Acute risk assessment trends in EU:

a case of compounded conservatism

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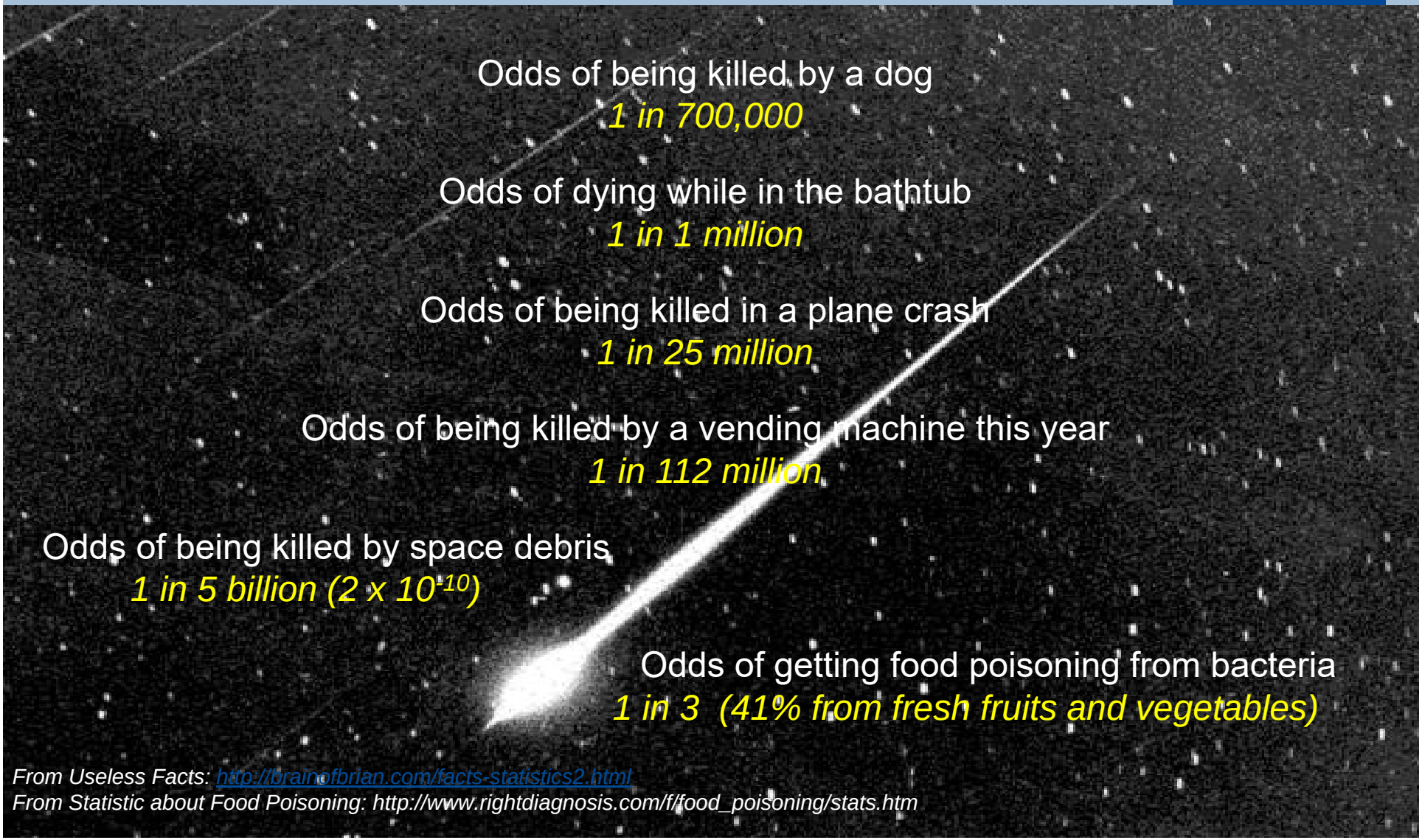
Are you safe?



