

Residue Trials/Data Generation

I 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