



# Using Risk21 to Prioritize Applications and Exposure-Driven Refinements for Plant Protection Products

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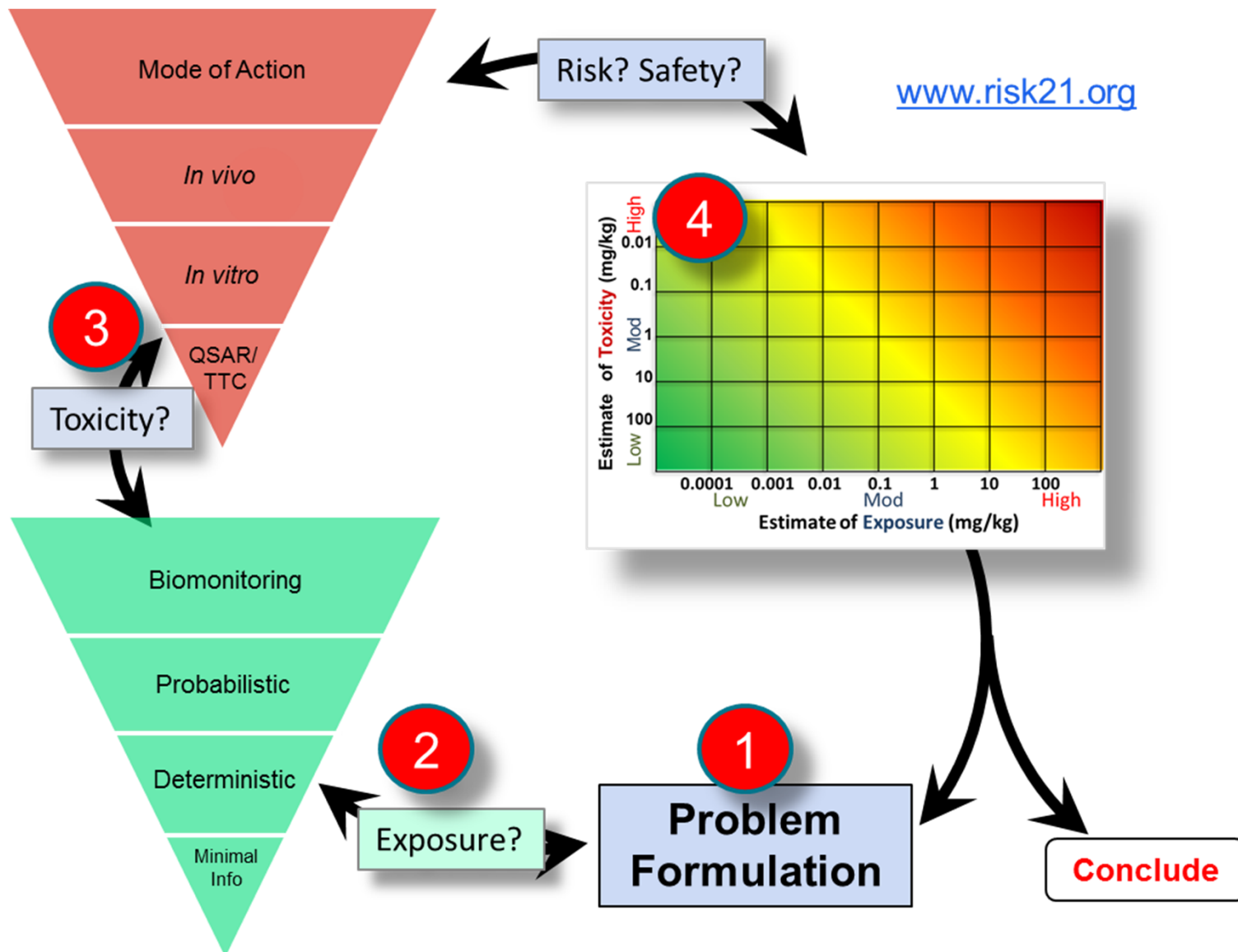
Human Health Risk Assessor

