



# Are Maximum Residue Limits a Food Safety Risk?

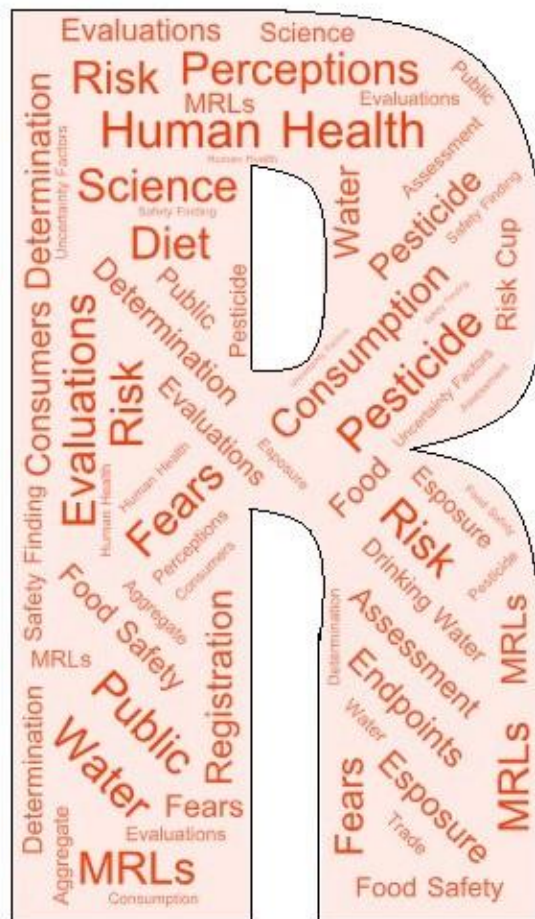
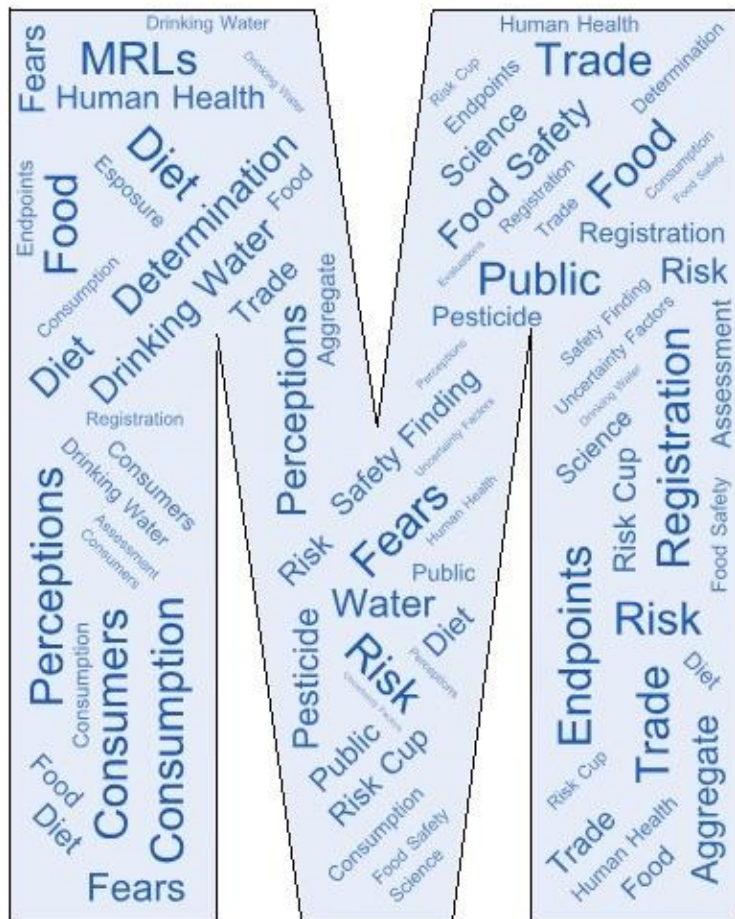
Carol Hayworth and Heidi Irrig, M.S,  
May 30, 2019

# Overview

- I. What Are We Talking About?
  - i. Purpose of Setting MRLs
  - ii. Setting Tolerances
- II. MRLs ...Safety?
  - i. Tolerance and Safety Determination
  - ii. Dietary Exposure
- III. Understanding Pesticide Exposure from Food Consumption
  - i. Real world example – PDP
  - ii. Risk Cup – Hazard + Exposure
- IV. Review/Conclusions

