A Generic Industry Viewpoint

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Introduction

- The generic industry shares the concern of lack of plant protection products (PPP’s) for minor uses.
- More solutions would come forward if reduced registration requirements would apply.
- What are practical solutions?
Potential solutions

1. Propagate the term “minor use” among the parties involved.
2. Use mutual recognition.
3. Use equivalence following FAO/WHO rules.
4. Use extrapolation.
5. Eliminate data protection or provide compulsory access with data compensation.
6. Provide databases.
7. Simplify registration procedures.
Propagate „Minor uses“

- Define what crops/pest combinations are considered a national minor use.
- Inform farmers and industry.
- Organise cooperation between the registration authority, farmers and industry to actively find solutions.
Mutual recognition

- Establish what registrations for minor crop exist in other countries under similar climatic and cultural conditions.
- Use mutual recognition to provide authorisation for use, if the dose rate is similar.
Equivalence

- Equivalence is determined by FAO/WHO rules for active ingredient(s) and product.
- If equivalence with an existing product can be established, the registration procedure can be vastly simplified.
Extrapolation

- Extrapolation from a suitable major to a minor crop should be used with respect to biological performance and residues.
- Registrations in another suitable country should also be considered, provided that climatic and cultural conditions are similar.
- The EU DG SANCO and the forthcoming EPPO listing of related crops are valuable guides for extrapolation.
Data protection

- For minor use products, either
  - Eliminate data protection for minor use products OR
  - Apply the new EU Regulation rules OR
  - Provide compulsory data access with data compensation.
1. Provide public access to a national listing of protected and non-protected data providing the source, study name, submission date, date of protection termination, etc.


3. Provide a national law for compulsory data access with justified data compensation.

4. Lift data protection in case a registrant terminates sales for a minor crop.
Database on trials

- Organise international databases, listing all biological and residue studies in minor (and if possible in major crops).
- To include: PPP, crop, country, climatic condition, dose rate, GEP/GLP compliance and data owner but NOT results.
- This would facilitate data access and save time and expenses where extrapolation is not possible.
Simplification of registration

- The situation is a complex of concerns:
  Authority: Safety for man and environment
  Farmers: Protection against losses in high value crops
  Industry: Limited sales but high cost of dossier preparation and registration process.

- Solutions for minor uses:
  Mutual recognition between countries
  Equivalence
  Extrapolation
  Reduced registration requirements including simplified data protection.