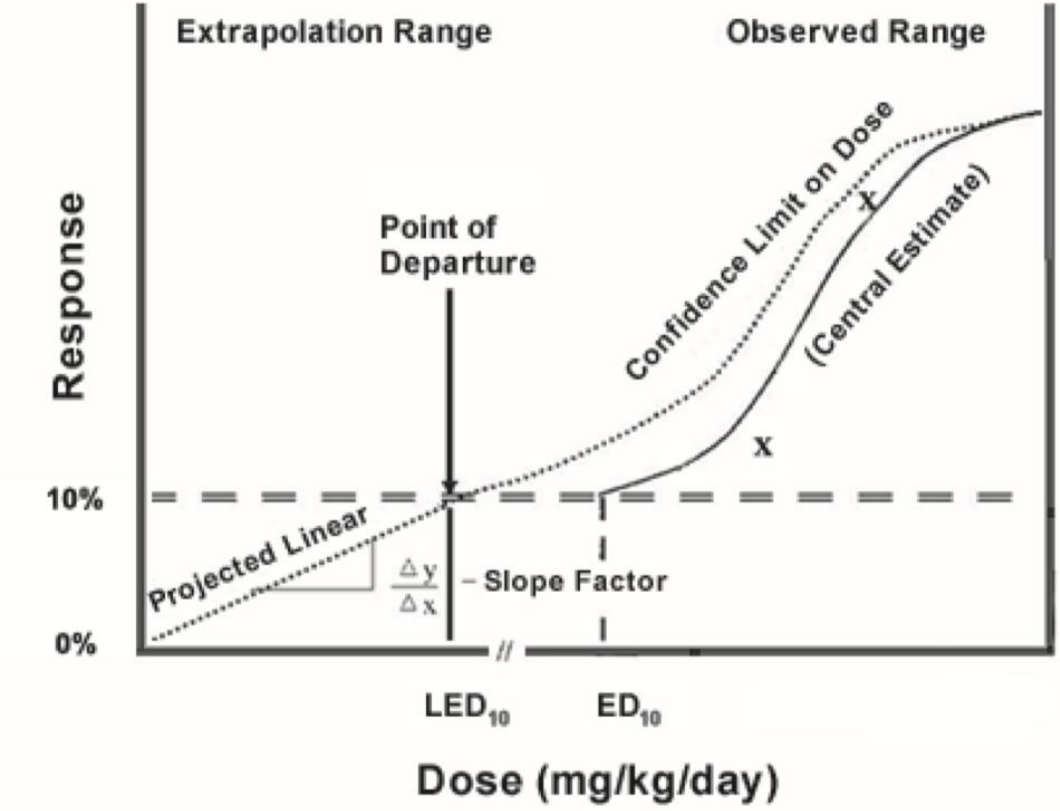
- Default values are a special case when no toxicity information is found on a chemical. In this case, a value of 0.1 µg/m^3 is adopted.

Carcinogens

- Basic assumptions of the slope factor assessment
- A small number of molecular events can evoke changes in a single cell that can lead to uncontrolled cellular proliferation and to a clinical state of disease



Derivation of Slope Factor



Carcinogens

- Estimating cancer risk using the slope factor
  - **Extra** lifetime cancer risk (i.e., probability that an individual will contract cancer over a lifetime) is estimated using estimated exposure and the slope factor:

- IRSL = 1 X 10^{-6} /Slope Factor

- Cancer Risk = Estimated Exposure x Slope Factor

Carcinogens

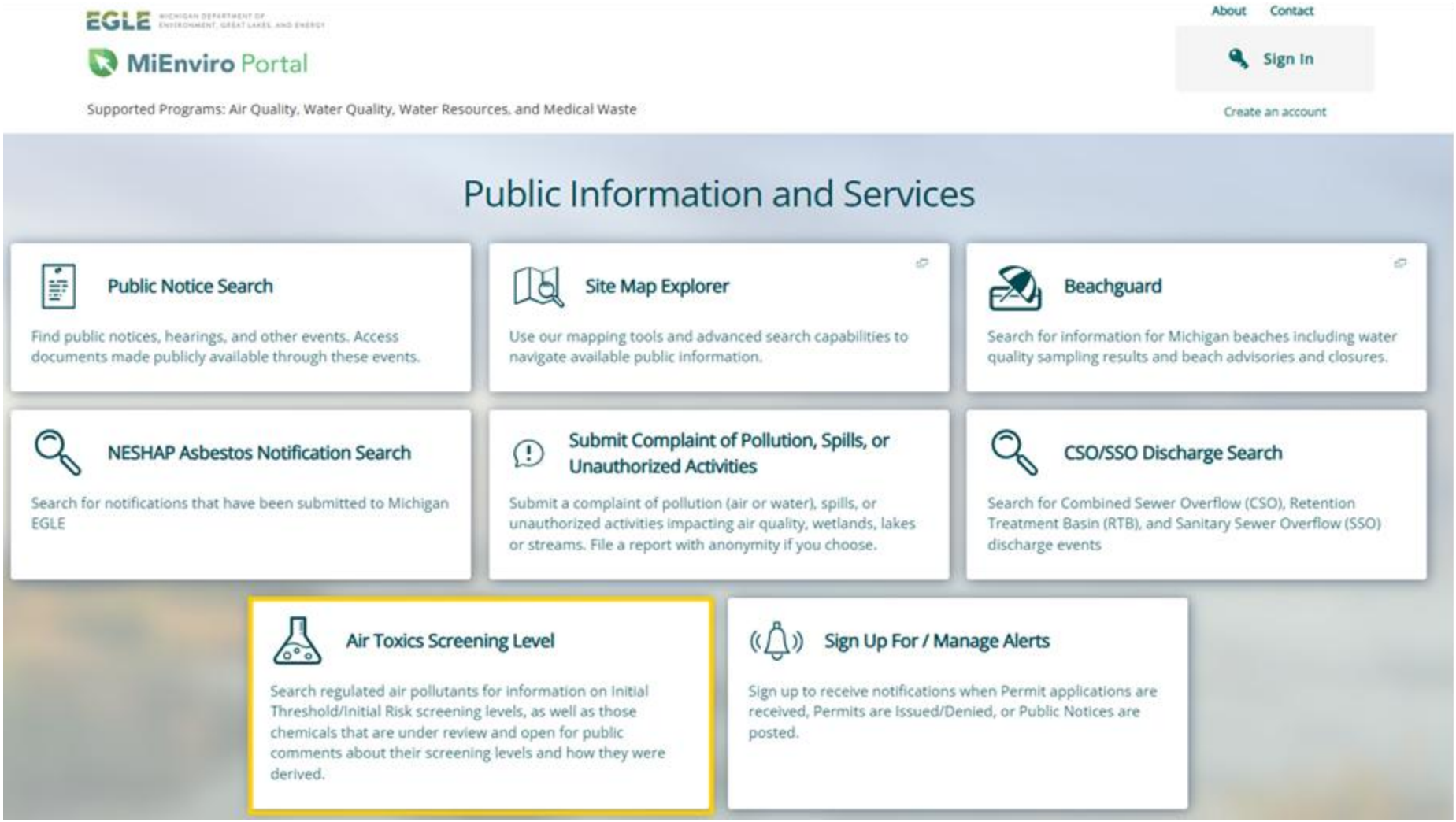
- Acceptable cancer risk
  - Generally considered to be 1/1,000,000 lifetime risk above the background (40%)
  - 1/10,000 to 1/100,000 may be acceptable, depending on the exposure scenario

