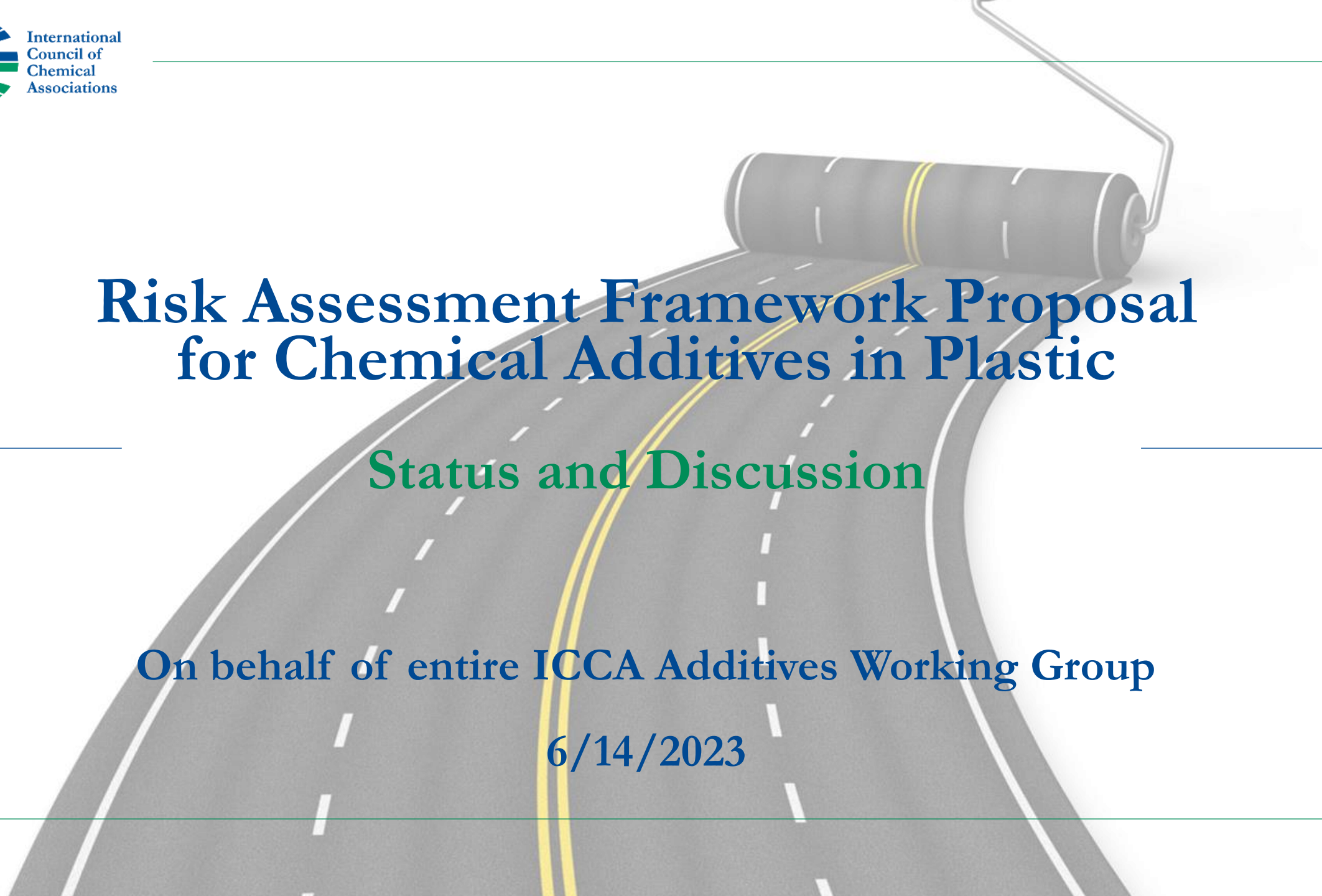
International Council of Chemical Associations

Risk Assessment Framework Proposal for Chemical Additives in Plastic

Status and Discussion



On behalf of entire ICCA Additives Working Group

6/14/2023

Agenda

Why Risk vs Hazard Assessment?