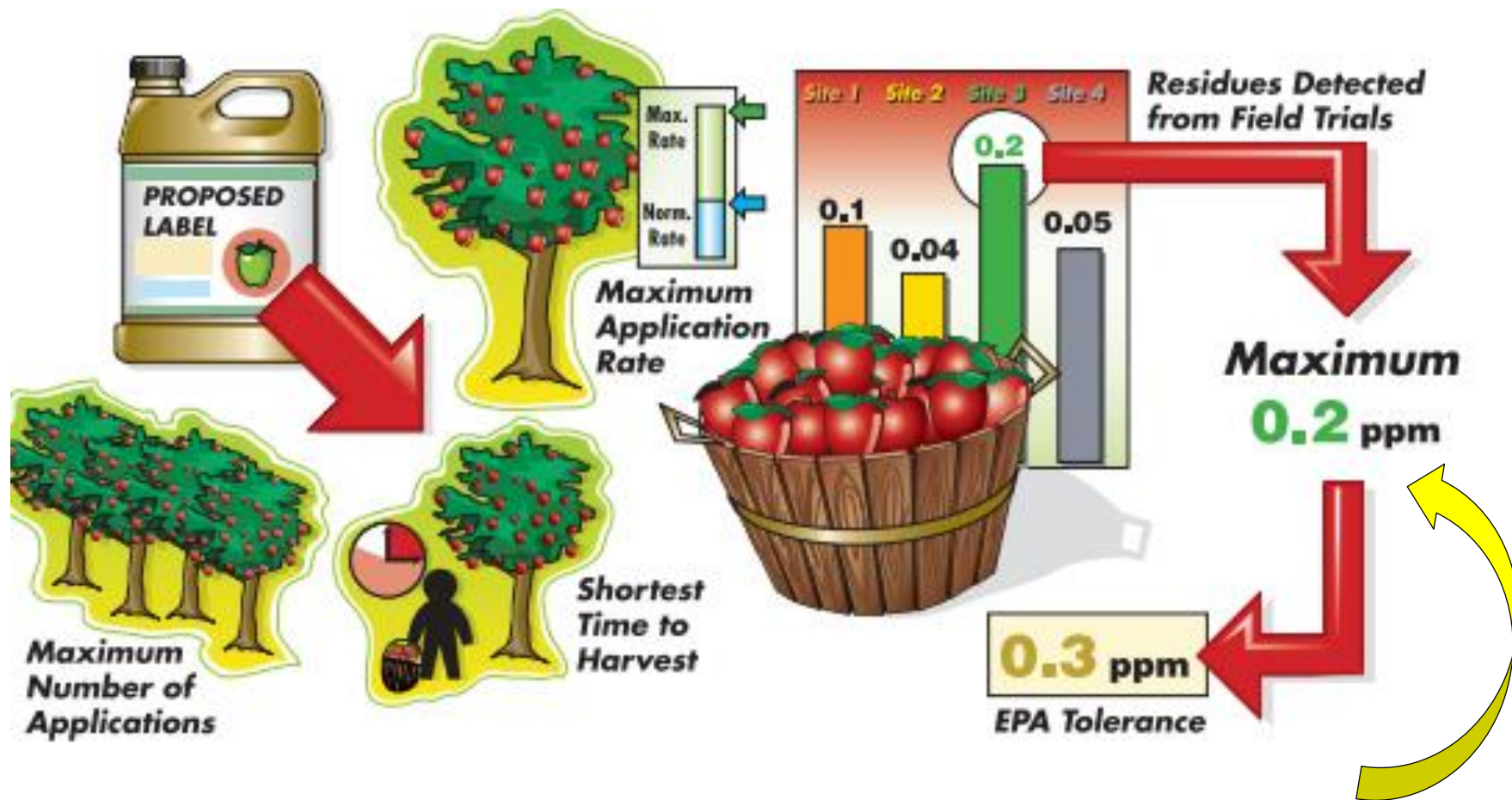


# What Are We Talking About?





# How Are MRLs Established?



EPA comparison of proposed MRL versus aggregate dietary risk assessment

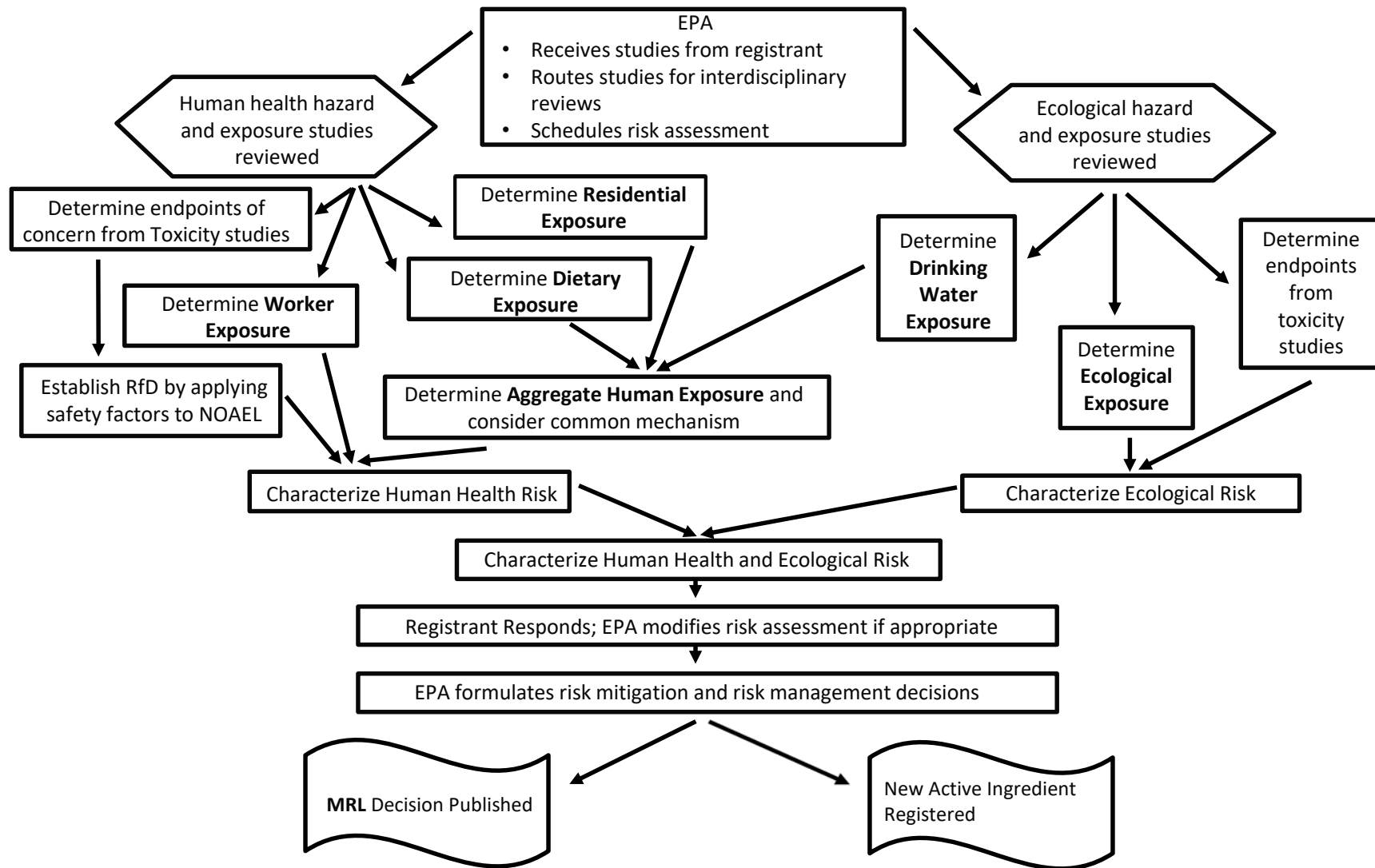
# Setting MRLs (US Tolerances)

## U.S. EPA Pesticide Registration

<b>Tolerance Determination</b>	<b>Safety Determination</b>
Pesticide Label	Hazard Evaluation
Residue Studies	Exposure Estimates
Tolerance Level	Risk Assessment
Registration Decision (FIFRA) Tolerance Establishment (FFDCA)	

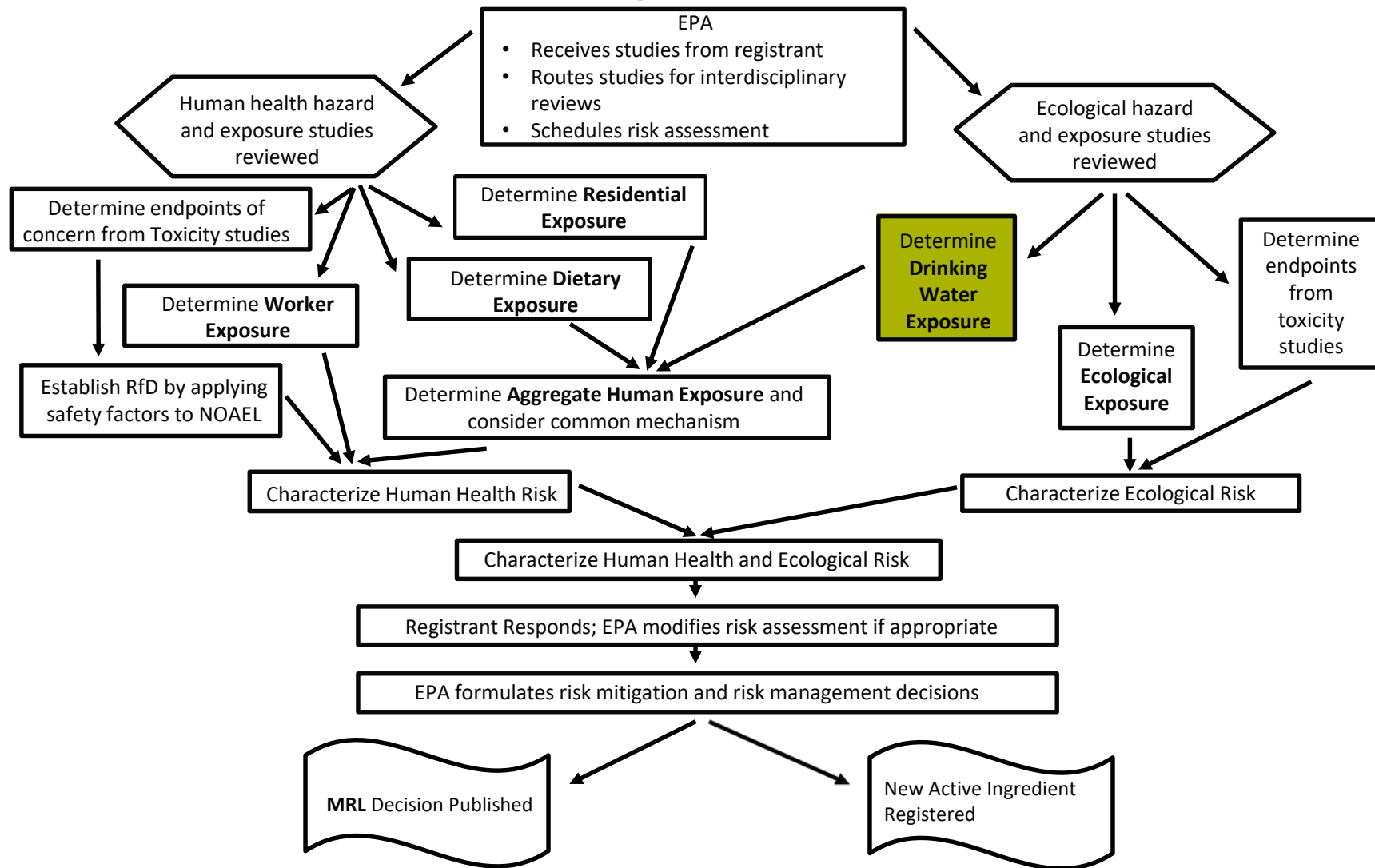
Reference: David Hrdy, Health Effects Division, Office of Pesticide Programs

