Tiers for Fears

Applying Fit-for-Purpose Risk Assessment in Environmental Stewardship

Session Overview

Paul DeLeo, Integral Consulting

Tiered environmental risk assessment – Why and How

Chris Holmes, Applied Analysis Solutions

Environmental fate and exposure assessment in detail

Kevin Kransler, SI Group

Supplier Perspective: Screening-level tools to identify portfolio risk

Andrea Carrao, Kao USA

User Perspective: High-throughput screening of portfolio

Part 2 – “Ruling the world” one tier at a time

Christopher Holmes

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https://AppliedAnalysis.solutions

Introduction

Product stewardship includes understanding & managing the potential for your product to enter the environment

So many ingredients,

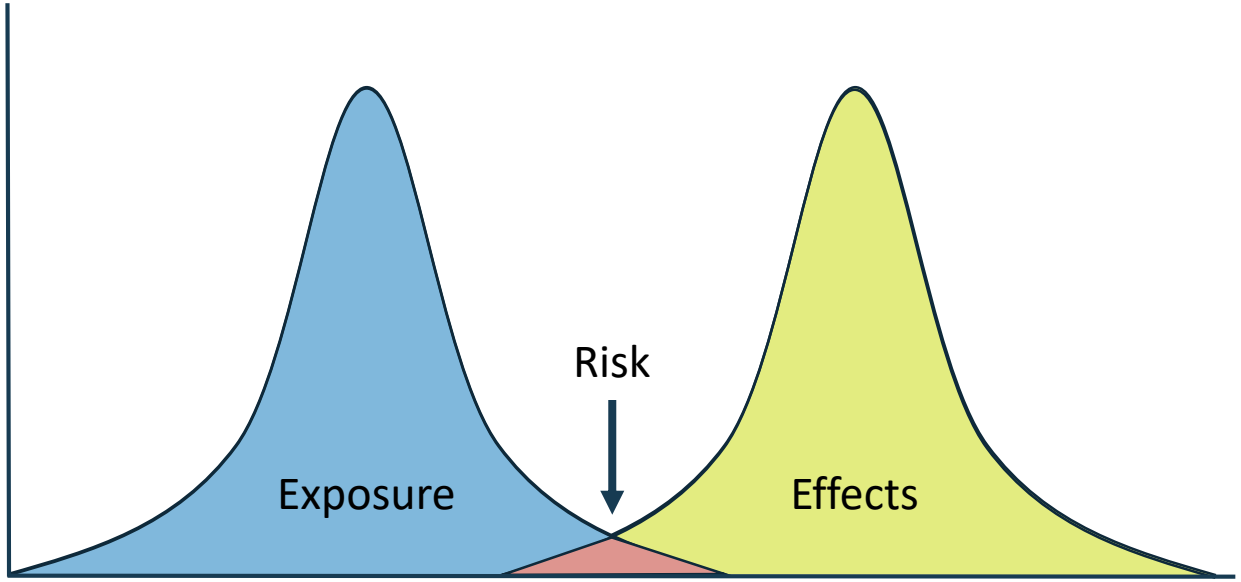
so much to know,

so little time …

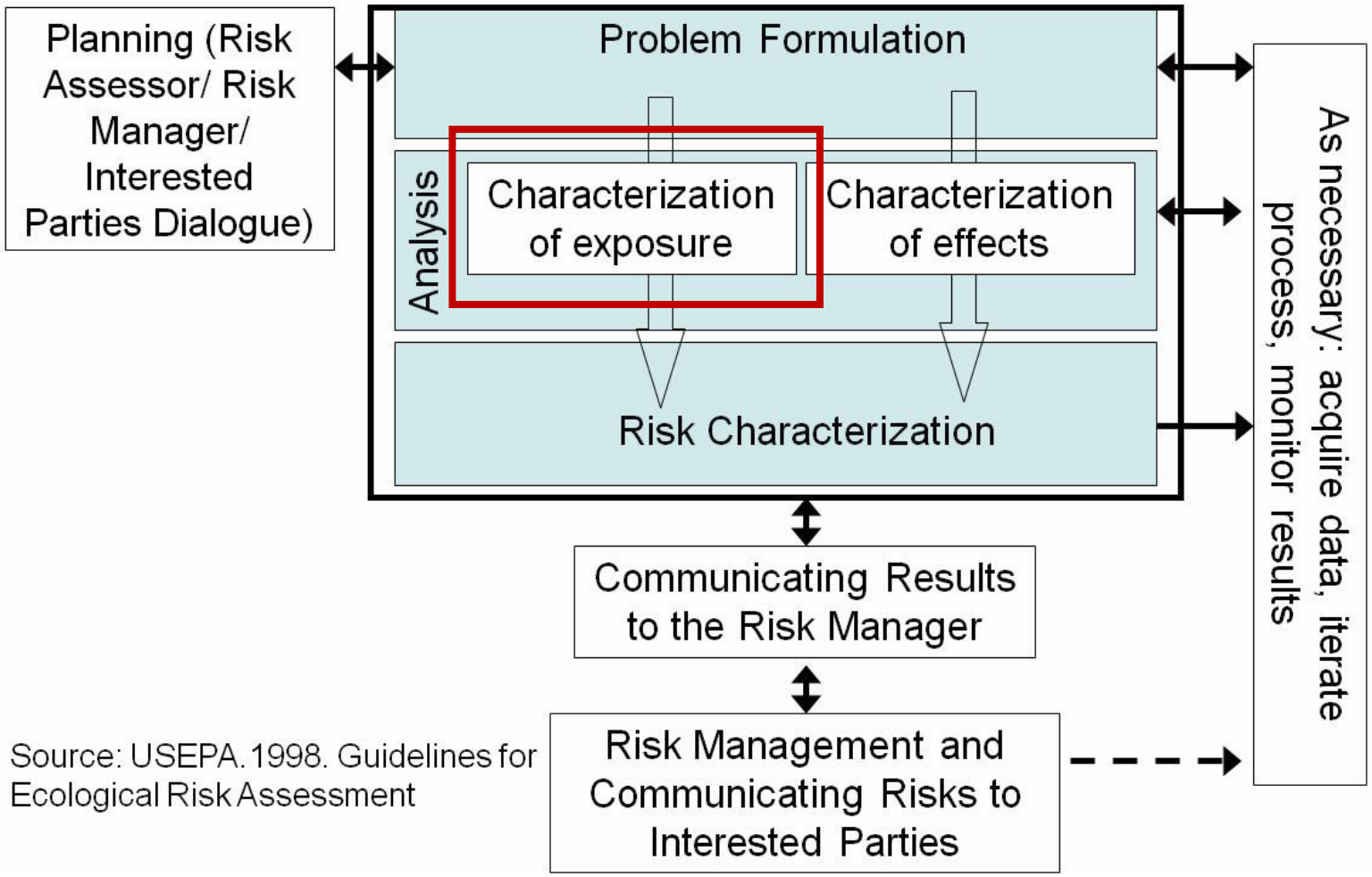
But don't *fear*, tools are available to help you efficiently apply your energy to the areas that contribute the most and achieve your needs