Odds of being killed by a dog
1 in 700,000

Odds of dying while in the bathtub
1 in 1 million

Odds of being killed in a plane crash
1 in 25 million

Odds of being killed by a vending machine this year
1 in 112 million

Odds of being killed by space debris
1 in 5 billion (2×10^{-10})

Odds of getting food poisoning from bacteria
1 in 3 (41% from fresh fruits and vegetables)

From Useless Facts: http://brainofbrian.com/facts-statistics2.html
From Statistic about Food Poisoning: http://www.rightdiagnosis.com/f/food_poisoning/stats.htm

Acute Dietary Risk Assessment in EU
present and future

IESTI Equations:
Proposal from EFSA / WHO workshop, 2015

Dietary exposure = consumption x residue

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

1. Replace all field data (HR and STMR) with MRL
2. Keep variability factor 3, but applies it to the MRL
3. Remove unit weight from Case 2a
4. Introduce new CF in order to use MRL
5. Use Large Portion (by body weight) data - not yet available

Proposed Acute Risk Assessment Model

IESTI – case 2a and 2b

Acute Exposure (mg/kg-bw/day) = LP x MRL x V x CF

- LP is Large Portion – 97.5 percentile consumption g/kg-bw/day
- V is variability factor – 97.5 percentile unit residue / mean residue
- CF is the conversion factor to convert monitored residue to risk assessment residue

The MRL

IESTI – case 2a and 2b

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

The MRL is the maximum of:

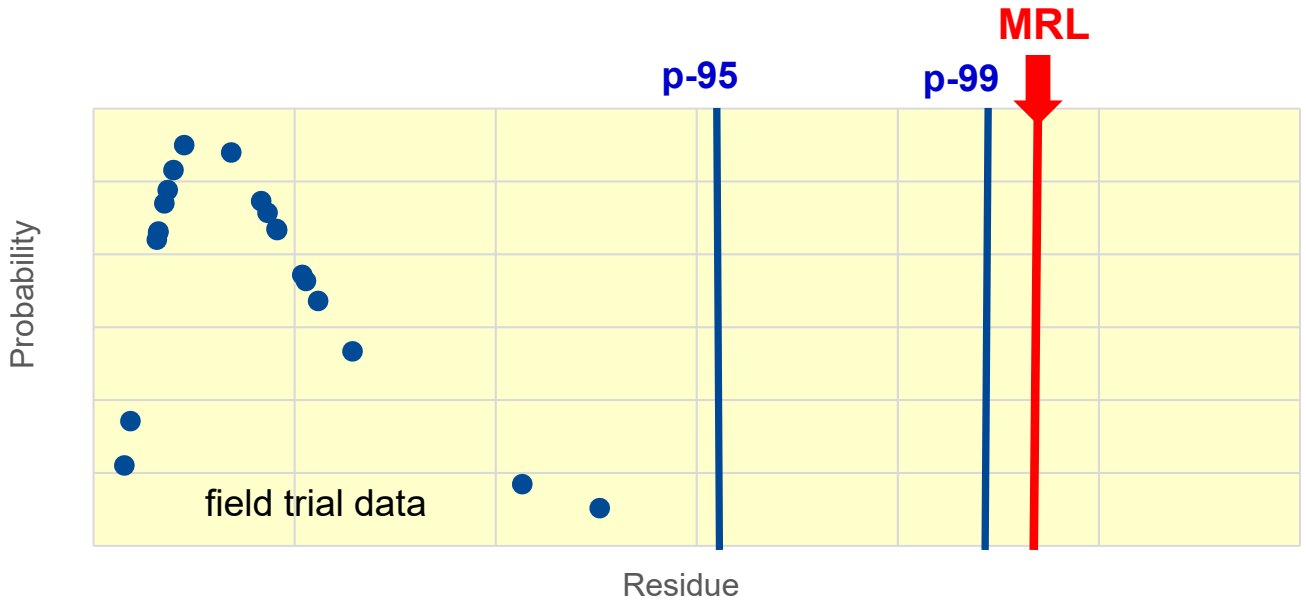
Mean + 4 SD, 3 x Mean x CF, or HR (highest residue)

*The equations used in the OECD MRL Calculator were selected to ensure coverage of at least the 95th percentile of the underlying residue population; however the actual calculation is conservative in that most of the calculated MRL proposals fall between the **95th and 99.9th percentile** of the residue distribution.*

