Perspectives on Proposed Changes to IESTI

April 2016 CCPR

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Crop Life International Delegation





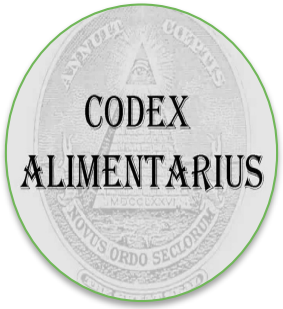

What is the Issue?

CropLife International is concerned the proposed change to the IESTI equation will lead to a significant loss of CODEX MRLs without international justification.

CropLife International is also concerned that the proposal leads to inflated dietary estimates for all commodities.

Outline of Talk

Background



Proposal on IESTI equation for dietary exposure

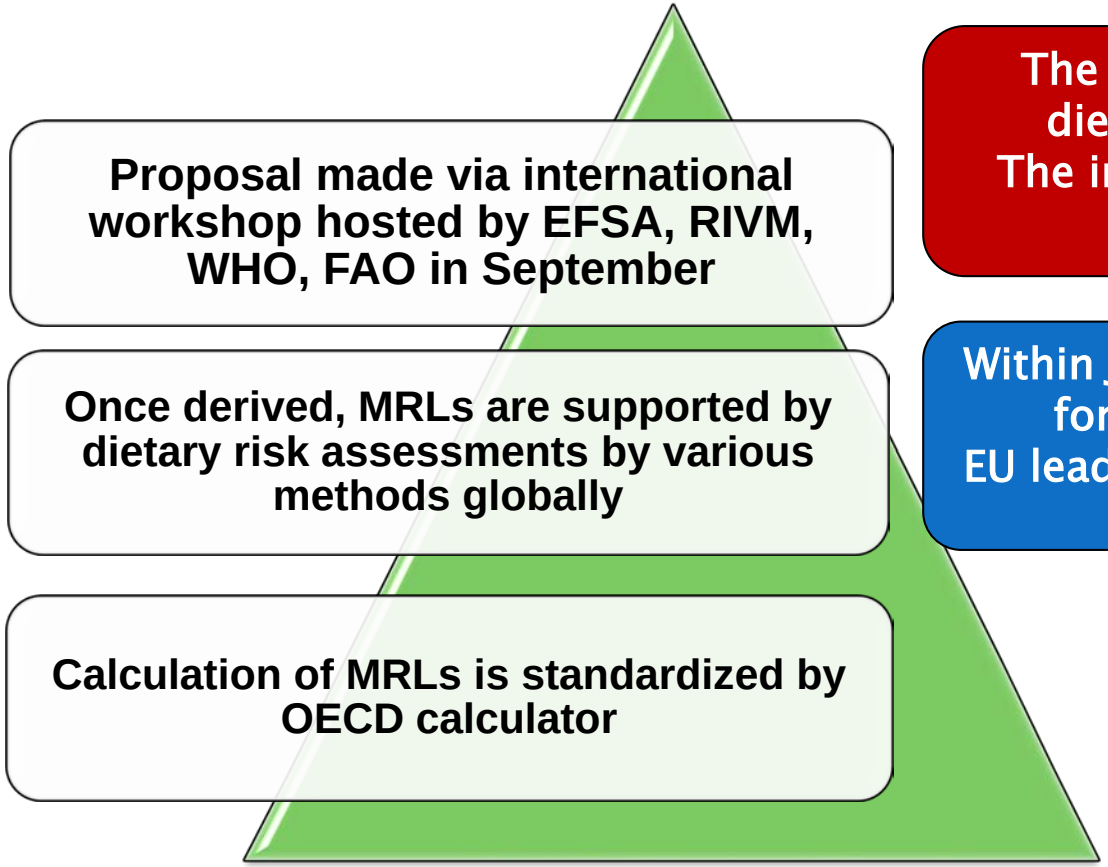
Impact: AI Example and Case Trends

What do we know about dietary exposure?

What are unresolved issues?