Risk

- Comparing toxicity information and the amount of a substance an organism may be exposed to in the environment
- A substance can be toxic at one exposure level, and have little or no effect at another
- Risk is the intersection of exposure and effects
- Environmental exposure may have a temporal and/or geospatial component



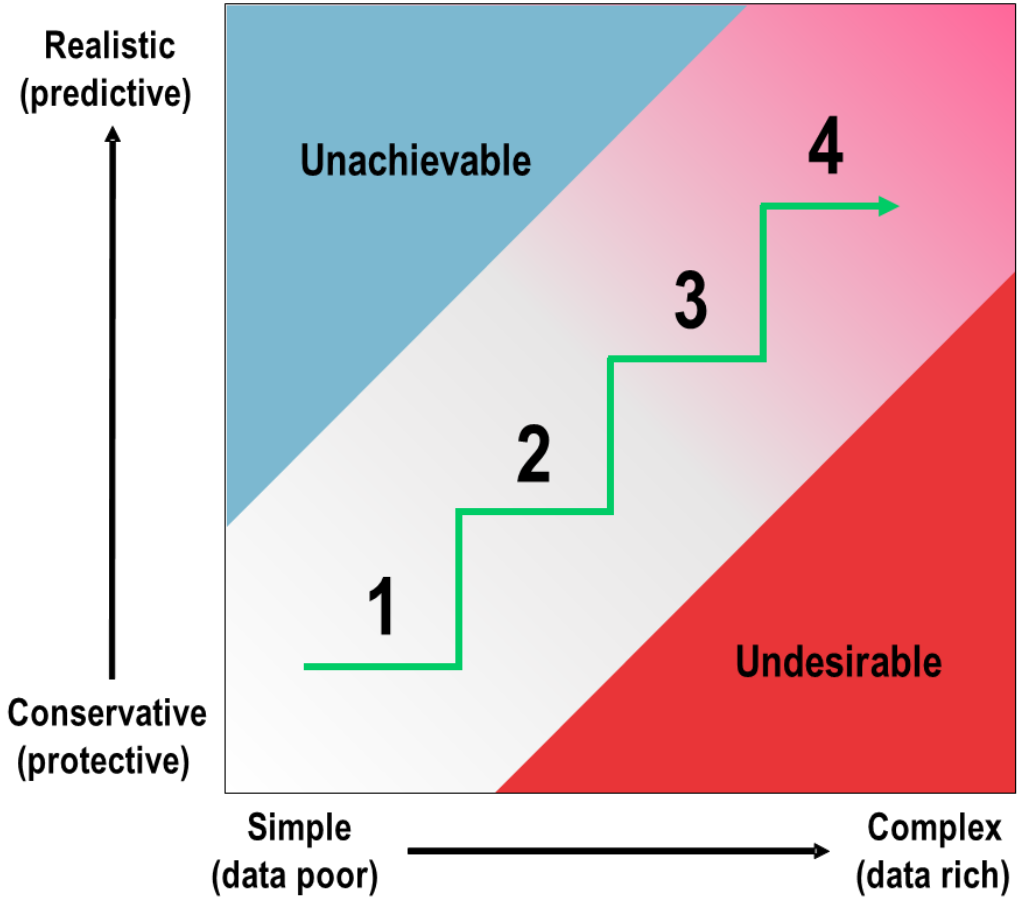
Risk assessment



Source: USEPA. 1998. Guidelines for Ecological Risk Assessment

Tiered approach

- Tiered system efficiently allocates resources
- Lower tiers use conservative assumptions to screen out negligible risks
- When a substance is not predicted to cause adverse effects at the screening-level
  - possibility of harming the environment is low and use is accepted
- Failing a lower tier indicates further refinement is needed