Food Contact Chemicals Database Example

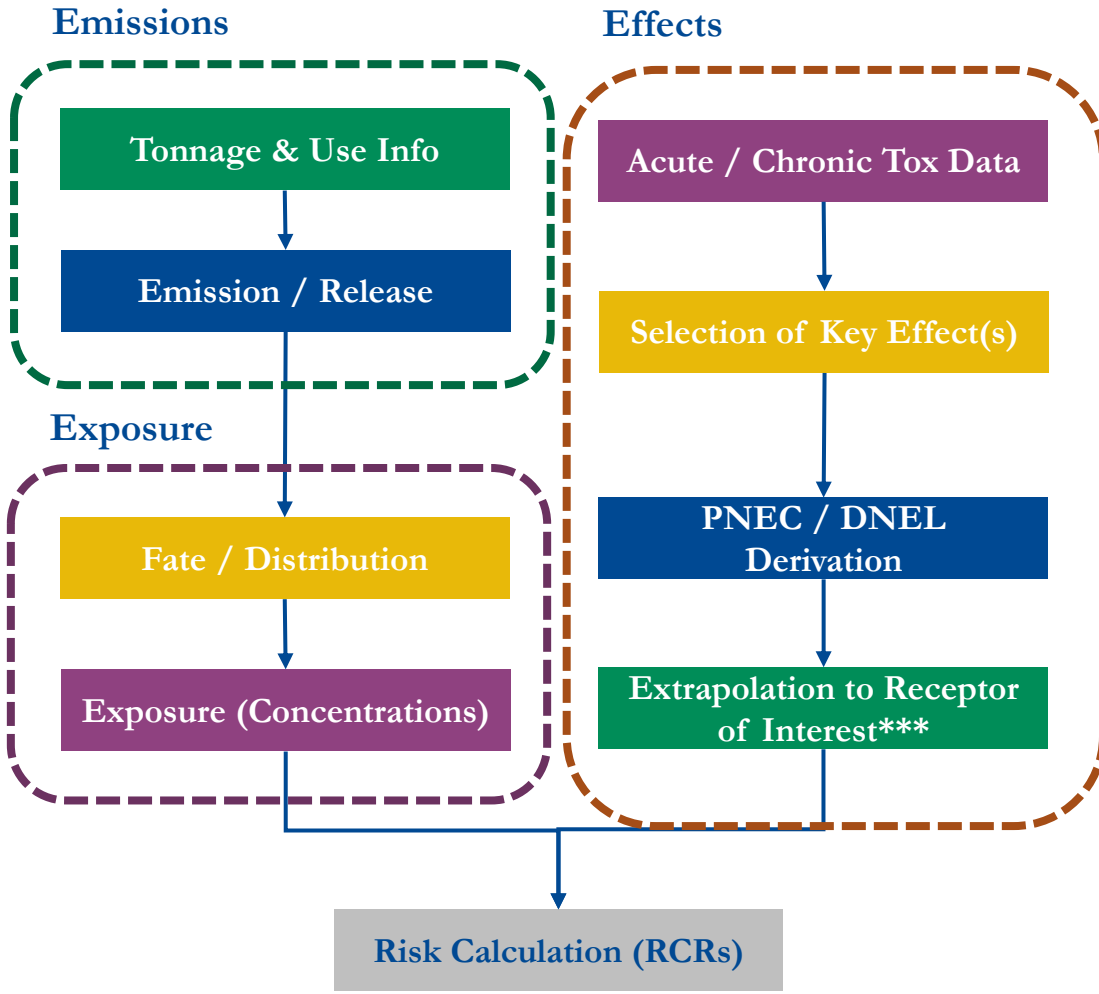
Risk Assessment Framework Elements

Breakout Activity

Why Risk Assessment?

Why Risk vs. Hazard Assessment?

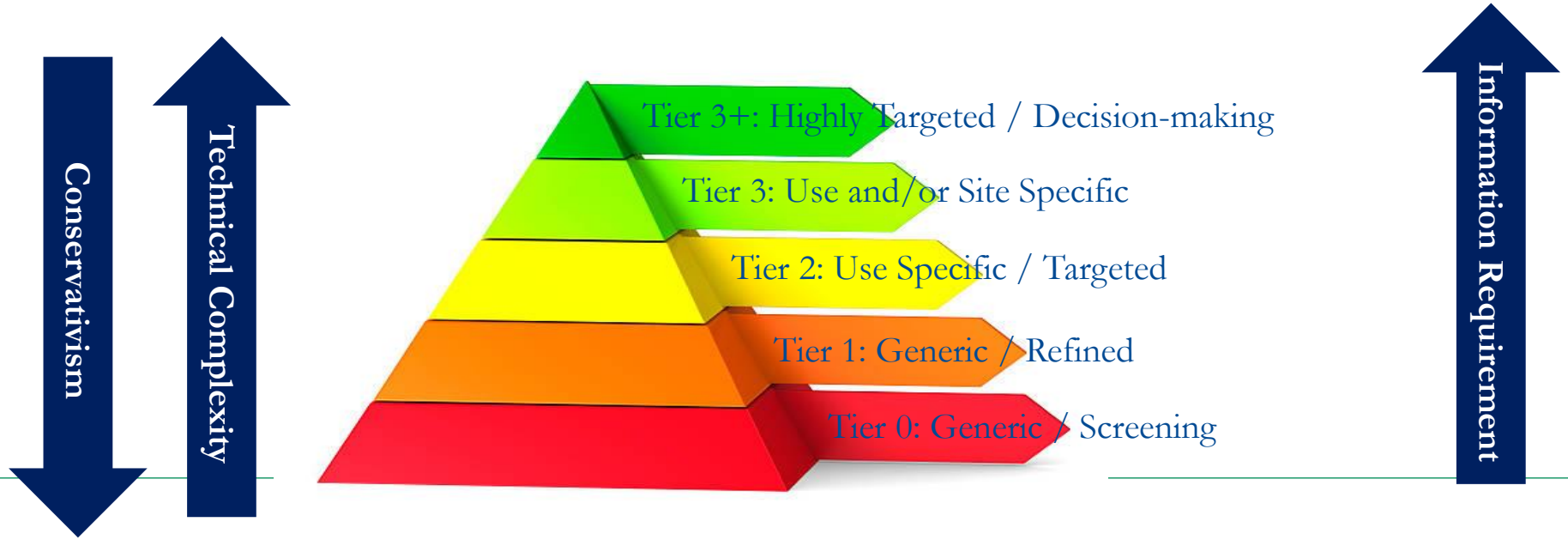
- **Defining clear objectives / protection goal(s) is a critical element of effective chemical management strategy**
  - Need the ability to ***quantitatively*** measure mitigated risk(s) and/or realized benefits as an outcome of that strategy and related decisions
  - Without this, effective deployment of technology, regulatory, and policy decisions are not possible
- **Risk assessment quantitatively compares exposure and hazard effects thresholds**
  - Outcome is quantitative (e.g., risk ratios – RCRs, RQs, MoE), easily interpreted, and comparable



