FARM TO TABLE: PESTICIDE RESIDUES AND RISK ASSESSMENT

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DISCUSSION OUTLINE

- Overview of U.S. Pesticide Registration
  - Purpose of Residue Chemistry Data
  - Residue Chemistry Considerations
- Dietary Exposure and Risk Assessment
  - Types of Dietary Assessments
  - Dietary Exposure Models
  - Food Consumption Data

OVERVIEW – U.S. PESTICIDE REGISTRATION

What is a Tolerance?

Definition: Maximum legally allowable pesticide residue in/on foods and feeds

Synonym: Maximum Residue Level (MRL)

Purpose: Enforcement tool to detect misuse and facilitate trade

PURPOSE OF RESIDUE CHEMISTRY

With the Food Quality Protection Act, Congress has mandated that when establishing a pesticide tolerance, the EPA must show…

"… that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

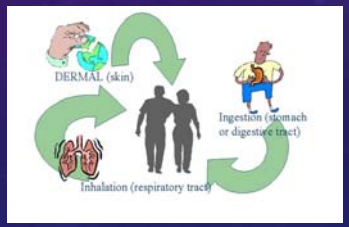
RESIDUE CHEMISTRY CONSIDERATIONS

Risk

=

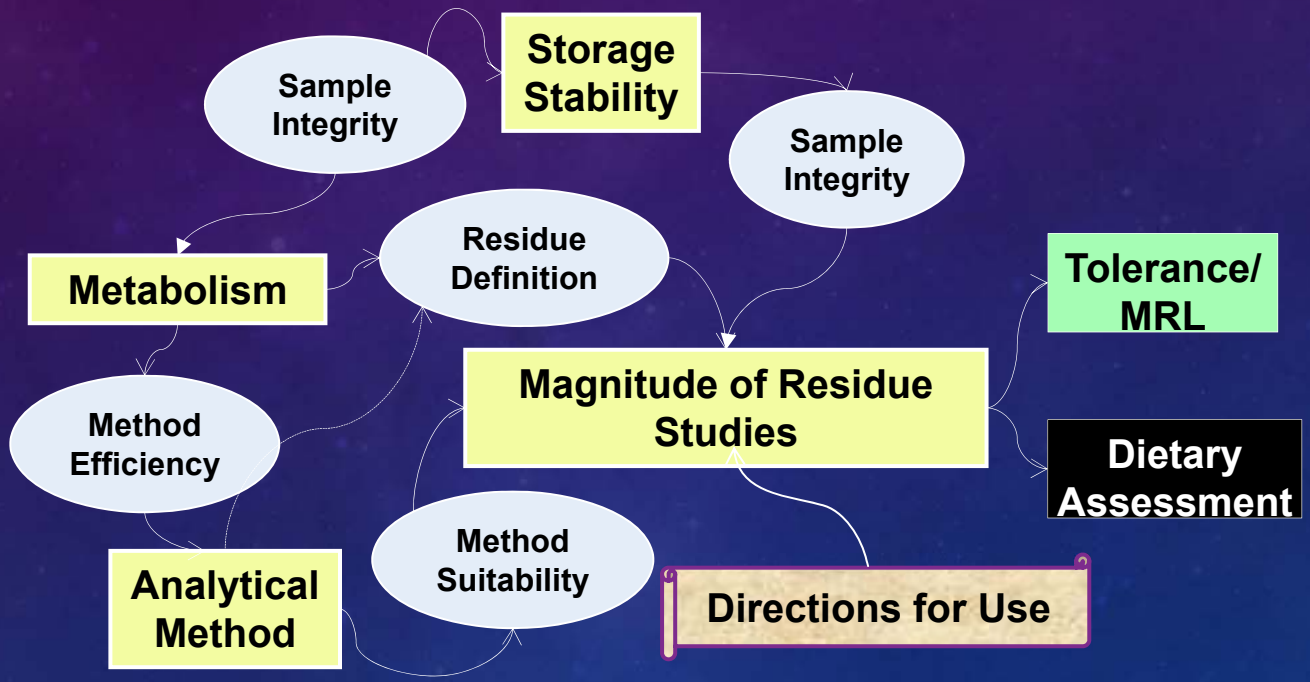
Hazard
(Toxicology)

X



Exposure
(Chemistry)