Adapted from K. Woodburn, Dow Performance Silicones

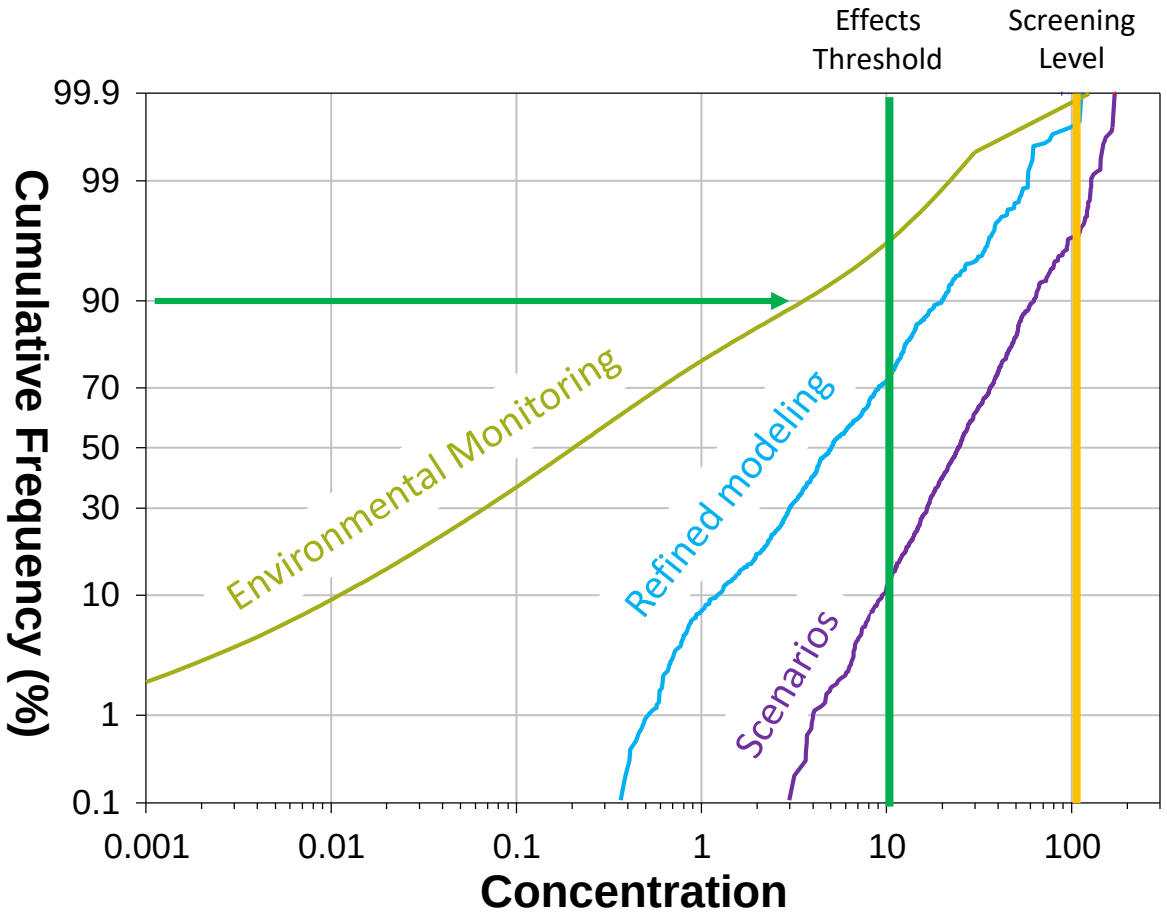
Exposure estimation

Lower tier (deterministic)

- Uses single values to make a determination
  - Risk Quotient (RQ) = exposure / toxicity
  - Toxicity Exposure Ratio (TER) : No Effect Concentration / exposure
- Results in a “bright line” = pass or fail

Higher tier (probabilistic)

- Accounts for variability
- Progressive refinement
- Distribution of results



Estimating aquatic environmental concentrations

- Concentration $= \frac{mass\ of\ ingredient}{volume\ of\ water}$
- Environmental Concdtd $= \frac{Mass\ used - \%removed\ in\ WWTP}{Water\ used}\ x\ dilution\ factor$

Dilution Factor $= \frac{WWTP\ flow + river\ flow}{river\ flow}$

- Screening level
  - Spreadsheet
  - Computer model (simple)
- Refined
  - Computer model
  - Larger range of data
  - Estimated or measured
  - May include spatial and temporal variability

Lower tier exposure models

- Simple models utilizing idealized scenarios and conservative assumptions
- Easy to use, appropriate for screening

- Exposure and Fate Assessment Screening Tool (E-FAST)
  - General population and aquatic ecological exposure and risk
  - Environmental releases to air, surface water, landfills, and by consumer products
  - EPA https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014
- European Union System for the Evaluation of Substances (EUSES)
  - Assess general risks posed by chemical substances
  - EC: https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances

Exposure and Fate Assessment Screening Tool

- Ecological exposure from “down the drain” emissions
- User supplies total annual emissions and WWTP removal
- Assumed even distribution of use and emission across entire population
  - Built in:
  - Per capita water use
  - Environmental dilution factor