Benefits of Tiered Risk Assessment (TRA)

1. **Use cases for Risk Assessment vary considerably**
   - Information availability / necessary for problem formulation may differ
2. **Tiered Risk Assessment allows for fit-for-purpose assessment / efficient use of resources**
   - Screening vs. definitive
3. **Requires alignment / clear communication of applicability & uncertainty**
   - Objective(s), stakeholder needs, ultimate utility of assessment

For Example:



Risk Assessment Framework Project

Overall Risk Assessment Goal and objective:

- Develop a framework/approach to evaluate the risks of additives in plastics to the environment and human health across the entire article service life, including impact to circularity;

Goal for today's presentation:

- Present a starting point for the conceptual risk assessment framework for chemical additives in plastics that together we can discuss, add to, modify and refine.
- Build consensus on a tiered based approach and criteria
- Identify any blind spots or difference in priorities
- Prioritize research / science needs for data gaps

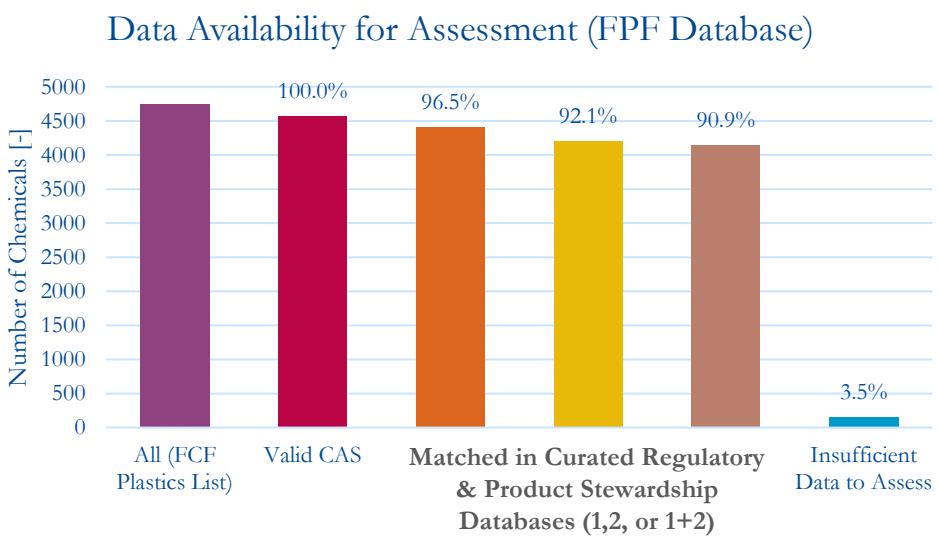
Approach for today's discussion:

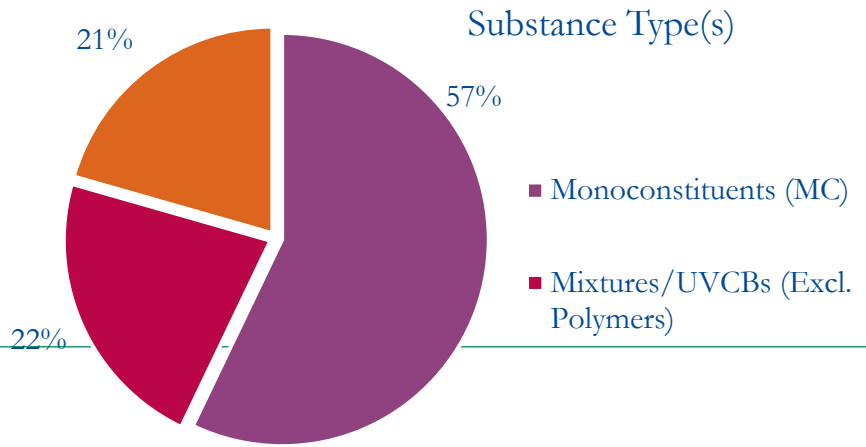
- Discuss complexities and challenges of risk assessment of chemical additives in plastics
- Develop and coalesce around elements / principles of a robust and scientific approach