# Tolerances and Safety Determination



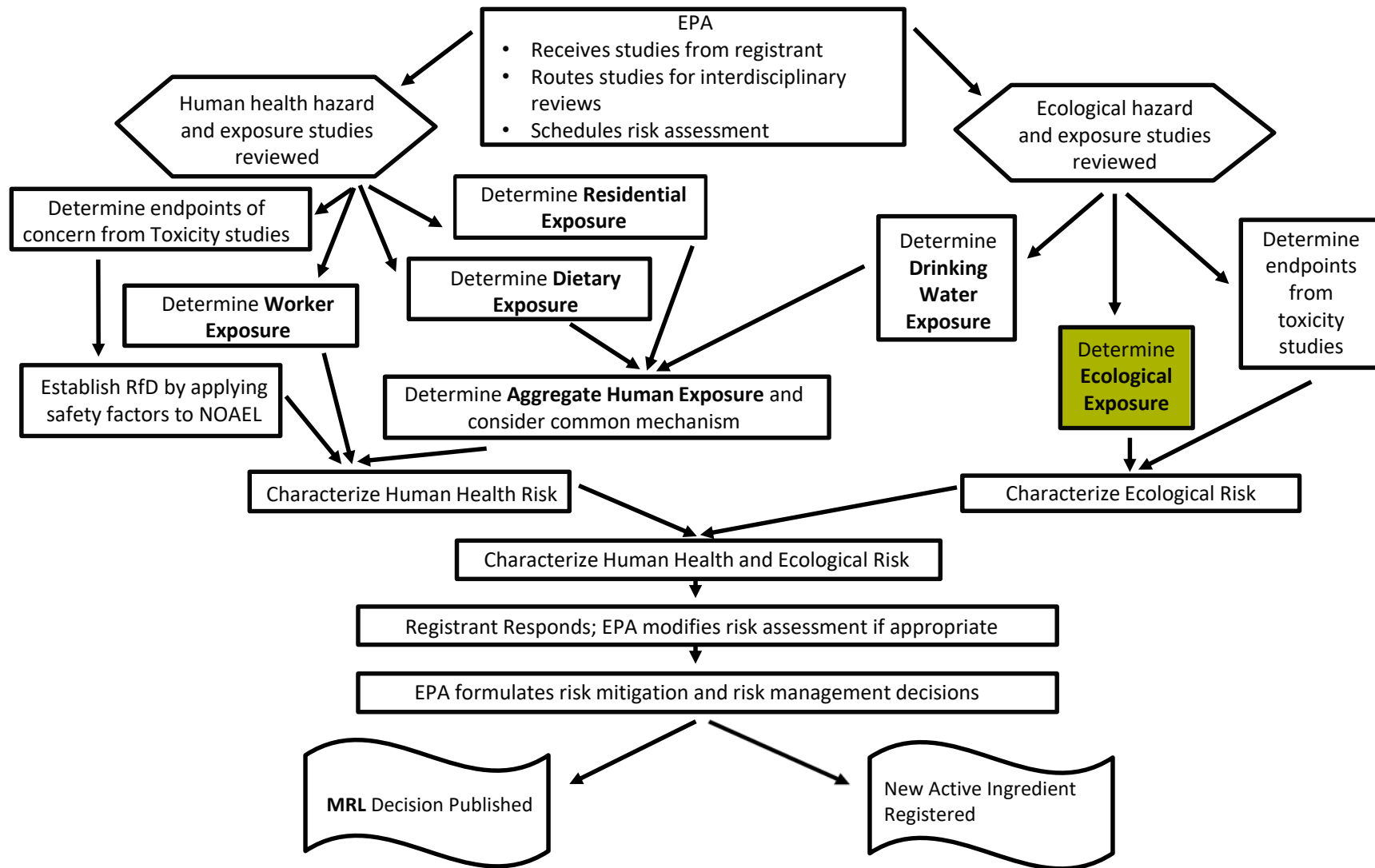
Reference: Luis Suguiyama, USEPA

# Tolerances and Safety Determination



Reference: Luis Suguiyama, USEPA

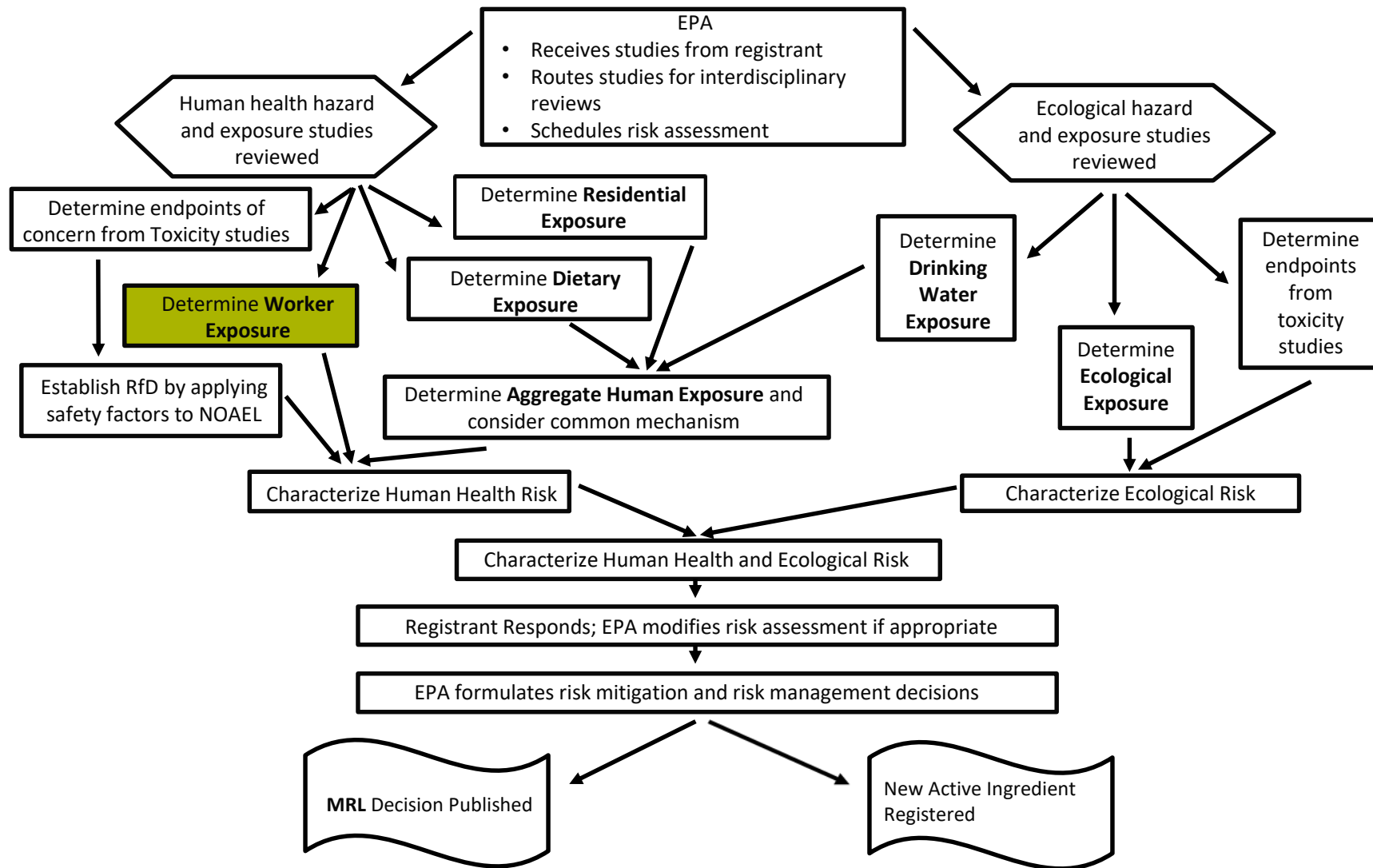