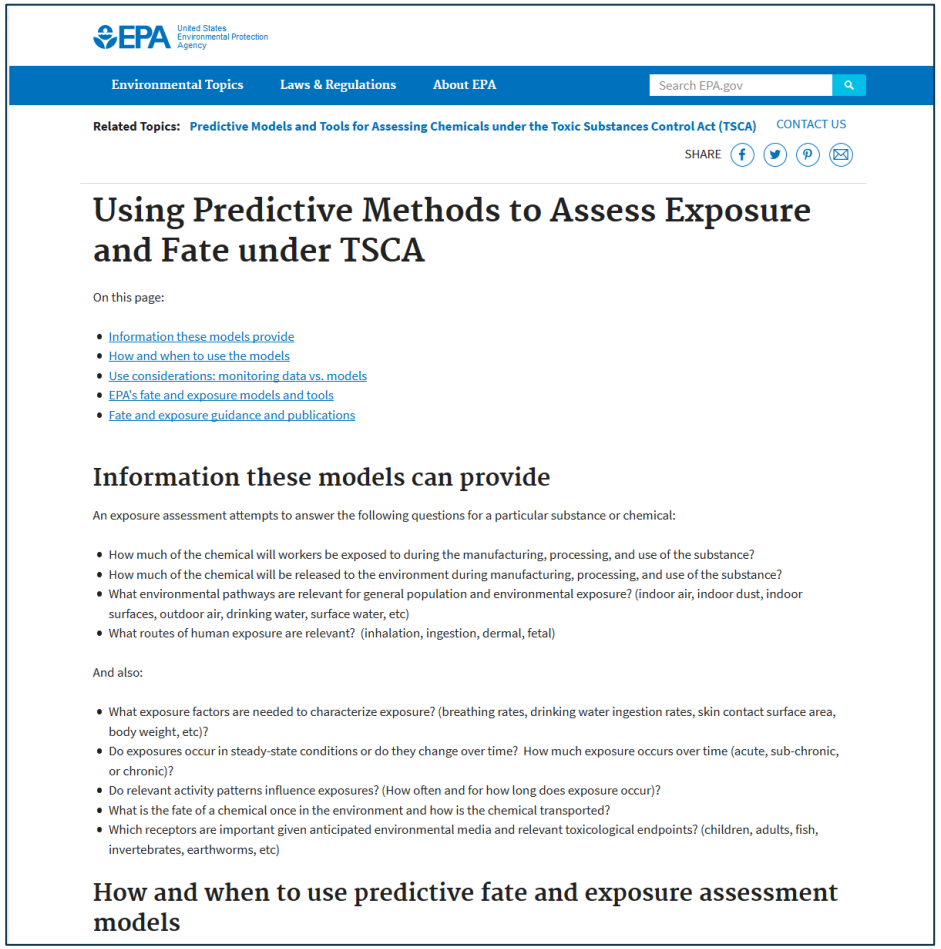
Exposure and Fate Assessment Screening Tool

- E-FAST is a screening level model with conservative assumptions
  - Assumes no stream dilution for ecological exposure
  - Considers only mixing zone concentration (no downstream attenuation)
  - Does not consider potential upstream sources
  - Does include variable dilution in Probabilistic Dilution Model (PDM)

Descriptor	Use	10th-percentile Stream Dilution Factor
7Q10 (lowest 7-day flow over 10 years)	Potential chronic aquatic life impacts	**1.00**
1Q10 (lowest 1-day flow over 10 years)	Potential acute aquatic life impacts	**1.00**
30Q5 (lowest 30-day flow over 5 years)	Acute human exposure via drinking water	1.80
Harmonic Mean Flow	Chronic human exposure via drinking water and fish ingestion	7.95

Higher tier exposure models

- More sophisticated estimation of exposure
- Requires more information on:
  - Usage / emissions
  - Fate
  - Transport
- EPA help - Using Predictive Methods to Assess Exposure and Fate under TSCA
  - EPA's fate and exposure models and tools



EPA United States Environmental Protection Agency

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Related Topics: Predictive Models and Tools for Assessing Chemicals under the Toxic Substances Control Act (TSCA) CONTACT US

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Using Predictive Methods to Assess Exposure and Fate under TSCA

On this page:

- Information these models provide
- How and when to use the models
- Use considerations: monitoring data vs. models
- EPA's fate and exposure models and tools
- Fate and exposure guidance and publications

Information these models can provide

An exposure assessment attempts to answer the following questions for a particular substance or chemical:

- How much of the chemical will workers be exposed to during the manufacturing, processing, and use of the substance?
- How much of the chemical will be released to the environment during manufacturing, processing, and use of the substance?
- What environmental pathways are relevant for general population and environmental exposure? (indoor air, indoor dust, indoor surfaces, outdoor air, drinking water, surface water, etc)
- What routes of human exposure are relevant? (inhalation, ingestion, dermal, fetal)

And also:

- What exposure factors are needed to characterize exposure? (breathing rates, drinking water ingestion rates, skin contact surface area, body weight, etc)?
- Do exposures occur in steady-state conditions or do they change over time? How much exposure occurs over time (acute, sub-chronic, or chronic)?
- Do relevant activity patterns influence exposures? (How often and for how long does exposure occur)?
- What is the fate of a chemical once in the environment and how is the chemical transported?
- Which receptors are important given anticipated environmental media and relevant toxicological endpoints? (children, adults, fish, invertebrates, earthworms, etc)

How and when to use predictive fate and exposure assessment models

https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca

Determining refined usage and emissions

- Market survey data
  - Capture variability in product purchase / usage
  - E.g., Mintel, Euromonitor

- Scenario Assembly Tool (ScenAT) - Unilever
  - Combines market data and population ability to purchase products based on GDP
  - Spatial differentiation within and between countries
  - Models ingredient used across multiple products

b

#	GDP Threshold	Example product
7	Very High	Machine Dishwash
6	High	Deodorants
5	Medium High	Conditioner
4	Medium	Shampoo
3	Medium Low	Toothpaste
2	Low	Bar Soap
1	Very Low	-

Figure 1 from Hodges et al (2012) HPC products aligned with different GDP threshold bands.

