MINOR USES REGISTRATION IN EU

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Topics

- General Regulatory frame
- Map & Zones
- Case of minor uses
- Explanations and examples
General Regulatory frame

- Registration in EU belongs to Directive 1107/2009
- for PPP (including Bio)
- Biocontrols
- Biostimulants
- Exception for fertilizers
Map & Zones
For non protected crops
Map & Zones
depending on Brexit issues, Hard of Soft

For non protected crops
Explanations and examples

- The EU Minor Uses Co-ordination Facility (MUCF) hopes that guidance on applying for agrochemical approvals for use on minor crops will be adopted by EU member states in early 2019.

- National considerations and assistance from authorities
Data package

- **EFFICACY**: 2 to 6 trials per use and per zone (instead of 8-15 for major use), and sometime none if we use EPPO extrapolation table.

- **RESIDUE**: If major crop: 8 North and 8 South. If minor crop: 8 North and 8 South. (ie: For minor use on major crop, 8 + 8 are needed but generally, the crop has been already supported for a major use.)
Data package
(assistance by third body like association, crop industry, ...)

- If applicant company already has residue data to support label extension and requirement for MRL are respected, a third body can submit a Art. 53 dossier, mentioning that risks evaluation are already covered (with only showing only data Efficacy fir this use and residue (see data package above) been already supported for a major use.
Costs

- In terms of price, this varies by MS. In the UK the fee will be approximately £4k or approx 2K€, (fee, plus co-ordination fee, plus off label fee)
- + approx 20 – 50 K€ for efficacy trials data package
- + approx 100 K€ for residue trials data package
Any question?

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Thank you for your attention!