# US EPA Registration and MRL Process



Reference: Luis Suguiyama, USEPA

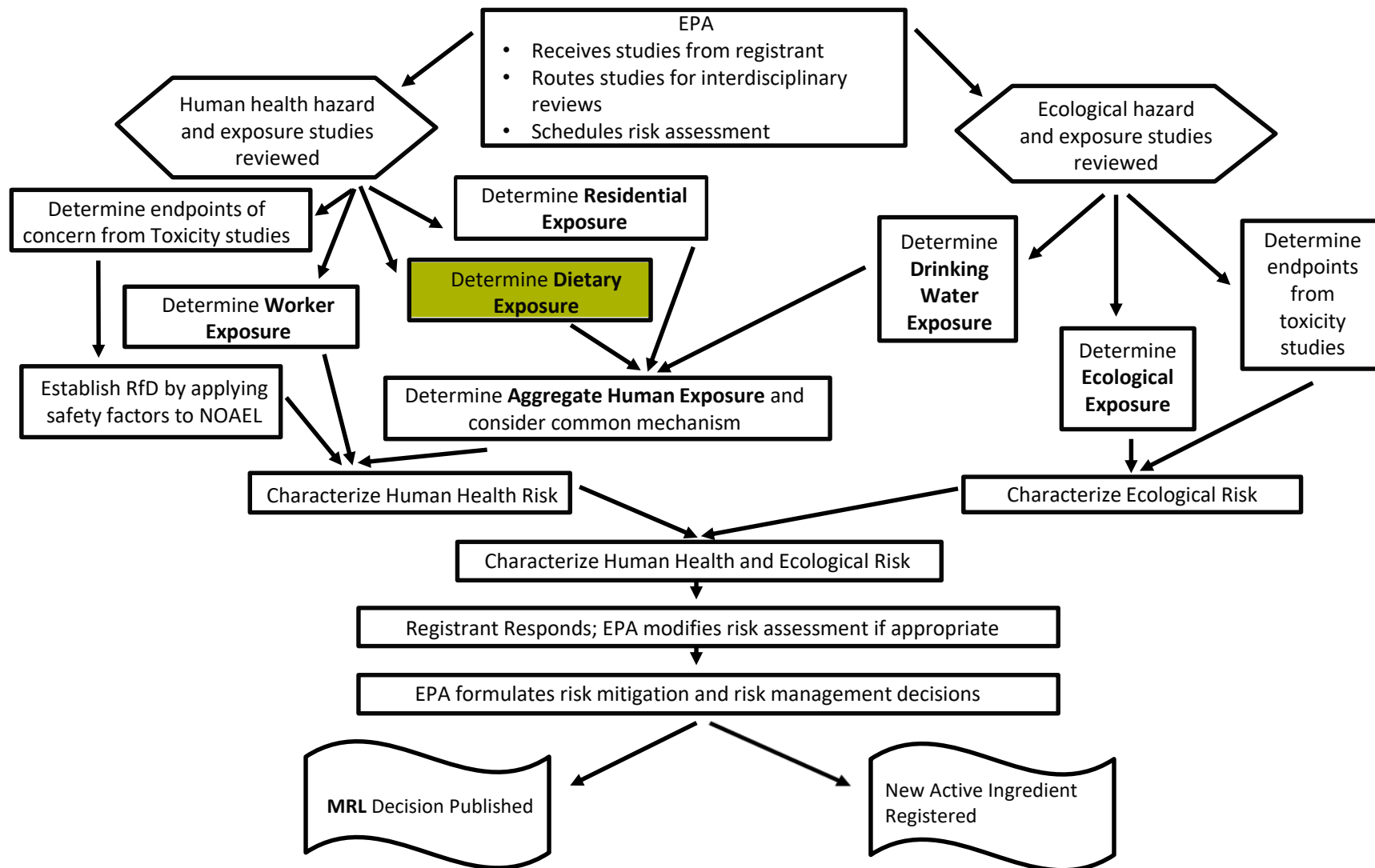


# US EPA Registration and MRL Process



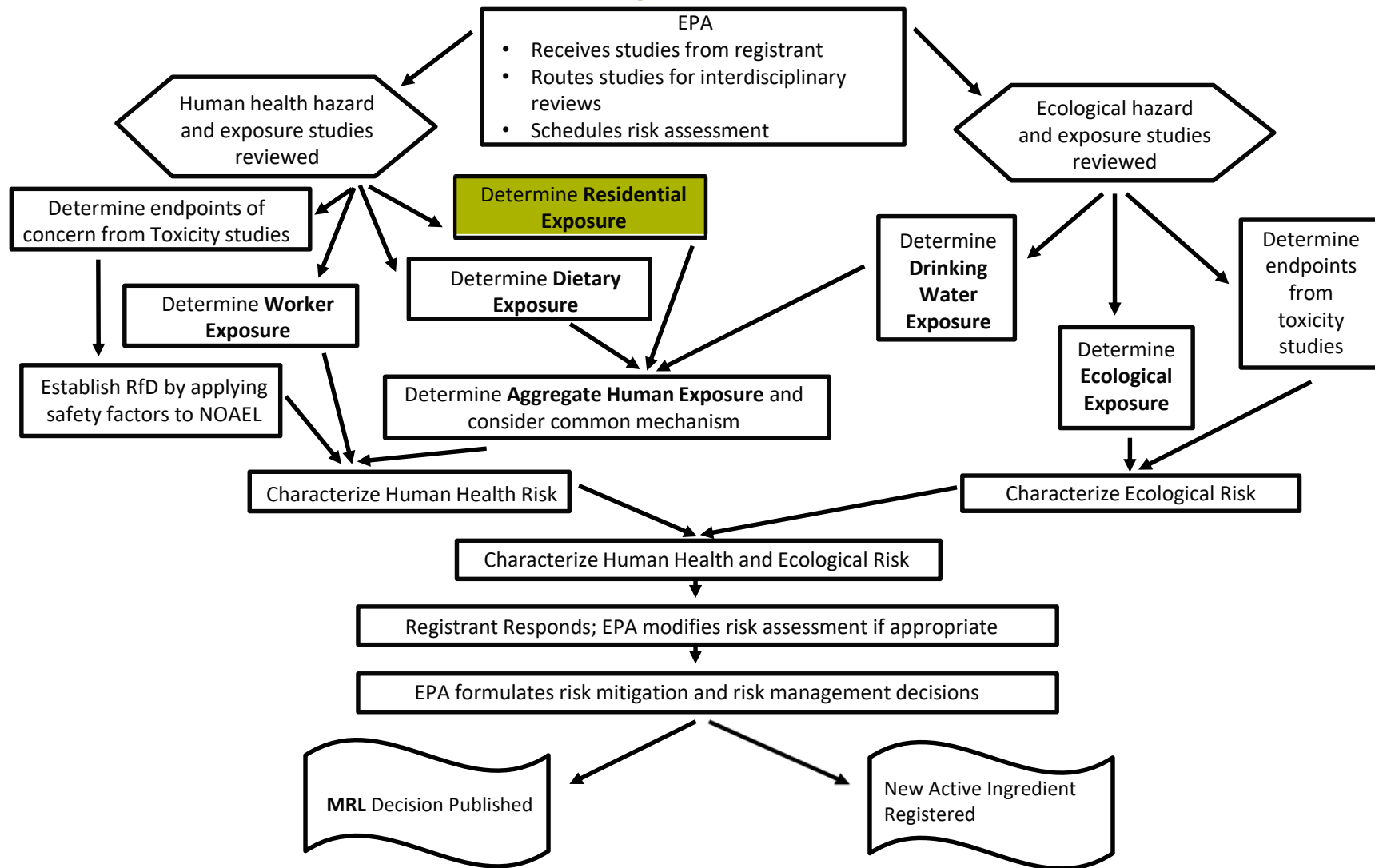
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# US EPA Registration and MRL Process



