Residue Trials/Data Generation
Strategies for identifying & collecting information on existing national/regional residue data generation programs

- Residue Trials –
  - Listing of information with a summary indicating if it is GLP, GEP or other.
  - Usually generated by MFG, Universities, Government, Grower organizations.
  - Large volume of data to load.
  - Much of the data has been summarized already.

- Core data (e.g. metabolism studies) – available/adequate or not?

- Validated/verified analytical methodology (ILV, storage stability etc.) – available/adequate or not?
III Identify mechanisms for storing, listing and sharing available residue (Magnitude of Residue, Supervised Field Trials) data for minor uses:

- Use at national level (accept a minor use petition) or at grower level to recommend or to determine approved use directions – summary data is adequate.

- To request import MRLs (more detailed review)

- Examples of applicable information:
  » Field Residue Studies (includes processing studies)
  » Dossiers
  » DERs (Data Evaluation Records)
Recommendations (for I and III):

- Develop a reliable public-access database (completed and ongoing work/studies)
- Determine the information available in the database (include as much information as possible, recognizing data ownership):
  - Proposed selection criteria:
    » Chemical
    » Crop (with EPPO/Codex code)
    » Zone/Country
    » Pest (include scientific name)
- Propose that FAO develop, populate and manage the database
II. Identify differences in national requirements for conducting residue trials and opportunities to harmonize requirements:

• OECD is currently working on this harmonization process (OECD writing groups should be looking at FAO Standards)

• OECD vs non-OECD countries
  – Link OECD and JMPR/FAO Code of Conduct
  – OECD Guidance document should allow national governments to incorporate their own national requirements as necessary

• Guidelines for determining major vs minor crops (minor crop in one country may be major in another)
Recommendation (II):

- To the extent possible harmonize FAO Standards with OECD guidelines recognizing the requirements of non-OECD countries
IV. Identify opportunities for collaborative data generation to support minor uses:

- **Zoning**
  - GAP/use pattern is similar or the same
  - Develop tools to normalize data (e.g. proportionality)
  - Need adequate distribution of supervised field residue trials to reflect grower production practices, not necessarily driven by climate
  - Considerations for greater flexibility for protected (e.g. glasshouse) or stored crops vs non-protected crops
IV

• Extrapolation in general
  – Wider extrapolation if no residues are expected (some pre-plant applications e.g. seed treatment or soil application of non-systemic active ingredient)
  – Extrapolation of crops (see crop grouping below), application methods, pests, formulations
IV

• Efficacy – covered by another break-out group

• Resources
  – Funding
  – Personnel (including Capacity-building and Training)
  – Less duplication of work (optimization) – see section on data-sharing (Section III)
Recommendation (IV):

- **Recommendation:**
  - Continue to promote and support initiatives for the best use of data such as zoning and extrapolation.
V. Critique effectiveness of current crop grouping harmonization efforts:

• Crop grouping and extrapolation criteria (Under development in Codex work plan)
• Current efforts appear to be making good progress (ICGC)
• Important to continue globally (identify “orphan crops” for inclusion as appropriate) to harmonize future efforts – bring forward for national level adoption via Codex
• Large crop groups may lead to difficulty in acquiring MRLs on some crop groups
• Crop groups may also lead to more rapid filling of the “risk cup”
• Ensure that all crops/commodities are represented where possible
Recommendation:

• Continue global efforts to harmonize crop grouping, encouraging input from as many countries as possible.
Over All Recommendation

• Encourage stakeholders to continue collaboration and communication after the Summit.
  • Possible “Summit II”
  • Possible Global Residue Study
  • Encourage organizing committee to continue support of the “list serve” or other forms of communication