Conclusions

Background



Proposal made via international workshop hosted by EFSA, RIVM, WHO, FAO in September

Once derived, MRLs are supported by dietary risk assessments by various methods globally

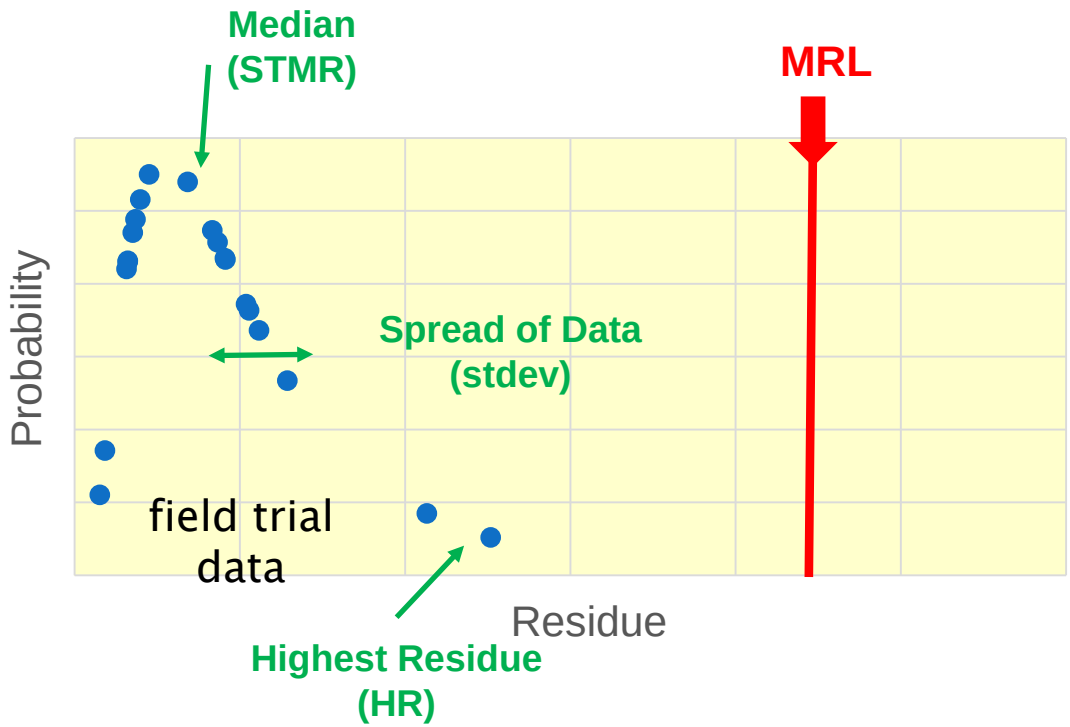
Calculation of MRLs is standardized by OECD calculator

The changes inflate the acute dietary exposure estimates
The increased conservatism will result in fewer MRLs

Within JMPR, IESTI equation is used for acute dietary exposure
EU leading proposal for changes to JMPR IESTI

- IESTI = International Estimate of Short Term Intake

How are MRLs Established? The OECD MRL Calculator



➔ **Process relies on conduct of field trials at critical or worse case GAP for highest residues (max rate, Max # applications, min RTI, min PHI)**