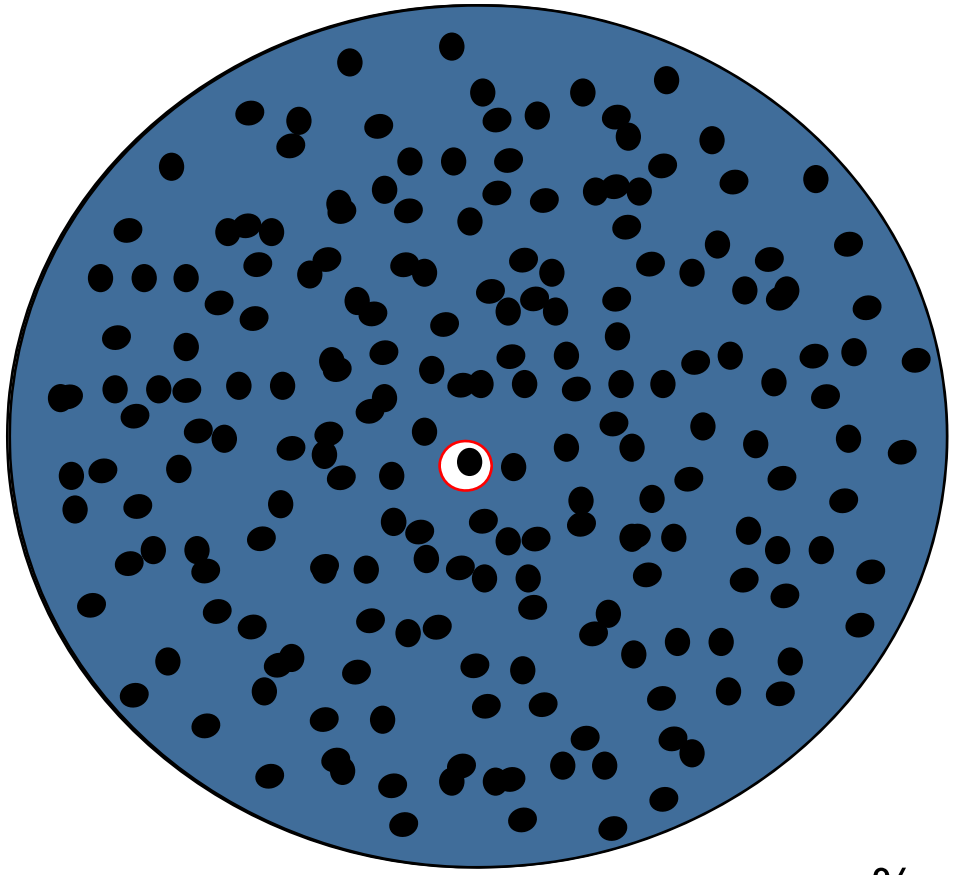
Performance of the OECD MRL Calculator

- During development emphasis was placed on not under-estimating the 95th percentile, while much less emphasis was placed 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.*



Are we safe yet?



The MRL represents on average the 99th percentile residue population

% outside the risk envelope: 1%

The Large Portion (high-end consumption)