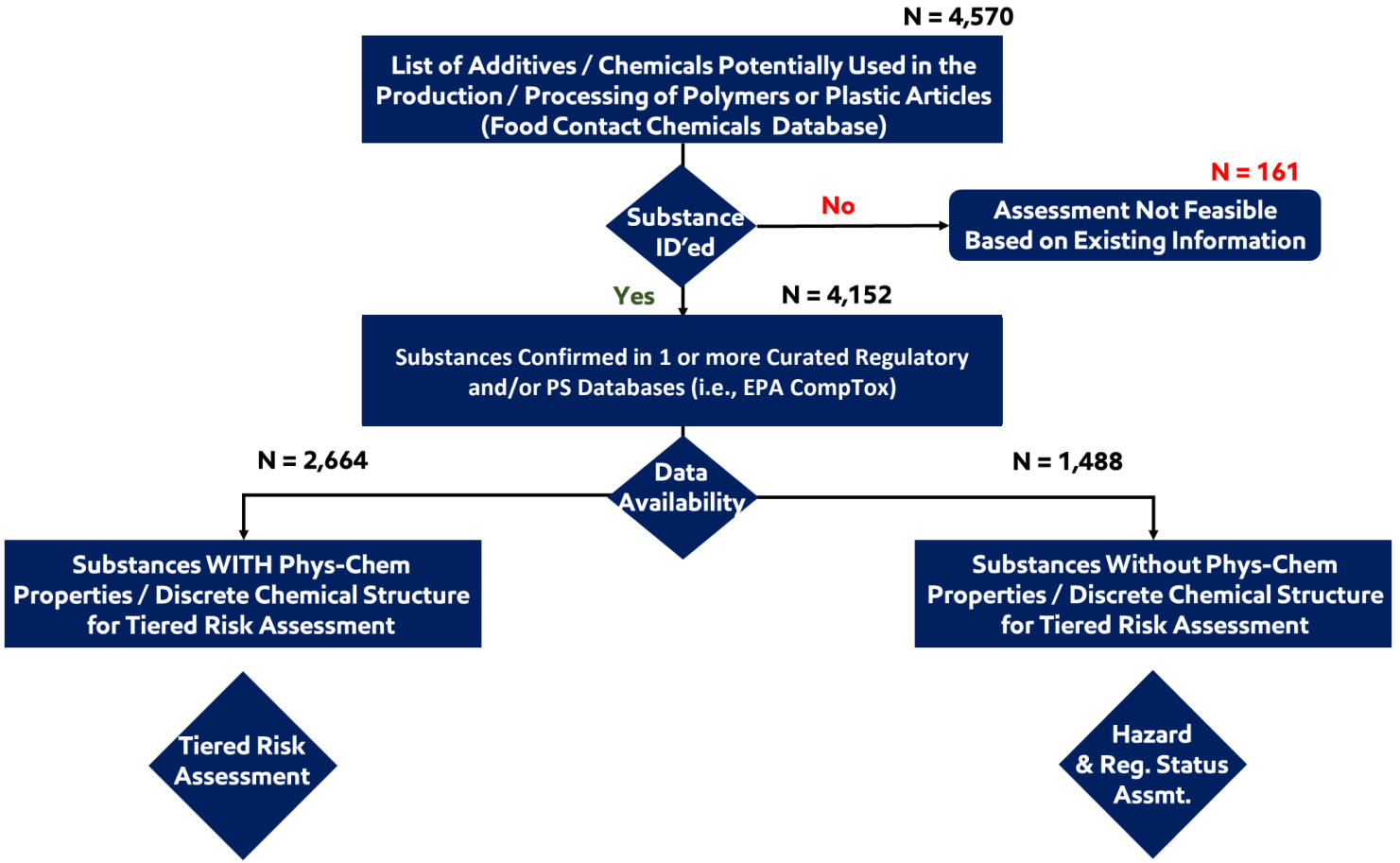
Currently Available Resource: Food Contact Chemicals Database Utility and Limitations

Data Collection & Workflow - Example

- **Food Contact Chemicals Database (FCCdb) developed by Food Packaging Forum (FPF) is a database of chemicals known or suspected to be associated with polymers (incl. additives, impurities, catalysts, & monomers)**
  - FPF database filtered for CAS # which were associated with plastic articles and polymers (rubber and adhesives were excluded at present) **N = 4,570**







Risk vs. Hazard Assessment (Data Availability)

- Substances with estimated phys-chem data (e.g., MW, log(Kow), SMILES) were assessed using a risk assessment framework (left).
- Substances for which this information was unavailable were assessed using a hazard assessment framework (right)

Tiered Risk Assessment

Assessment Scope	Assessment Tier	Exposure Assessment	Hazard Assessment
Indirect, Non-Occupational Oral Exposure (e.g., Man via Environment)*	1	100% Migration / Bioavailability	Toxicological Threshold of Concern (TTC)
	2	Equilibrium Partitioning	Established Threshold Value (ToxVal data)
	3	Migration Modeling (e.g., US EPA AMEM)	Substance-Specific Refined Assessment(s)

Tiered Hazard Assessment*

Prioritization Category	Hazard Properties (e.g., CMR, STOT)	Regulatory Action /Evaluation & Perception List(s)
5	Severity of hazard conclusion / classification	Restricted or Banned Chemicals Lists
4		Regulatory or Authoritative Evaluation(s)
3	Quantity & Quality of Data (WoE)	Screening & Potential Hazard Lists (Non-authoritative)
1 - 2		No List(s) / Inventory Only (Presence or Absence)

Note: Polymers assessed using risk framework (MW > 1000, log(Kow) > 10). UVCBs which are well-characterized (US EPA) were assessed using risk framework.