Corteva Agriscience

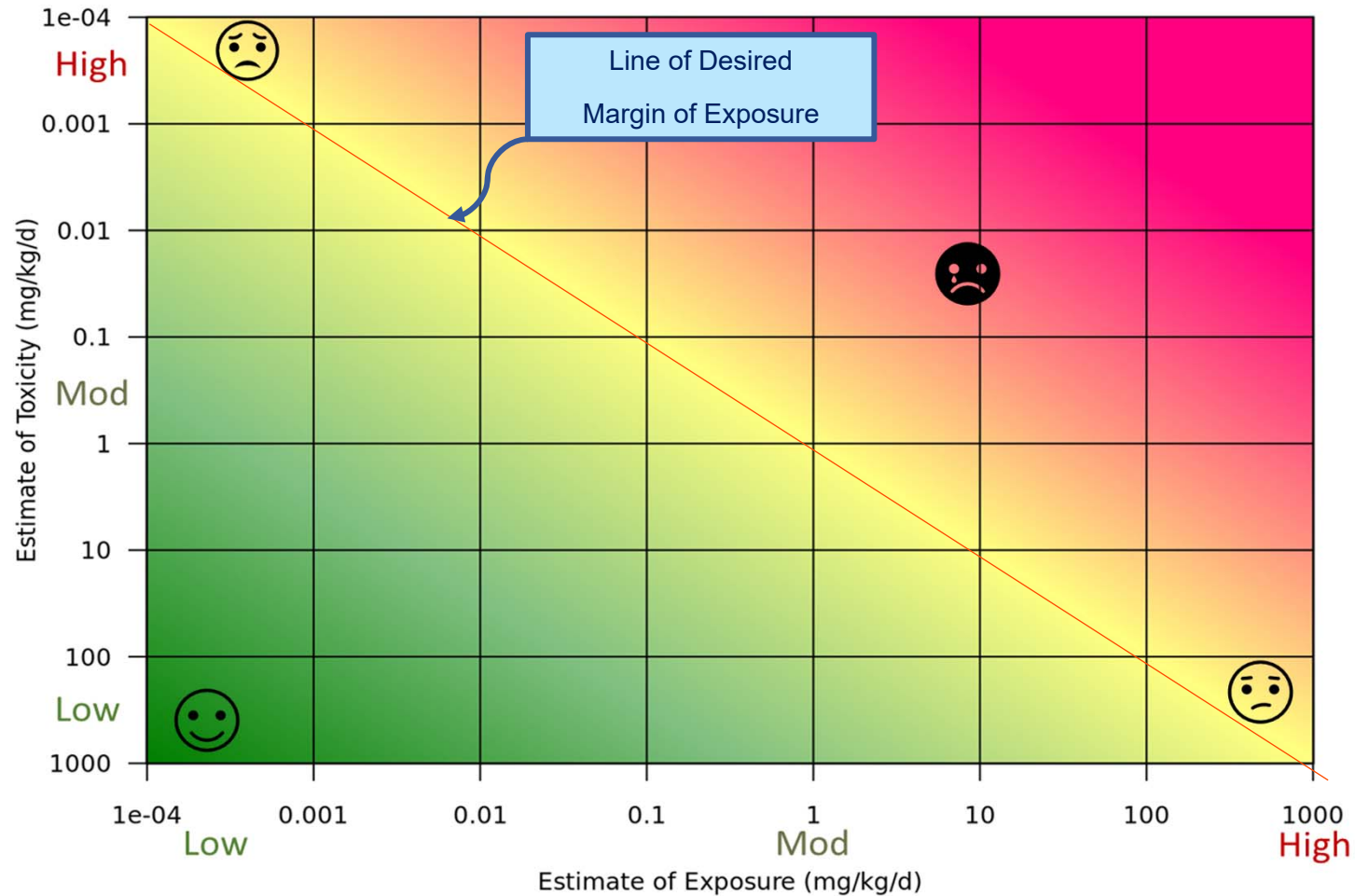
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# RISK21

- Risk communication tool
- Gives appropriate weight to exposure and hazard
- Highly visual, flexible, and transparent
- Multiple applications in Ag risk assessment



# Plant Protection Products Human Health Risk Assessment



# CASE STUDY

- Formulated product with three fungicide active ingredients (A.I.s)
- Toxicological endpoints from published registration documents
- Exposure data estimated for operators/handlers, re-entry workers, and residents
- Possible Refinements include
  - ✓ Crop restrictions
  - ✓ Personal Protective Equipment (PPE)
  - ✓ Dermal Absorption Study (A.I. specific)
  - ✓ Dislodgeable Foliar Residue (DFR) study (A.I. specific)
  - ✓ Exposure Study (A.I. and subpopulation specific)