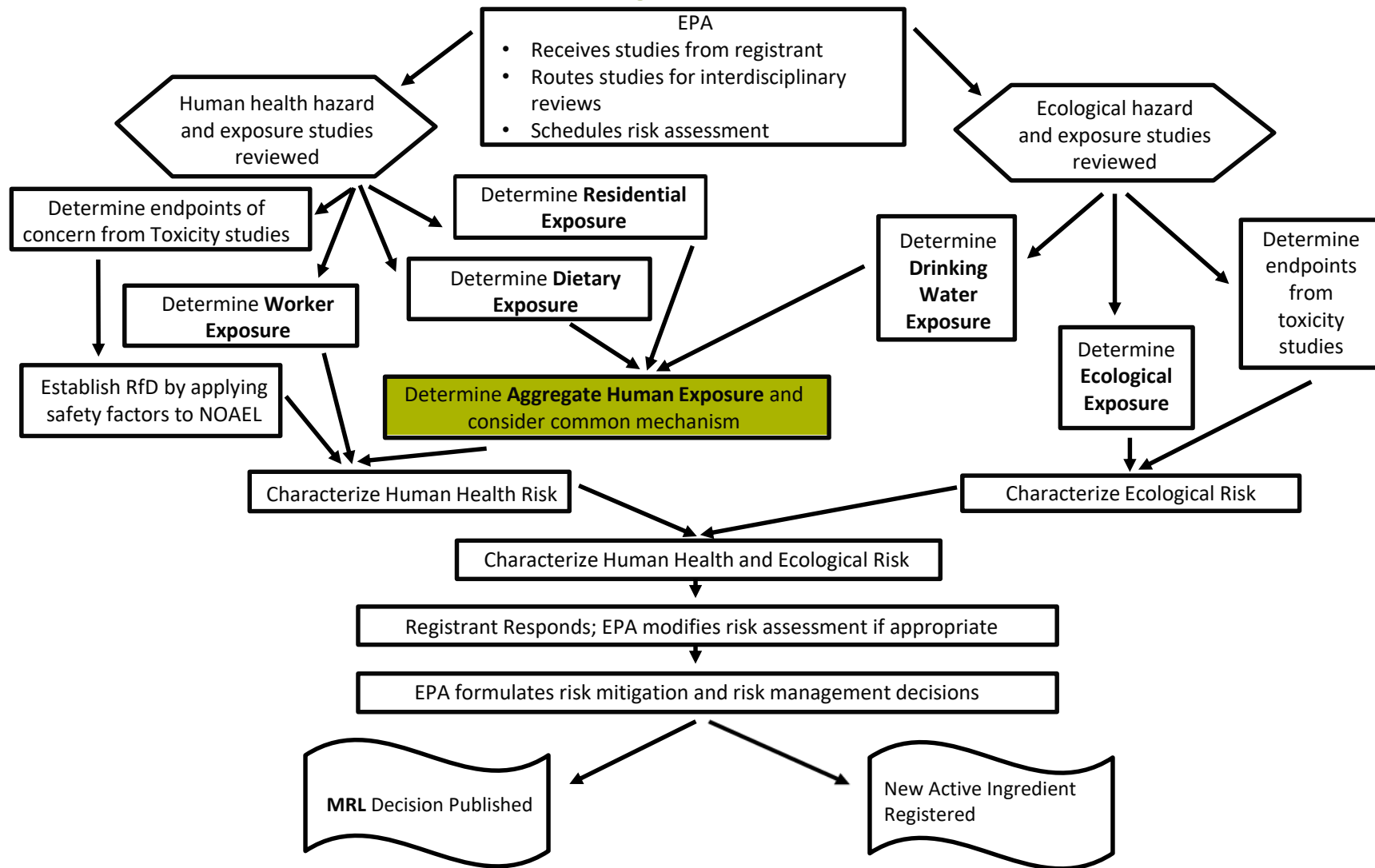
Reference: Luis Suguiyama, USEPA

# Tolerances and Safety Determination



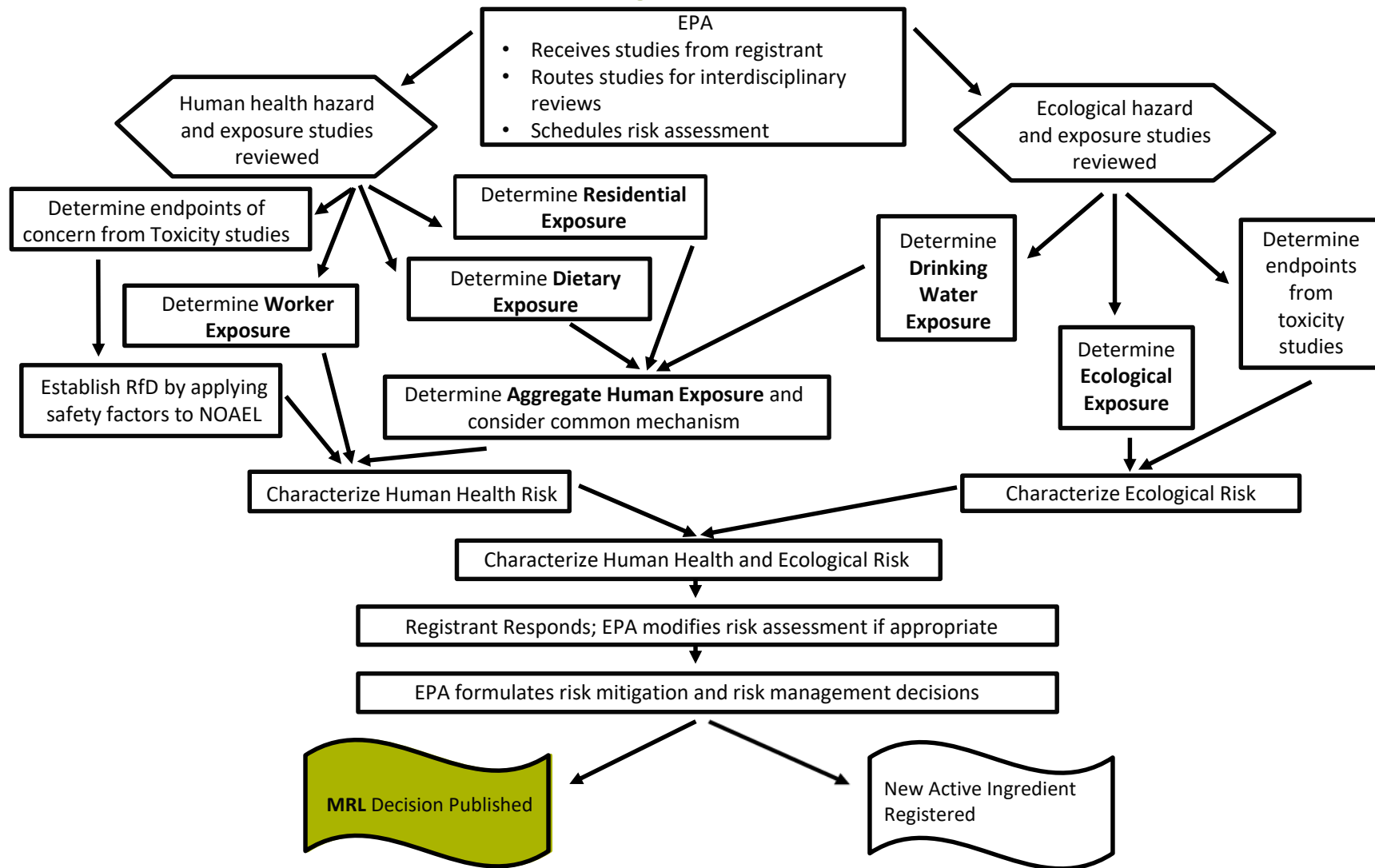
Reference: Luis Suguiyama, USEPA

# Tolerances and Safety Determination



Reference: Luis Suguiyama, USEPA

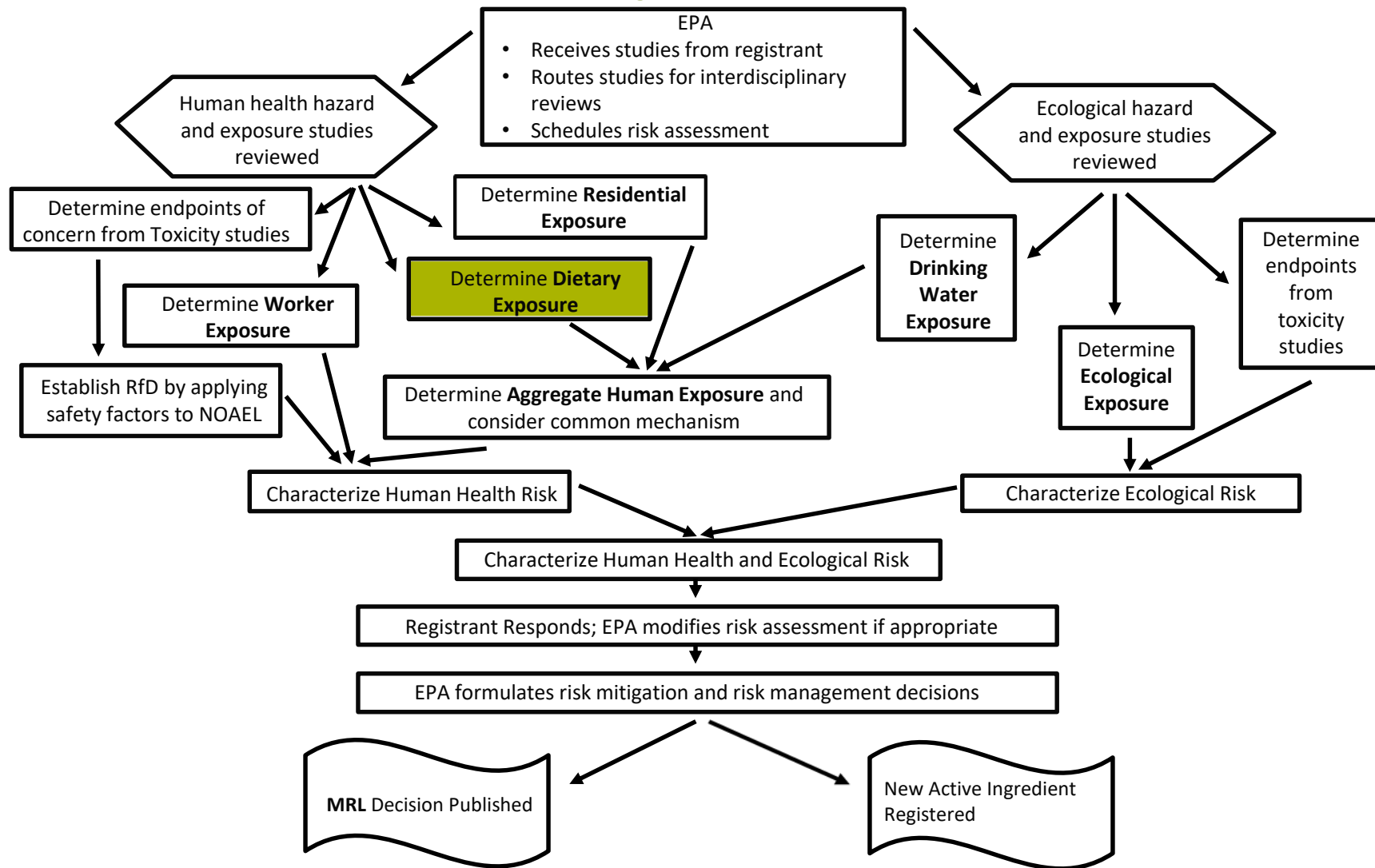
