

# **Appendix A:**

## **Final Workbook for Proposed CEC Framework**

**NJ DEP SAB  
CEC Workgroup  
August 8, 2012**

# CEC Sub-Committee

- John Dyksen - Chair
- Clinton Andrews
- John Gannon
- Jonathan Husch
- Robert Laumbach
- Peter Lederman
- Paul Lioy
- Mark Robson
- Nancy Rothman
- Judith Weis

## **NJ DEP Support to CEC Sub-Committee:**

- Gary Buchanan
- Bob Mueller
- Gloria Post

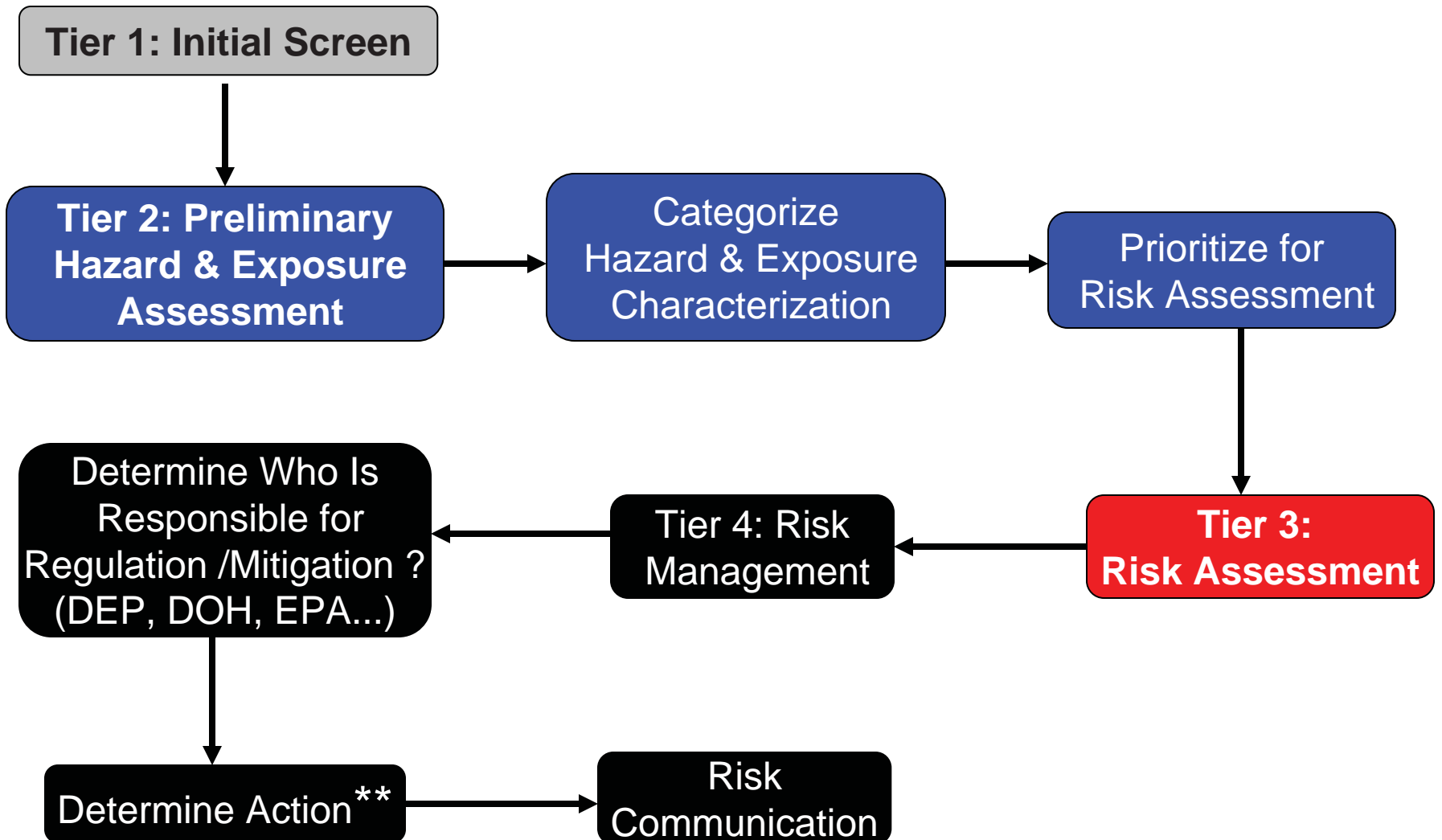
# CEC Issue

- **What are the contaminants of emerging concern (surface water, ground water, air, biota, wastewater, & sediment) and what technical (e.g., monitoring, research) steps should DEP take to understand and manage them?**

# Objective

- **Develop a NJ-specific CEC framework that assesses hazard and exposure potential of chemicals found in the NJ environment and/or biota and prioritizes chemicals for regulatory action based on risk assessment.**

# CEC Evaluation Process Overview



**\*\* Management, policy development, interagency coordination....**

# **Tier 1 - Initial Screen**

# Tier 1 - Initial Screen

## Reason for Concern?

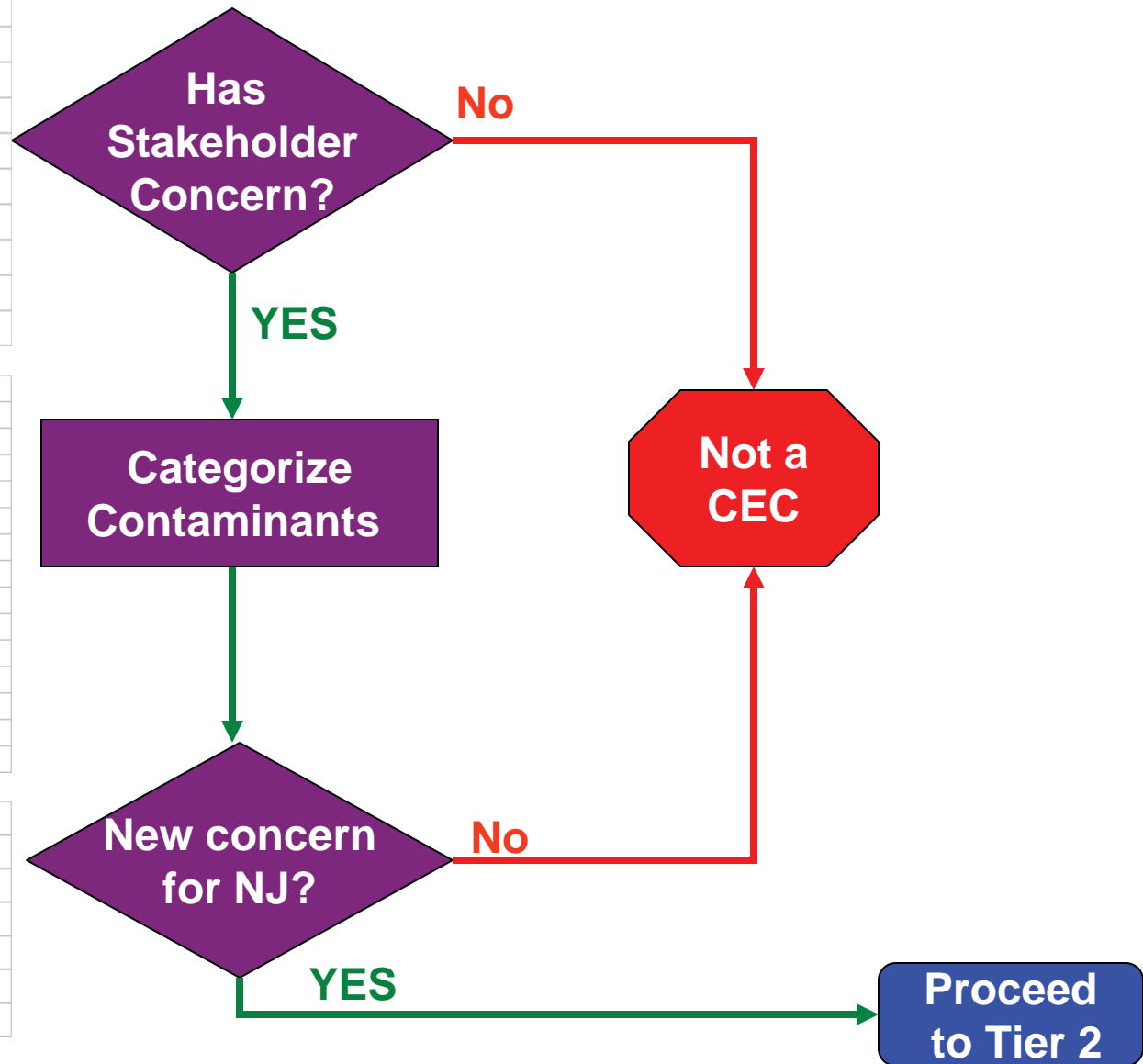
- a. Monitoring-Occurrence data from DEP or USGS
- b. Research – human/ecological impacts
- c. Federal regulators - EPA
- d. Media
- e. Citizens
- f. Legislature
- g. NGOs
- h. Growing usage of chemical
- i. Shrinkage of competing concerns
- j. Industry emerging in NJ
- k. New technology byproducts form CEC

## Contaminant Category ?

- a. Pharmaceuticals
- b. Personal care products
- c. Nanoparticles
- d. Pesticides
- e. Steroids
- f. PAHs
- g. Radionuclides
- h. Synthetic organic compounds
- i. Inorganic compounds – metals
- j. Perfluorinated compounds
- k. Disinfection (oxidation) by-products
- l. Algal toxins
- m. Microbial contaminants
- o. Other - Define

## New concern for NJ ?

- a. New chemical / ramped up production
- b. New type of use
- c. New effect identified
- d. New detection / increasing levels
- e. New source
- f. New exposure / exposure route



