

# MRL Harmonization

Group C

# Technical Issues

1. GAP varies among countries
2. Crop Groupings – different crop grouping work currently being done by different groups; choice of representative crops an issue
3. Different Residue Definitions among countries

# Technical Issues

4. Different methodologies (eg calculations) currently used to establish MRLs leads to different MRLs. (often limited data set for many minor uses);
5. Different risk assessment evaluation and uncertainty factors
6. Country specific zone requirements for residue trials leads to different data sets
7. GLP vs GEP field trials

# Policy Issues

1. Not all countries adopt CODEX MRLs
  - risk assessments using CODEX MRLs differ from a country specific perspective because of different diets
  - Lack of CODEX MRLs for many actives
2. Safety factors: safety factor policies differ among countries leading to different toxicological endpoints.

# Policy Issues

3. Lack of concurrent active ingredient registrations in all countries leads to the requirement of import tolerances.
4. Different statistical methodologies currently used to establish MRLs leads to different MRLs.
5. Not all countries have a process for establishing import MRLs.

# Other Issues

1. Risk Communication
2. Not clear on how and why we use MRLs
3. Establishment of private standards (eg retailers)

# Technical Solutions

- GAP varies among countries
  1. identify and collect all GAPs for “minor” uses
  2. analyze the critical parameters which will lead to different residue levels
  3. provide residue data covering the critical GAPs
  4. Mutual acceptance of GAP

# Technical Solutions

- Crop Groupings – different crop grouping work currently being done by different groups; choice of representative crops an issue
  1. Support Codex classification for crop grouping
  2. Incorporate crop grouping into legislation or regulations.
  3. Define criteria for representative crops and their commodities within a crop group

# Technical Solutions

- Different Residue Definitions among countries
1. Use the OECD Residue Definition Guidance Document for determining the residue definition.

# Technical Solutions

- Different methodologies (eg calculations) currently used to establish MRLs leads to different MRLs. (often limited data set for many minor uses); different uncertainty factors for risk assessment evaluation
  1. Ongoing work within OECD/JMPR to recommend methodology for establishing MRLs
  2. Consistent application of UFs.

# Technical Solutions

- Country specific zone requirements for residue trials leads to different data sets
  1. Look at the results from the Global Zoning Project currently in progress (US EPA)
  2. Ongoing OECD/JMPR zoning work (Phase III OECD work)

# Technical Solutions

- GLP vs GEP field trials
  1. apply GLP (or its equivalent) for field trials but compulsory for residue analysis

# Prioritization/Recommendation

1. Different GAPs: High priority  
Recommendation: OECD Expert Group on Minor Use, OECD Residue Chemistry Expert Working Group and CropLife address this issue.
2. Crop Grouping schemes (on-going collaborative work by Codex, International Crop grouping Consulting Committee, US EPA, OECD,) High Priority  
Recommendation: Regular updates to Summit Participants
3. Different Residue Definitions (completed work): high priority  
Recommendation: Government Bodies adopt use of guidance document.

# Prioritization/Recommendation

4. Different Methodologies for establishing MRLs (on-going work by OECD, NAFTA, JMPR): high priority  
Recommendation: Regular updates to Summit Participants
5. Different Uncertainty Factors and risk assessments: high priority  
Recommendation: Regulatory agencies be consistent with interpreting and applying uncertainty factors and use global joint reviews as a forum for discussion
6. Country Specific Zone Requirements (on-going collaborative work by OECD, NAFTA); high priority  
Recommendation: Regular updates to summit participants

# Prioritization/Recommendation

- 7. GLP vs GEP for residue field trials low priority  
Recommendation: Training, education for GLP

# Additional Recommendations

- Proposal to establish a working group at FAO/CCPR to facilitate the dialogue among countries, industry and growers for minor use and to track the on-going activities resulting from the Minor Use Summit
- Alignment of global joint reviews with JMPR review.