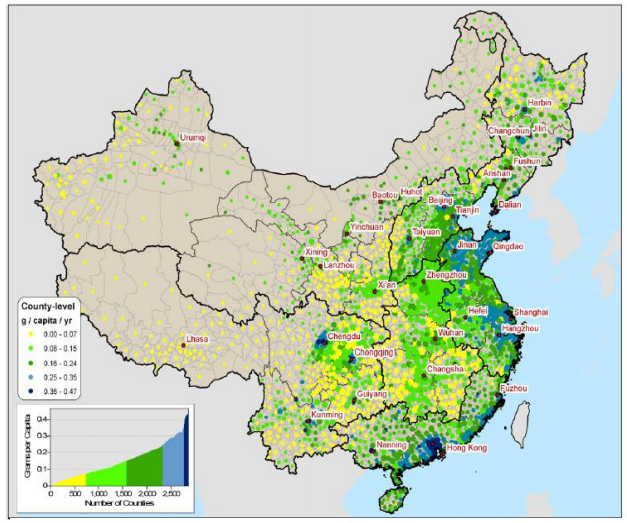
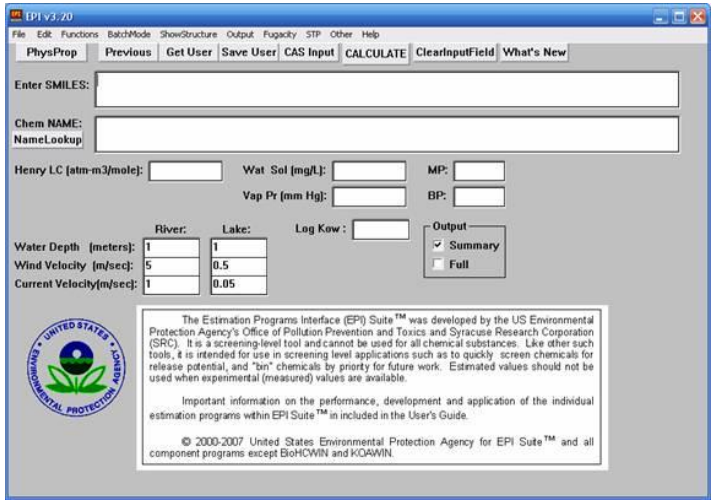


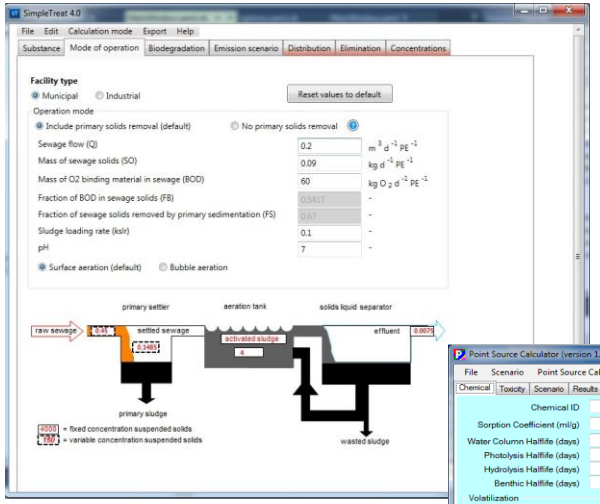
Figure 6 from Hodges et al (2012) Distribution of hypothetical chemical used in multiple product types across China.

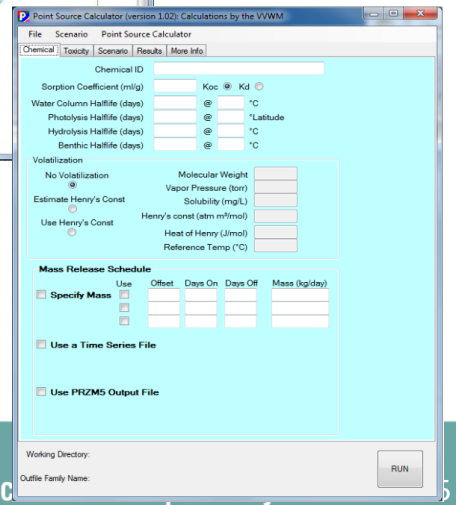
Hodges JE, Holmes CM, Vamshi R, Mao D, Price OR. 2012. Estimating chemical emissions from home and personal care products in China. Environ Pollution. 165:199–207

Methods to refine fate estimation

- Laboratory studies
- EPI Suite™
  - Provides estimates of physical/chemical and environmental fate properties
  - Multiple programs / modules
  - EPA: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface
- SimpleTreat
  - Assess fate of substances in waste water treatment plants
  - Considers volatilization, mixing, adsorption and degradation
  - RIVM: https://www.rivm.nl/en/soil-and-water/simpletreat
- EPA Point Source Calculator (VVWM-PSC)
  - Refined environmental fate in aquatic systems
  - Concentrations in water column, porewater, and sediment
  - Based on pesticide model (Variable Volume Water Model)
  - EPA: https://www.epa.gov/tsca-screening-tools/point-source-calculator-version-105-psc-v105