# Tier 2 - Preliminary Hazard & Exposure Assessment

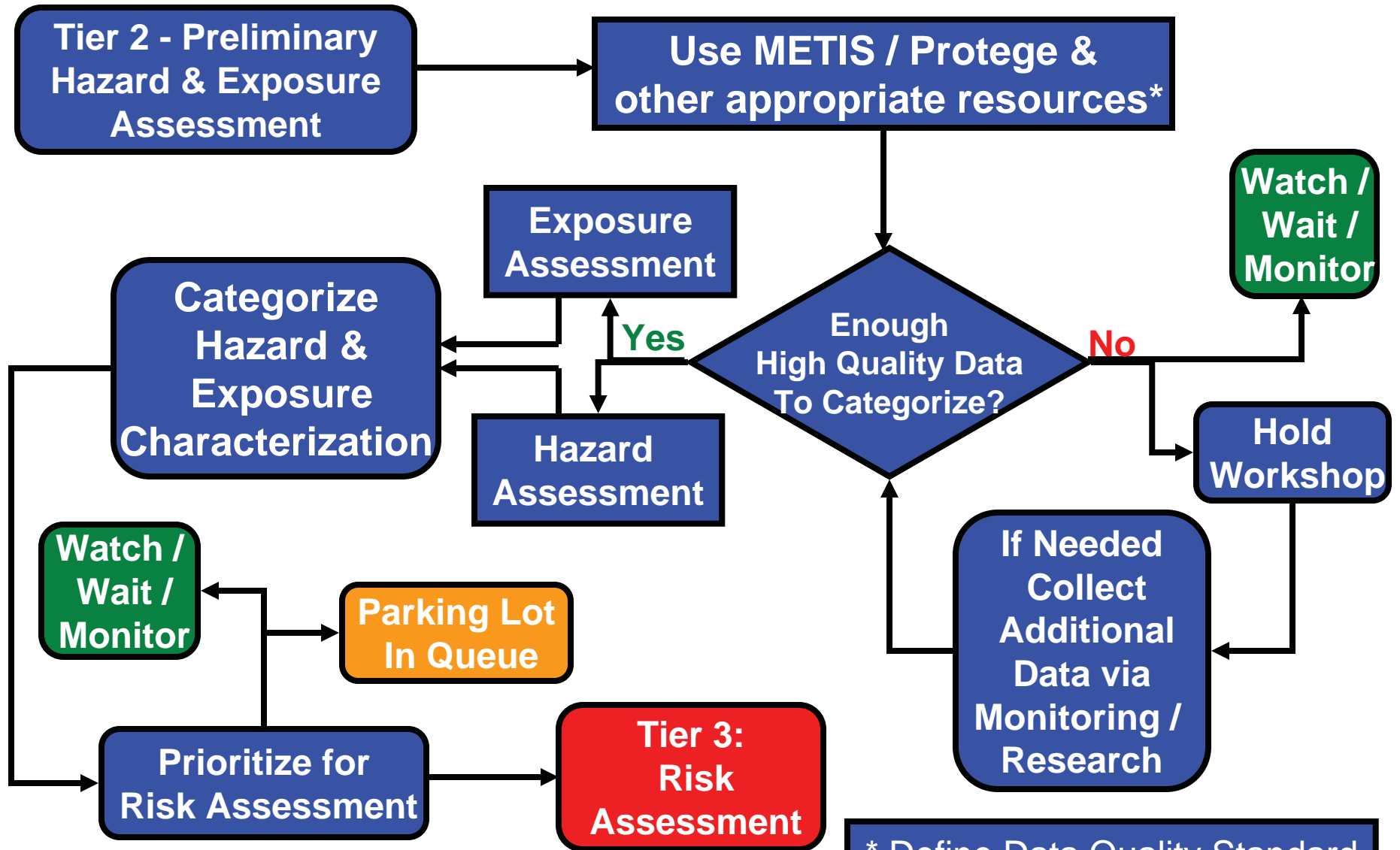
**Key elements:**

**Hazard Assessment - METIS**

**Exposure Assessment - PRoTEGE**



# Tier 2 - Preliminary Hazard & Exposure Assessment



# DuPont METIS: Chemical Screening Visualization Tool

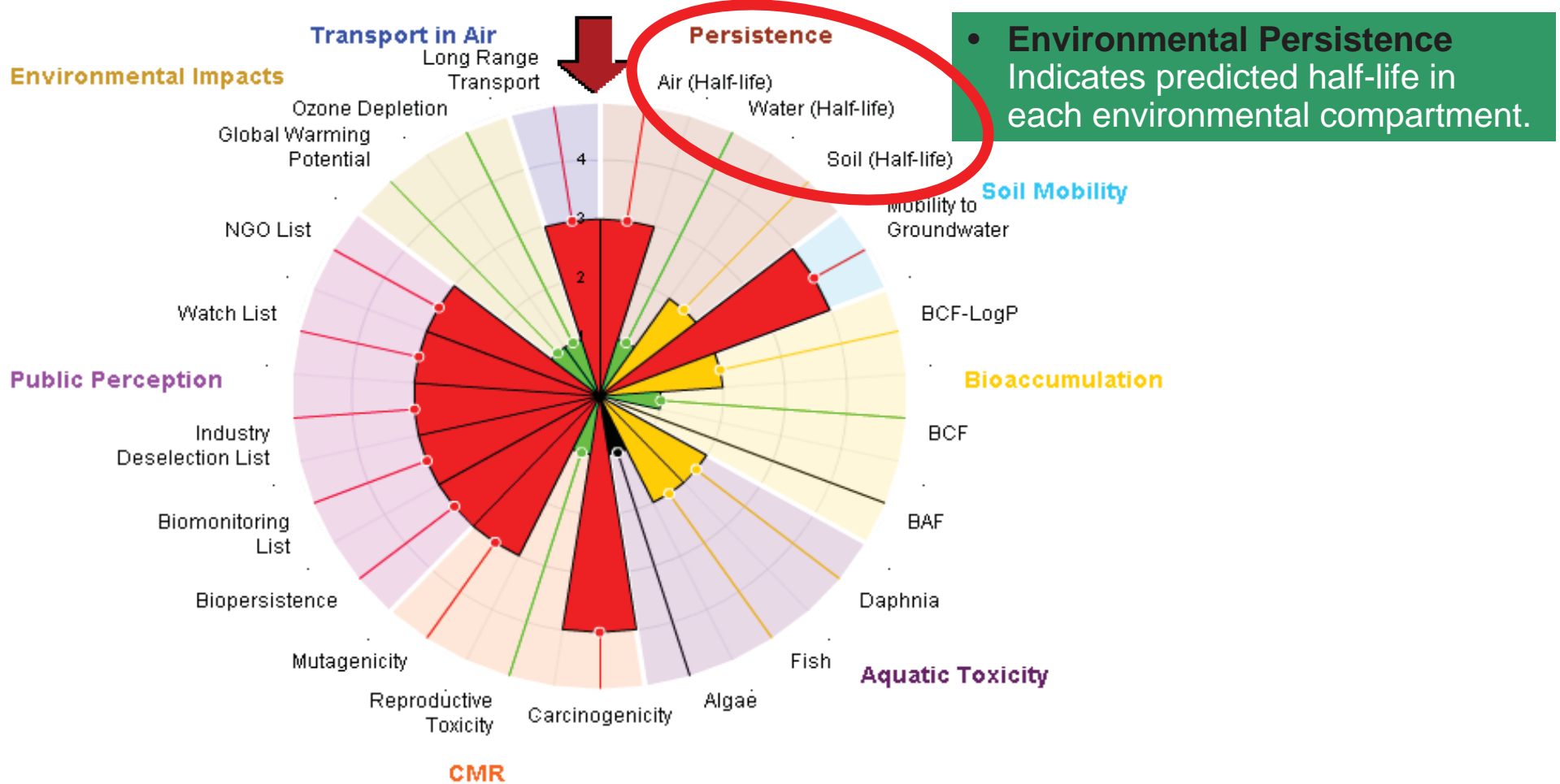
- **Metanomics Information System (METIS) is a chemical informatics platform that provides screening level view of potential**
  - Environmental fate & effects
  - Human health concerns
  - Societal perception issues
- **Built on open-source software that provides access to an aggregated database and estimation tool set**
  - 1400+ publicly available databases
  - Input: Chemical name, CAS #, or chemical structure.
- **Comprehensible view in seconds to minutes versus weeks to months by conventional searches.**