IESTI Equations:
Proposal from EFSA / WHO workshop, 2015

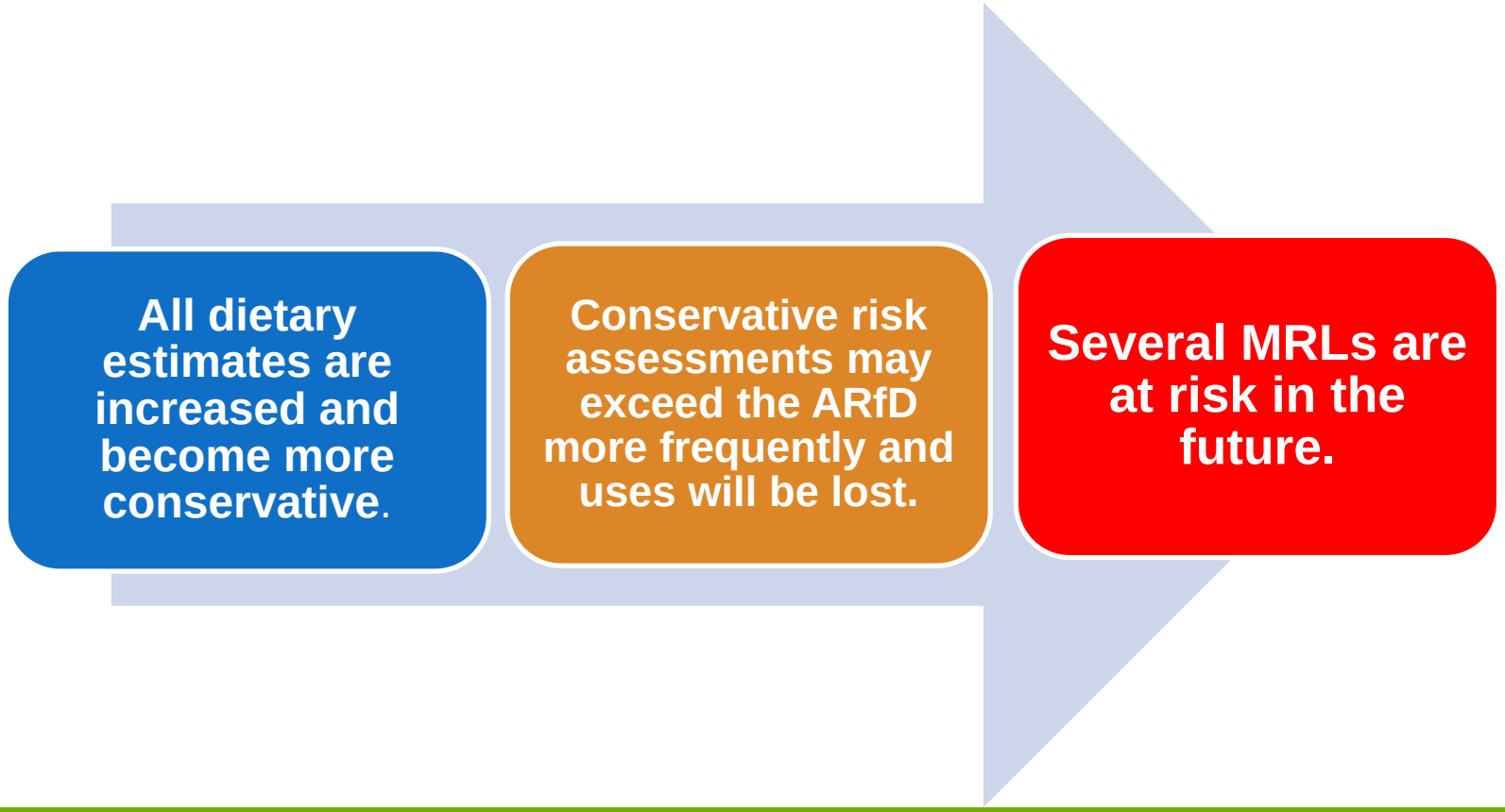
Dietary exposure = consumption X residues

Case	Current IESTI (mg/kg bw)	*Proposed IESTI (mg/kg bw)*
1	$\frac{(LP \times (HR \text{ or } HR-P))}{bw}$	$LP_{bw} \times MRL \times CF \times PF$
2a	$\frac{((Ue \times (HR \text{ or } HR-P) \times v + (LP-Ue) \times (HR \text{ or } HR-P))}{bw}$	$LP_{bw} \times MRL \times v \times CF \times PF$
2b	$\frac{((LP \times (HR \text{ or } HR-P) \times v))}{bw}$	$LP_{bw} \times MRL \times v \times CF \times PF$
3	$\frac{(LP * STMR-P)}{bw}$	$LP_{bw} \times MRL \times CF \times PF$

The proposal . . .

- Replaces all field data (HR and STMR) with MRL as exposure
- Keeps variability factor 3, but applies it to the MRL
- Removes unit weight from Case 2a
- Introduces new CF in order to use MRL
- Projects use of LP_{bw} data not yet available

What is the Impact?



- Assessment gives idea on impact; also provides indications for further work
- 70% of new AI have ARfD in JMPR and could be impacted

Impact on MRL approvals:

Case Study Ethephon (2015): ARfD: 0.05 mg/kg bw

Crop	Residue (mg/kg)			PF	Case	IESTI (%ARfD)	
	STMR	HR	MRL			2015	Future
Apple	0.15	0.49	0.8	1	2a	57.4	199.8
Cherry	0.65	2.7	5	1	1	62.7	116.1
Grape	0.19	0.52	0.8	1	2b	70.9	109.1
Table olive	1.9	4.3	7	0.01	1	0.3	0.5
Fig	0.73	0.75	3	1	2a	25.9	156.5
Pineapple	0.42	0.72	1.5	0.29	2b	37.0	77.2
Tomato	0.52	0.79	2	1	2a	61.1	196.2
Tomato (dried)	0.52	0.79	2	5	1	101.5	257.0
Barley	0.13	0.73	1.5	0.19	3	2.8	31.8
Rye	0.10	0.31	0.5	1	3	1.2	5.9
Wheat	0.10	0.31	0.5	1	3	5.2	25.8
Olive (oil)	1.9	4.3	7	0.02	3	0.1	0.4

- Increased exposure for all commodities presents new communication issues
- Fewer MRLs will be approvable in the proposed system