RESIDUE CHEMISTRY CONSIDERATIONS



Product Label + Residue Chemistry = Tolerance

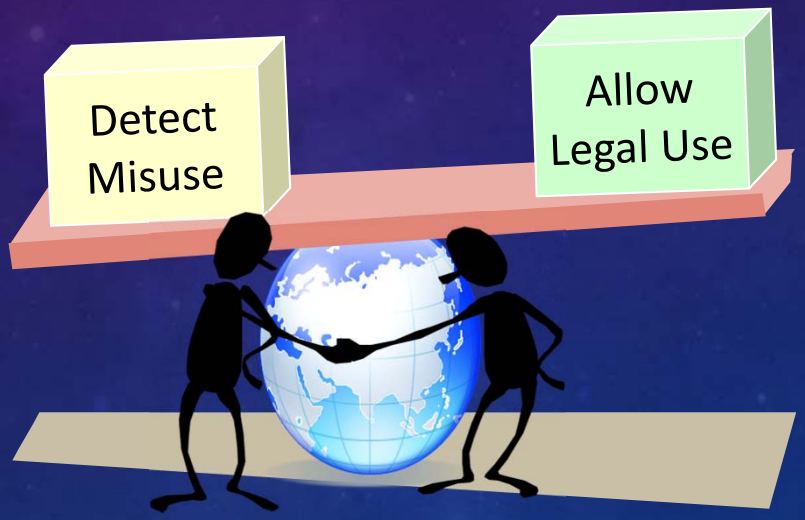
RESIDUE CHEMISTRY CONSIDERATIONS

- A tolerance enforcement method must be available before a tolerance (MRL) can be established
- Multi-Residue Methods (MRMs) = methods that measure many pesticides and metabolites in a single analysis

No approved method = no use

RESIDUE CHEMISTRY AND TOLERANCE SETTING

Regulatory Enforcement With International Harmonization



HOW ARE MRLS CALCULATED?

- Organisation for Economic Cooperation and Development (OECD) MRL Calculator
- Benefits of the OECD MRL Calculator
  - Simple to use
  - Avoid/minimize trade barriers
  - Improve work sharing/joint review process

OECD MRL CALCULATOR OUTPUT

Compound
Crop
Region / Country
GAP

Residues (mg/kg)	
6.050	
4.780	
→ 10.420 ←	
3.690	
9.220	
2.150	
3.440	
4.680	
5.100	
1.420	
2.490	
1.770	
2.090	
4.100	
2.430	
1.610	

Compound
Crop
Region / Country
GAP

Total number of data (n)	16
Percentage of censored data	0%
Number of non-censored data	16
Lowest residue	1.420
Highest residue	10.420
Median residue	3.565
Mean	4.090
Standard deviation (SD)	2.638
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

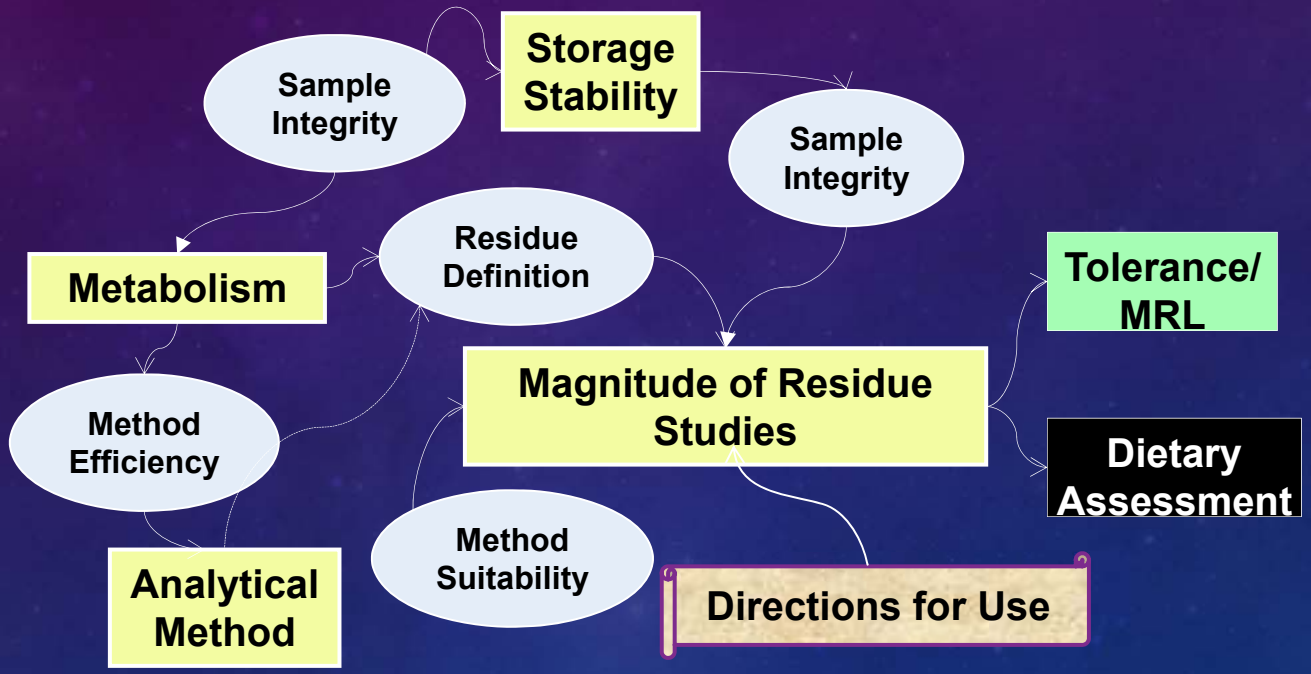
- Highest residue	10.420
- Mean + 4 SD	14.642
- CF x 3 Mean	12.270
Unrounded MRL	14.642
Rounded MRL	→ 15 ←