# Problem Formulation



# Crop Restrictions: Multi-crop Application

- Chosen Crops had similar application rates for two of the actives

## Cereals



## Grapes

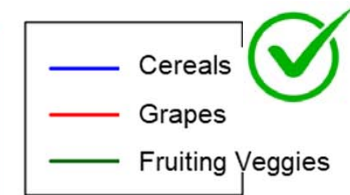
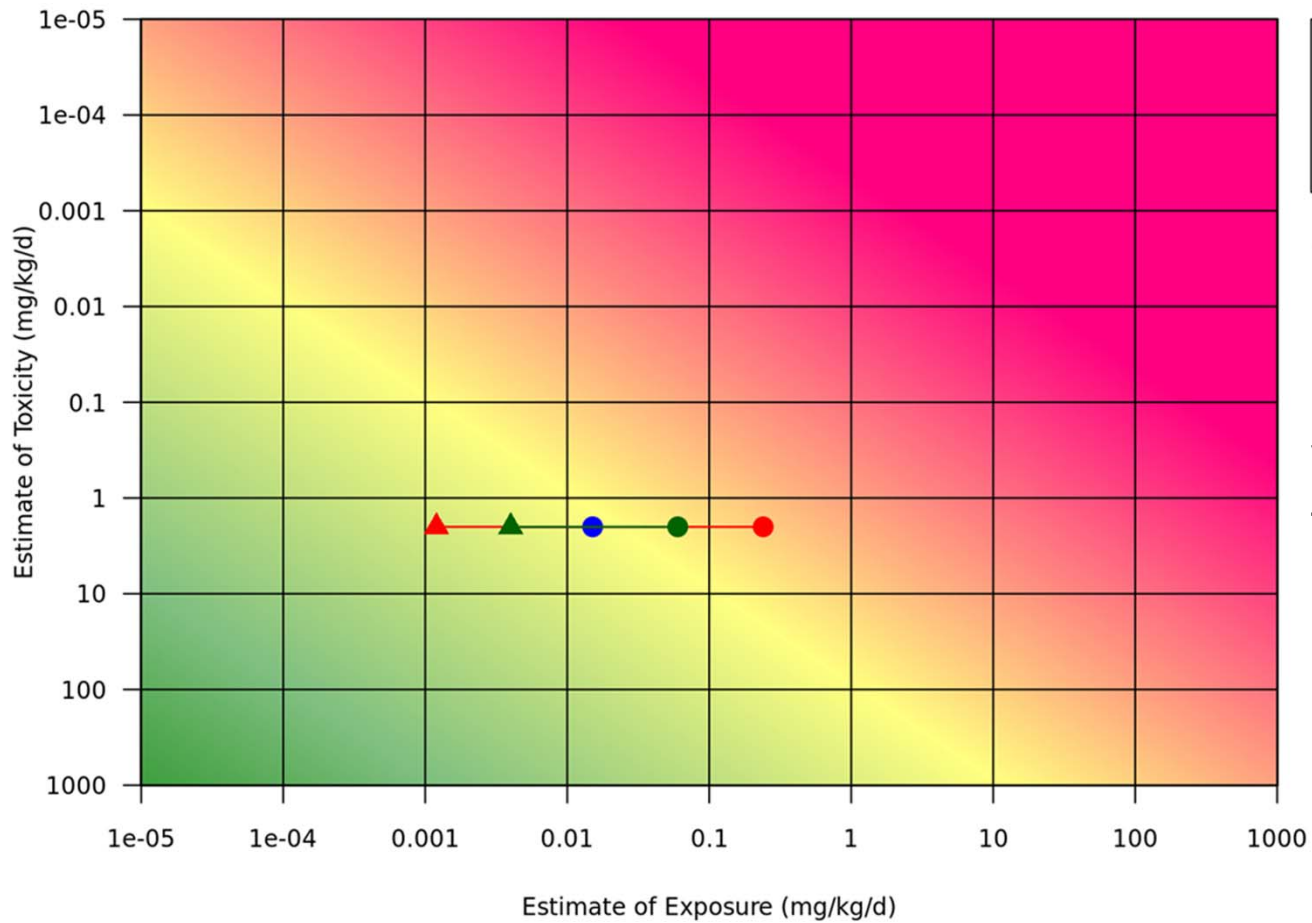


## Fruiting vegetables/Solanaceae



# Multi-crop Use for A.I.1

A.I 1 - Multicrop use



Grapes and Fruiting Vegetables need further refinements



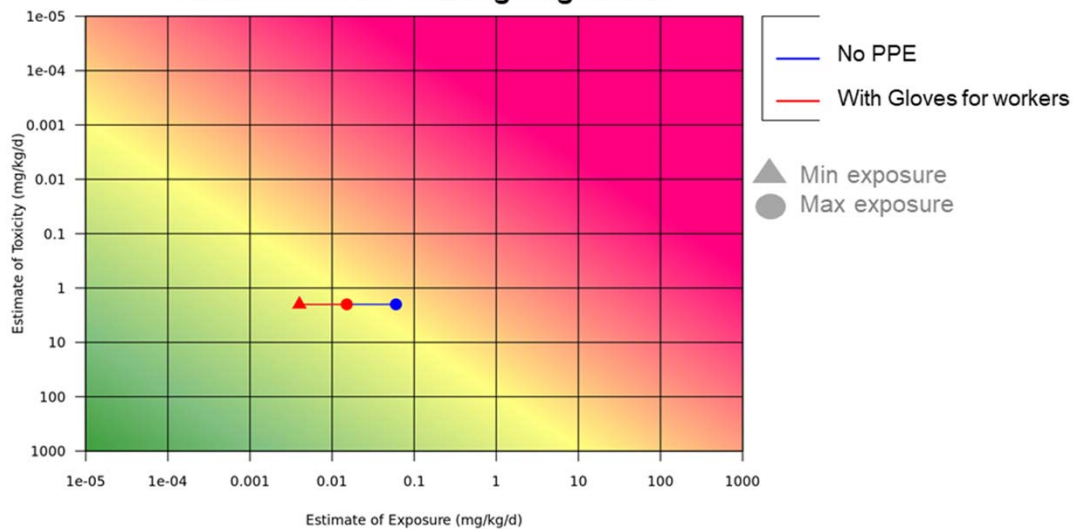
## Worker Re-entry Activities for Grapes and Tomatoes