# DuPont METIS

## Potential for Concern

Indicated by Color: **Red: High / Very High; Orange: Moderate; Green: Low**  
or

Indicated by Wedge Length: 1 = Low; 2 = Moderate; 3 = High; 4 = Very High

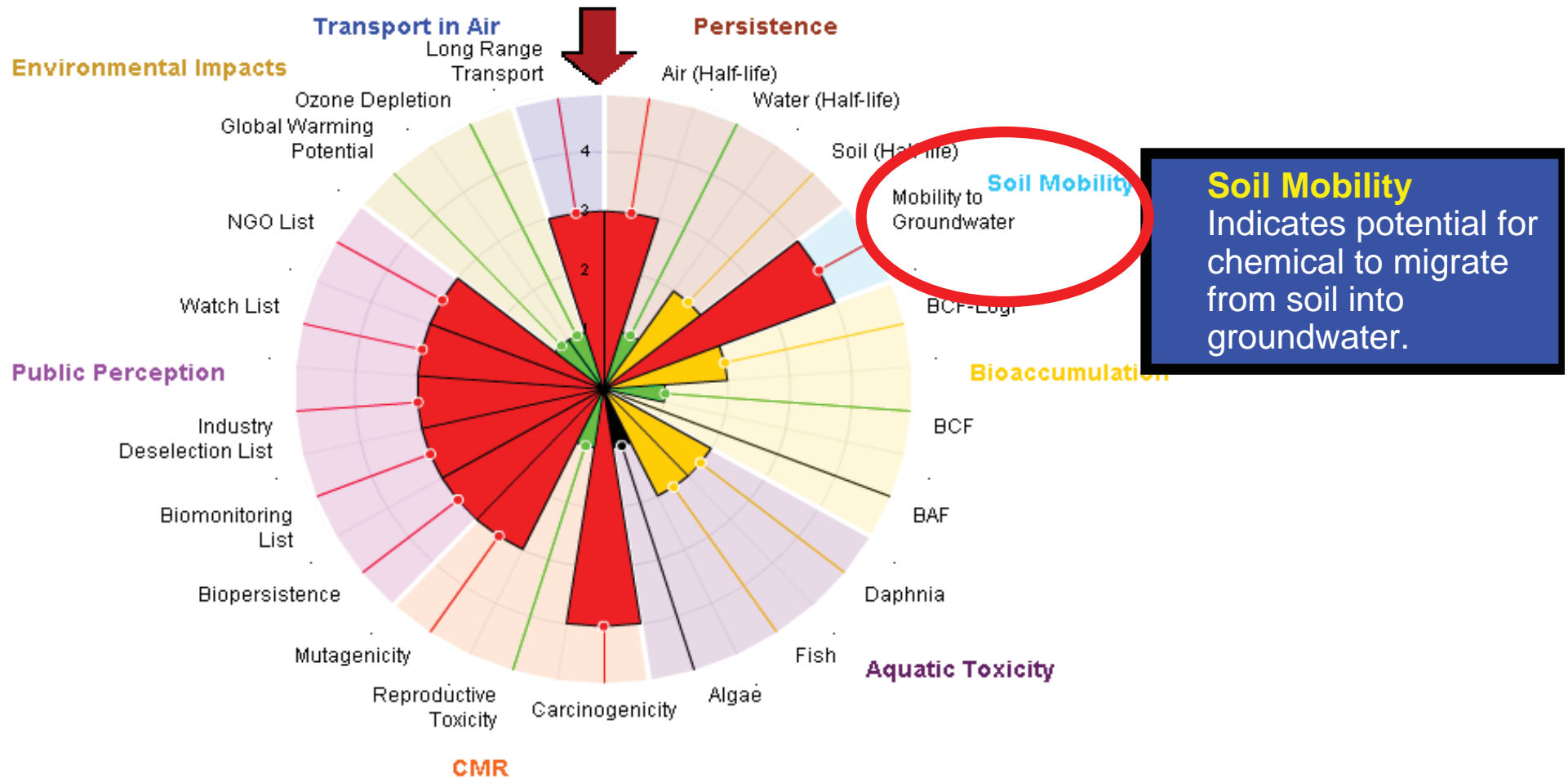


# DuPont METIS

## Potential for Concern

Indicated by Color: **Red: High / Very High; Orange: Moderate; Green: Low**  
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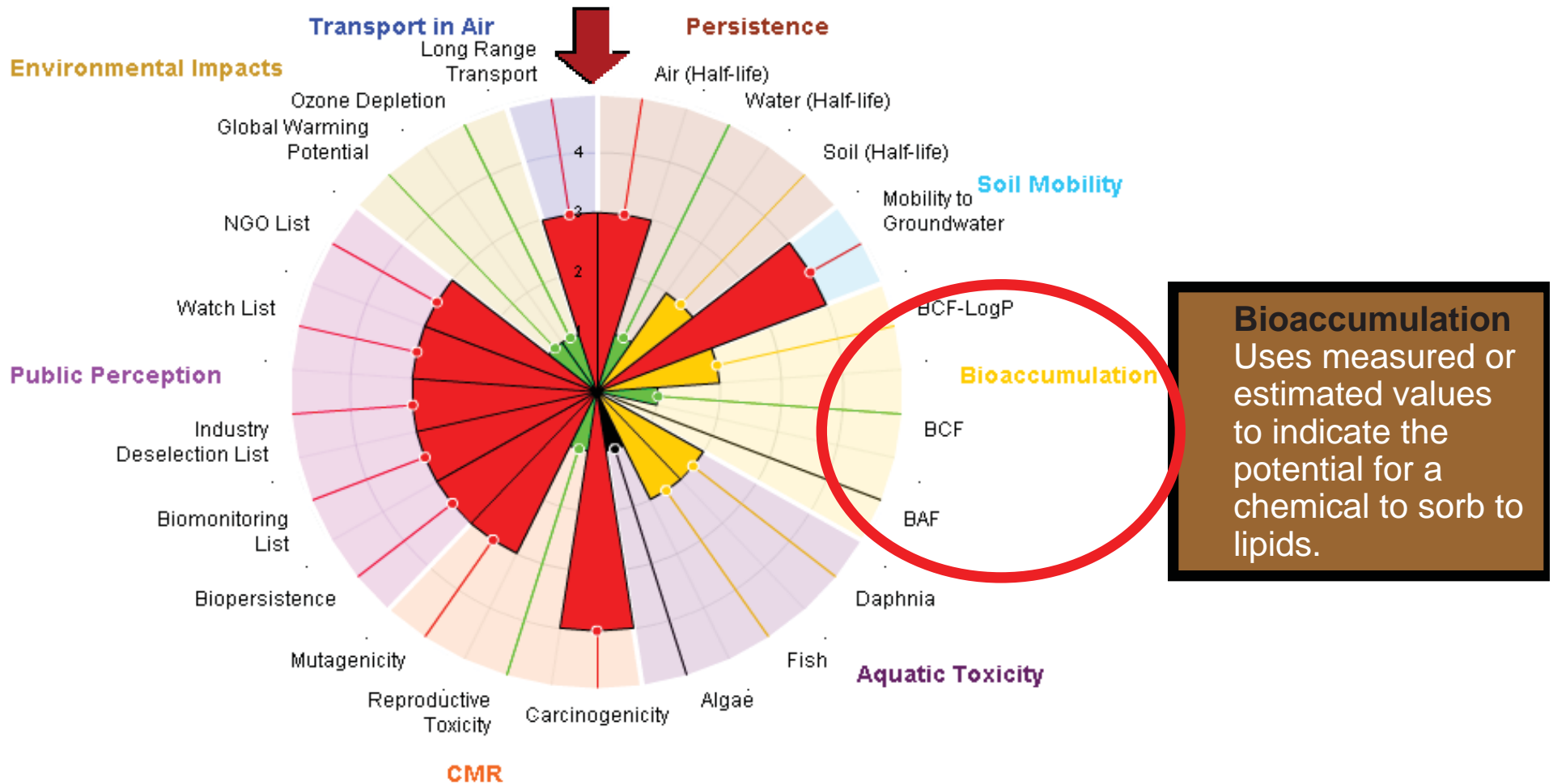
**Soil Mobility**  
Indicates potential for chemical to migrate from soil into groundwater.

# DuPont METIS

## Potential for Concern

Indicated by Color: **Red: High / Very High; Orange: Moderate; Green: Low**  
or

Indicated by Wedge Length: 1 = Low; 2 = Moderate; 3 = High; 4 = Very High

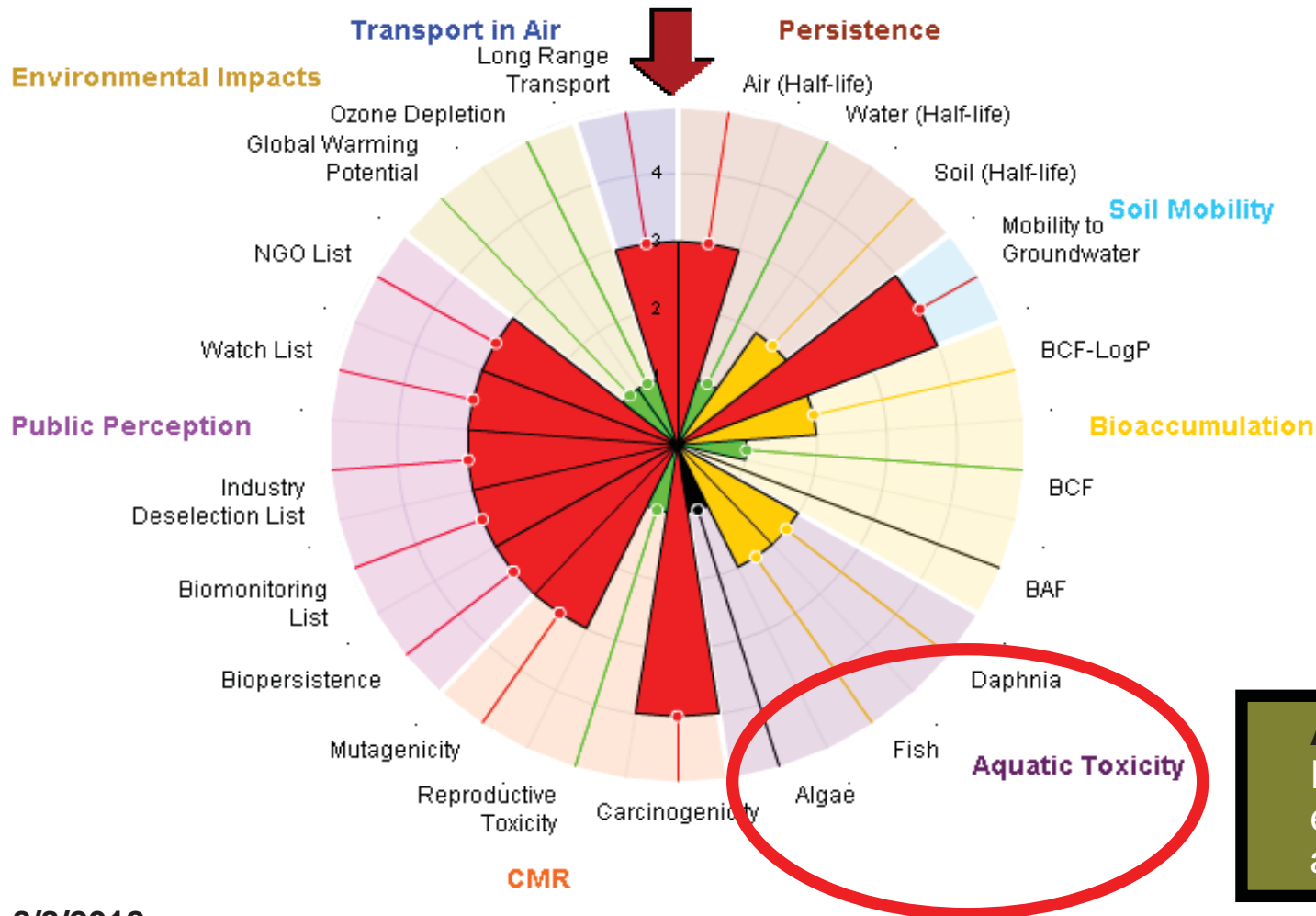


# DuPont METIS

## Potential for Concern

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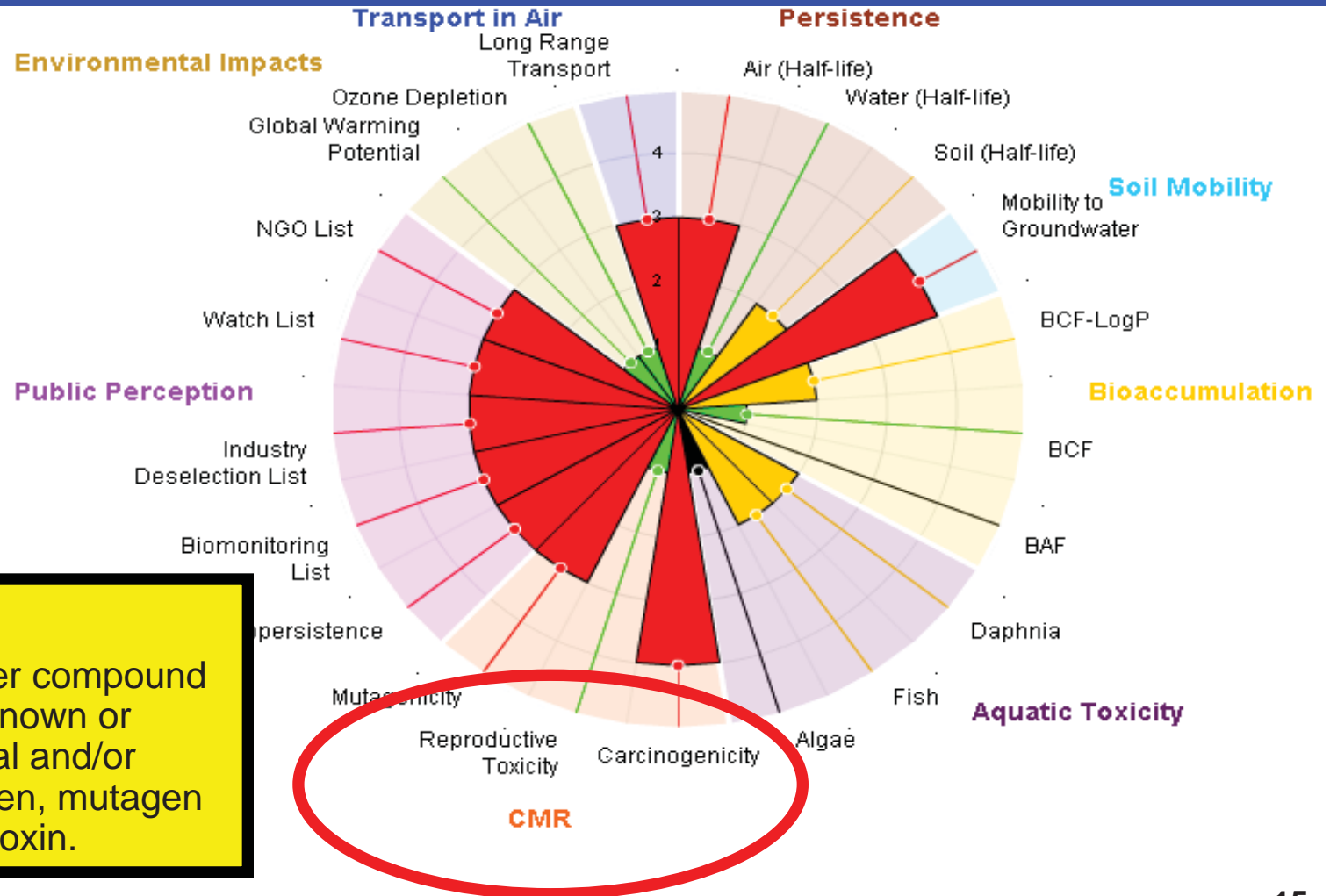


# DuPont METIS

## Potential for Concern

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or

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### CMR

Indicates whether compound is classified as known or suspected animal and/or human carcinogen, mutagen or reproductive toxin.