Preliminary impact assessment - Revision of the IESTI equation

Case	Crops / commodities	Increase of Calculated exposure
1	  **Meal portion < 0.025 kg** *including meat, eggs*	1.7X
2a	  **Meal portion > 0.025 kg** Ue<LP *Use of 3 x MRL for all food*	3.5X
2b	  Ue>LP	2.3X
3	   **Bulked and blended**	5.2X

- **Prior to change: Investigations on the use of variability factor recommended**
- **Prior to revision: Investigations on blending procedures recommended**

Preliminary impact assessment - Revision of the IESTI equation

Commodity MRLs most impacted:

- Citrus fruits: Oranges, mandarins
- Lettuce and leafy vegetables
- Apples
- Apricots and other stone fruits

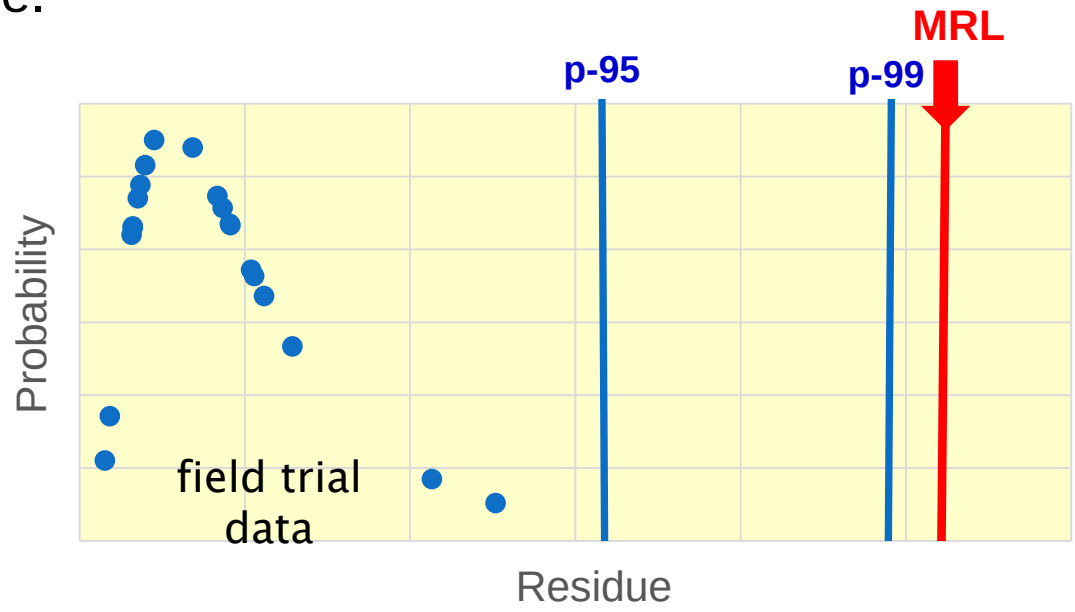
Assessment is Preliminary because . . .

- Consumption data (LP_{bw} and raw/processed data)
- Processing Factors
- Conversion Factors

➔ **Highest "CXL failure" rate for leafy vegetables followed by stone fruits and apples (above 10% of investigated cases)**

What do we know about MRLs? The OECD MRL Calculator

- During development emphasis was on not under-estimating the 95th percentile, little emphasis was on *not over-estimating* the 95th percentile.



- *On average, the OECD MRL calculator proposes MRLs which are approximately 2 x p95, corresponding to the **99th percentile** of the residue distribution.*

What do we know about Dietary Exposure?

- The MRL is not a good measure of ACTUAL dietary exposure because . . .
  - *not all commodities are treated at the critical GAP and a variety of timings and actives are used*
  - *residue levels decline significantly between harvest and transportation to consumers*
  - *reduction of residues typically occurs in household preparation, cooking or industrial processing*
- Most global dietary models use field data (HR/STMR) - initial refinement in dietary exposure
- Monitoring data allows a *reality check* on models

Comparing MRLs, Field Trial & Monitoring: Example with US PDP Data

MRL Levels

- Single upper bounds from MRL calculator

Field Trial Residues

- Residues under "worst-case conditions"