Elements of a Risk Assessment Framework

Brainstorm – First Pass

High-Level Overview

1. Problem Formulation and Scope

- Define Purpose of the Assessment
- Define the Plastic Article
- Define the Additives and how they are incorporated
- Define the Plastic Article Life Cycle (*i.e.* use, end of life, and circularity)

2. Regulatory Screening

- Identify if/what regulations exist for this additive and/or for this use?

3. Hazard Assessment

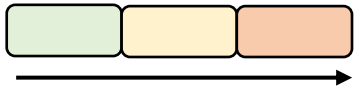
- Additive Hazard Prioritization Criteria (e.g. potential additive of low concern)
- Determine the hazard profile
- Are there potential transformation products of the additives and what are the associated hazards ?

4. Exposure Assessment

- Determine the migration from the plastic across the life cycle and end-of life
- Intended use and end of life risk Assessment
- Fate, Further Modification, and circularity

5. Risk Characterization

- Characterize risk to humans and environment



Data/Research Needs

Risk Assessment Framework Considerations

Complexity

- **Additive Perspective**
  - Homogeneity of additive (blended, encapsulated)
  - Migration potential
  - Bioavailability / uptake
- **Plastic Article**
  - Type, size, shape, porosity, chemistry of Plastic
- Cumulative additive addition across the value chain (visibility)

Methods (Models & Data)

- Analytical methods to measure additives *(and **degradants**)* at levels needed in different matrices
  - Modeling Approaches (currently limited) that can be used for refinements before analytical methods are needed
- Standardization of methods/best practice
  - Evaluating what's there; Leverage existing ASTM standards and NIST standards if existing
  - Standardized final articles – standard film, rigids, durables

Hazard

What are the intrinsic environmental and human health hazards of additives?

- Additives Database (*separate project)
- GHS Classification
- Degradants of Concern?

Exposure

How are humans and the environment exposed?

Exposure Scenarios

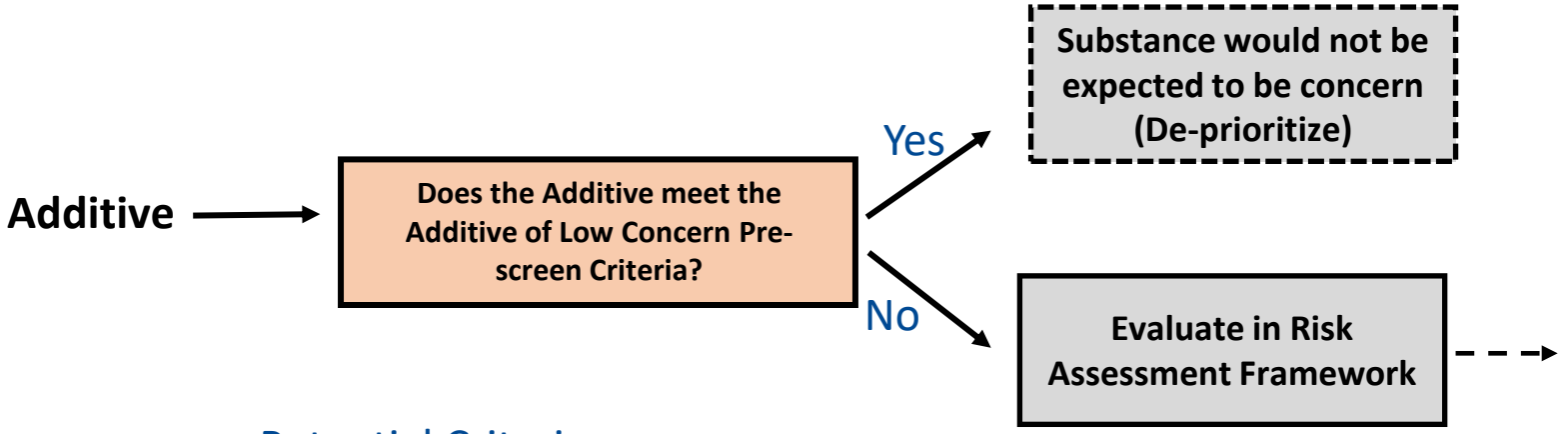
- Consumer and Direct Environment exposure from intended use
- Consider Unintentional Uses/Misuse

What happens specifically from a fate perspective?