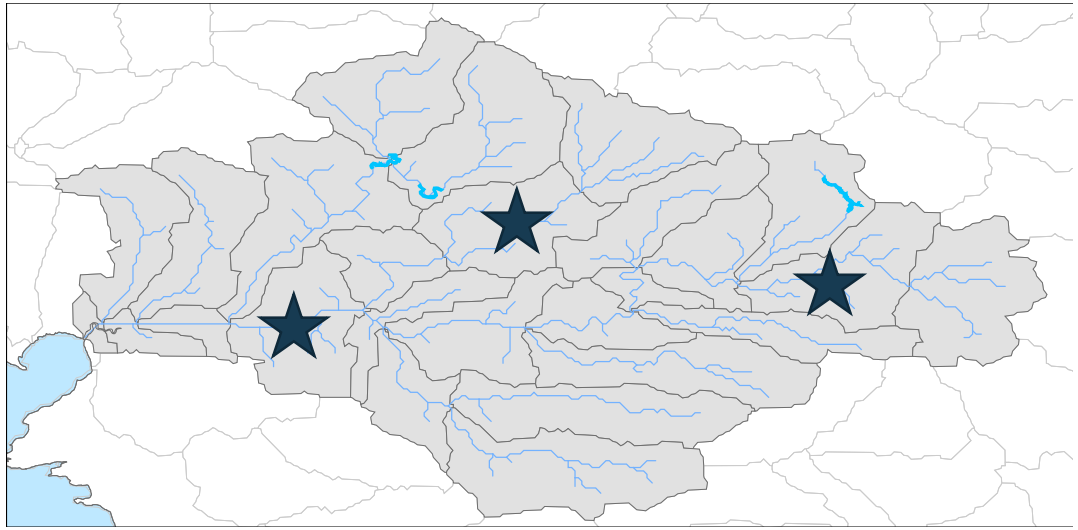


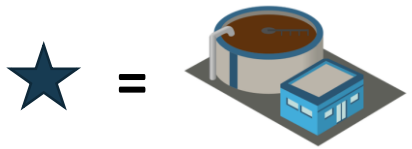




Refined hydrologic transport

- Georeferenced emissions linked to river network with downstream transport
- In-STRream Environmental Exposure Model (iSTREEM®) https://www.istreem.org/
  - Web-enabled public model to predict concentrations of "down-the-drain" ingredients
  - Maintained by American Cleaning Institute (ACI)
- PhATE®
  - Proprietary model from Pharmaceutical Research and Manufacturers of America (P*h*RMA)
  - Point source emissions to rivers in 11 representative watersheds in US
- Geo-referenced Regional Exposure Assessment Tool for European Rivers (GREAT-ER) http://cefic-lri.org/toolbox/great-er/
  - Public model for 16 representative European watersheds
  - European Chemical Industry Council (CEFIC)





References:

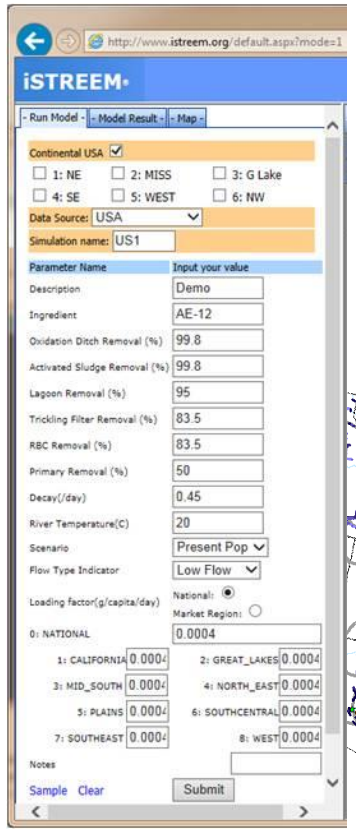
iSTREEM - Kapo et al., 2016. iSTREEM®: An approach for broad-scale in-stream exposure assessment of “down-the-drain” chemicals. Integr Enviro Assess Manag 12:782-792 DOI: 10.1002/ieam.1793

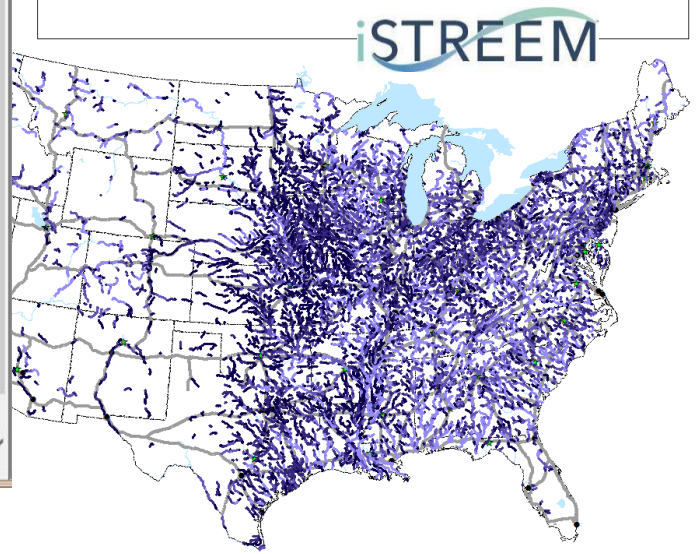
PhATE - Anderson et al, 2004. Screening analysis of human pharmaceutical compounds in U.S. surface waters. Environ. Sci. Technol. 38, 838e849

GREAT-ER - Kehrein et al., 2015. Modeling the fate of down-the-drain chemicals in whole watersheds: new version of the GREAT-ER software. Environ. Model. Software 64, 1e8.