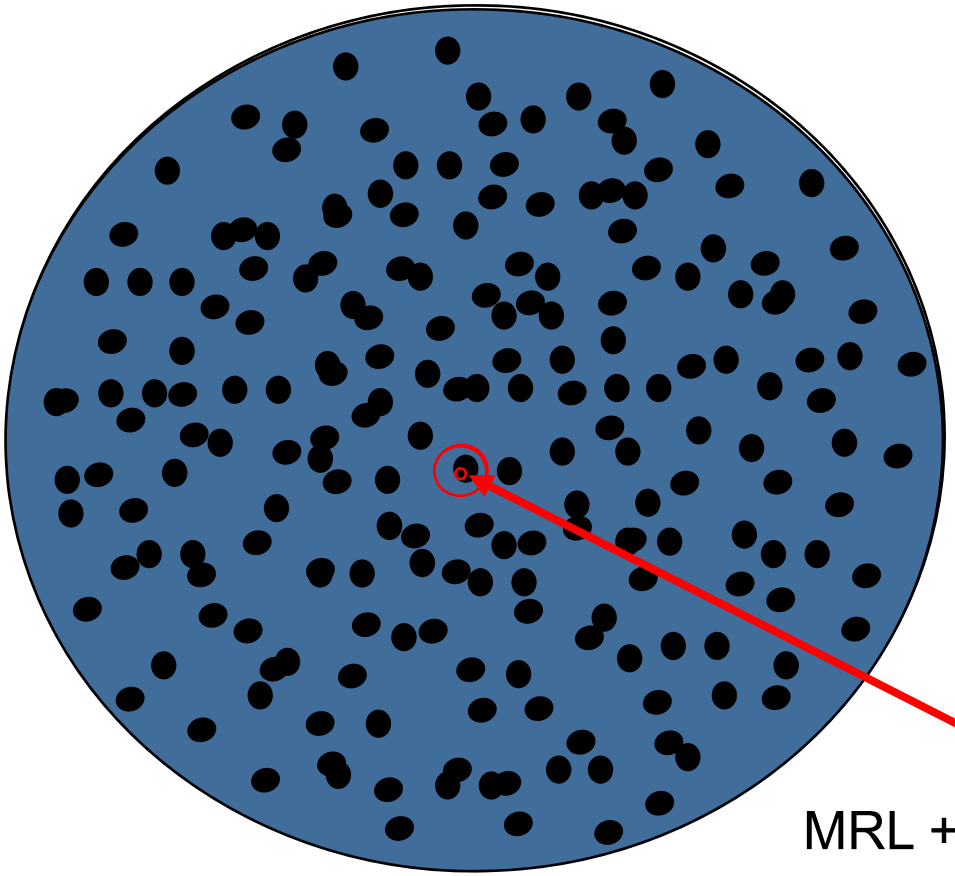
IESTI – case 2a and 2b

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

Code	Commodity	Pr	Processing	wc	HR or HR-P mg/kg	diet corr factor	Preset codes (case 1, case 3)	Country	Population group	n	Body weight (kg)	Large portion g/kg bw/day	Expressed as	Large portion, g/person	Plausible large portion?
FC 0005	Pummelo and Grapefruits	98	sec processing / composite foods			1.000		NL	toddler, 8-20 m	447	10.2	0.173	PP	1.76	Yes, n>120
002	**POME FRUITS**	–				-		-	-	–		–		–	
FP 0226	Apple	0	Total	wc	2	1.000		US	Child, 1-6 yrs	-	15.0	41.630	EP	624.45	Yes, g/kg bw/d < 1.5x robust g/kg bw/d
FP 0226	Apple	1	raw with peel (incl consumption without peel)		2	1.000		CN	Child, 1-6 yrs	1314	16.1	25.000	EP	403.39	Yes, n>120
DF 0226	Apple	7	dried		2	4.730		AU	Child, 2-6 yrs	154	19.0	1.372	PP	26.07	Yes, n>120
JF 0226	Apple	9	juice (pasteurised)			1.000		DE	Child, 2-4 yrs	1605	16.2	44.839	PP	724.15	Yes, n>120

The IESTI spreadsheet contains data from 12 countries, and the LP data for each commodity is the p97.5 taken from the highest value of these countries.

Are we safe yet?



The Large Portion represents 97.5 percentile of the consumption

MRL + LP - % outside the risk envelope:

100 x 0.01 x 0.025 = 0.025%

The Variability Factor

IESTI – case 2a and 2b

$$\text{Acute Exp (mg/kg-bw/day)} = \text{LP} \times \text{MRL} \times \mathbf{V} \times \text{CF}$$

The Variability factor is included to account for the possibility that residues in unit samples could be higher than residues in composite samples:

$$V = \frac{\text{97.5th percentile Unit Residue}}{\text{Mean (composite) Residue}}$$

A variability factor of 3 for Case 2 implies unit samples could be 3X the composite sample HR.