# Tolerances and Safety Determination



Reference: Luis Suguiyama, USEPA

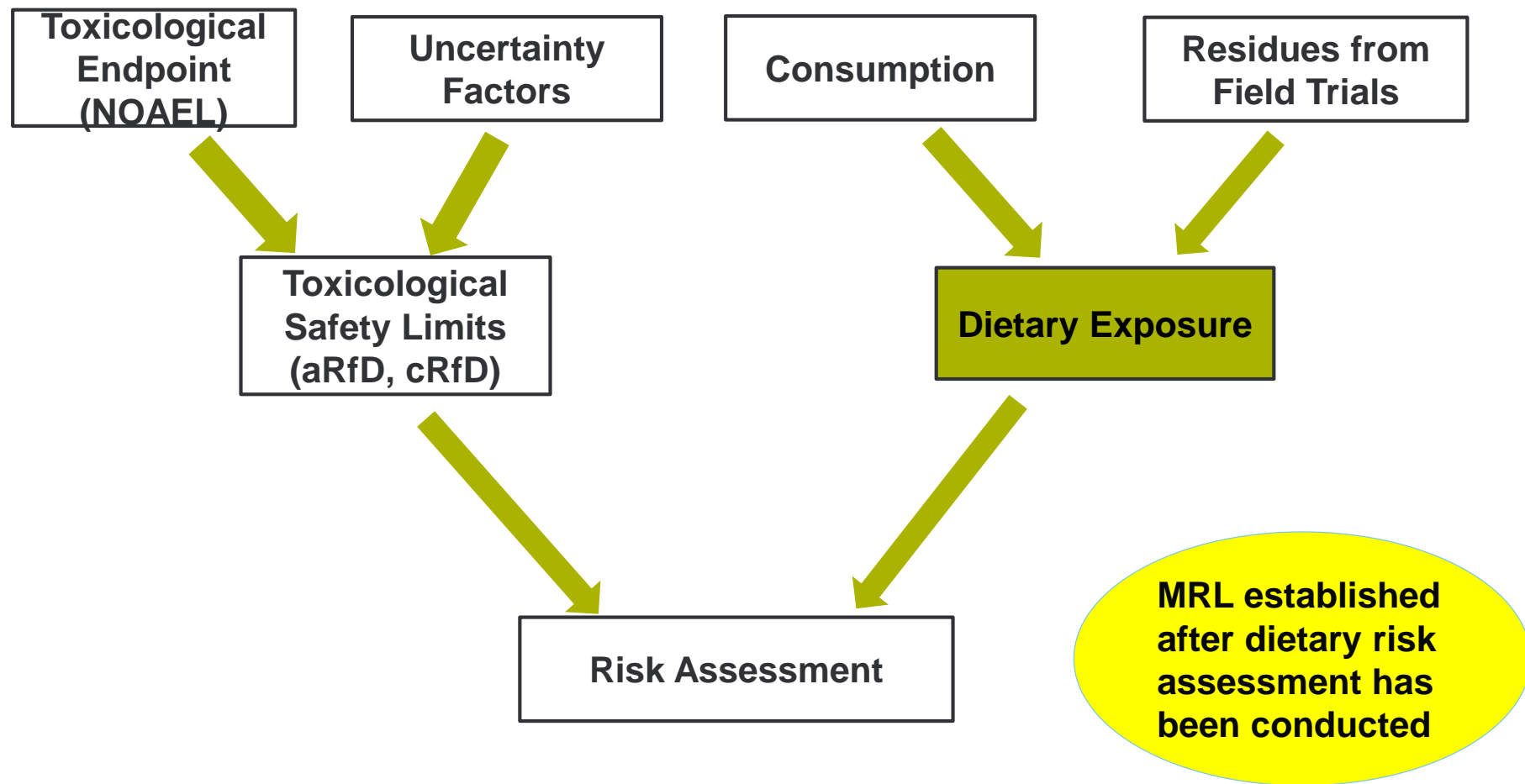


# Tolerances and Safety Determination



Reference: Luis Suguiyama, USEPA

# Determining Food Safety – Dietary Exposure



# Consumer Update – Actual Kale Data Shown for Mandipropamid



Alarming!

