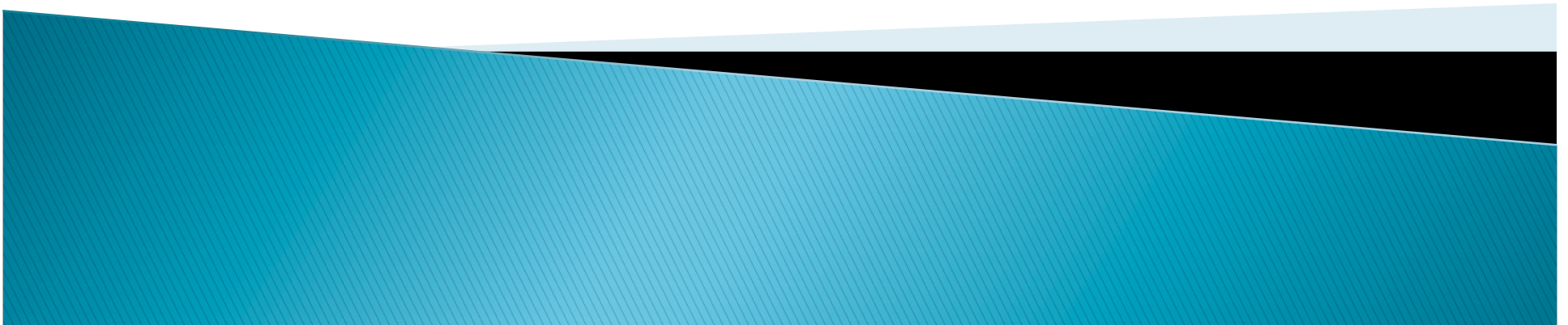


Current Issues Affecting MRL Harmonization

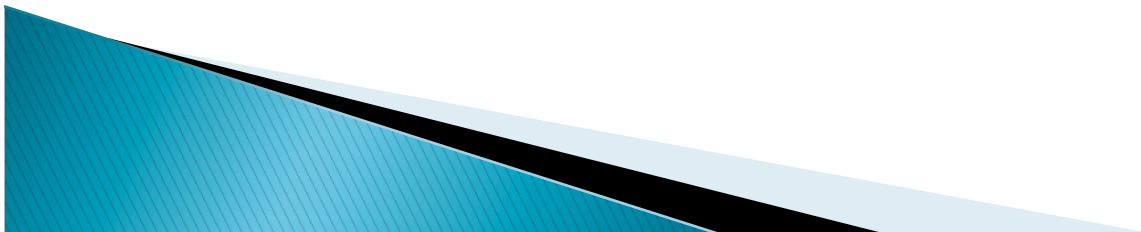
Cindy Baker Smith, AMVAC

June 1, 2016



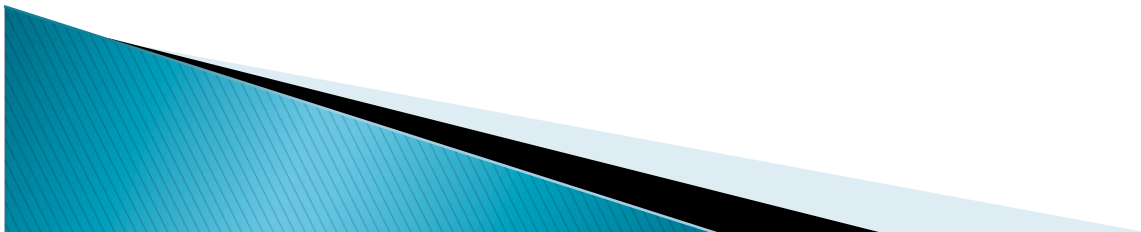
Issues Impacting MRLs

- ▶ CODEX
- ▶ Countries Setting their own MRLs
- ▶ Differing Data Requirements and Standards
- ▶ Changing Practices
- ▶ Increasing Costs, Regulatory Burdens and Challenges



CODEx

- ▶ Real Improvements made over the last decade
- ▶ Significantly more MRLs approved
- ▶ CODEX MRLs still generally come after approvals by other regulatory authority –CODEX can't work on MRL until a registration is issued by a country
- ▶ Real concerns about tight resources for both FAO and WHO. WHO needs \$\$, FAO needs experts – especially to catch up
- ▶ Still real challenges achieving agreement from major participants – EU, Australia, etc.