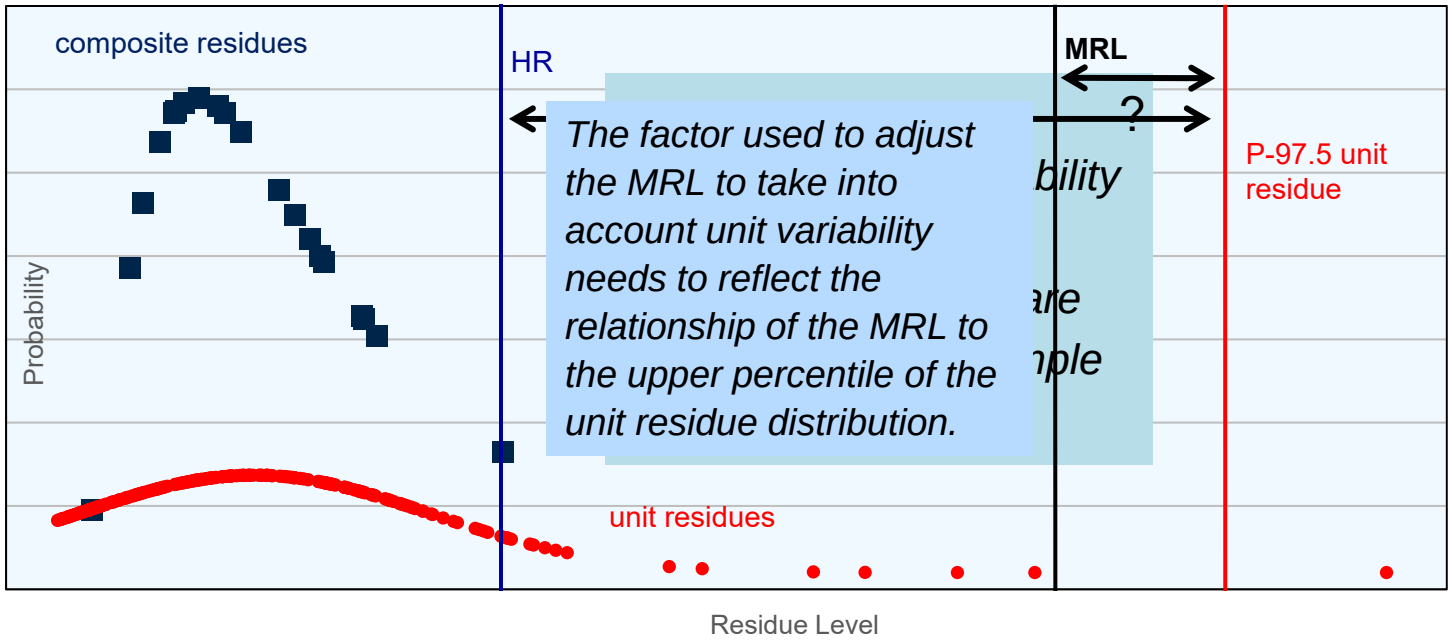
The Variability Factor

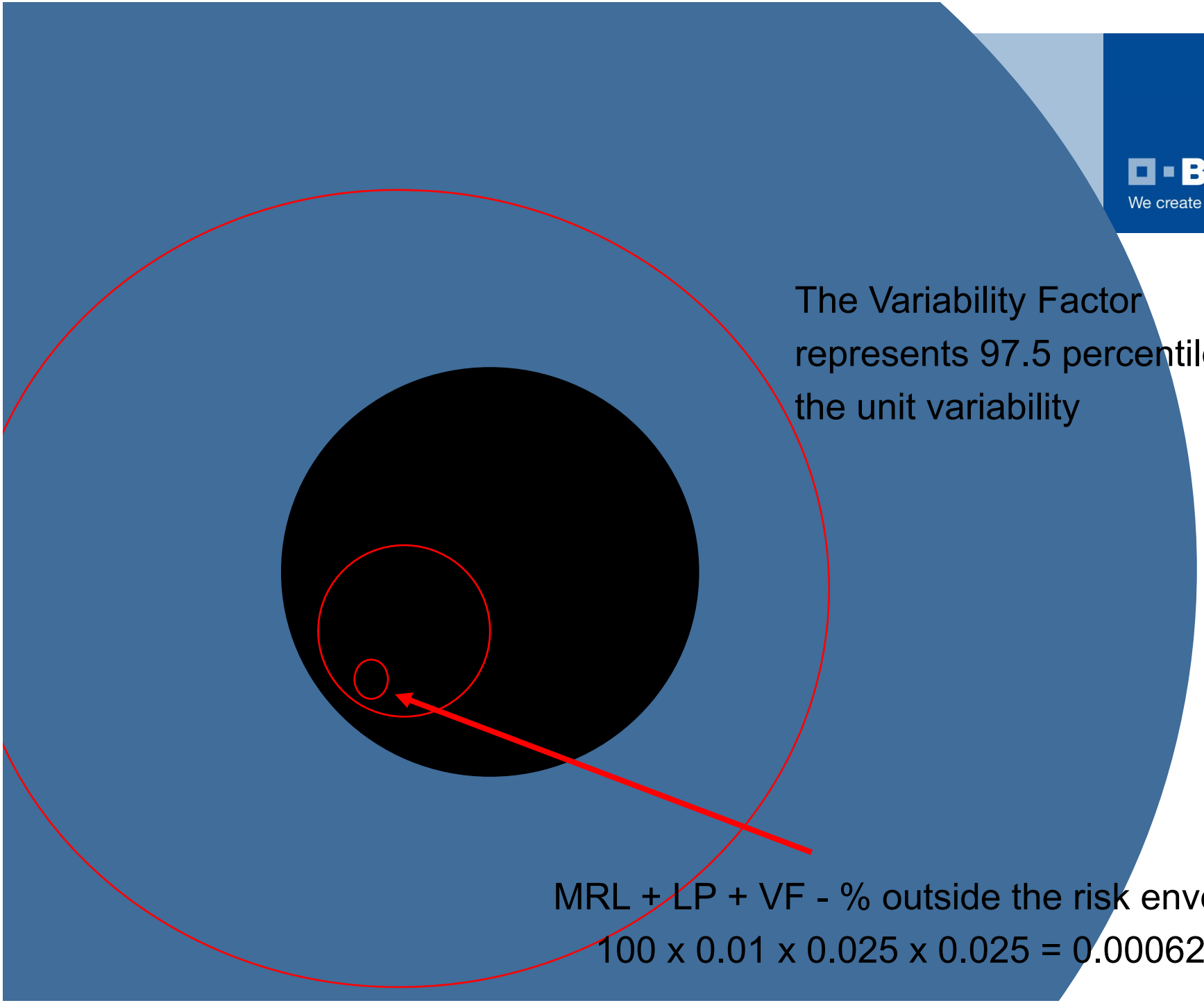
Is V=3 appropriate when used with the MRL?