MRLS

MRLs are enforcement based, but are supported by a risk assessment and a safety finding; however…

No Safety Finding = No MRL

QUICK RECAP


Sample Integrity
Storage Stability
Sample Integrity
Metabolism
Residue Definition
Tolerance/ MRL
Magnitude of Residue Studies
Method Efficiency
Dietary Assessment
Method Suitability
Analytical Method
Directions for Use

DIETARY EXPOSURE

Exposure =	Residue	x	Consumption
(mg/kg bw/day)	(mg/kg food) (mg/L water)		(kg food/kg bw per day)

Tolerance, Anticipated Residues

[FT or Monitoring Data]

Dietary Exposure Models

DIETARY ASSESSMENTS: ACUTE, CHRONIC, AND CANCER

- Acute:
  - Risk resulting from 1-day exposure
  - Residue level, food consumption, and endpoint all must represent 1-day exposure or dosing
- Chronic:
  - Risk resulting from 6 months to lifetime exposure
  - Residue level, food consumption, and endpoint all represent long term exposure or dosing
- Cancer:
  - Assess the risk from a chemical using the cancer potency factor, Q*

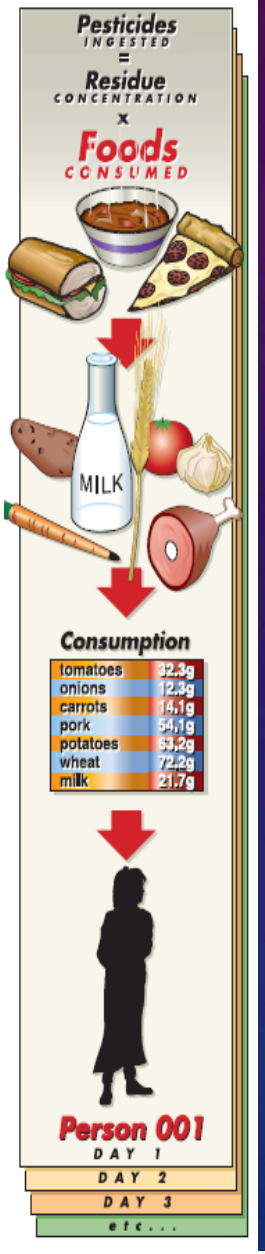
DIETARY EXPOSURE REFINEMENTS

Unrefined Assessment: Tolerance-level residues and 100%CT

- **% Crop Treated**
- **Field trial data**
- **PDP/FDA**
- **Processing studies**
- **Cooking Factors**
- **Bridging studies**
- **Residue degradation/decline studies**
- **Market basket data**

Highly Refined Assessment

DIETARY EXPOSURE ASSESSMENT



Food Consumption (WWEIA)

Food Recipe Database (FCID)