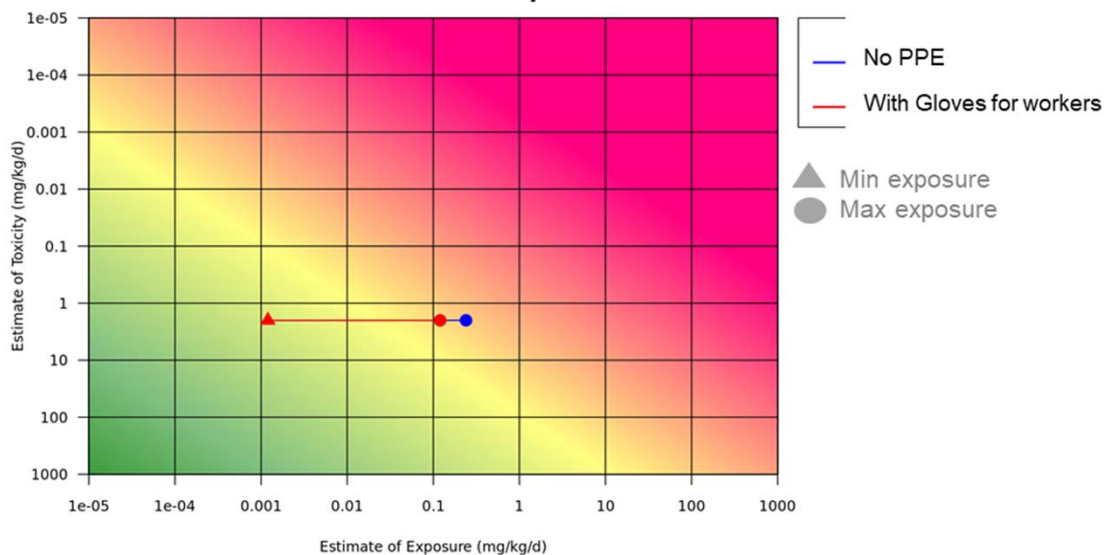
- Girdling/ring-barking
- Pruning
- Hand harvesting
- Trelis Repair & Tying
- Transplanting



### Refinements for Fruiting Vegetables



### Refinements for Grapes

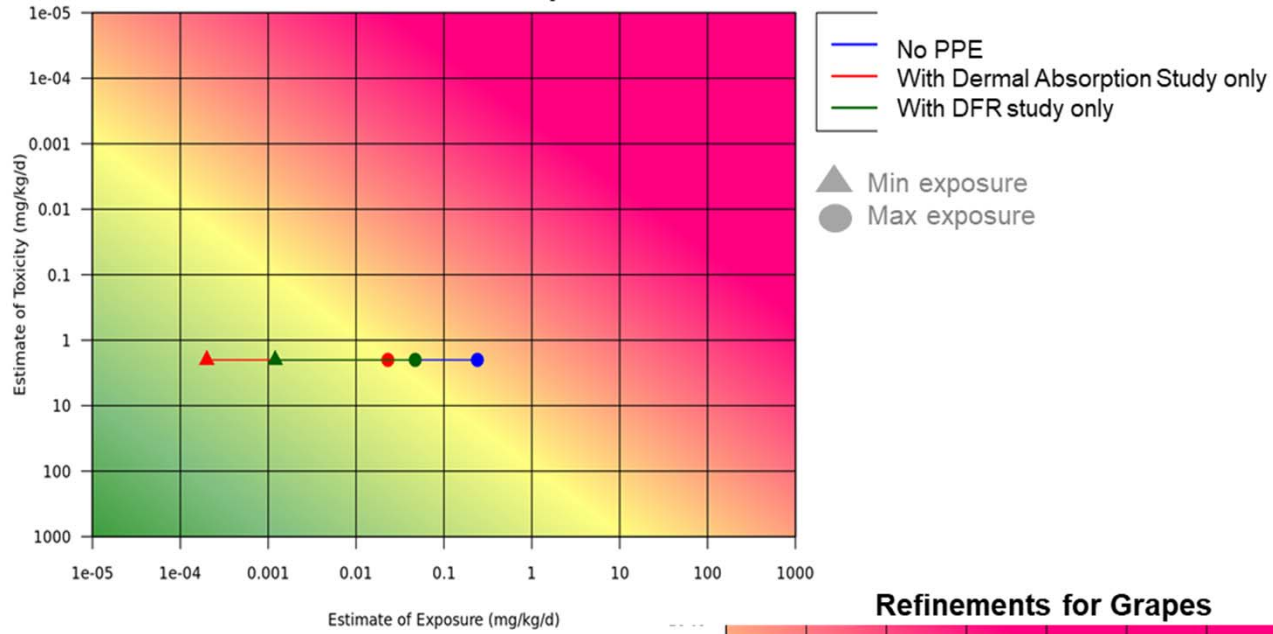


### Grapes Possible Refinement/Mitigation

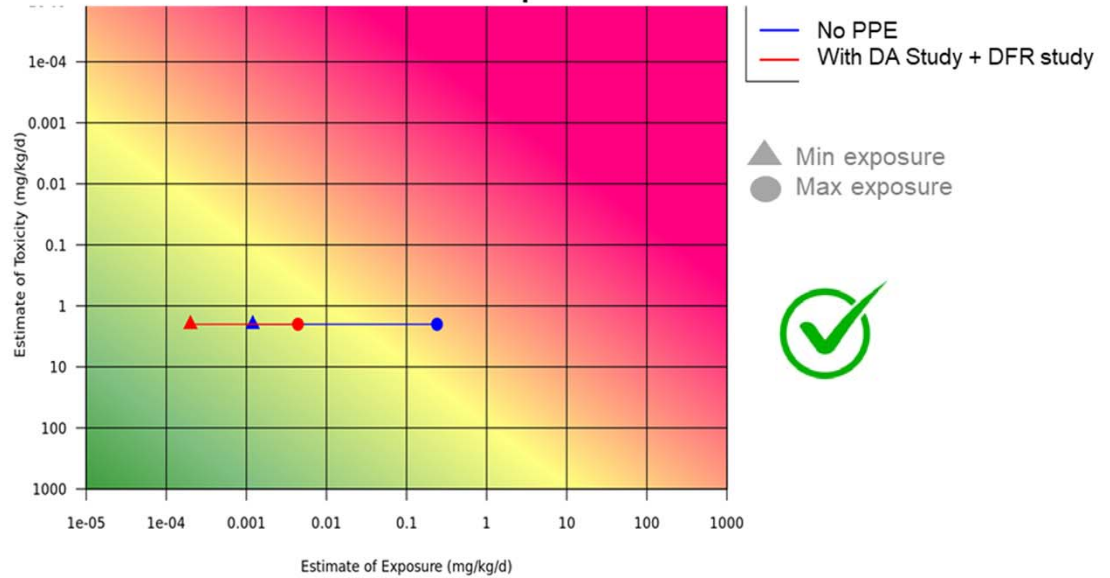
#### Measures:

1. Rate Reduction
2. Dermal Absorption Studies
3. Dislodgeable Foliar Residue Study
4. Removal from label?

## Refinements for Grapes



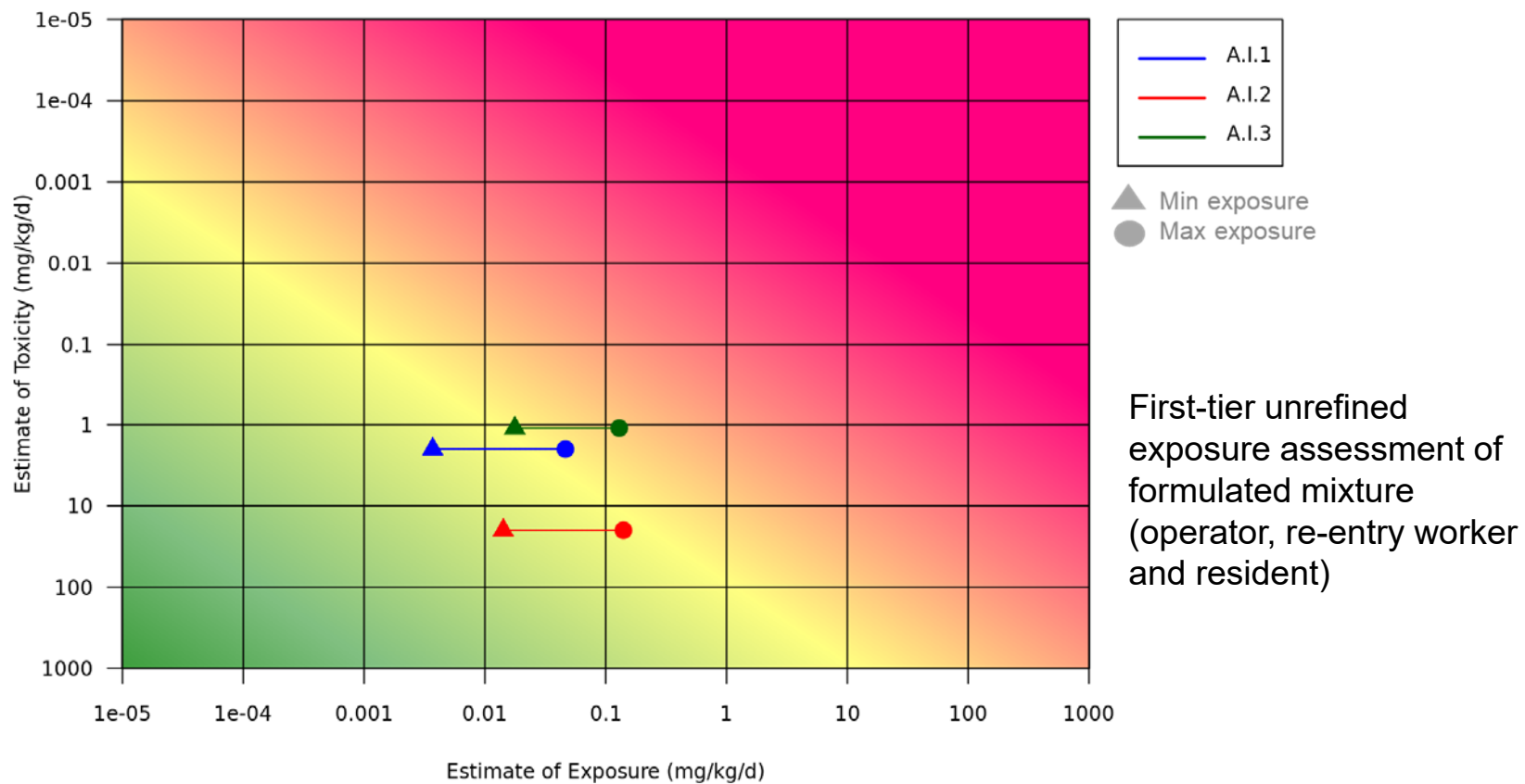
## Refinements for Grapes



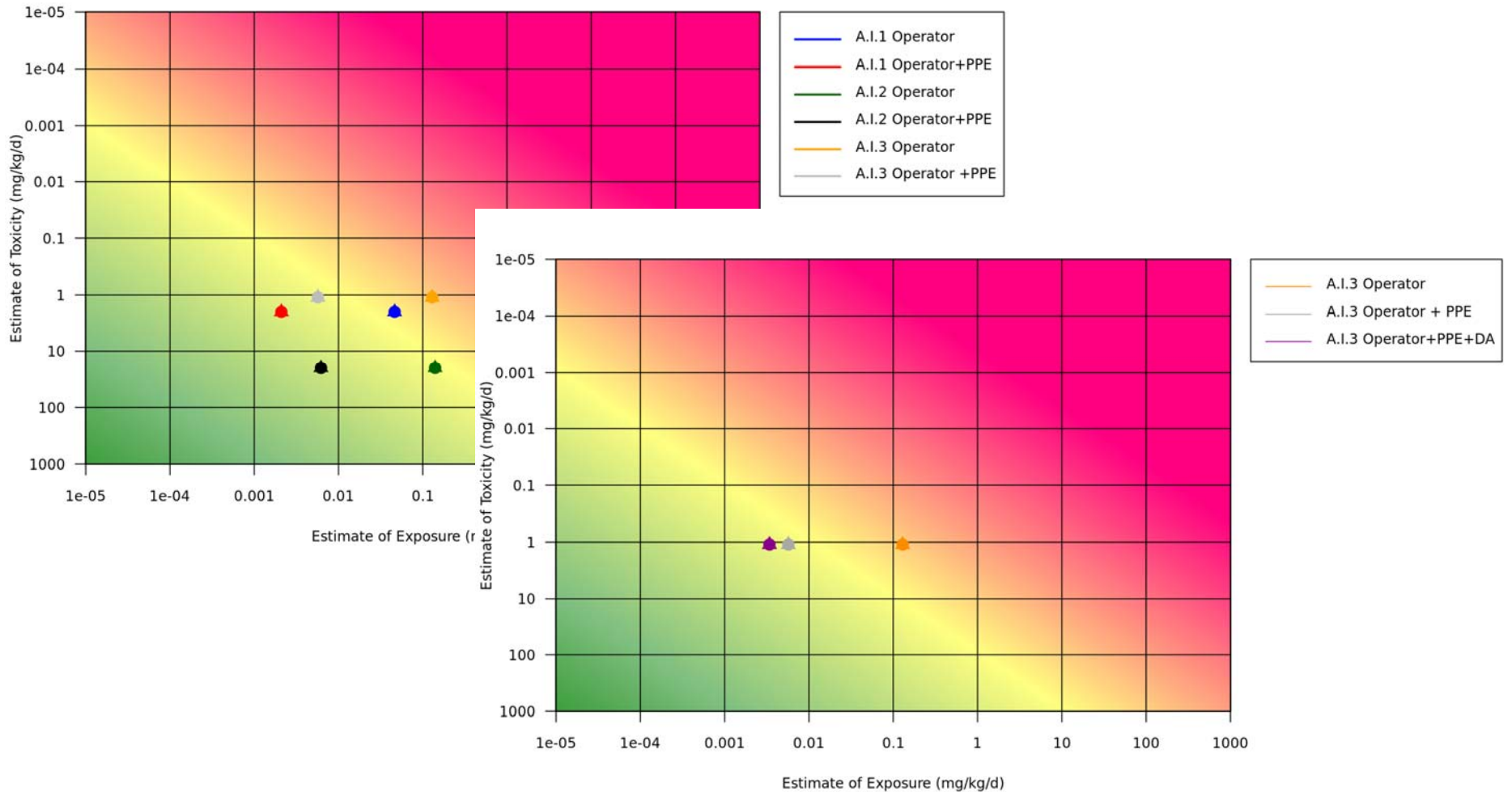