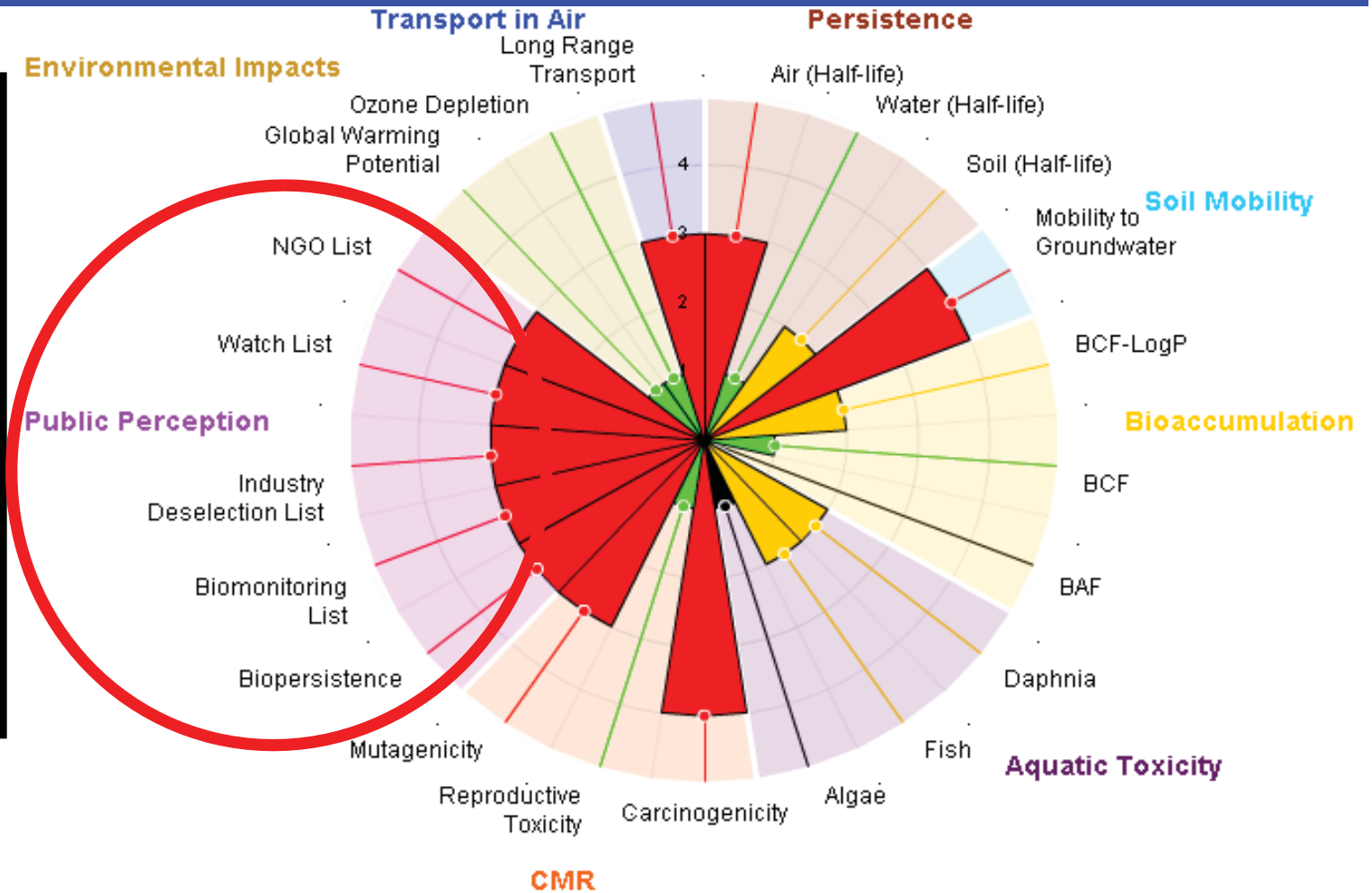
# DuPont METIS

## Potential for Concern

Indicated by Color: **Red: High / Very High; Orange: Moderate; Green: Low**  
or

Indicated by Wedge Length: 1 = Low; 2 = Moderate; 3 = High; 4 = Very High

**Public Perception**  
Indicates chemical is present on a variety of regulatory, industrial and/or non-governmental list that may influence how public views a particular chemical.





# DuPont METIS

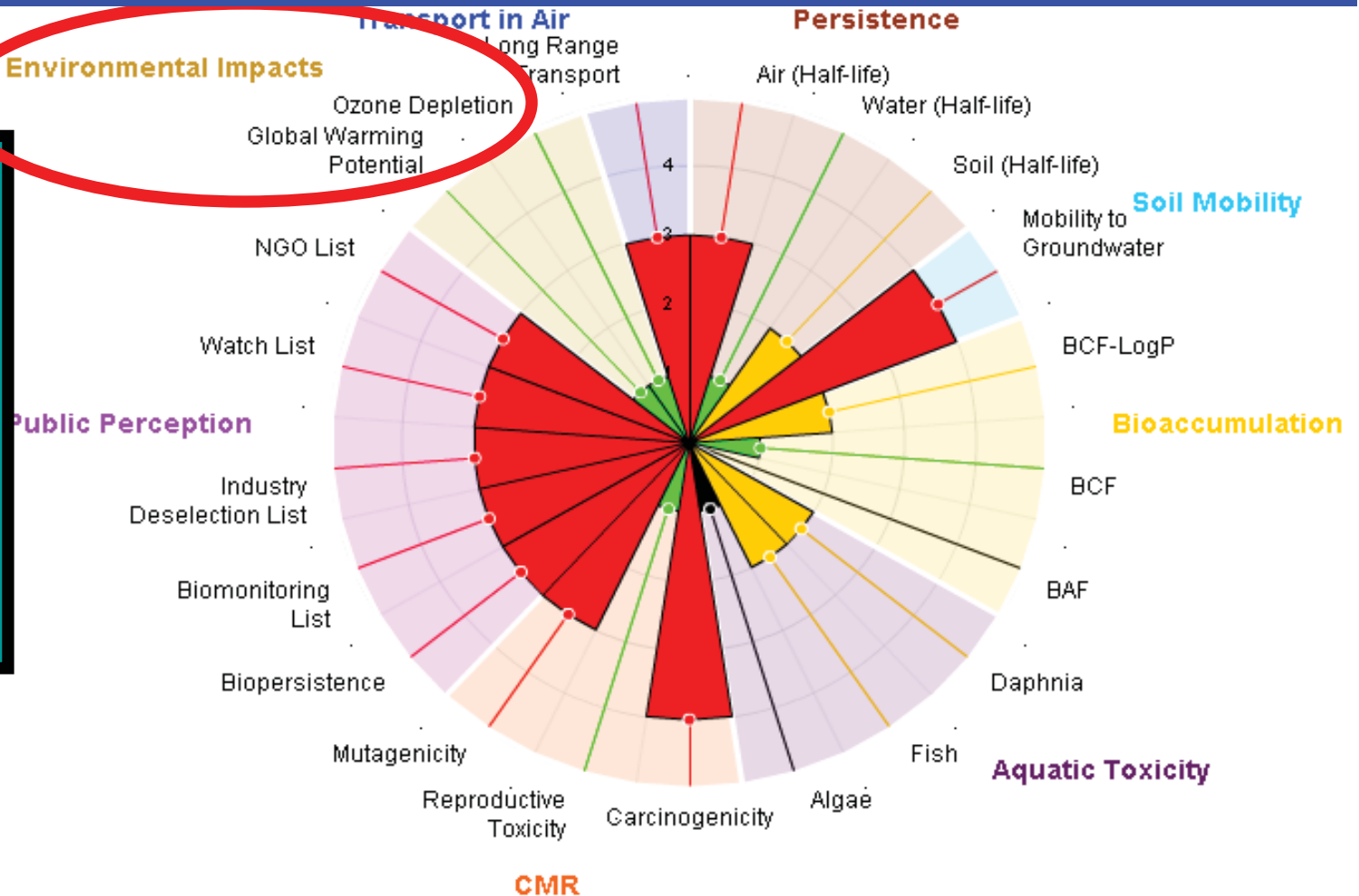
## Potential for Concern

Indicated by Color: **Red: High / Very High; Orange: Moderate; Green: Low**  
or

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### Environmental Impacts

**Environmental Impact**  
Indicates potential for chemical to affect global warming and ozone depletion as compared to reference compounds.



