



# 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!**