## **CASE STUDY – CEREAL APPLICATION**

- Formulated product with three active ingredients (A.I.s)
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  - ✓ Crop restrictions
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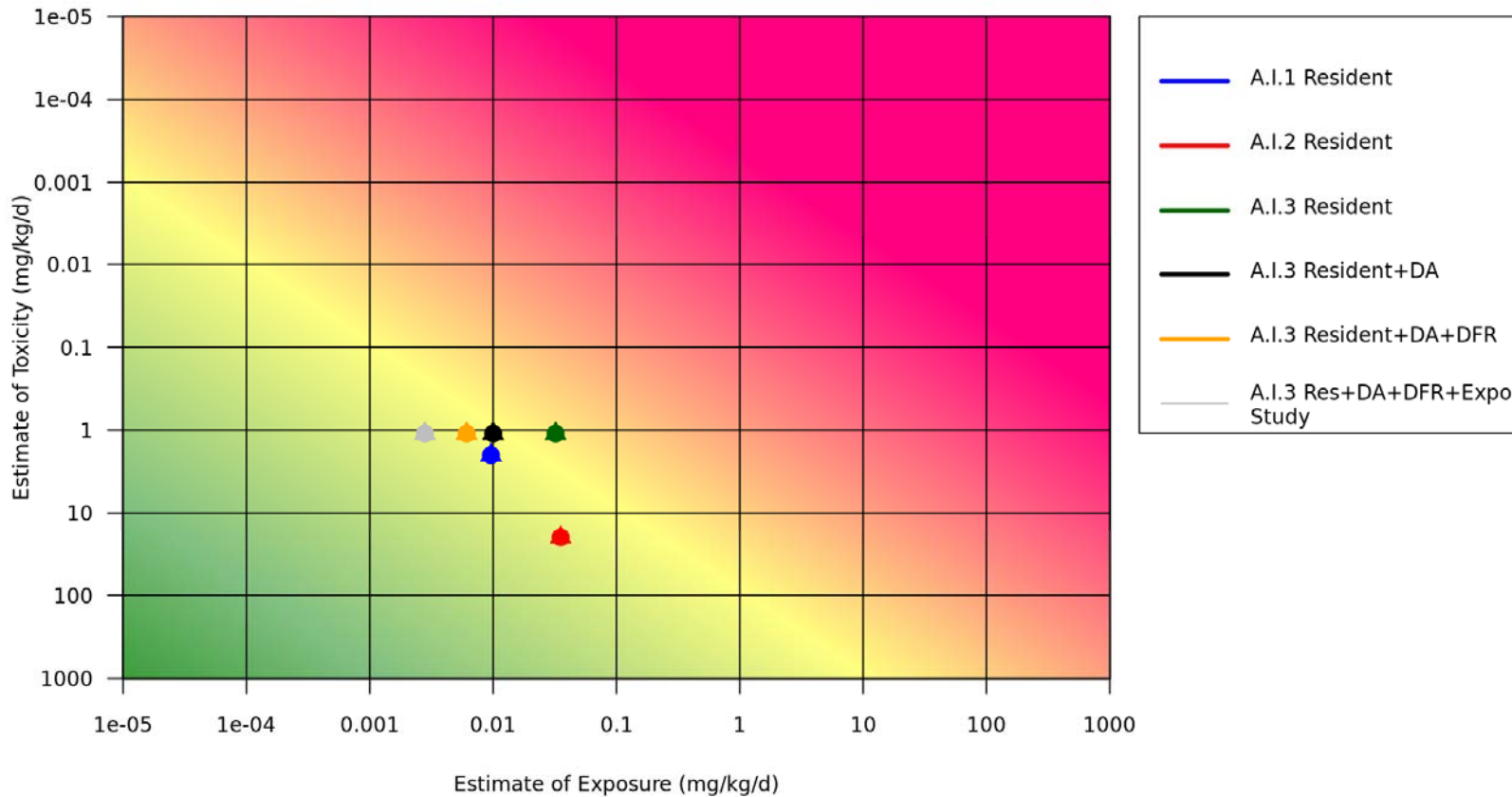
# Formulated Product – Cereal Application