Risk (% PAD) = Exposure x 100 / PAD

Raw Agricultural Commodity (RAC) Consumption

X

RAC Pesticide Residue

=

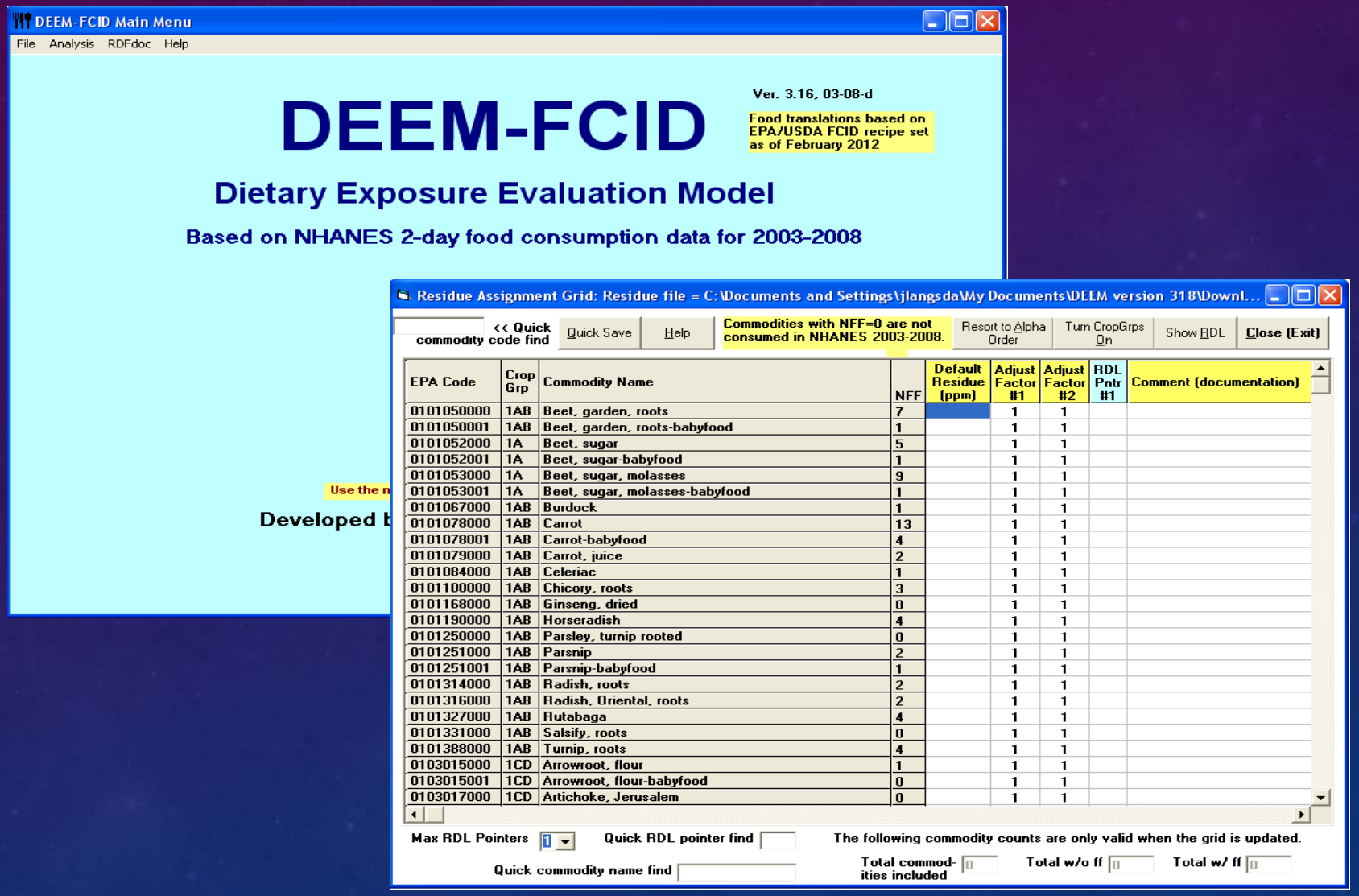
Dietary Exposure

Acceptable Level
aPAD, cPAD, etc.

USE OF MODELS BY OPP

- OPP uses DEEM for:
  - Acute, chronic, and cancer single-chemical dietary assessments
  - Cumulative assessments (acute)
    - Food + drinking water
- OPP uses Calendex for:
  - Multiple-day (longitudinal) assessments
  - Aggregate, Cumulative
- Other Models accepted by EPA:
  - Lifeline
  - CARES