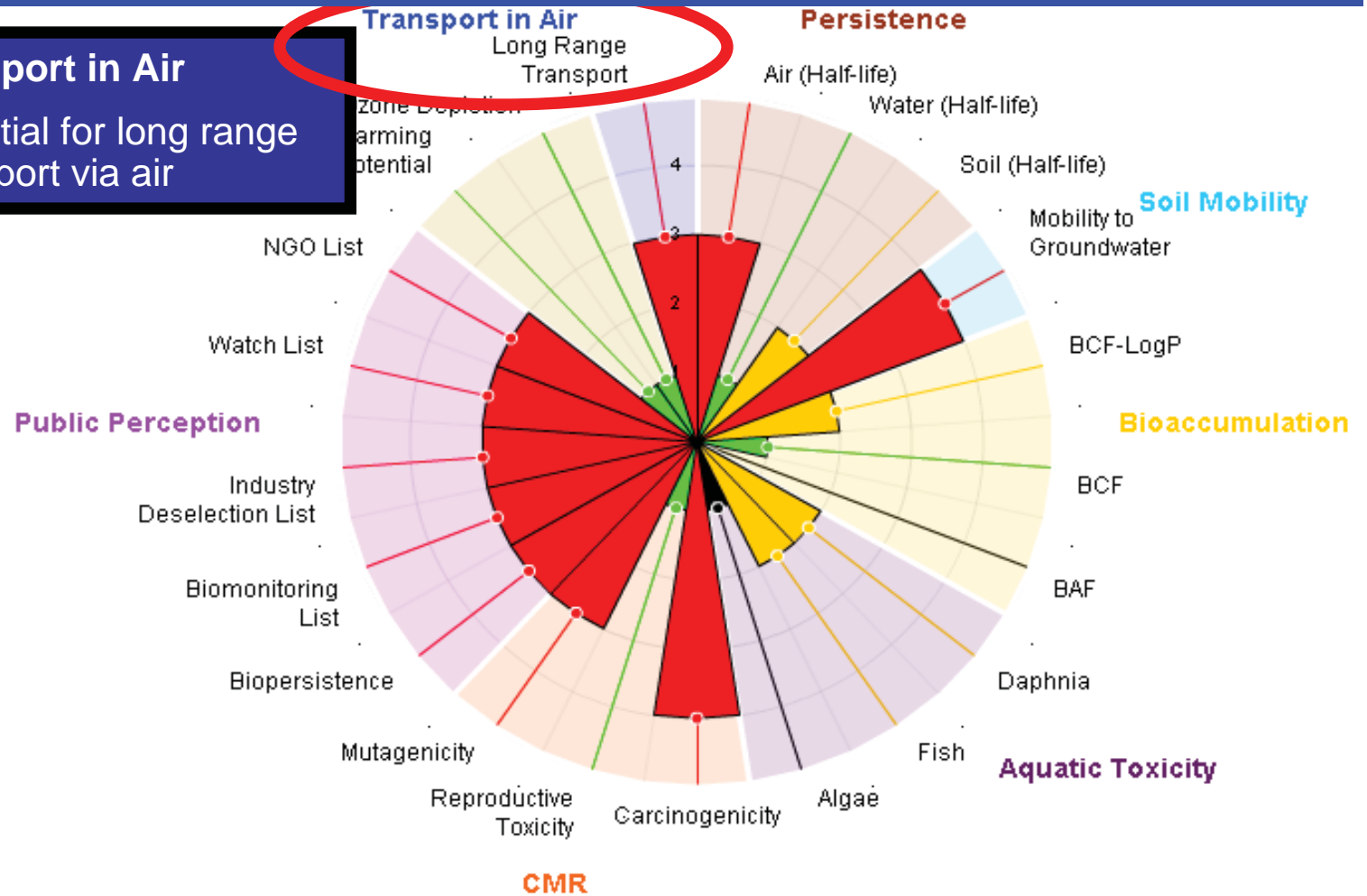
# DuPont METIS

## Potential for Concern

Indicated by Color: **Red: High / Very High; Orange: Moderate; Green: Low**  
or

Indicated by Wedge Length: 1 = Low; 2 = Moderate; 3 = High; 4 = Very High

**Transport in Air**  
Indicates potential for long range transport via air



# **PRoTEGE**

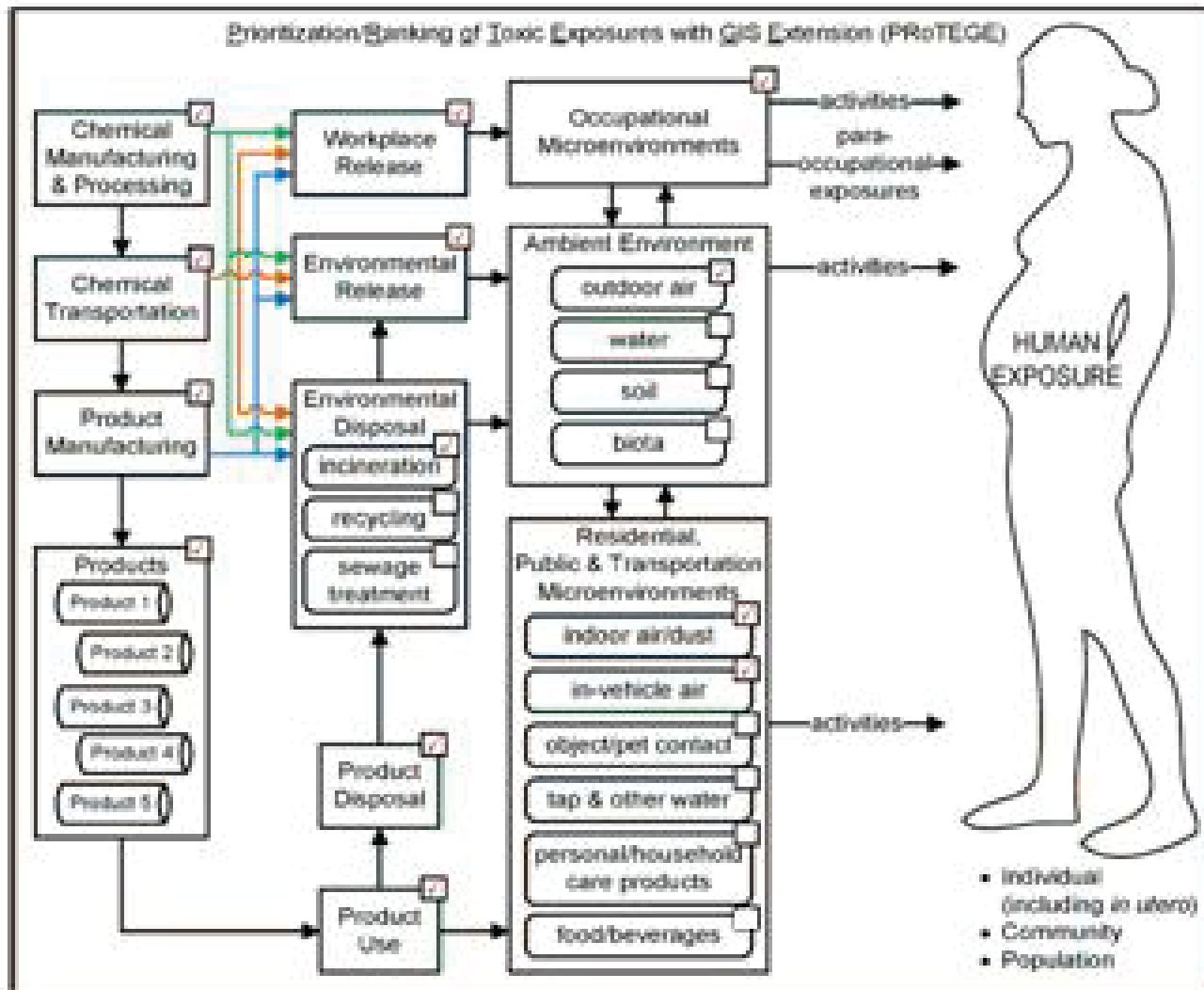
## **Exposure-Based**

### **Prioritization of Chemicals**

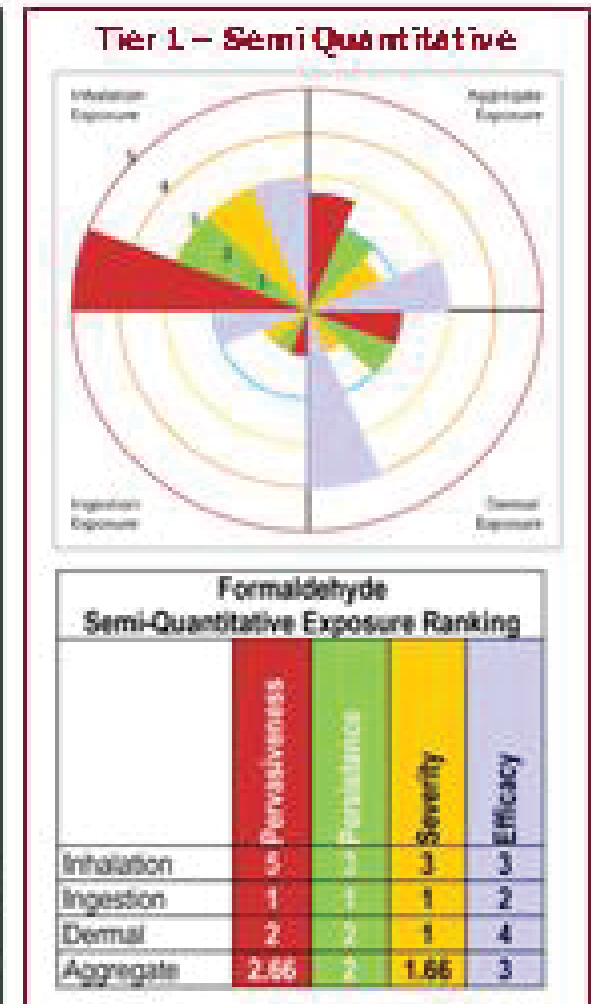
**Environmental and Occupational  
Health Sciences Institute (EOHSI)**

# PRoTEGE - a three-tier system that supports exposure-based prioritization of chemicals

PRoTEGE utilizes reduced components of the comprehensive HENRIK system to provide a simplified modeling platform employing extant data and modules for the "screening" assessment of human exposures associated with toxics in various (micro)environments and products



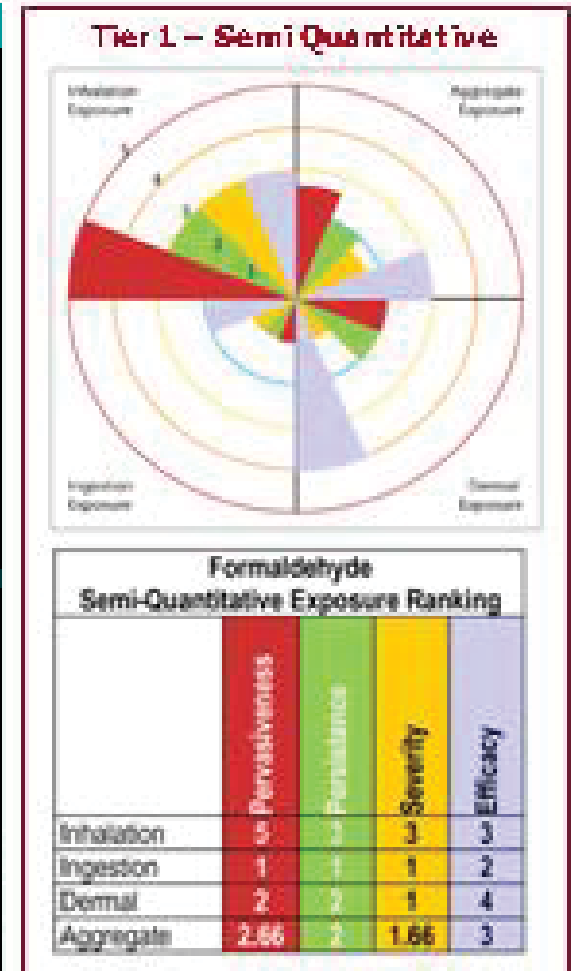
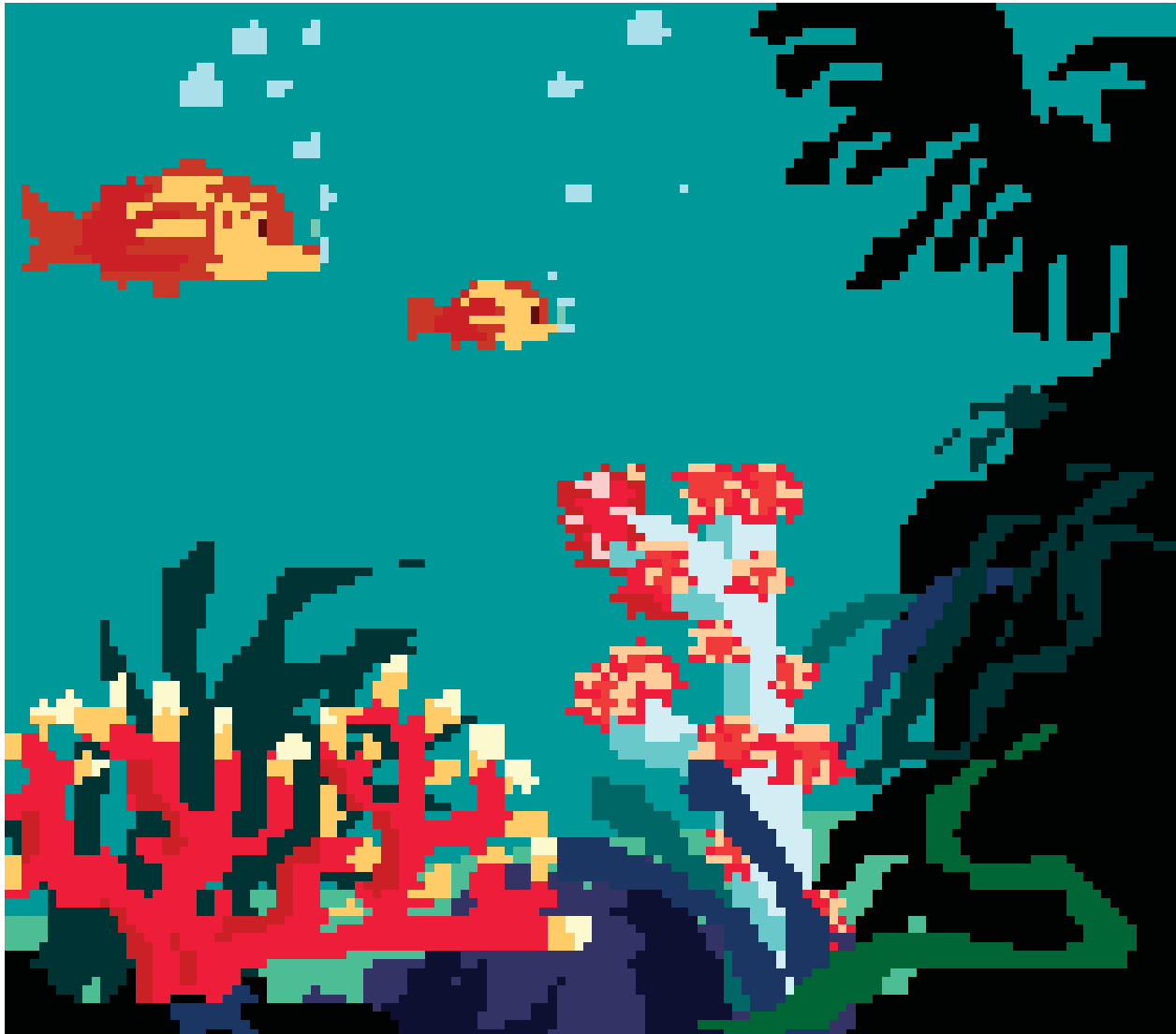
Modeling Environment for Total Risk studies; development supported by USEPA, ATSDR, USDOE, NIDEP, ACC, and other government and private agencies.