Screening Levels

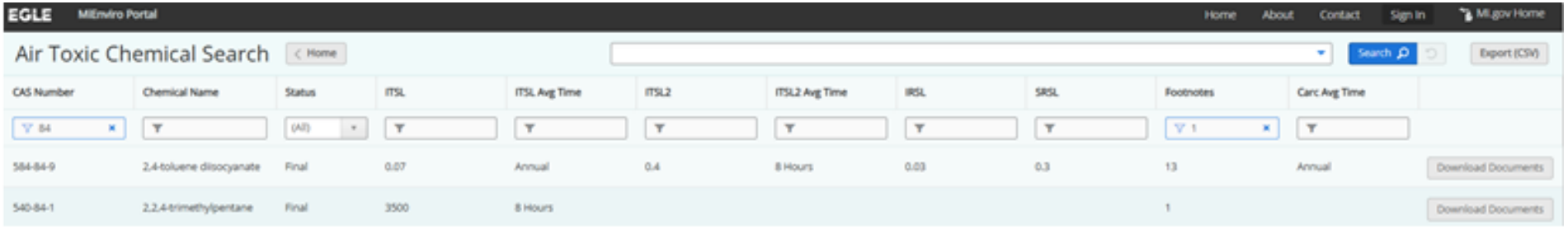
There are over 1200 chemicals for which we have screening levels which are publicly available. This is not a defined list (open-ended).

Developed by AQD toxicologists based on the methodologies in rules (Rules 231 through 233, and 229).

Associated with footnotes when nuances make a difference

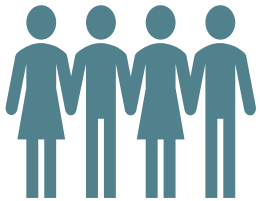

EGLE
MiEnviro Portal
Supported Programs: Air Quality, Water Quality, Water Resources, and Medical Waste
About
Contact
Sign In
Create an account
Public Information and Services
Public Notice Search
Find public notices, hearings, and other events. Access documents made publicly available through these events.
Site Map Explorer
Use our mapping tools and advanced search capabilities to navigate available public information.
Beachguard
Search for information for Michigan beaches including water quality sampling results and beach advisories and closures.
NESHAP Asbestos Notification Search
Search for notifications that have been submitted to Michigan EGLE
Submit Complaint of Pollution, Spills, or Unauthorized Activities
Submit a complaint of pollution (air or water), spills, or unauthorized activities impacting air quality, wetlands, lakes or streams. File a report with anonymity if you choose.
CSO/SSO Discharge Search
Search for Combined Sewer Overflow (CSO), Retention Treatment Basin (RTB), and Sanitary Sewer Overflow (SSO) discharge events
Air Toxics Screening Level
Search regulated air pollutants for information on Initial Threshold/Initial Risk screening levels, as well as those chemicals that are under review and open for public comments about their screening levels and how they were derived.
Sign Up For / Manage Alerts
Sign up to receive notifications when Permit applications are received, Permits are Issued/Denied, or Public Notices are posted.

Example



Footnote 13: “This chemical has two ITSLs with different averaging times. Ambient air impacts cannot exceed either ITSL. Both ITSLs also apply for determinations of PTI exemptions under R336.1290 (Rule 290).

Screening Levels



Screening levels must undergo Public comment Rule 230.

Candidate chemicals for future review are put on a Chemicals Under Review list.

EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

New and updated screening levels – May 2026

The Michigan Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD) develops health-based air toxics screening levels to provide protection to the public when breathing the ambient (outdoor) air. These screening levels are used by AQD permit engineers in their evaluation of new or modified industrial processes, which may emit air toxics.

Every month, AQD toxicologists determine which air toxic chemicals, if any, need to be reviewed.

One chemical was updated on the Air Toxics Screening level list this past month.

CAS No.	Chemical	ITSL ($\mu g/m^3$)	Averaging Time
363-24-6	Prostaglandin E2	6	1-hour

The initial threshold screening level (ITSL) for prostaglandin E2 (CAS# 363-24-6) of 6 $\mu g/m^3$ with a 1-hour averaging time was derived to protect against premature labor induction (reproductive and developmental effects), while also protective of potential respiratory irritation.

Questions?

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