# Operator/handler Risk Assessment

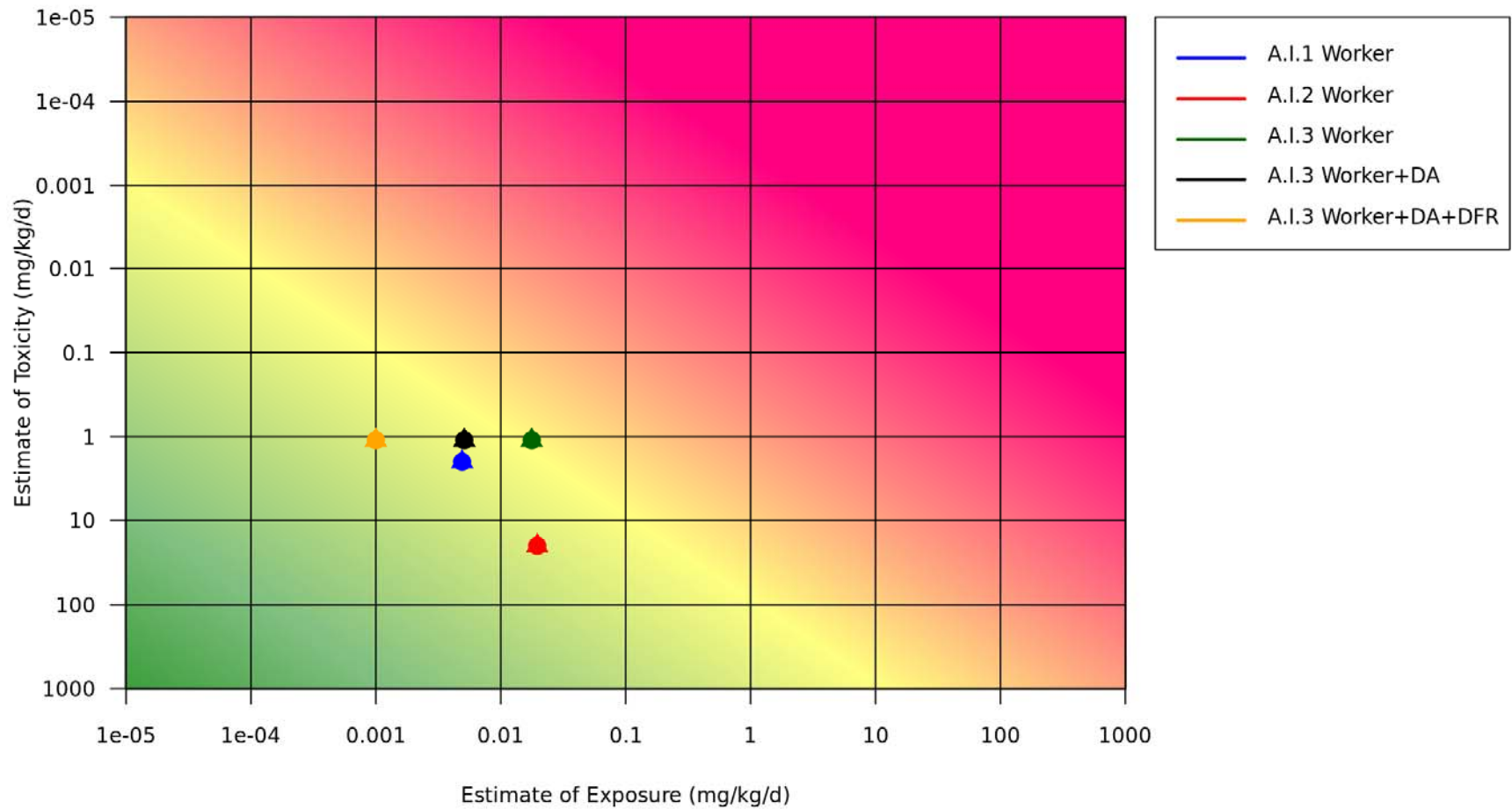


# Resident Assessment



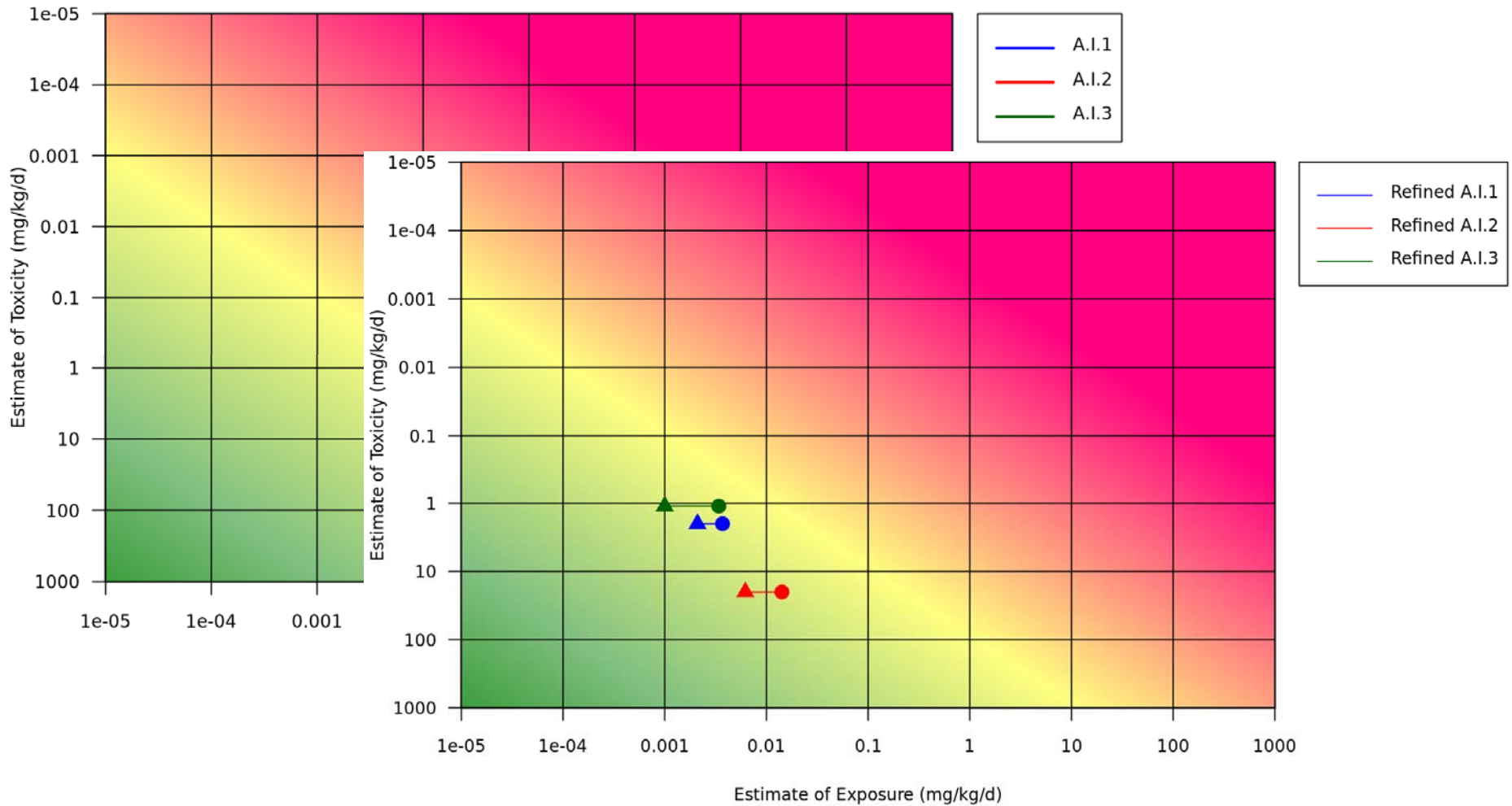
Targeted resident exposure studies for A.I. 3 showing only refinement of highest resident exposure

# Re-entry Worker Assessment





# Final Risk Assessment



# Conclusion

The Risk21 framework and matrix can be used:

- To communicate a clear picture of risk associated with multiple active ingredients in a formulated product
- By risk managers (agency/registrant)
  - ✓ To determine active ingredient-specific and generalized formulated product risk mitigation measures to drive specific refinement data needs
  - ✓ To track what refinements have been done and their impact on the risk assessment
- To support business decisions that are data driven and align with scientific refinements needed for risk mitigation

# Acknowledgements

- Marcela Giachini
- Sean Gehen
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