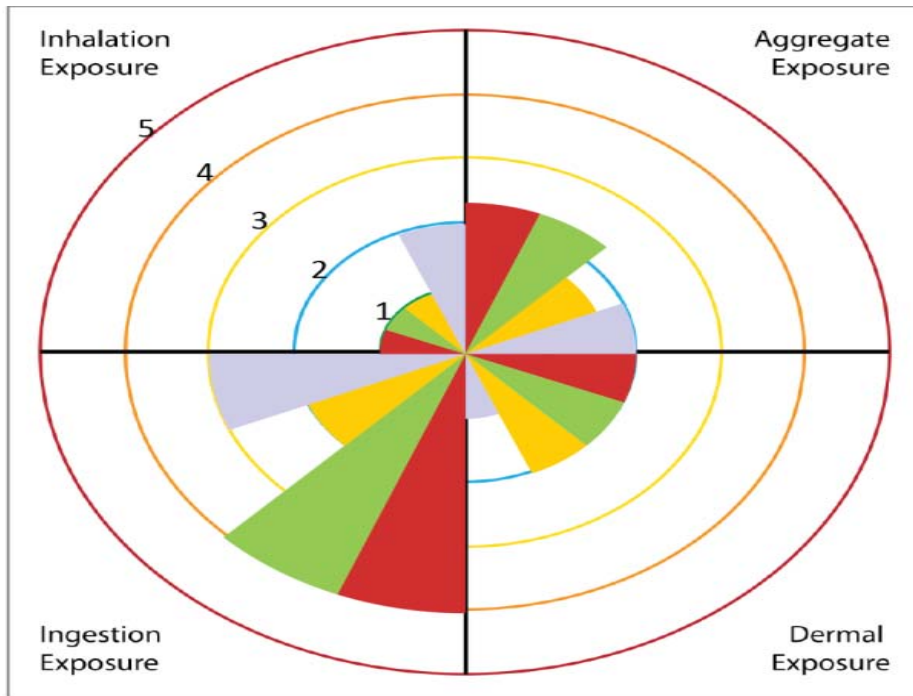


Tier 2 - Probabilistic distributions for the US population 5

## PROTEGE - a three-tier system that supports exposure-based prioritization of chemicals

PROTEGE utilizes reduced components of the comprehensive HENRIK system to provide a simplified modeling platform employing extant data and modules for the "screening" assessment of human exposures associated with toxics in various (micro)environments and products





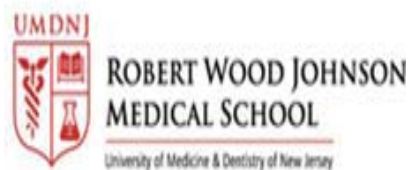
	Pervasiveness	Persistence	Severity	Efficacy
Inhalation	1	1	1	2
Ingestion	4	4	2	3
Dermal	2	2	2	1
Aggregate	2.33	2.33	1.66	2

- “Tier 1” exposure metrics
  - Pervasiveness - how widespread the exposures are within the general US population
  - Persistence - the temporal frequency and/or duration of such exposures
  - Severity - the potential for high levels of such exposures
  - Efficacy - the potential of the contact with the chemical to result in intake/uptake

**Tier 1 Exposure Levels:**  
 1 – Very Low; 2 - Low  
 3 – Moderate; 4 – High;  
 5 – Very High

# Development of Exposure/Hazard Assessment Tool for NJ DEP: Proposal for Merger of METIS & Protege

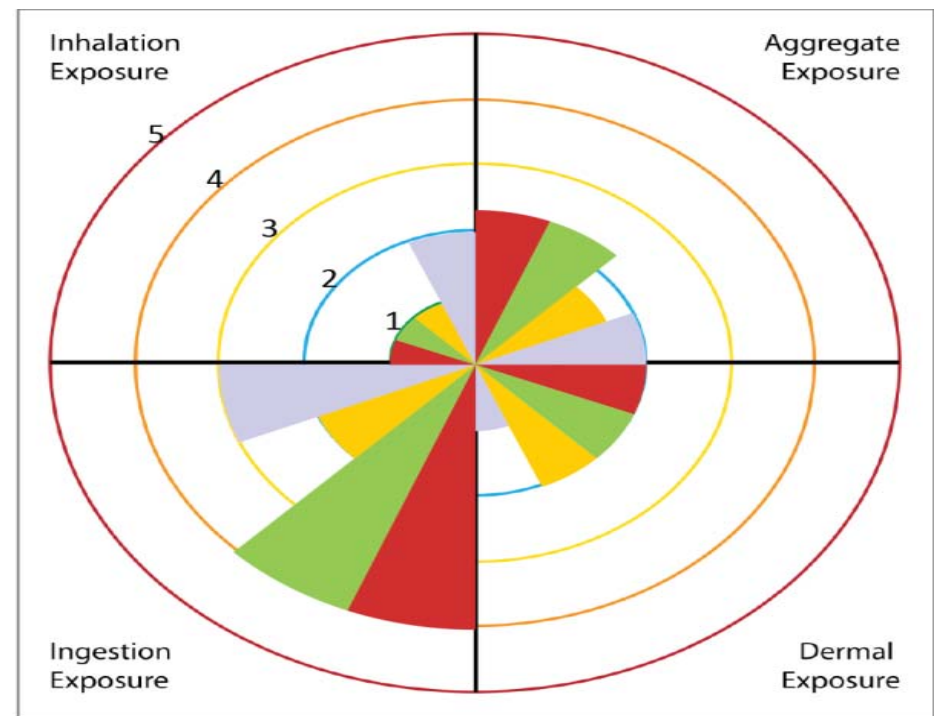
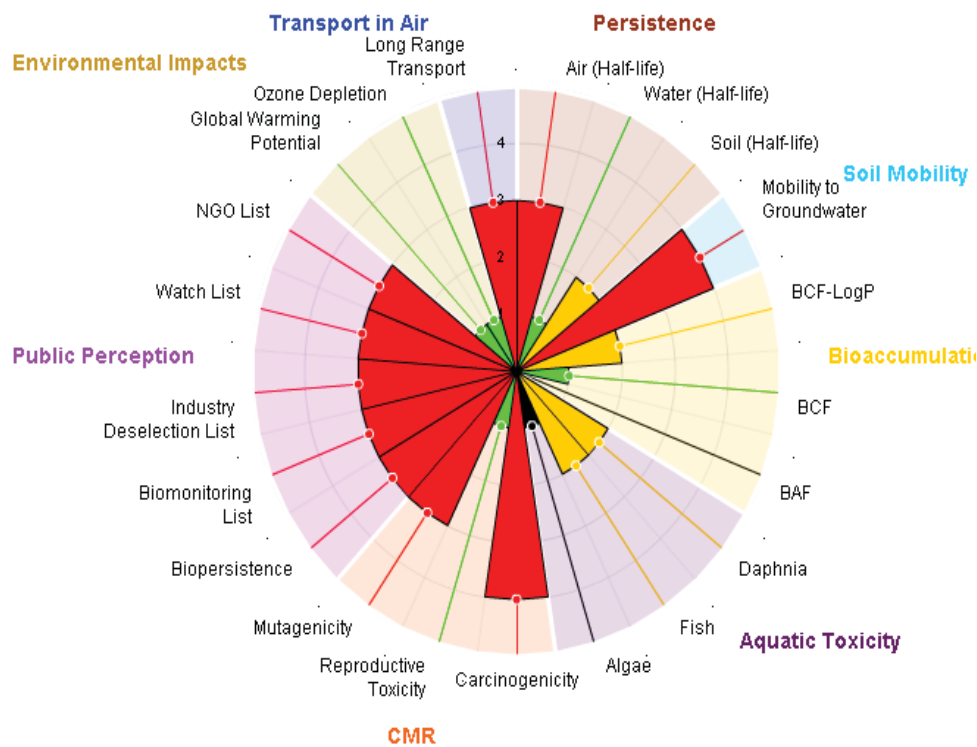
- The proposed system will be developed by systematically selecting, adapting, linking, testing, and eventually merging components from two available and currently evolving state-of-the-art platforms for hazard and for exposure characterization and ranking:
  - *METIS* (Metanomics Information System), developed by DuPont.
  - *PRoTEGE* (Prioritization and Ranking of Toxic Exposures with GIS extension), developed by the Computational Chemodynamics Laboratory of EOHSI.



# Proposed METIS-Protege Tool

**METIS**

**PRoTEGE**





# **Tier 2 - Categorize Hazard & Exposure Characterization**

# Guidance for Initial Prioritization of Chemicals for Risk Assessment

**Prioritization Score** = Hazard category x Exposure category

**Hazard or Exposure Categories:**

**3 - High**

**2 - Moderate**

**1 - Low**

- **A "3" in any Hazard or Exposure Category defaults to a "3" value for the Initial Prioritization.**
  - Assures that any chemical with a high level endpoint of concern will be ranked for prioritization in the CEC framework.