Fate Scenarios

- Environmental conditions of compartments
- Degradation potential or chemical modification of the additive
- Dosage and threshold of concern

Considerations for Additive Prioritization (Additive of Low Concern Pre-screen Criteria)

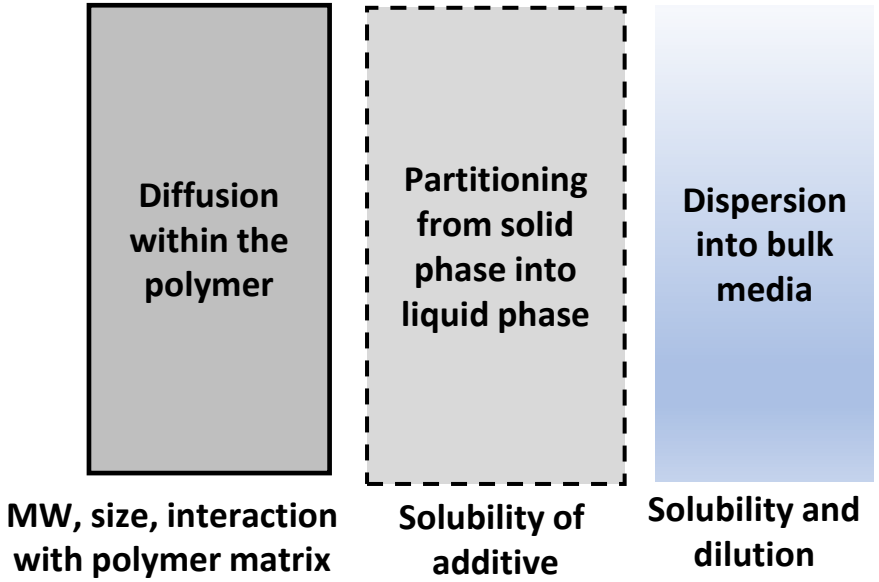


Potential Criteria

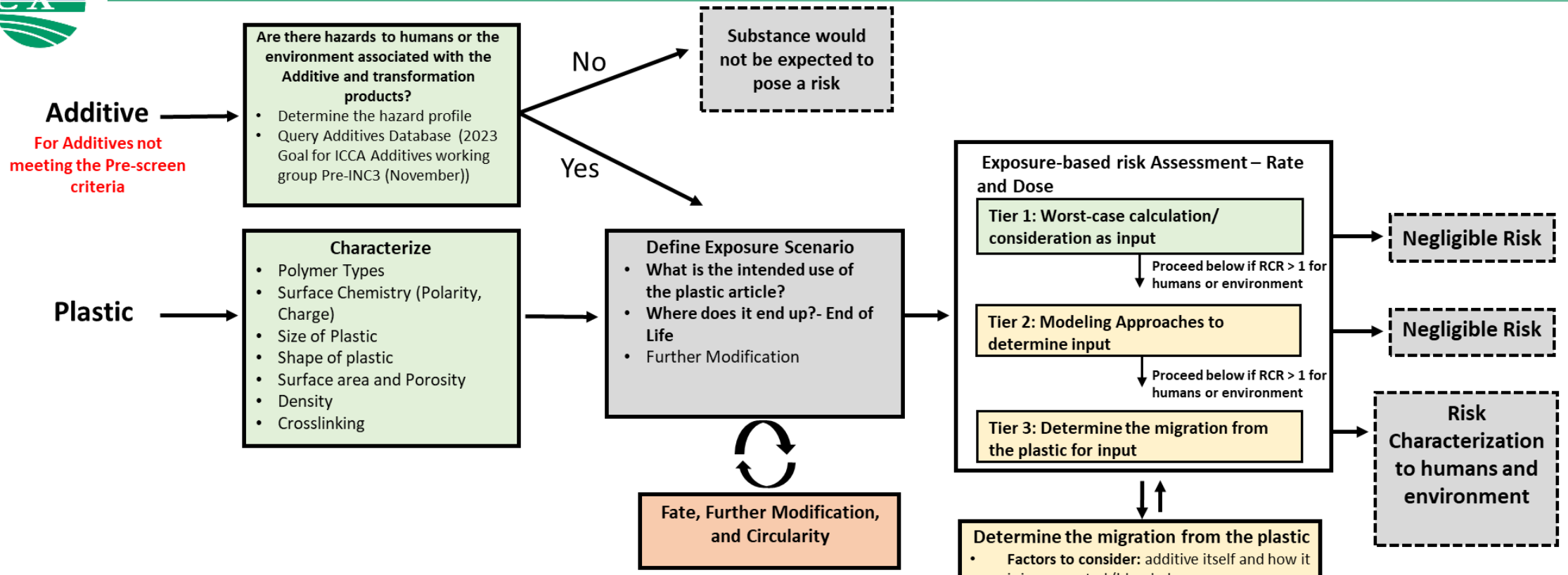
Physical/Chemical Properties mediating Migration and Bioavailability

Is the additive expected to migrate out of the plastic article?

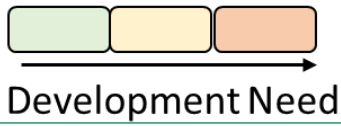
Is the additive expected to be bioavailable if it does migrate out?