DIETARY EXPOSURE MODEL



EPA Code	Crop Grp	Commodity Name	NFF	Default Residue (ppm)	Adjust Factor #1	Adjust Factor #2	RDL Pntr #1	Comment (documentation)
0101050000	1AB	Beet, garden, roots	7		1	1		
0101050001	1AB	Beet, garden, roots-babyfood	1		1	1		
0101052000	1A	Beet, sugar	5		1	1		
0101052001	1A	Beet, sugar-babyfood	1		1	1		
0101053000	1A	Beet, sugar, molasses	9		1	1		
0101053001	1A	Beet, sugar, molasses-babyfood	1		1	1		
0101067000	1AB	Burdock	1		1	1		
0101078000	1AB	Carrot	13		1	1		
0101078001	1AB	Carrot-babyfood	4		1	1		
0101079000	1AB	Carrot, juice	2		1	1		
0101084000	1AB	Celeriac	1		1	1		
0101100000	1AB	Chicory, roots	3		1	1		
0101168000	1AB	Ginseng, dried	0		1	1		
0101190000	1AB	Horseradish	4		1	1		
0101250000	1AB	Parsley, turnip rooted	0		1	1		
0101251000	1AB	Parsnip	2		1	1		
0101251001	1AB	Parsnip-babyfood	1		1	1		
0101314000	1AB	Radish, roots	2		1	1		
0101316000	1AB	Radish, Oriental, roots	2		1	1		
0101327000	1AB	Rutabaga	4		1	1		
0101331000	1AB	Salsify, roots	0		1	1		
0101388000	1AB	Turnip, roots	4		1	1		
0103015000	1CD	Arrowroot, flour	1		1	1		
0103015001	1CD	Arrowroot, flour-babyfood	0		1	1		
0103017000	1CD	Artichoke, Jerusalem	0		1	1		

INTRODUCTION TO DEEM™ SOFTWARE (CONT.)

- Inputs include
  - Toxicity information (PAD)
  - Exposure information
    - Residues
    - Food consumption (from NHANES/WWEIA)
- Output includes
  - Exposure levels (mg/kg bwt/day)
  - Risk (% PAD occupied)
  - Risk “drivers”

DEEM™ EXPOSURE AND RISK CALCULATIONS

- Utilizes individual daily consumption as reported in NHANES/WWEIA
- The consumption values are combined with randomly selected residue values and analyzed to result in a distribution of exposure values

Exposure = Consumption x Residue

(mg/kg bwt-day) = (kg food/kg bwt-day) x (mg pesticide/kg food)

DEEM™ EXPOSURE AND RISK CALCULATIONS (CONT.)

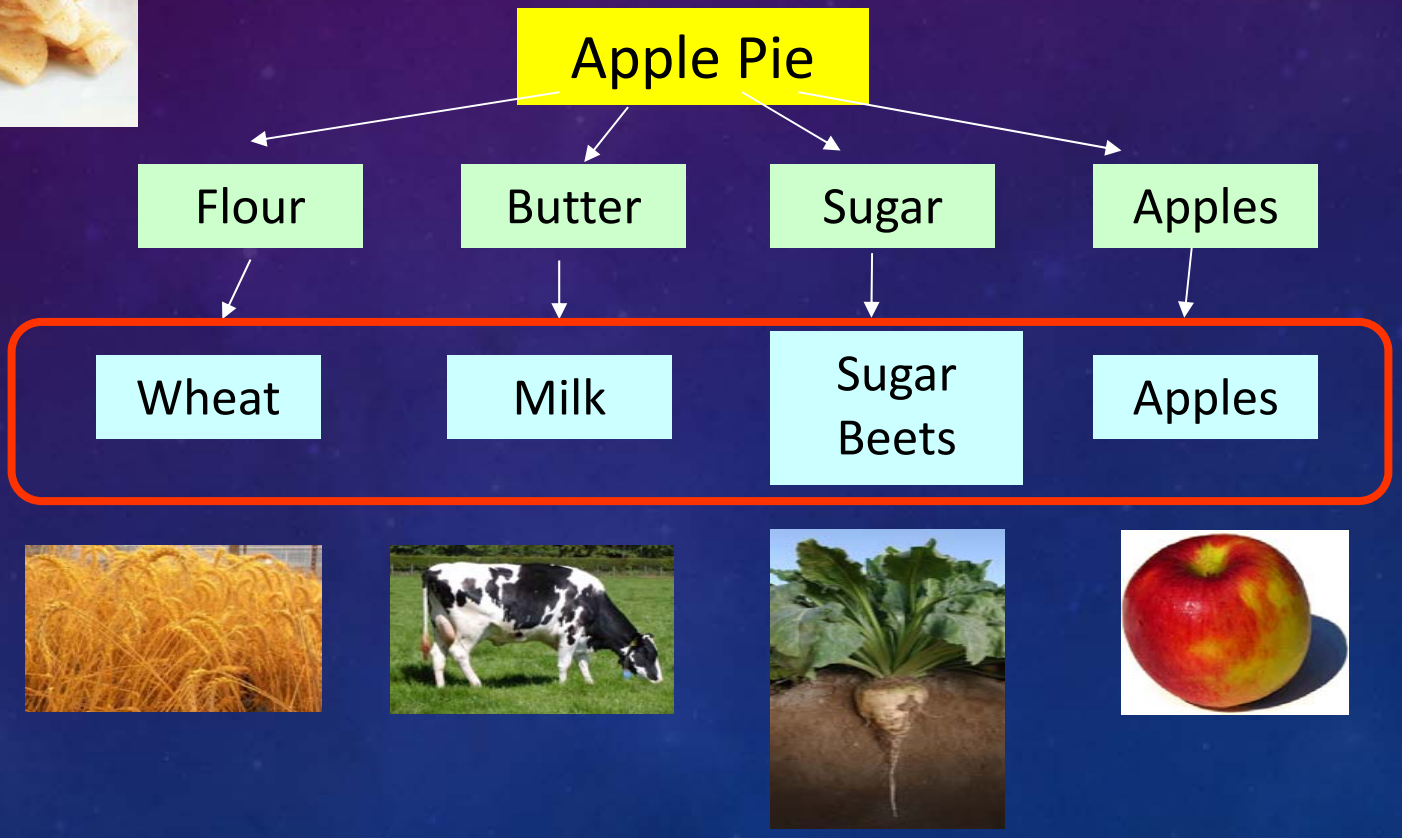
- DEEM™ then compares the exposure as calculated based on pesticide residues on food and NHANES food consumption data to the toxic reference point.
  - aPAD or cPAD
- Output of DEEM™ identifies the foods, residues, and consumption values that contribute the most to acute and chronic exposure.