Monitoring Values

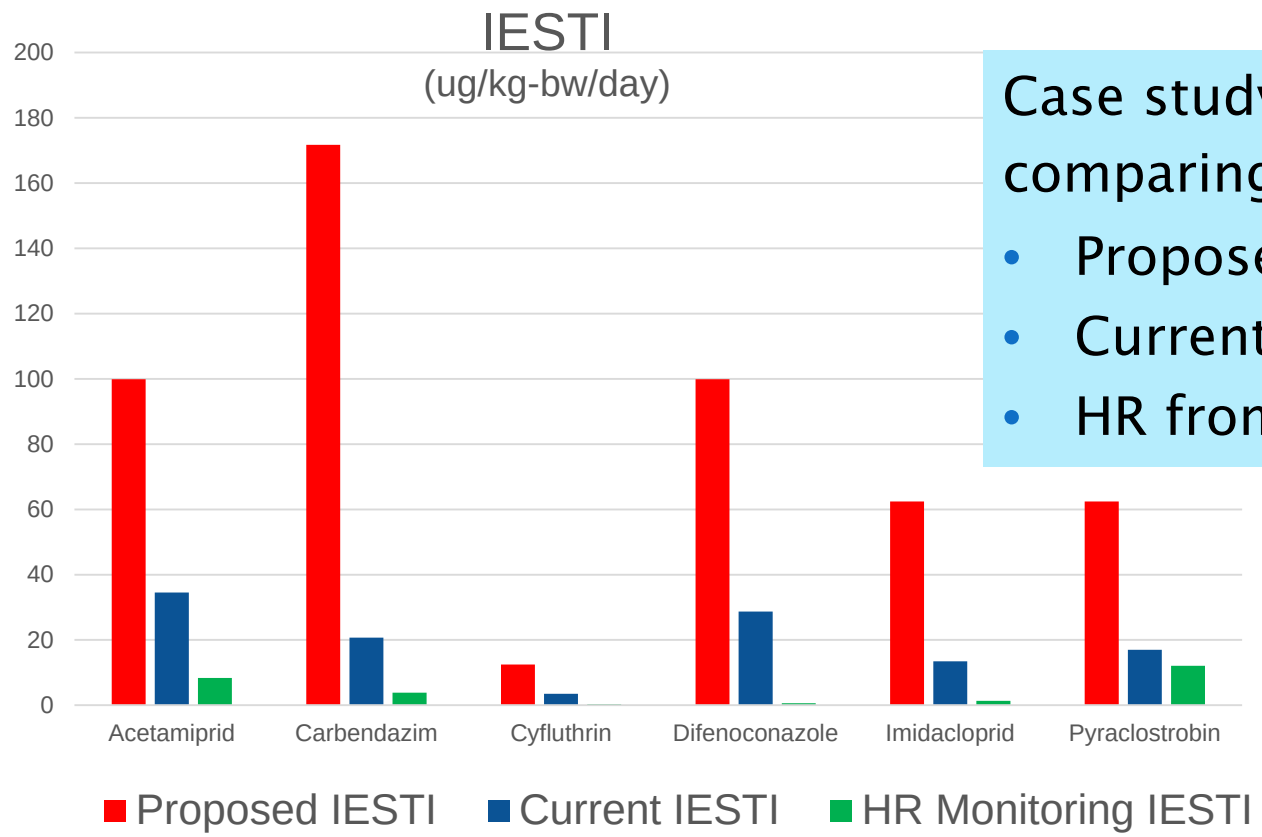
- Monitored commodities in food supply

Field Trial residues ~ 3X lower

USDA PDP residues ~ 4X-400X lower

- Likelihood of exceeding MRL levels at consumer level is very small

Comparison of calculated exposure (IESTI) with monitoring data for apples



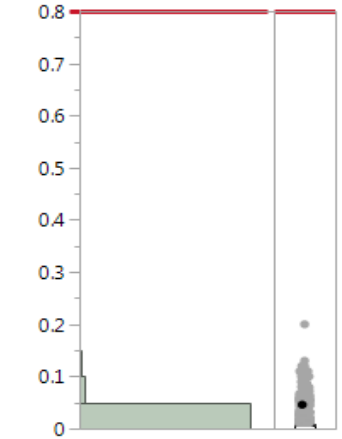
Case study for apples comparing:

- Proposed Use of MRL,
- Current Use of HR,
- HR from US monitoring

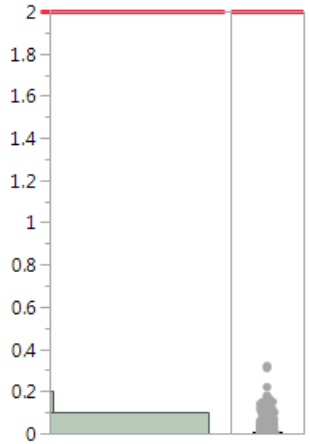
➔ **Monitoring Data provides a benchmark for current and proposed IESTI**

