

GLOBAL DATASETS & DATA EXCHANGEABILITY

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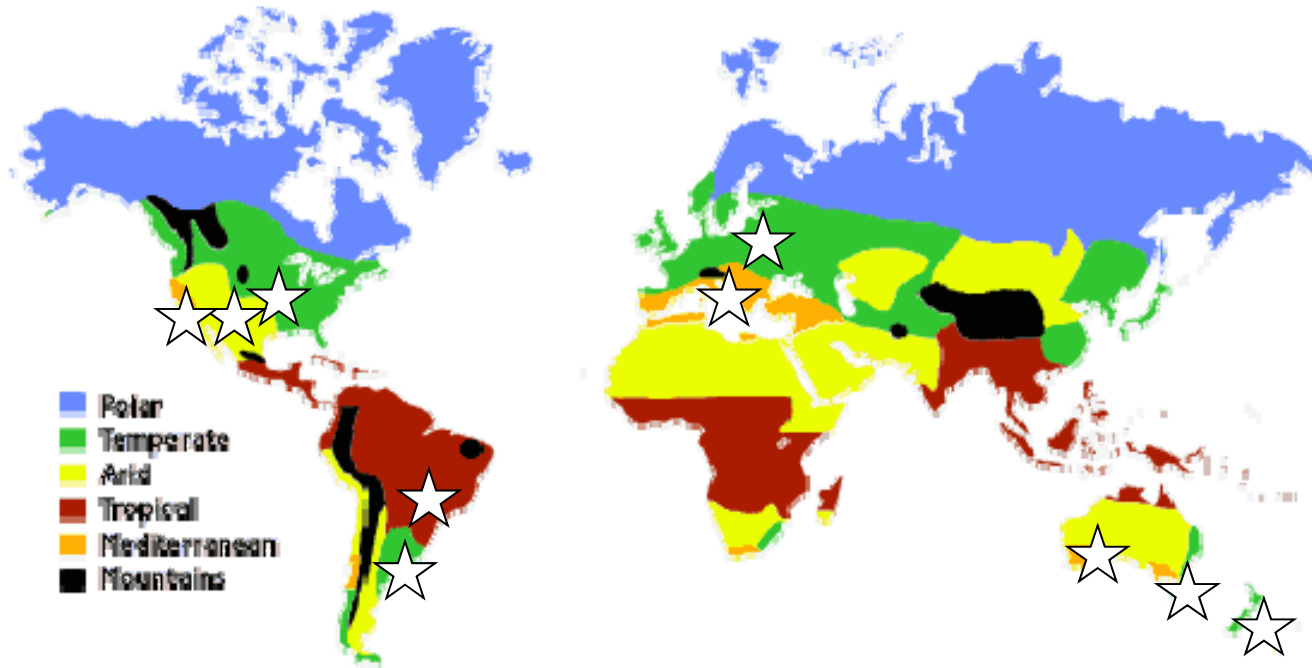


Dow AgroSciences

Solutions for the Growing World

Global Residue Programs

- Located in 2+ climatic zones representative of typical growing areas
 - > Temperate
 - > Mediterranean
 - > Tropical



www.climate-zone.com (Image courtesy of the UK Meteorological Office)

Precedents

- **Global Zoning Concept**
- NAFTA Pilot Project to Validate Residue Zone Maps, 2001
- OECD/FAO Zoning Project (2003)
- Bourma Paper exchange of efficacy & crop safety (2005)
- **Regulatory Framework**
- OECD 509: 40% less trials for global programs (2009)
 - > Guidance document needed more support for zoning
- JMPR 2012 requested evidence proportionality

Global Zoning Analysis

QUESTION: Are there systematic differences in pesticide residue concentrations between zones?

- > If not, residue data from various zones conducted under the same or similar application scenarios could be combined to develop globally harmonized MRLs (to include all possible variability)