Addressing all three aspects with iSTREEM®

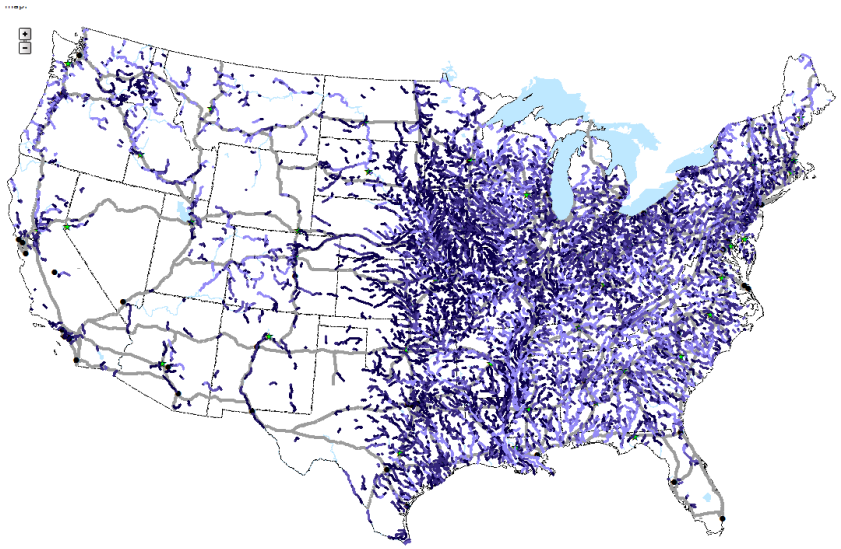
- Usage / emissions
  - Product usage based on market region
  - Per capita water use specific to 12,000+ facilities based on EPA data [1]
- Fate
  - WWTP removal assigned to 6 treatment types
  - In-river removal using first-order decay
- Environmental
  - Site specific dilution factors
  - Hydrologic transport for 300,000 river miles downstream of WWTPs [2]





[1]US EPA Clean Watersheds Needs Survey – includes NPDES permit numbers, treatment type information, population data, effluent flow
[2]USGS/EPA National Hydrography Dataset Plus

Processing flow in iSTREEM®



iSTREEM https://www.istreem.org/

Influent to WWTP
(per capita use x population served)

Removal in WWTP
(Varies by treatment type)

WWTP Effluent
Calculates effluent concentration

Inputs to segment
- WWTP effluent
- Tributary water & chemical
- Tributary water without chemical

Calculates PEC_{sw} for effluent discharge "mixing zones"

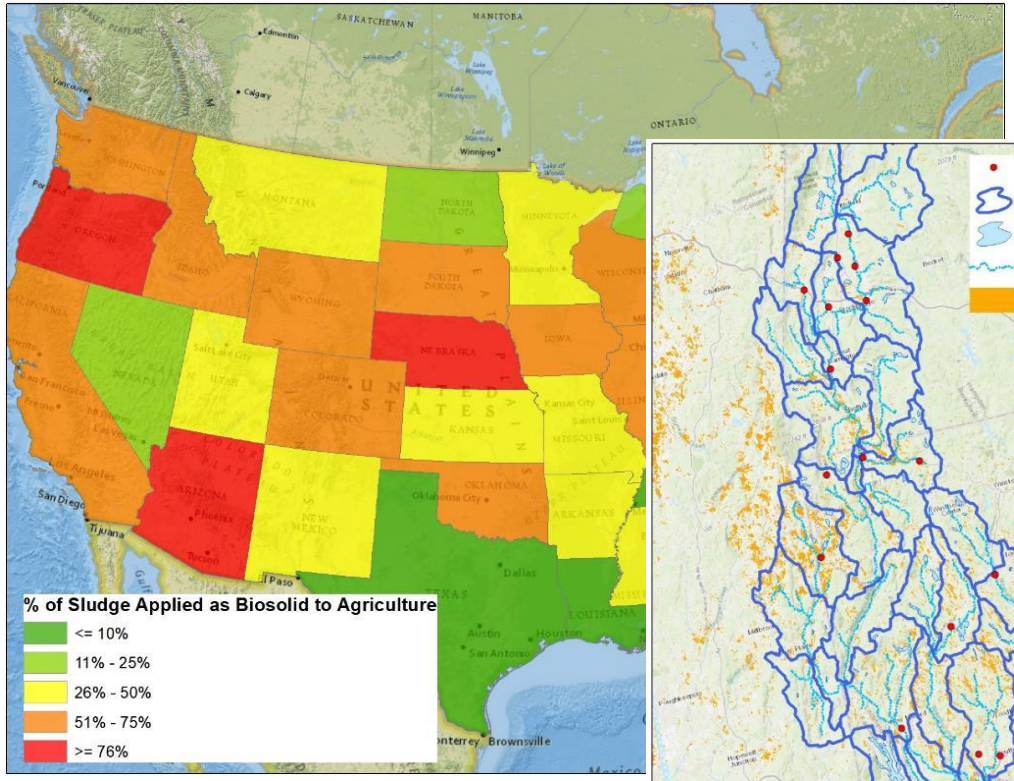
Removal from water column within segment
- 1st order decay proxy for:
  - Biodegradation
  - Adsorption
  - Deposition