Risk Assessment Framework Workflow



Lower Complexity →	Higher Complexity
Known transformation products	Unknown transformation products
Consumer Use	Risk assessment of recycled products
End of Life	
Role in Recycling technologies – *Impact of plastic additives on this*	



Discussion on Additive Prioritization Criteria and Conceptual Framework

- **What do you see as some benefits to taking this approach?**
- **What are some risks with using this approach?**
- **What are the gaps in the conceptual framework as it is?**

Breakout / Discussion

Types of Information / Data Needed

Polymer & Additive Properties

- Polymer Category (thermoset, thermoplastic, rubber, sol-gel, etc…)
- Polymer chemistry (PE, PP, PVC, etc…)
- Bulk Properties (melt index, crystallinity, tacticity, diffusivity)
- Surface Properties (zeta potential, surface active chemistries)
- Additive Chemistries / Composition (e.g., organic, inorganic, UVCB, polymer)

Environmental Fate & Transport Data

- Bioavailability / hydrophobicity (e.g., logKow)
- Volatility / stability in water
- Mass Transfer Potential / Diffusion through polymer matrix (e.g., D)
- Degradability / potential to form transformation products
- Sorption affinity to organic phases (e.g., DOM, marine snow)

Use Scenario & Emissions Information

- Tonnage (t/yr)
- Use Category (i.e., industrial, professional, consumer)
- Product / Article Type (i.e., disposable, durable, packaging, etc…)
- Region / Geographic Information

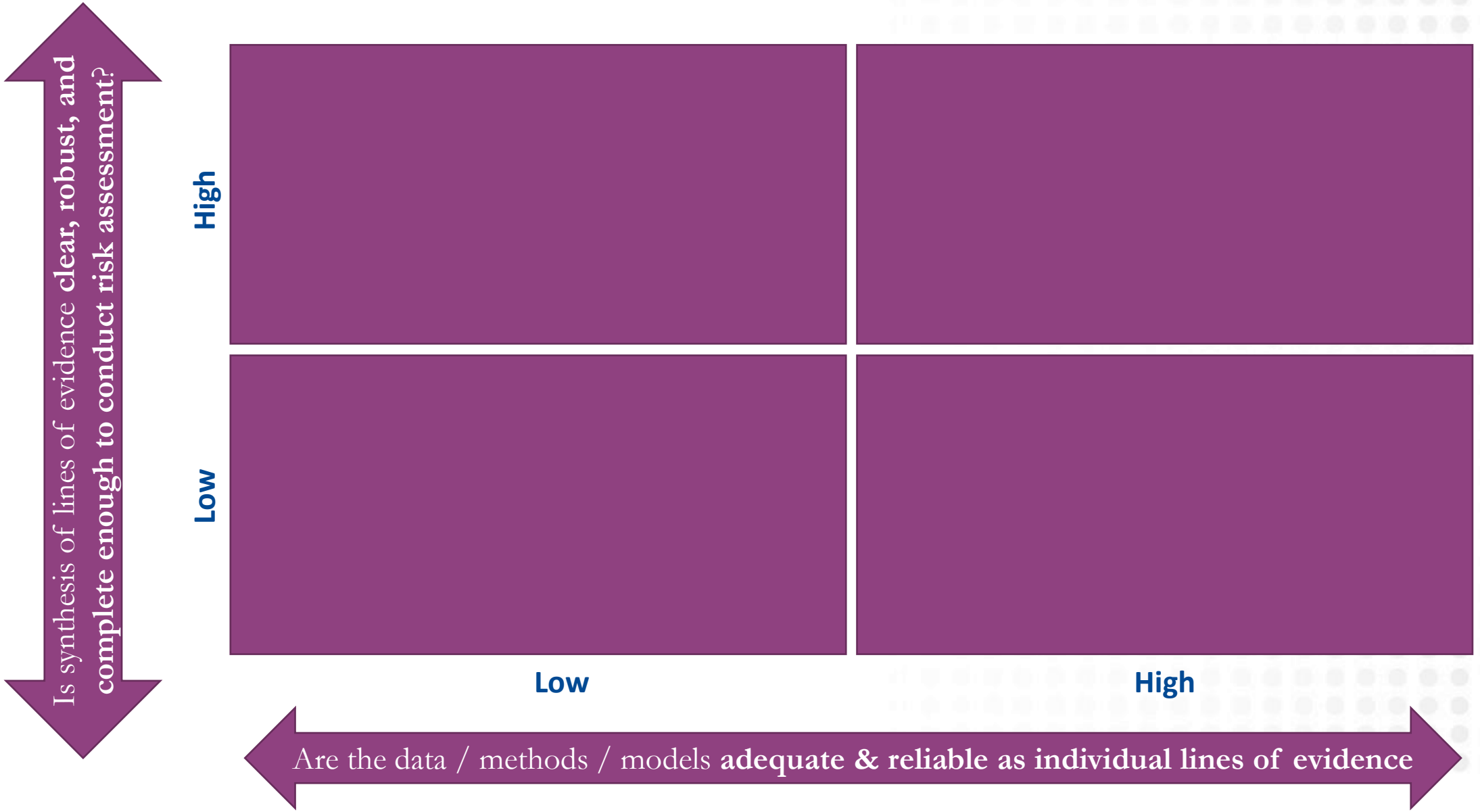
Ecological & HH Hazard(s) Information

- Acute / Chronic Eco-Toxicity (known MoA)
- Potential to bioaccumulate (exposure via diet)
- Potential higher severity HH effects (e.g., MoA, STOT, EDC)
- Potential lower severity effects (sensitization, irritation, etc…)