- US-EPA
- Canadian PMRA
- OECD-RCEG
- JMPR/CCPR
- CropLife
- IR-4
- EFSA

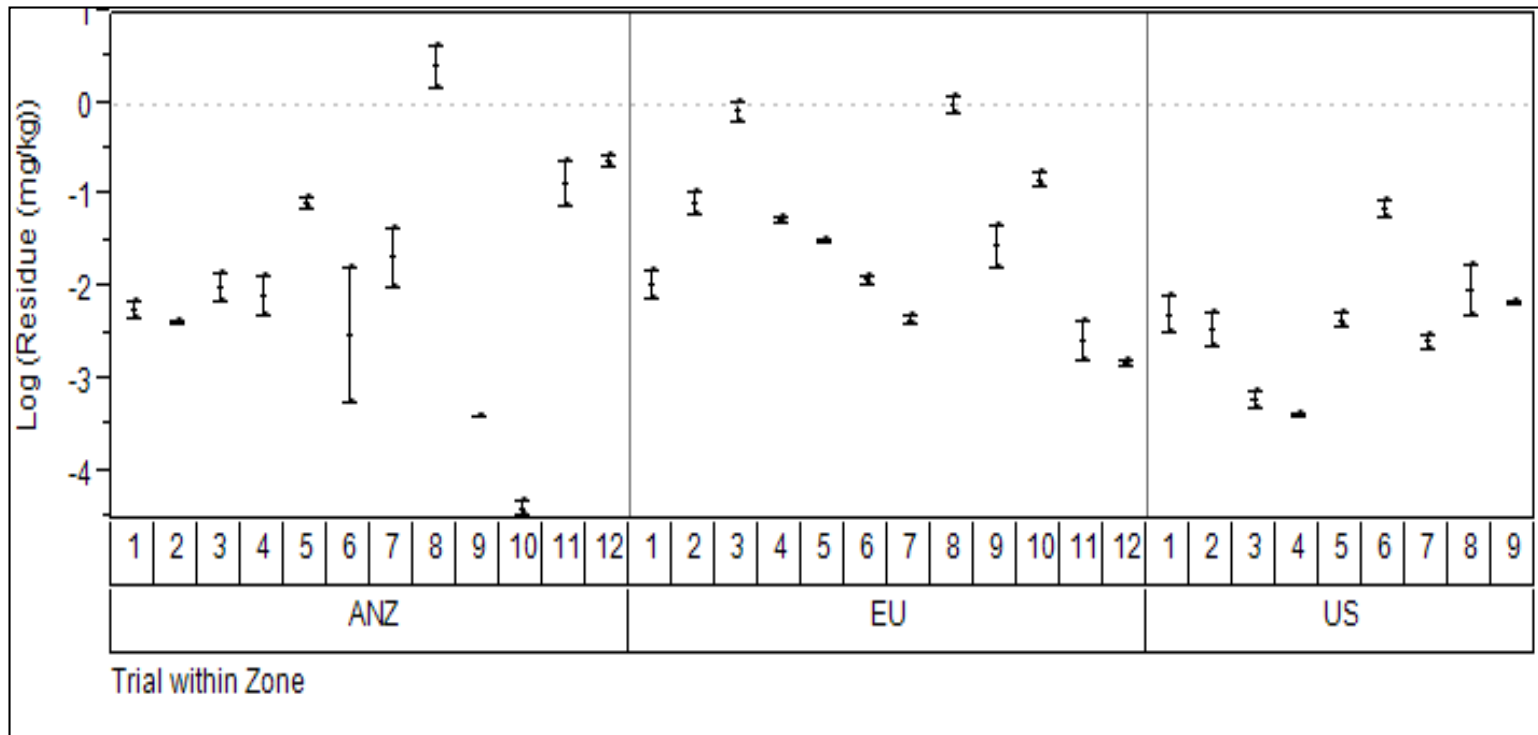
Proposed Tiered Methodology

- **Tier 1 – non parametric normalized rank-sum**
 - if significant zonal differences-
- **Tier 2 – parametric mixed effect model**
 - if differences are significant -
- **Tier 3 – variance components analysis, by crop**
 - if zones significant contributor –
- **Tier 4 – estimate global and zonal MRL to select the higher**

Method validation

- EPA's synthetic data, real data from DAS, IR-4, CropLife, PMRA
 - > Real datasets: 73 crops, 76 pesticides, 2-4 regions, > 4,000 datapoints

Example of Zoning Analysis, by Crop



Tier 2

Variance Components

Component	Var Component	% of Total	20 40 60 80	Sqrt(Var Comp)
Zone	0.00121004	8.2		0.03479
Trial[Zone]	0.01283664	87.1		0.11330
Within	0.00068965	4.7		0.02626
Total	0.01473632	100.0		0.12139

Tier 3

Global Zoning Analysis

Results of Analysis

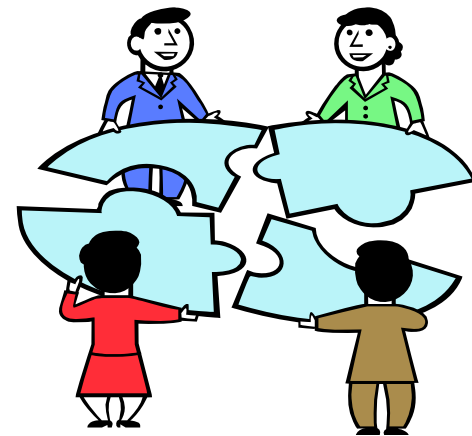
- The majority of variation in the field trial residues was contributed by **within zone** variation. This is consistent with what the analysis of 2003 OECD/FAO Global Zoning Concept.
 - between zone variation is ~ **20%** of the total (i.e. 0.1925)
 - within zone variation is estimated ~ **80%** of the total variation (i.e. $0.7749 = 0.7077 + 0.0672$)

Covariance Parameter Estimates		
Cov Parm	Subject	Estimate
Intercept	CropPest	3.0788
Zone	CropPest	0.1925
Field Trial (CropPest)		0.7077
Residual		0.0672



CONCLUSION

1. For the global zones analyzed, the data suggest that systematic differences **between zones** are avg. 12 % and are **not statistically significant**
 - Confirms findings from OECD/FAO 2003 Zoning Project
 2. Analyses were also done to compare **by-pair** (USA vs. Canada) and (EU-NZ vs. EU-SZ) and were **not statistically significant**
 - Systematic differences where small (< 8%) and support combining data to “North America” and “Europe” zones for regional zoning analysis
- This additional evidence supports the exchangeability of data
 - > Useful to extrapolate between countries
 - > Support Codex-MRLs
 - > Global OECD Joint Reviews



Thanks & Acknowledgements

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Thank You

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