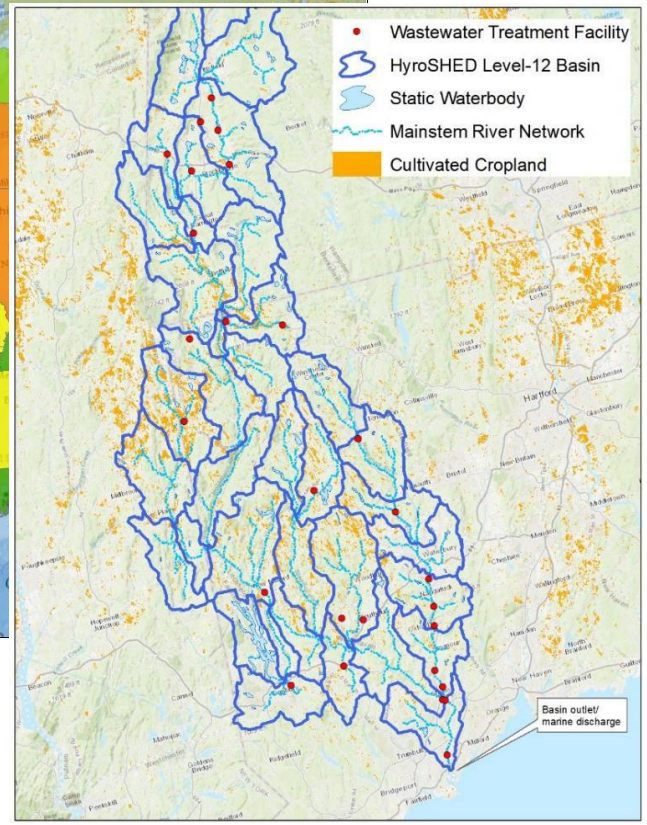
Calculates PEC_{sw} for all effluent-impacted streams

Calculates concentration for abstraction points (DWI)

Sewage sludge and the terrestrial environment

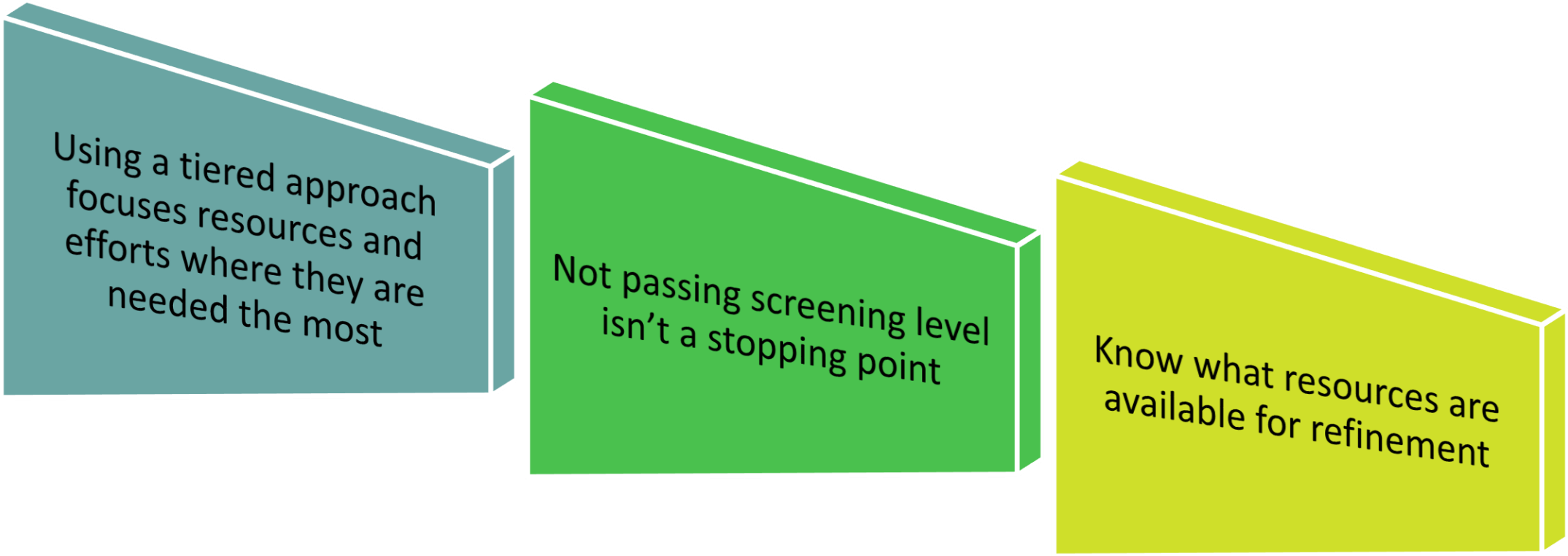
- Not all substances removed during wastewater treatment are eliminated
- May be captured in WWTP solids
  - E.g., microplastics, metals
- Disposition of sludge depends on local and regional practices
  - May be land applied to soil
  - Potential for subsequent movement to surface water





Images from Holmes et al, 2018. Estimating environmental emissions and aquatic concentrations of sludge-bound CECs using spatial modeling and US datasets. SETAC NA 39th Annual Meeting. Sacramento, CA. Nov 2018
Biosolid data from U.S. and State-by-State, Biosolids Regulation, Quality, Treatment, and End Use and Disposal Data APPENDIX D. Version - FINAL - Part 1 of 2, December 31, 2007, https://www.nebiosolids.org/

Final thoughts



"*Nothing ever lasts forever*" - Exposure and risk are episodic in time and place

Thank You for your attention

- Please ask questions now …
- … at the end of the session …

- … or follow up later

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Tears for Fears, 1985
Songs from the Big Chair

- "*Shout*" and fill out the session evaluation via the mobile app!
  - Tiers for Fears: Applying fit-for-purpose risk assessment in environmental stewardship