Prevention WEIGHT LOSS HEALTH

## “Dirty Dozen” Foods List Has a Surprising Offender, EWG Report Confirms

Strawberries topped the Dirty Dozen list for the fourth year in a row—but **kale** made it's way to #3.



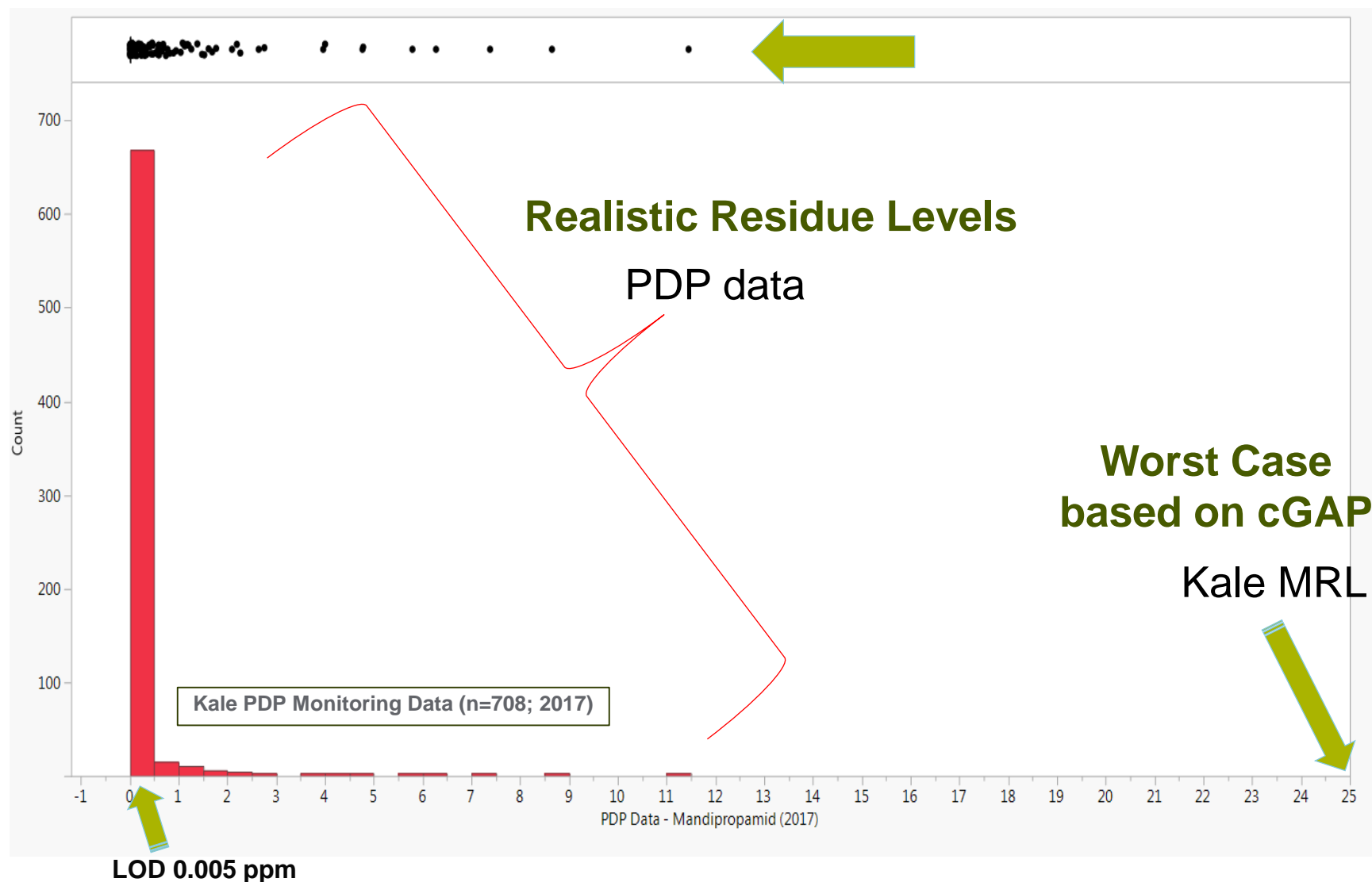
By [Korin Miller](#) Mar 20, 2019

# Pesticide Data Program

- Data generated by PDP are specifically designed to be used by EPA for dietary risk assessments
- Statistical sampling designed to be representative of the US food supply
- Data targets foods highly consumed by children
- PDP data contains ~24 million records from 1994 to 2014.


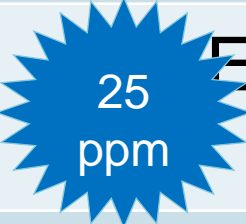



# Mandipropamid Residues on Kale in 2017

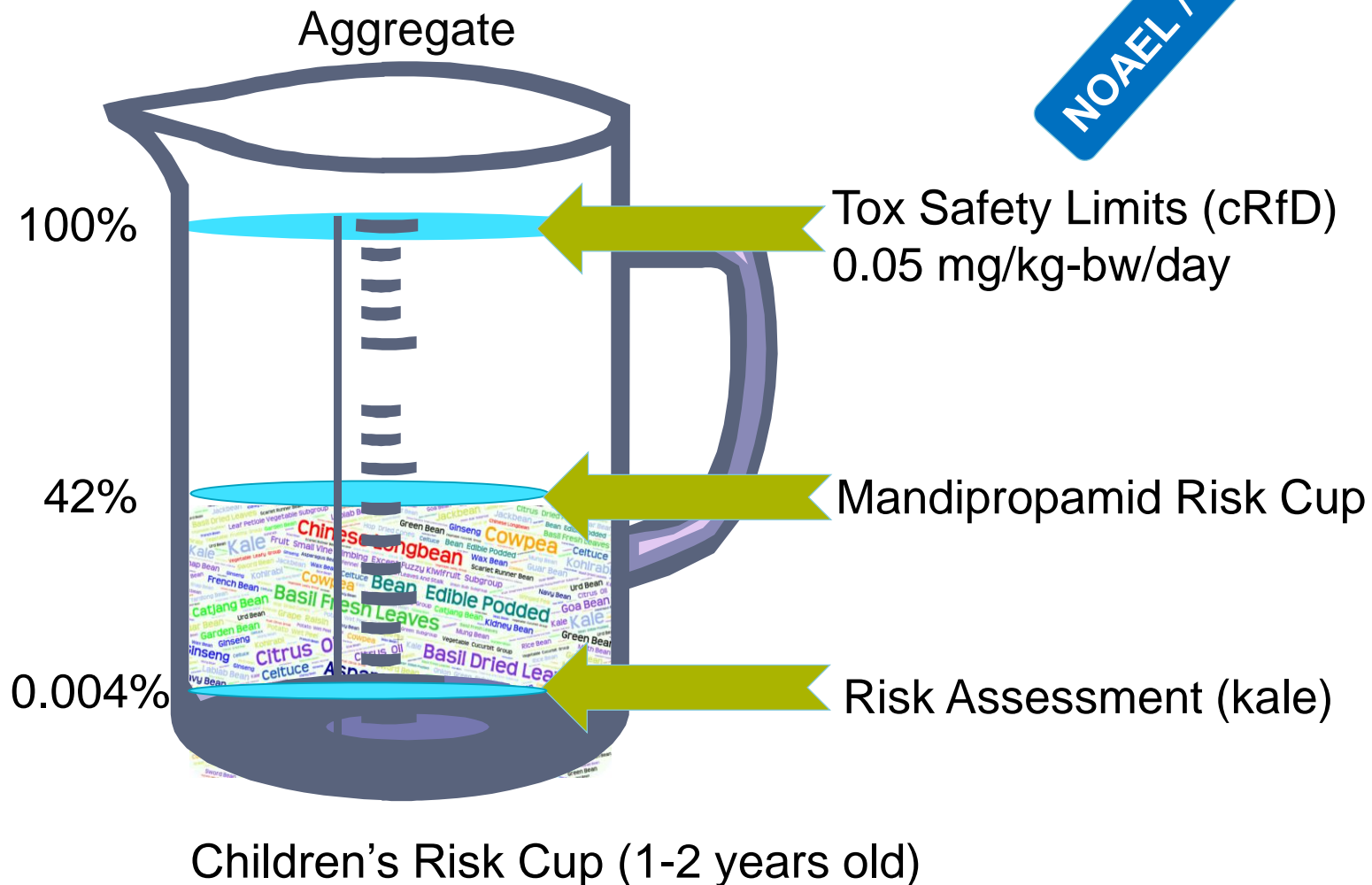




## Establishing a Kale MRL

Tolerance Determination	Safety Determination
<p><b>Pesticide Label</b> active ingredient mandipropamid</p>	<p><b>Hazard Evaluation</b> 0.05 mg/kg-bw/day cRfD</p> 
<p><b>FT Residue Studies</b> 0.4ppm to 11ppm</p>	 <p><b>Exposure Estimates</b> 0.000002 mg/kg-bw/day</p>
<p><b>Tolerance Level</b></p> 	<p><b>Risk Assessment</b> 0.004% of risk cup from kale uses</p>