➔ **Proposed additional conservatism with high impact is not justified**

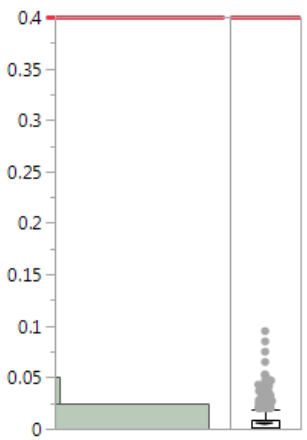
USDA Pesticide Data Program for Apples (2009, 2010, 2014) Distribution for 6 actives with highest residue % of MRL



Acetamiprid

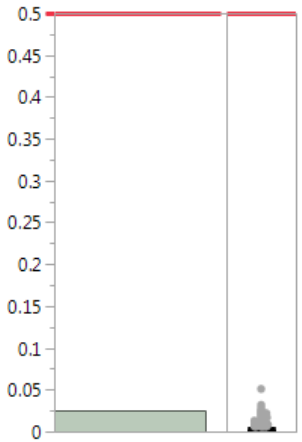


Boscalid

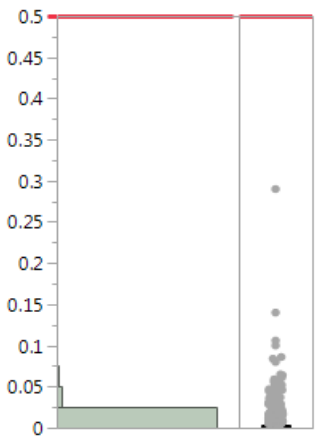


Chlorantraniliprole

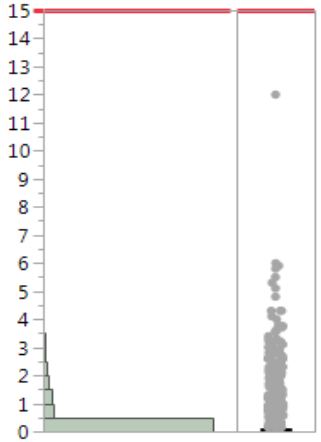
CODEX MRL



Imidacloprid



Pyraclostrobin



Pyrimethanil

CODEX MRL

➔ **The deterministic HR from monitoring is conservative for the remainder of the full distribtution**

What are unresolved issues?

- No change to the IESTI should be made without comprehensive review of interplay of all factors.
- The current $v = 3$ used with the HR for was not mathematically derived for use with an MRL
- Nor is it reasonable to apply $v = 3$ to all units in a large portion for consumption
- The CRD lists multiple items as “future work” which need to be addressed before
  - e.g. information on bulking and blending or improved LP_{bw} for consumption

The Variability Factor

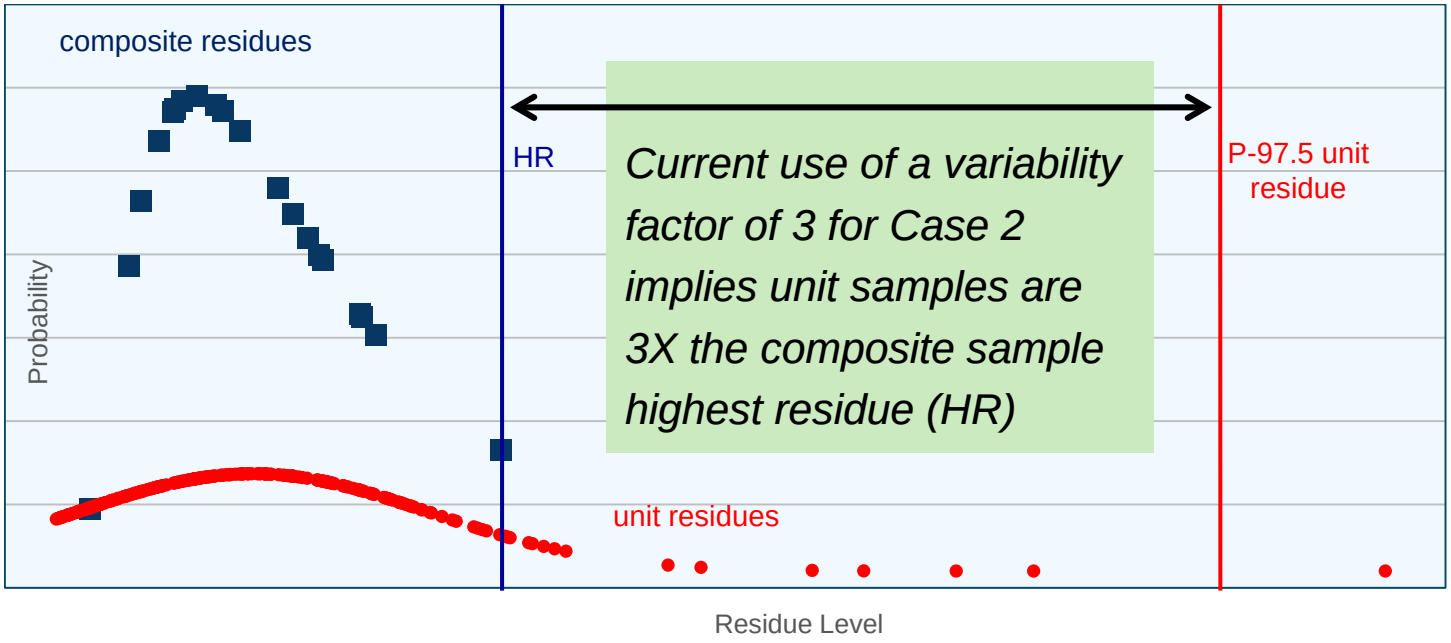
Is V=3 appropriate when used with the MRL?