# Guidance for Hazard Characterization

- Evaluate evidence for mammalian or environmental toxicity:
  - Acute Systemic Toxicity
  - Carcinogen, Mutagen, Reproductive / Developmental Toxicity (including endocrine disruptors)
  - Neurobehavioral Toxicity
  - Repeated dose target organ toxicity
  - Chemical Respiratory Sensitizer
- Hazard criteria based on:
  1. EPA - TSCA Work Plan Chemicals: Methods Document (2/2012)
  2. EPA - Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation (8/2011)

# Categorization of Mammalian Hazard

3

- Strong weight of evidence for mammalian toxicity:
  - Acute Systemic Toxicity
  - Carcinogen, Mutagen, Reproductive / Developmental Toxicity (including endocrine disruptors)
  - Neurobehavioral Toxicity
  - Repeated dose target organ toxicity
  - Chemical Respiratory Sensitizer

2

- 
- Uncertainty about or moderate weight of evidence or no data for mammalian toxicity:
    - Acute Systemic Toxicity
    - Carcinogen, Mutagen, Reproductive / Developmental Toxicity (including endocrine disruptors)
    - Neurobehavioral Toxicity
    - Repeated dose target organ toxicity
    - Chemical Respiratory Sensitizer

1

- 
- Weak weight of evidence for mammalian toxicity

**Table 1-A. Criteria for Determining Mammalian Hazard Score**

	High	Moderate	Low	Hazard Score
Ranking	3	2	1	
<b>Chemical X</b>				
<b>Acute Mammalian Toxicity</b>				
Oral LD50 (mg/kg)	≤ 50 - 300	> 300 - 2,000	> 2,000	
Dermal LD50 (mg/kg)	≤ 200 - 1,000	> 1,000 - 2,000	> 2,000	
Inhalation LC50 (gas/vapor) (mg/L)	≤ 2 - 10	> 10 - 20	> 20	
Inhalation LC50 (mist/dust) (mg/L/day)	≤ 0.5 - 1.0	> 1.0 - 5	> 5	
<b>Carcinogenicity</b>	GHS 1A, 1B, GHS2	Limited Animal	Negative or SAR	
<b>Mutagenicity/Genotoxicity</b>	GHS 1A, 1B, GHS2	Positive <i>in vivo</i> or <i>in vitro</i>	Negative	
<b>Reproductive Toxicity</b>				
Oral (mg/kg/day)	< 50	50 - 250	> 250	
Dermal (mg/kg/day)	< 100	100 - 500	> 500	
Inhalation (gas/vapor) (mg/L/day)	< 1	1 - 2.5	> 2.5	
Inhalation (mist/dust) (mg/L/day)	< 0.1	0.1 - 0.5	> 0.5	

**Table 1-B. Criteria for Determining Mammalian Hazard Score**

	High	Moderate	Low	Hazard Score
<b>Ranking</b>	3	2	1	
<b>Chemical X</b>				
<b>Developmental Toxicity</b>				
Oral (mg/kg/day)	< 50	50 - 250	> 250	
Dermal (mg/kg/day)	< 100	100 - 500	> 500	
Inhalation (gas/vapor) (mg/L/day)	< 1	1 - 2.5	> 2.5	
Inhalation (mist/dust) (mg/L/day)	< 0.1	0.1 - 0.5	> 0.5	
<b>Neurotoxicity</b>				
<b>Oral (mg/kg-bw/day)</b>				
90-day (13 weeks)	< 10	10 - 100	> 100	
40-50 days	< 20	20 - 200	> 200	
28-days (4 weeks)	< 30	30 - 300	> 300	
<b>Dermal (mg/kg-bw/day)</b>				
90-day (13 weeks)	< 20	20 - 200	> 200	
40-50 days	< 40	40 - 400	> 400	
28-days (4 weeks)	< 60	60 - 600	> 600	

**Table 1-C. Criteria for Determining Mammalian Hazard Score**

	High	Moderate	Low	Hazard Score
Ranking	3	2	1	
<b>Chemical X</b>				
<b>Repeated Dose (Chronic) Toxicity</b>				
<b>Oral (mg/kg-bw/day)</b>				
90-day (13 weeks)	< 10	10 - 100	> 100	
40-50 days	< 20	20 - 200	> 200	
28-days (4 weeks)	< 30	30 - 300	> 300	
<b>Dermal (mg/kg-bw/day)</b>				
90-day (13 weeks)	< 20	20 - 200	> 200	
40-50 days	< 40	40 - 400	> 400	
28-days (4 weeks)	< 60	60 - 600	> 600	
<b>Inhalation (vapor/gas) (mg/L/6hrs/day)</b>				
90-day (13 weeks)	< 0.2	0.2 - 1.0	> 1.0	
40-50 days	< 0.4	0.4 - 2.0	> 2.0	
28-days (4 weeks)	< 0.6	0.6 - 3.0	> 3.0	
<b>Inhalation (dust/mist/fume) (mg/L/6hrs/day)</b>				
90-day (13 weeks)	<0.02	0.02 - 0.2	> 0.2	
40-50 days	< 0.04	0.04 - 0.4	> 0.4	
28-days (4 weeks)	< 0.06	0.06 - 0.6	> 0.6	

**Table 1-D. Criteria for Determining Mammalian Hazard Score**

	High	Moderate	Low	Hazard Score
Ranking	3	2	1	
Chemical X				
<b>Respiratory Sensitization</b>	GHS 1A and 1B Occurrence of respiratory sensitization; Evidence supporting potential for respiratory sensitization		No evidence supporting potential for respiratory sensitization	



# Categorization of Environmental Hazard

- 3** • Strong weight of evidence for Environmental toxicity:
  - Acute or Chronic Aquatic Toxicity
    - » Fish toxicity
    - » Crustacea toxicity
    - » Algal toxicity

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- 2** • Uncertainty about or moderate weight of evidence or no data for Environmental toxicity:
  - Acute or Chronic Aquatic Toxicity
    - » Fish toxicity
    - » Crustacea toxicity
    - » Algal toxicity

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- 1** • Weak weight of evidence for Environmental toxicity

**Table 2. Criteria for Determining Environmental Hazard Score**

	High	Moderate	Low	Hazard Score
<b>Ranking</b>	3	2	1	
<b>Chemical X</b>				
<b>Acute Aquatic Toxicity</b>				
Fish 96 hr. LC <sub>50</sub>	< 1.0 - 10.0	> 10 - 100	> 100	
Crustacea sp. 48 hr. EC <sub>50</sub>	< 1.0 - 10.0	> 10 - 100	> 100	
Algal sp. 72 or 96 hr. EC <sub>50</sub>	< 1.0 - 10.0	> 10 - 100	> 100	
<b>Chronic Aquatic Toxicity (NOEC or EC<sub>50</sub>)</b>				
Fish Early Life Stage	< 0.1 - 1	> 1 - 10	> 10	
Daphnia Reproduction	< 0.1 - 1	> 1 - 10	> 10	
Algal Growth Inhibition	< 0.1 - 1	> 1 - 10	> 10	

# Supplemental Evaluation of Environmental Hazard

- Consider any available data for sublethal - growth, reproduction, development, etc. responses or "real" ecological responses at the population or community level.

# Evaluation of Endocrine Activity

- Evaluate endocrine activity rather than characterize hazard in terms of “endocrine disruption”.
- Endocrine activity can be defined as a change in endocrine homeostasis caused by a chemical or other stressor from human activities (e.g., application of pesticides, the discharge of industrial chemicals to air, land, or water, or the use of synthetic chemicals in consumer products.).
- Data that will be considered include:
  - In vitro data such as hormone receptor binding assays or ex vivo assays
  - In vivo data from studies of intact animals or wildlife (including aquatic organisms)
  - Ethically conducted human studies
  - In vivo short term exposures or altered (e.g., ovariectomized) animal models
  - Structural similarity to known endocrine active substances using SAR tools such as AIM, QSAR, etc.
  - Additional information gleaned from studies that are indicative of a chemical’s endocrine system interactions, such as changes in hormone profiles or reproductive organ weights.

# Categorization of Endocrine Activity

- Available data for each chemical will be evaluated for evidence of the presence of endocrine activity.
- 

**3** – If data show evidence of endocrine activity then the chemical will be designated as potentially endocrine active, while noting caveats and limitations.

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**2** – If there are no data available to evaluate this endpoint, endocrine activity is unknown, untested and would be marked with a “ND” indicating the absence of information.  
(No Data)

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**1** – If data conclude no evidence of activity (no binding, perturbation, or evidence of endocrine-related adverse effects) then the chemical will be designated as having no evidence of endocrine activity, noting caveats and limitations.

# Input for Exposure Characterization

- **For Each Chemical**
  - **Emissions and products**
  - **Exposure pathways**
  - **Vulnerable populations**
  - **Exposure routes**
  - **Frequency of contact**
  - **Fate in the environment**
  - **Eco-exposures**

# Categorization of Exposure Characterization

3

- Presence in NJ environmental media / biota at significant concentrations or as significant biomarker measurements, and relative ranking of exposure based upon distributional estimates for 3 the main routes of exposure (inhalation, dermal and ingestion) (ug/kg/day)
  - Presence in food, children's toys, cosmetics/ personal care products, consumer product and relative ranking of exposure based upon distributional estimates for 3 the main routes of exposure (inhalation, dermal and ingestion)
- 

2

- Presence in NJ environmental media / biota at concentrations less than which may be steadily increasing due uses or emission sources
  - Uses/applications with estimated moderate exposure potential
- 

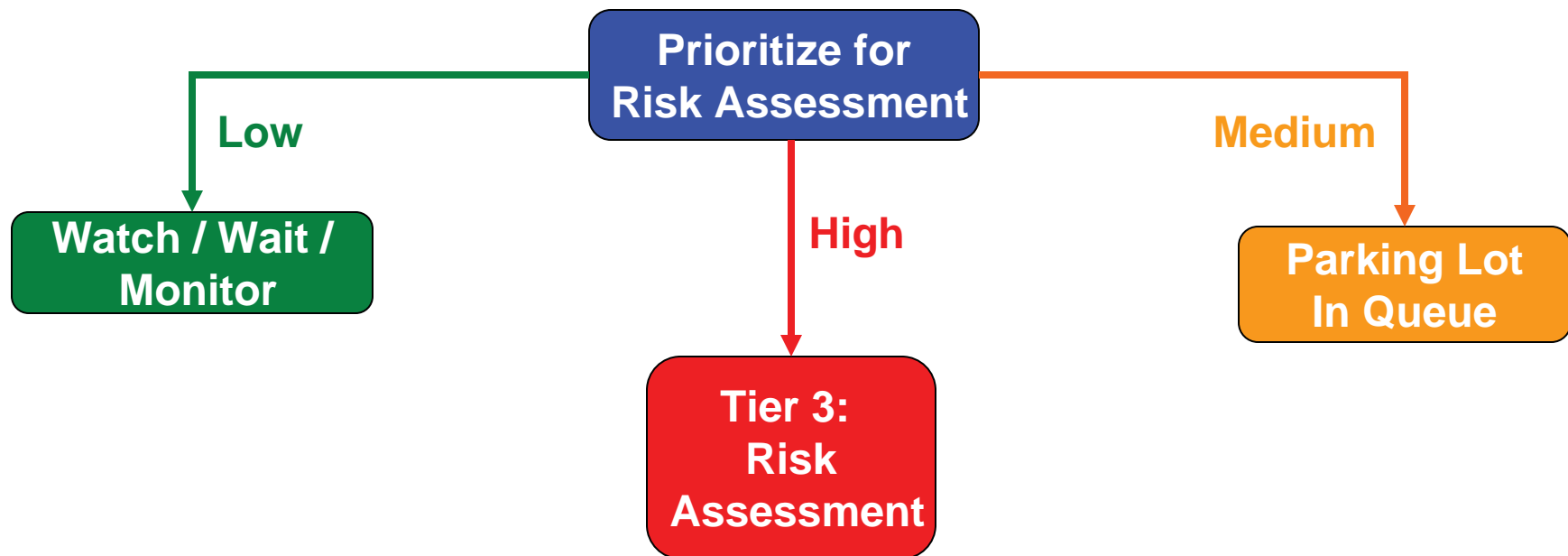
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- Detectable concentrations of new pollutants found in NJ environmental media / biota
- Manufacturing intermediate detected in NJ environmental media/ biota
- Uses/applications with estimated low exposure potential for NJ residents/biota

