Data Generation An Industry Perspective

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Data generation: Expectations

Data for minor uses:
• Must comply with regulatory requirements in country of origin
• Meets crop safety requirements
• Efficient weed, disease & pest control
• Robust data set available to get MRLs, import tolerances and Codex MRLs
• A minor use is reliable to maintain growers confidence in branded products!

Expectations on the quality of data generated for minor uses do not differ from those for major uses!
Data generation: Observations

• Lack of Industry’s support for minor uses due to limited commercial interest leading to a lack of data for approved uses
• Off-label uses: (off-label uses not sustainable in the EU)
• ‘Non-approved uses’ as there is no pest control option: product is not legally used on a minor crop/use but based on information from a major use)
• Data generation by private (grower groups) & publically financed programs
• Still lack of data

Is a change in data requirements a viable option without compromising data quality?
Data requirements: Extrapolation

- Data extrapolation: The solution of the problem? What does it mean for minor uses?
- Different approaches for pest control (efficacy) and residues:
  - Efficacy: Does the GAP that can control pest ‘x’ on crop ‘y’, control the same pest on crop ‘z’?
  - Residues: Do residue levels on crop ‘y’ compare with levels on crop ‘z’? Approach needs international harmonized crop classification system.
- Acceptance of data generated in other countries/regions: Need scientific (re)-evaluation of zoning concepts and flexibility in ‘pesticide legislation’.
‘Extrapolation’: Additional concepts

- **Residue level proportionality: Proposed next steps**
  - Provide additional evidence for the concept to gain global acceptance (OECD, JMPR & rest of the world).
  - Investigate whether this concept can be extended to other uses than foliar.

- **Developing residue profiles for active substances:**
  - Given that the initial residue level and the decline kinetics are documented for a number of ‘model’ crops, what opportunities do exist to estimate sufficiently robust residue levels for MRL setting for other crops.
    - This approach is used by AUS to set MRLs on persimmon based on combined apple, peach, nectarine data sets.
  - Proposed next step: analysis of existing databases to identify ‘model crops’. The idea is to extend extrapolation criteria to become less dependant of crop classification (crop groups?)
Conclusion on ongoing work & proposed next steps

• CropLife fully supports and actively contributes to the ongoing OECD residue test guideline harmonization and minor use activities.
• Huge residue databases are available containing thousands of studies: To date these data are mainly used to set MRLs on Crop ‘A’ based on data for Crop ‘A’ and in some cases for crop group MRLs.
• However these data could be analysed e.g. to verify the proportionality of residue levels, geographical zones and for residue ‘profiles’. This needs agreement on scientific approaches and exploratory analysis: CropLife companies like to encourage all stakeholders to take further steps to evaluate existing data for extended extrapolation opportunities and are willing to contribute!
THANK YOU VERY MUCH FOR YOUR ATTENTION!