IESTI – case 2a and 2b

Acute Exp (mg/kg-bw/day) = MRL x **V** x LP

The variability factor is an upper percentile estimate of the ratio between the pesticide residue in the unit samples and the residue in the composite samples

$$V = \frac{\text{97.5th percentile Unit Residue}}{\text{Composite Residue}}$$



Current use of a variability factor of 3 for Case 2 implies unit samples are 3X the composite sample highest residue (HR)

➔ **Preliminary calculations demonstrate that a more appropriate variability factor <<3 could be derived for use with the MRL**

The Variability Factor

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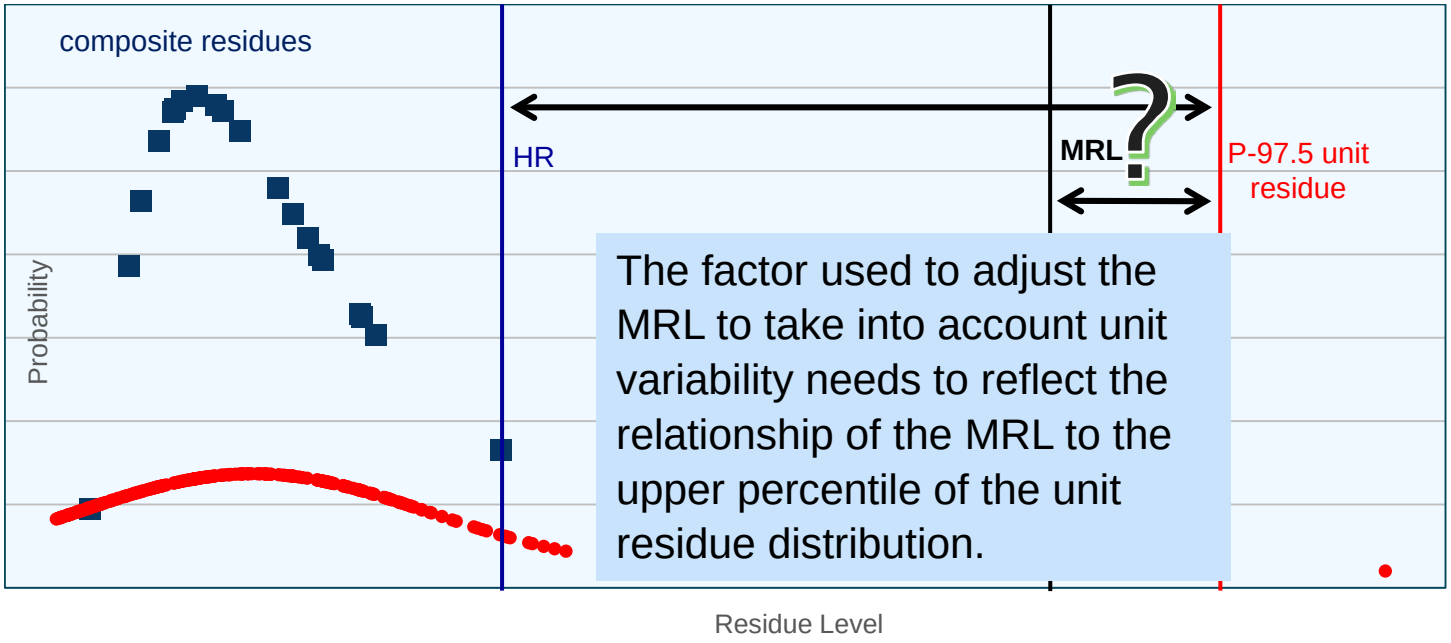