# **Tier 2 - Prioritize for Risk Assessment**



# Prioritizing for Risk Assessment



# Initial Prioritization Grid for Risk Assessment

		Potential Exposure		
		Low 1	Moderate 2	High 3
Potential Hazard	High 3	3x1 = 3	3x2 = 6	3x3 = 9
	Moderate 2	2x1 = 2	2x2 = 4	2x3 = 6
	Low 1	1x1 = 1	1x2 = 2	1x3 = 3

\* Red Boxes = Score of 9, then Score of 6 considered for Tier 3 Risk Assessment

# Initial Prioritization Grid for Risk Assessment

## "High Priority (red boxes)"

Potential Hazard

Potential Exposure

Low Moderate High

1 2 3

High 3

Moderate - 2

Low - 1

3x1 = 3	3x2 = 6	3x3 = 9
2x1 = 2	2x2 = 4	2x3 = 6
1x1 = 1	1x2 = 2	1x3 = 3

\* RED - SEND TO TIER 3 RISK ASSESSMENT

# Initial Prioritization Grid for Risk Assessment

## "Medium Priority (orange boxes)"

Potential Hazard

Potential Exposure  
 Low Moderate High  
 1 2 3

High 3  
 Moderate - 2  
 Low - 1

High 3	3x1 = 3	3x2 = 6	3x3 = 9
Moderate - 2	2x1 = 2	2x2 = 4	2x3 = 6
Low - 1	1x1 = 1	1x2 = 2	1x3 = 3

\* ORANGE - PARKING LOT, IN QUEUE

# Initial Prioritization Grid for Risk Assessment

## "Low Priority" (green boxes)

Potential Hazard

Potential Exposure

Low  
1

Moderate  
2

High  
3

High 3

$3 \times 1 = 3$

$3 \times 2 = 6$

$3 \times 3 = 9$

Moderate - 2

$2 \times 1 = 2$

$2 \times 2 = 4$

$2 \times 3 = 6$

Low - 1

$1 \times 1 = 1$

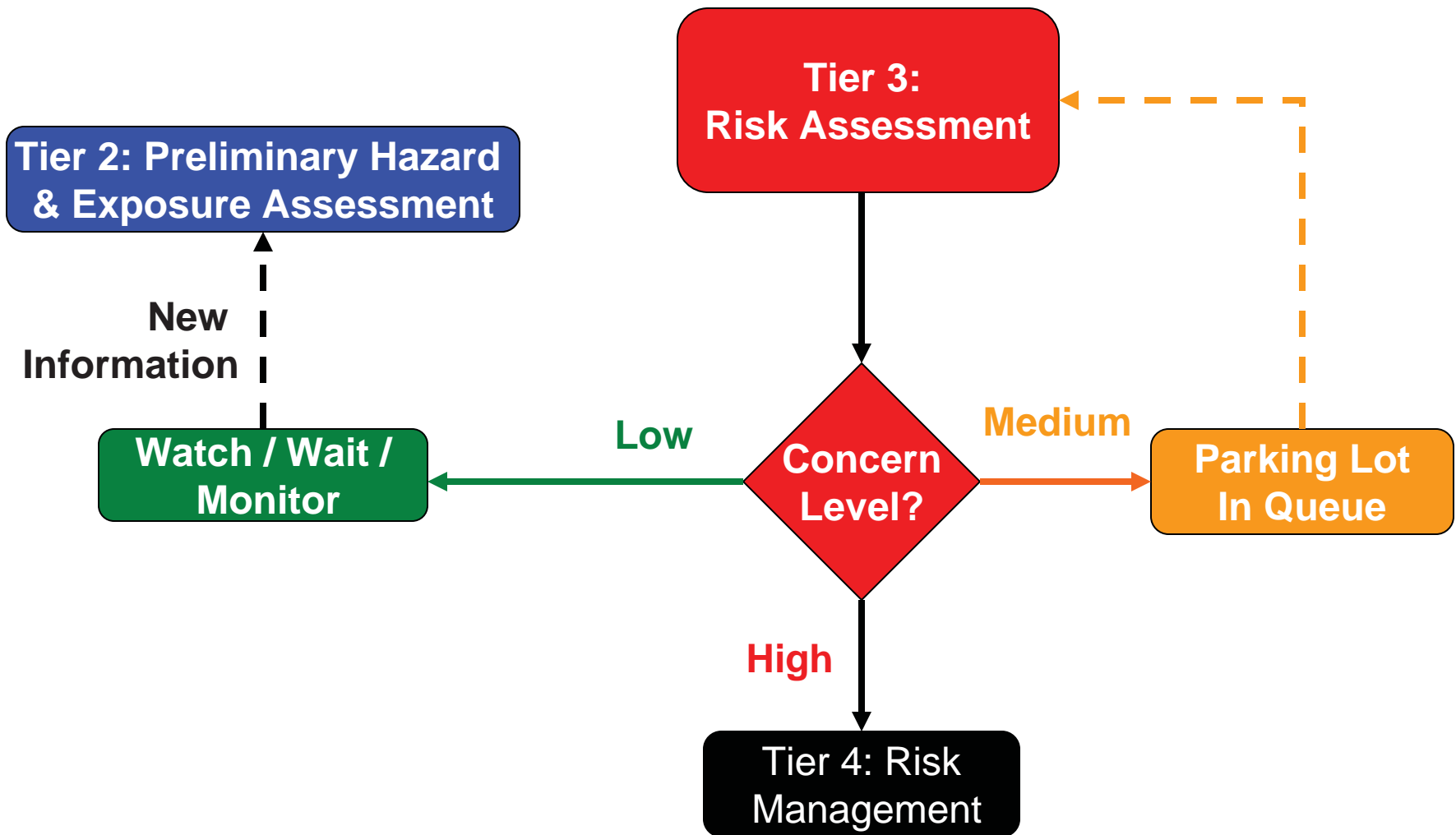
$1 \times 2 = 2$

$1 \times 3 = 3$

GREEN - WATCH, WAIT, MONITOR

# Tier 3 - Risk Assessment

# Tier 3 - Risk Assessment



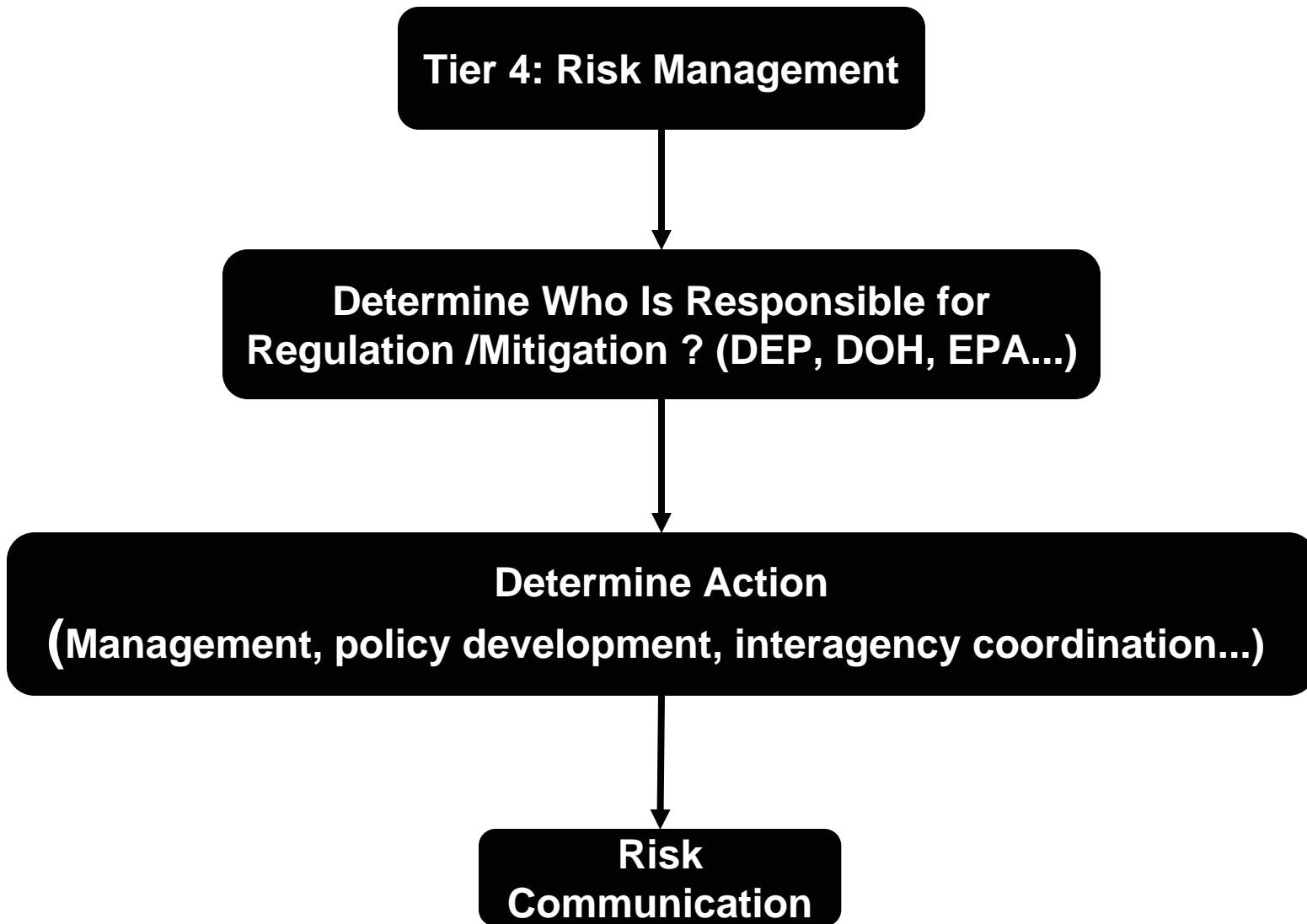
# Tier 3: Risk Assessment

- Includes both Human (mammalian) & Ecological Risk Assessments.
- Risk assessment will determine whether or not CEC candidate is a significant risk that merits consideration on the NJ CEC prioritization list.



# Tier 4 - Risk Management

# Tier 4 - Risk Management



# Tier 4: Risk Management

- Risk management of chemicals placed on the NJ CEC prioritization list will include recommended control or replacement options.
- Note: list needs to be manageable for NJ DEP with focus on mitigating risk of most critical CECs for NJ.

## Deliverables

1. Determine who is responsible
2. Determine action
3. Risk Communication