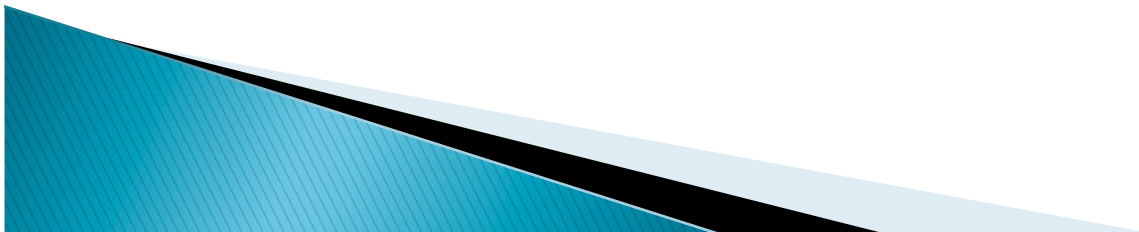
Countries Setting Own MRLs

- ▶ Several doing for years
 - US – driven by statutory requirement
 - Canada – still have default –rumored to be moving away from default
 - EU –still have default
 - Japan – still have default
- ▶ More in Process
 - Taiwan
 - South Korea
 - APEC – document from Australia circulated at the CODEX meeting



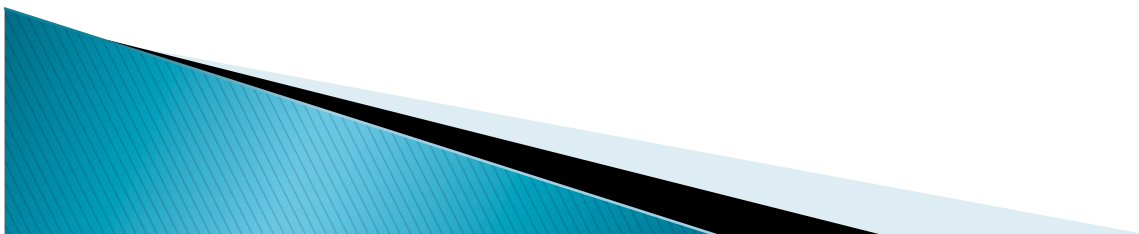
Differing Requirements and Standards

- ▶ All require toxicology data
- ▶ All require residue data
- ▶ All require a label representative of the generated data
- ▶ Not all assess the tox and residue data in the same way
- ▶ Residue definitions not always the same
- ▶ Not all recognize crop groups in the same way
- ▶ Full registrations or import tolerances? Allowable?



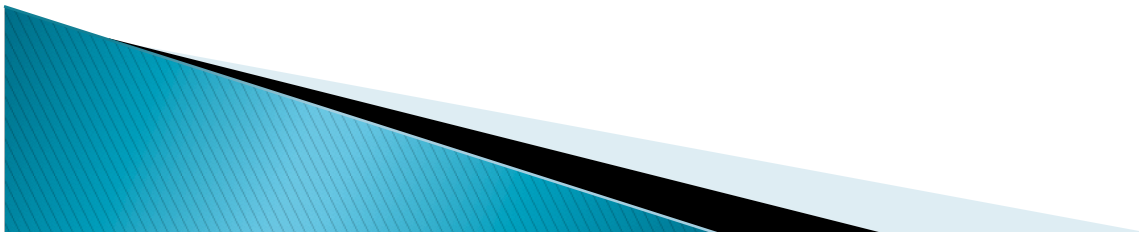
Changing Practices

- ▶ Calculation of Short Term Dietary Intake
 - Use of MRL rather than residue value-overestimates risk
- ▶ Acceptance of Global Residue Trials
 - US and Canada project –presented at CODEX
- ▶ Impact of Uncertainty Factors
 - US - FQPA 10x
 - EU discussion with respect to the Risk Principles for CODEX
- ▶ Impact of Dietary consumption assumptions and differences
- ▶ Impact of Drinking water risk assessments



Increasing Costs and Regulatory Challenges

- ▶ Cost of bringing a new ai to the market
 - Approaching 300 million –over 50% increase since turn of the century – environmental safety and tox data
 - Time to market has increased from 8 years in 1995 to 11 years in 2014
 - Industry spent over 2.6 billion in 2014 bringing new technology to the global marketplace
- ▶ Increasing cost to defend existing products
- ▶ Increasing Challenges – Environmental Risk



Thank You