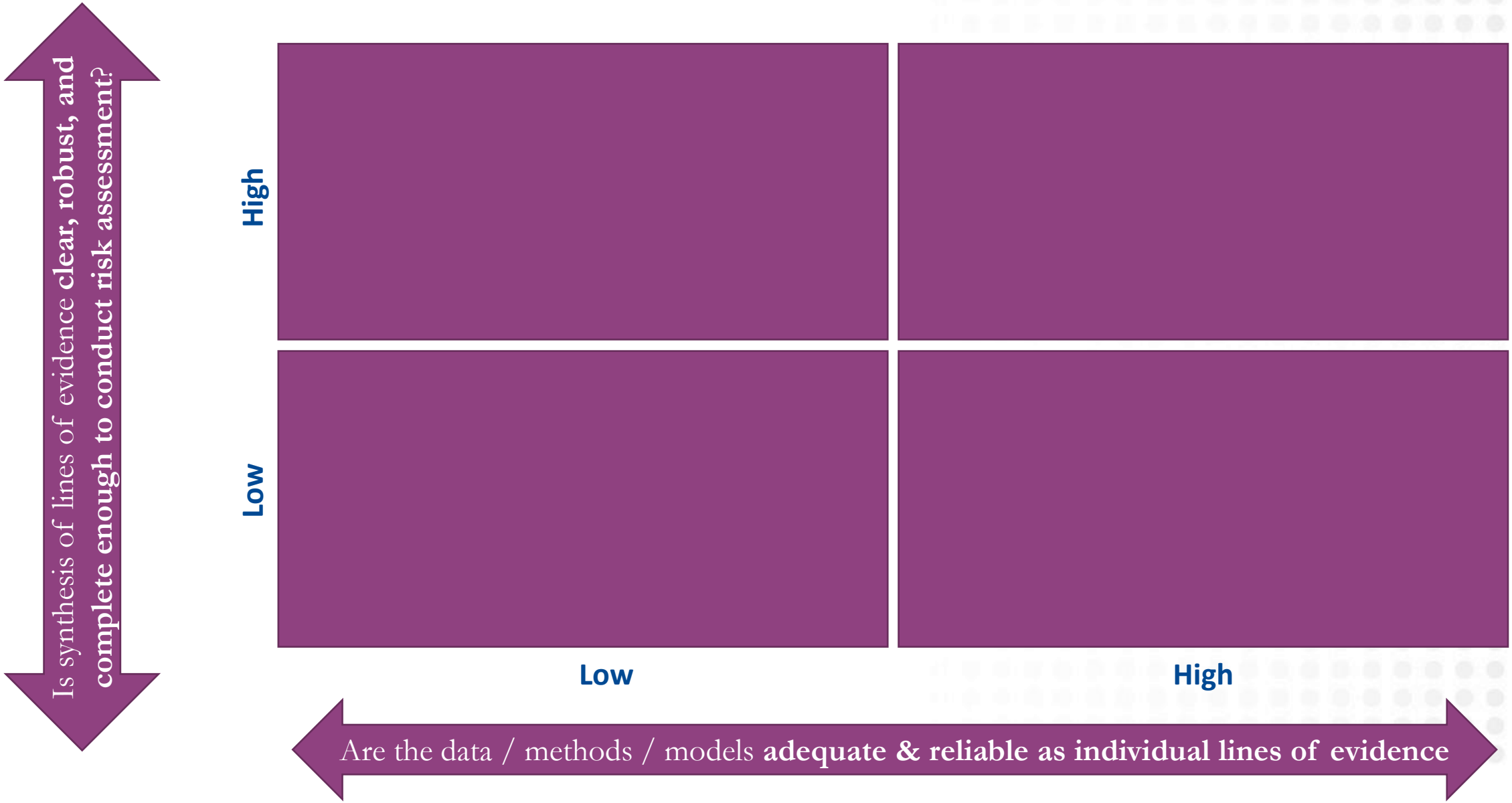
Critical Data Needs / Minimum Information Req's

	Particle / Polymer / Additive Information	Tonnage / Use / Emissions Scenario Information	E-Fate, Human Health & Eco Hazard Information
Tier 0 (Generic)			
Tier 1-2 (Refined / Use Specific)			
Tier 2+ (Action-based)			

Adequacy of Existing Data, Models, & Assumptions (Current State)



Adequacy of Existing Data, Models, & Assumptions ("MVP" State)



Particle/Polymer/Additive information