IESTI – case 2a and 2b

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

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





The Variability Factor represents 97.5 percentile of the unit variability

MRL + LP + VF - % outside the risk envelope:

100 x 0.01 x 0.025 x 0.025 = 0.000625%

A closer look at the variability factor

IESTI – case 2a and 2b

$$\text{Acute Exp (mg/kg-bw/day)} = \text{LP} \times \text{MRL} \times \mathbf{V} \times \text{CF}$$

For case 2b, the LP size is larger than the unit size.

The JMPR IESTI spreadsheet states that the LP consumption of apples for children 1-6 years is 624.45 g, and the edible unit size of an apple is 127 g. Therefore the LP consists of approximately 5 apples.

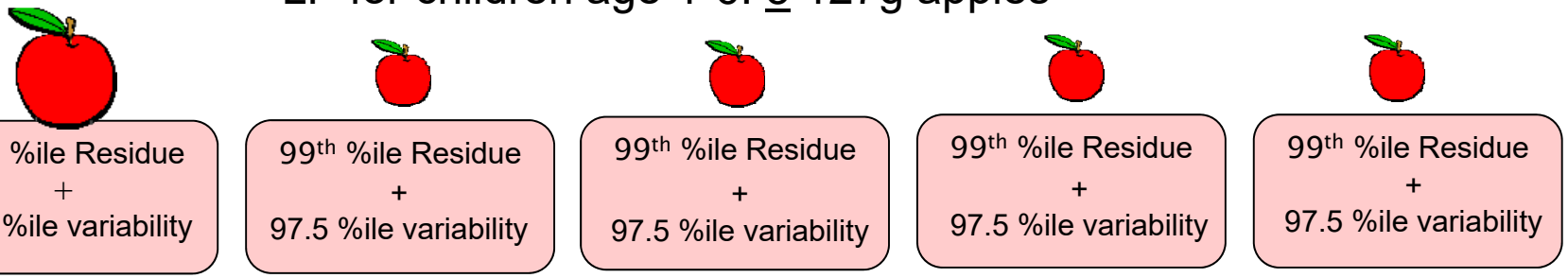
Without taking the unit size into account in the equation, the p97.5 unit variability is applied to all 5 apples in the LP.