# What is the Children's Risk Cup for Mandipropamid Kale?



# Consumer Update – Actual Kale Data Shown for Mandipropamid



## “Dirty Dozen” Foods List as a Surprising New Offender, EWG Report Confirms

Strawberries topped the Dirty Dozen list for the fourth year in a row—but **kale** made it's way to #3.



By [Korin Miller](#) Mar 20, 2019

<https://www.safefruitsandveggies.com/>



## Pesticide Residue Calculator

Learn how low pesticide residues really are, if  
present at all.

**Calculate**

# Kale Consumption by a Child



A **child** could consume

**7401**

servings of **kale** in one day

without any effect even if the **kale** have the highest pesticide residue recorded for **kale** by USDA.

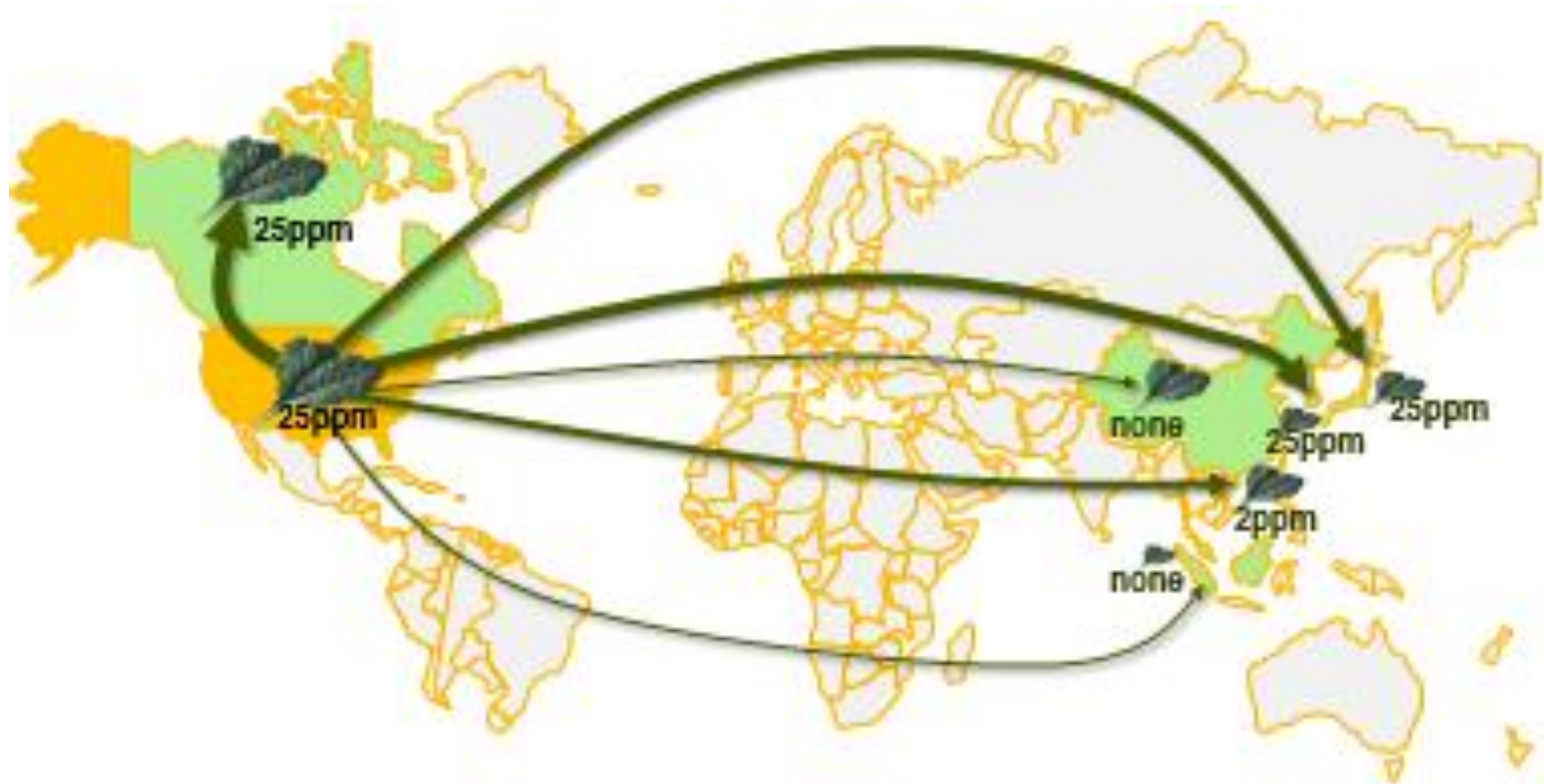
<https://www.safefruitsandveggies.com/>



# Review; Are MRLs a Food Safety Risk? **NO!**

- How MRLs are set
- Evaluation of risk is a complex process which reviews each active ingredient for confidence in safety and setting MRLs
- Actual residue data in the food we eat are typically lower than the field trial data
- Compared data used to set MRL to food consumption survey data
- MRLs are set at levels protective of safety concerns
- Not about safety but are about trade!

# Conclusion; MRLs Are About Trade



- Are a trading standard used to confirm the pesticide was applied according to the label
- Foreign MRLs can differ from U.S. MRLs, creating trading challenges



Thank you for your attention!



# Backup Slides

- Reference notes

# Definitions/Terms (continued)

## Tox Endpoints

- NOAEL (No Observable Adverse Effect Level) The highest exposure level at which no adverse effects can be identified in tests.
- ARfD (Acute Reference Dose) – A toxicological safety limit specifying the amount of a substance which can be ingested on a single day without an effects on the health of the consumer.
- CRfD (Chronic Reference Dose/Acceptable Daily Intake) – A toxicological safety limit specifying the amount of a substance which can be ingested every day over an entire lifetime without any recognizable risks to the health of the consumer.

## Safety Factors

- UF – Uncertainty factor
- $UF_A$  = extrapolation from animal to human (interspecies)
- $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies)
- FQPA SF = FQPA Safety Factor



# Definitions/Terms

## Pesticide Application/Trade

- Maximum Residue Level (MRL)
  - A legally fixed maximum concentration for a particular active ingredient on a fresh or processed food commodity.
  - A trade standard, intended primarily to check that a pesticide has been applied correctly.
  - They serve to verify whether a crop protection product has been correctly applied or not.

# Legal

Product performance assumes disease presence.

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**IMPORTANT:** This information is intended to be an initial reference source only. Please note that this information may not be up-to-date, complete or error free; national, regional and international regulations affecting permissible maximum residue levels (MRLs) frequently change; commodity nomenclature and residue definitions and methodologies for calculating MRLs may vary; and country policies regarding deferral to national, regional and international standards are not always transparent. Please verify all MRLs for the pertinent crops/uses and ensure that residues do not exceed MRLs in the pertinent export markets. Syngenta shall not be liable for any losses, damages, claims, actions, expenses or other liabilities which are caused by or arise from use of or reliance on this information.