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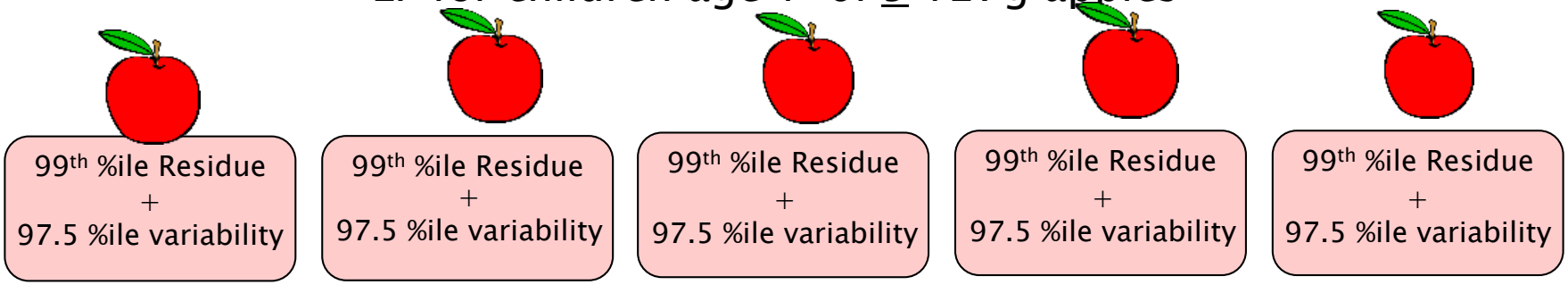
The Variability Factor

Is V=3 appropriate when used with the MRL?

Case 2a – apples and oranges

IESTI = MRL x V x LP

LP for children age 1–6: 5 127g apples



The proposed IESTI equation assumes that EACH apple included in the large portion consumption will have MRL-level (p-99) residue AND p-97.5 level unit variability.

Smaller case 2a commodities like apricots, kiwi, fig, garlic, carrot, mandarin are even more affected by this compounded conservatism.

➔ **The variability factor is SIGNIFICANTLY over conservative for case 2a commodities**

Blending and bulk:
Case 3 Study on wheat

- There are 38 CODEX MRLs on wheat
- USDA PDP monitoring data for wheat (2012) had 51 analytes
  - Only 4 had detections above the LOD;
- Use of the MRL inflates the actual exposure 20 to 100X

Compound	Highest monitoring (ppm)	STMR field (ppm)	CODEX MRL (ppm)	MRL/ STMR Factor	MRL/ monitoring Factor
Azoxystrobin	0.004	0.01	0.2	20X	50X
Boscalid	0.005	0.075	0.5	7X	100X
Deltamethrin/ Cypermethrin	0.042	1.38	2	1.4X	48X
Metconazole	0.007	-	None 0.15 (US)	-	20X

➔ **The current STMR is more appropriate than MRL for blended and bulk commodities**

Conservatism in Current and Proposed IESTI

Current IESTI already has much conservatism built in

- Acute RfD has **100X** Safety Factor from No Adverse Effect Level
- Use of a **point Estimate of HR** at the critical GAP is highest point in full distribution of potential residue values
- **Variability factors very conservative**
- **Field** trial data **does not account for degradation** during transport and food preparation

Proposed IESTI would add even more conservatism

- Use of the **MRL** is set above **worse case** field trial
- Continued use of variability factor in Case 2 sets exposure at **3X MRL!**
- Use of **MRL for blended** commodities **not justified**
- **Monitoring** data does not support use of MRL for **dietary exposure estimate**

➔ **Assessment of entire equation needed prior to modification**

Conclusions

- **Monitoring data show that MRL is an overestimate for dietary exposure**
- Proposed **changes** introduce **more conservatism**, without clear justification
- **CropLife International offers technical support** in any future EWG.
- **Partial implementation** of change without all data and factors **should not be made**
- Change should not be introduced until **full impact assessment** on trade and developing countries is understood

THANK YOU

Special Thanks to:
Monika Bross, Jane Stewart, Arpad Szarka, Phil Brindle, Frank LaPorte, Michael Kaethner, Bruce Young, Kent Rupprecht, Dave Johnson, Angela Klemmens