FOOD CONSUMPTION DATA

- National Health and Nutrition Examination Survey – What We Eat in America (NHANES/WWEIA)
- Current model uses 2003 – 2008 surveys
- > 20 thousand individuals
- 2 non-consecutive days per person
- Foods as consumed

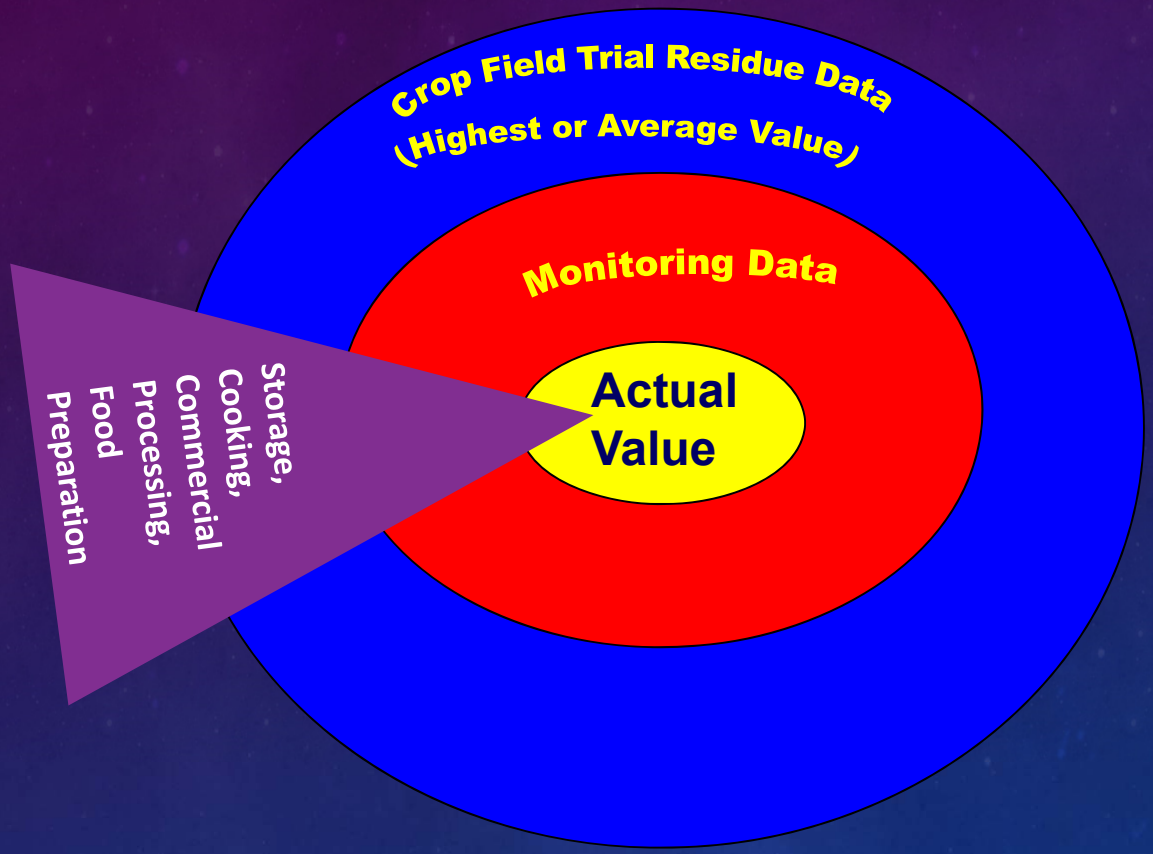
Additional Information: http://www.ars.usda.gov/Services/docs.htm?docid=13793