The Variability Factor – apples and oranges

Case 2a – apples and oranges

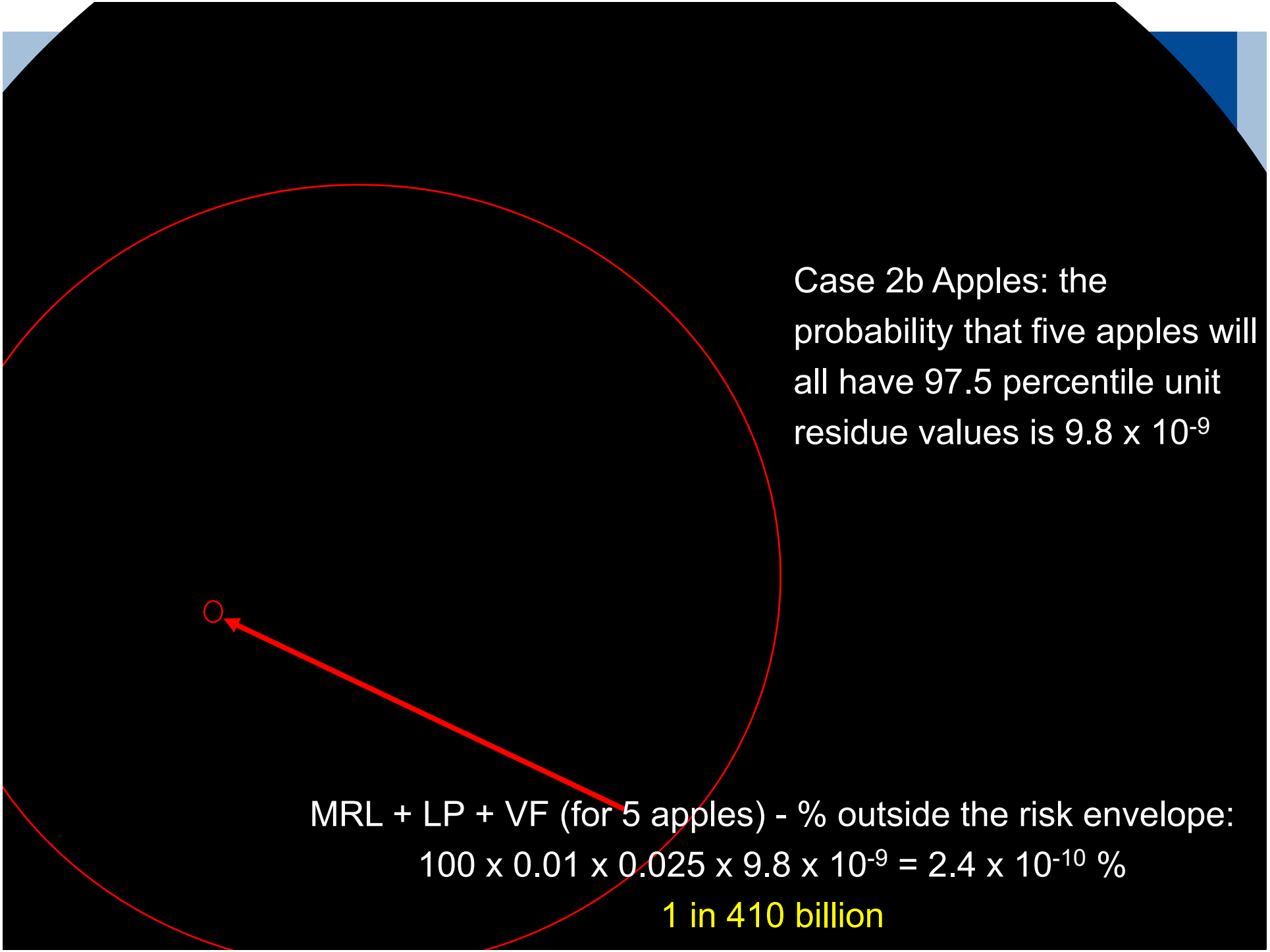
IESTI = LP x MRL x **V** x CF

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.

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



Case 2b Apples: the probability that five apples will all have 97.5 percentile unit residue values is 9.8×10^{-9}

MRL + LP + VF (for 5 apples) - % outside the risk envelope:

$100 \times 0.01 \times 0.025 \times 9.8 \times 10^{-9} = 2.4 \times 10^{-10}$ %

1 in 410 billion

Taking a step back

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International Working Groups are forming to take a second look at the EU proposals.

The US EPA is already involved in the discussion.

Crop Life International, ECPA and other stakeholder groups are assessing the impact of the changes and voicing concerns.

- *Thanks for your attention!*

Countries that rely upon EU or Codex standards are getting involved.

We are looking forward to a very interesting discussion!