Global Residues & MRL’s Harmonization

A Registrant’s Perspective

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Presentation Outline

1. Requirements for residues & MRLs
2. Harmonization opportunities
3. Global residue program - example
4. Challenges for MRLs harmonization
5. Conclusions & Recommendation
1. Global Residues Requirements

Current regulatory framework set by OECD

- Crop Field Trials: OECD 509 + guidance
  - Comprehensive global packages
  - 40% fewer trials than nationally required
  - 50% data from overseas
- OECD global joint-reviews
- OECD MRL-calculator
## 2. Harmonization Opportunities

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3. Global Residue Programs

- Harmonized GAP (or worst case critical-GAP)
- Similar number of trials as current national requirements, yet larger global packages
- More robust data representative of global climates, regions, soils, use patterns, pest intensity
- Enables harmonized MRL’s globally
- Significant benefit on global trading of ag-commodities and reduction of food-chain issues
Example of a global program

• New insecticide with wide spectrum of use
  ➢ 600 trials in 4 continents
  ➢ 39 crops (fruits, veggies, grains, oilseeds)
  ➢ 8 – 44 trials/crop, in 2 - 4 geographies ★
  ➢ Harmonized GAP’s per crop @ c-GAP
Global residue program pre-OECD

- GAP’s globalized (allowing proportionality for regional flexibility to account for pest spectrum & intensity)
- Number of trials based on contribution
  - Weighted (1-3 scale) from 3 variables (size of planted area, food consumption intensity, frequency of trading)
  - Location in countries/regions representative for each crop (one from each N and S-hemisphere, or from the tropical belt)
  - Minimum number trials per zone dictated by the relevance of statistical interpretation (6-8?)
- Crop grouping/extrapolation
  - As per ICGCC (25% reduction of # trials), or
  - Super-crop grouping, as supported by GAP’s across crop-groups and countries (further reduction, as supported by statistical relevance of data)
## Ideal Global Residue Package (example)

<table>
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<tr>
<th>Crops</th>
<th>Area</th>
<th>Consumption</th>
<th>Trading</th>
<th>Total Score</th>
<th>Min # trials</th>
<th>NAFTA</th>
<th>EU</th>
<th>BRAZIL</th>
<th>AUS&amp;NZ</th>
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<td>*</td>
<td>*</td>
<td>*</td>
<td>6 (***, ****)</td>
<td>5-20</td>
<td>8-16</td>
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<td>**</td>
<td>9 (******, ******)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>*** high</td>
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<td>12 (*******, ********)</td>
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<tr>
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<td>**</td>
<td>12 (*******, *********)</td>
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<tr>
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<td>***</td>
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<td>12 (*******, *********)</td>
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<td>6</td>
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<td>12</td>
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<tr>
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Benefits from this Global Program

- Supported new regulation updates (OECD 509)
- Proved homogeneity of residue data produced in different regions at the same GAP
  - Variability of data across regions (avg 12%) is much lower than within any particular region (avg 78%)
- Concurrent registration submissions & reviews
  - OECD joint review (EPA, PMRA, APVMA)
  - Codex (draft-MRL’s available)
  - EU
- Cost optimization by crop, more MRLs proposed
4. Challenges for MRL harmonization

A. GAP (Good Agricultural Practices)
   - Rate, # applications and intervals, PHI
   - Variety of use practices for same crop
   - Variety of pests and their intensity
   - Agencies' flexibility around 25% GAP variation

➢ Harmonization at critical GAP (cGAP) globally
Challenges for MRL harmonization

B. Inputs for OECD-MRL calculator

- Single vs. replicate samples
- Average vs. highest across replicates
- Treatment of outliers
- Treatment of censored data (ND-non detects, LOD, LOQ)
- Bundling data across regions
- Bundling of data across crops (apricot, peach)

➢ Harmonized inputs for global data, average replicates (>8 trials), data as reported, bundling & outliers as supported by statistics
Challenges for MRL harmonization

C. Supporting Risk to Consumers

– Tiered approach for exposure
  1. MRL/tolerances
  2. Actual field data
  3. Monitoring

– Acceptance of refinement factors
  • Edibility, processing/cooking, % crop treated

– Agencies’ policies to incorporate drinking water

➢ Globalization of exposure refinement options
Challenges for MRL harmonization

D. Other Challenges (just a few more…)

- Raw Agricultural Commodity description (fruits w/wo pits, peel, forage, etc)
- Crop groups differences (ICGCC, Codex, EPA)
- GLP global implementation
- Analytical data reports (LOQ/LOD, corrected/uncorrected)
- Statistical interpretation of results (mean/median, HR/HAFT, U-test similarity subsets, Dixon-outliers)
- Agencies’ policies about residue definition, proportionality, zoning, bundling, extrapolation, mutual acceptance
Conclusion & Recommendation

• Technically it is feasible to develop **global residue packages** following OECD guidelines recently updated with representative trials at global locations

• Faster **availability MRLs and new technologies** to more countries

• **Minor crops** need special consideration through regulating extrapolation and mutual acceptance

• Further **guidelines updates** is needed for harmonized criteria to use global datasets and mutual acceptance of reviews between countries.
Let’s go global!

Please forward comments to:

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