FOOD CONSUMPTION DATA: APPLE PIE



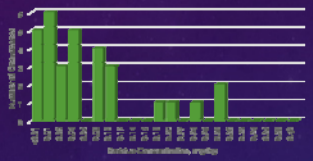
Tolerances vs. Actual Residues

Tolerance Level

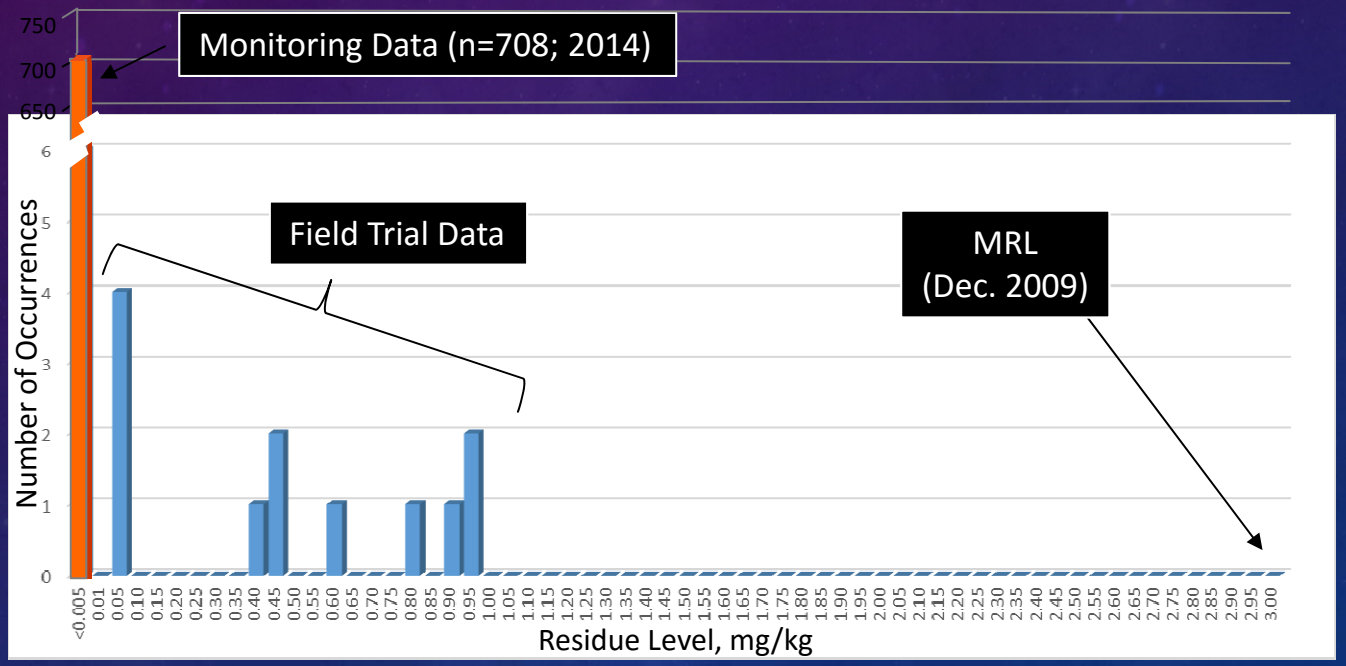


REAL WORLD EXAMPLE RESIDUES

Refinements & Data



Clothianidin Residues in Celery



CONCLUSIONS

- Risk is calculated from an equation which combines toxicity information and exposure information.
- Exposure is calculated by combining reported consumption values (NHANES/WWEIA) of foods with pesticide residues on those foods.
- Our dietary models allow the Agency to take full advantage on the information inherent in distributions of residue data and consumption patterns.
- Available residue data support the establishment of a MRL for enforcement purposes.
- The risk assessment supports that the Agency can make a safety finding.

ACKNOWLEDGEMENTS

- Christina Swartz (Branch Chief)
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- Michael A. Doherty, Ph.D. (Mentor)

CONTACT INFORMATION

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THANK YOU!

QUESTIONS????

EXTRA SLIDES

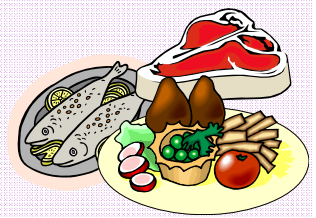
REFINEMENTS & DATA

RESIDUE DATA SOURCES

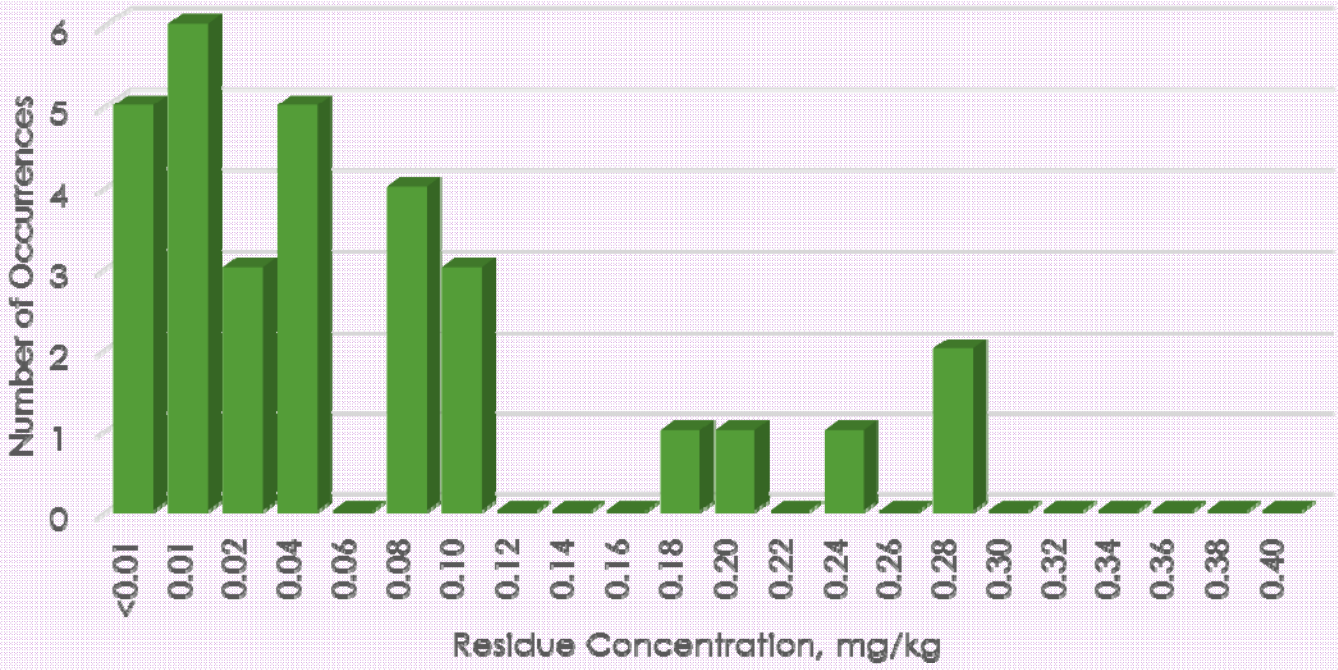
Screening Level	Moderately Refined	Highly Refined
MRLs	Crop Field Trials Feeding Studies % Crop Treated Blending	Monitoring Data
Default Processing Factor		
	Processing Studies	Cooking Studies

Simple → Complicated

DIETARY EXPOSURE



Exposure = Residue x Consumption



FOOD CONSUMPTION

- Recipe files
  - Standardized ingredients for foods as consumed