

MINOR USES REGISTRATION IN EU

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Topics

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



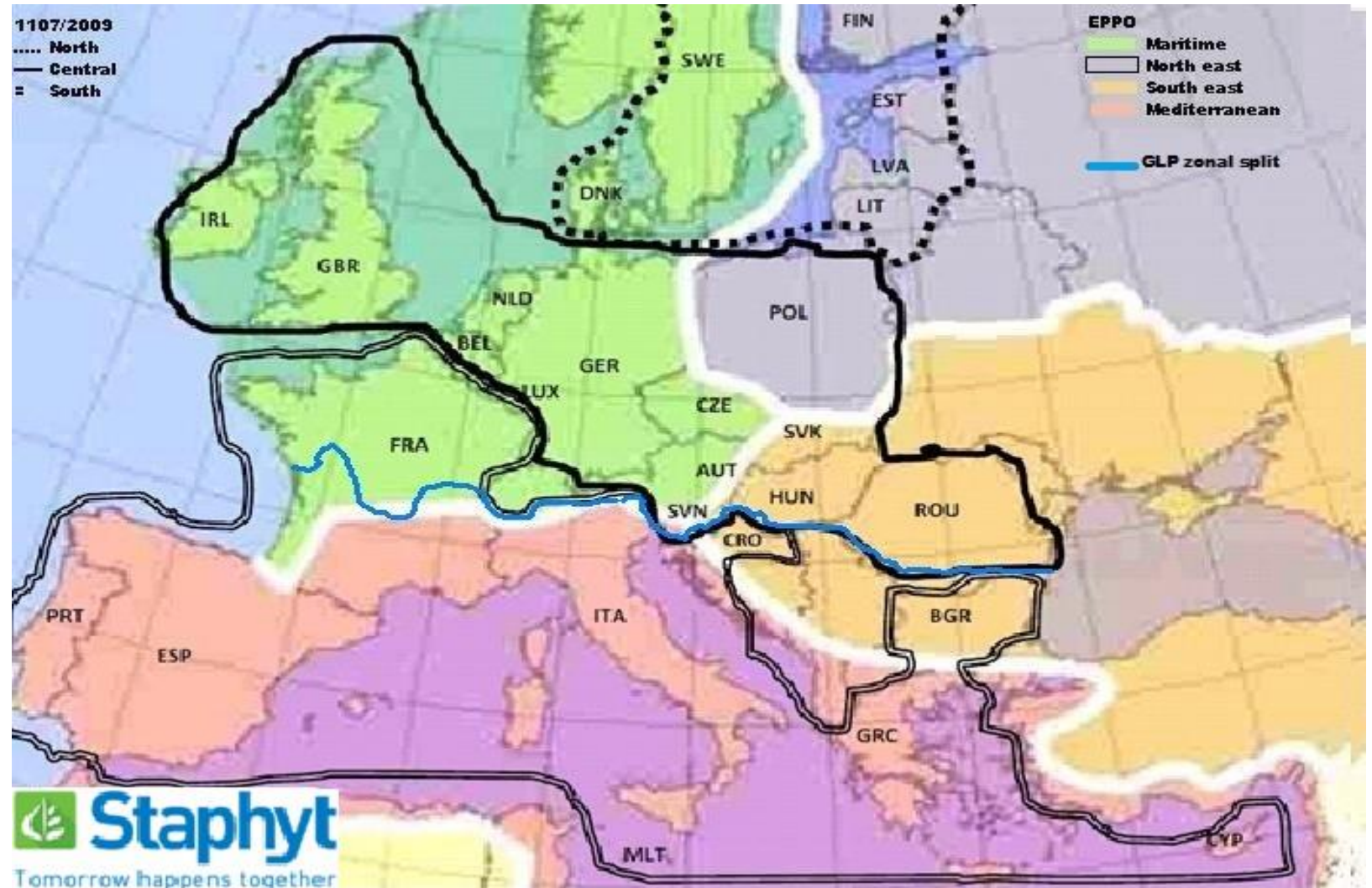
General Regulatory frame

- Registration in EU belongs to Directive 1107/2009
- for PPP (including Bio)
- Biocontrols
- Biostimulants
- Exception for fertilizers



Map & Zones

For non protected crops

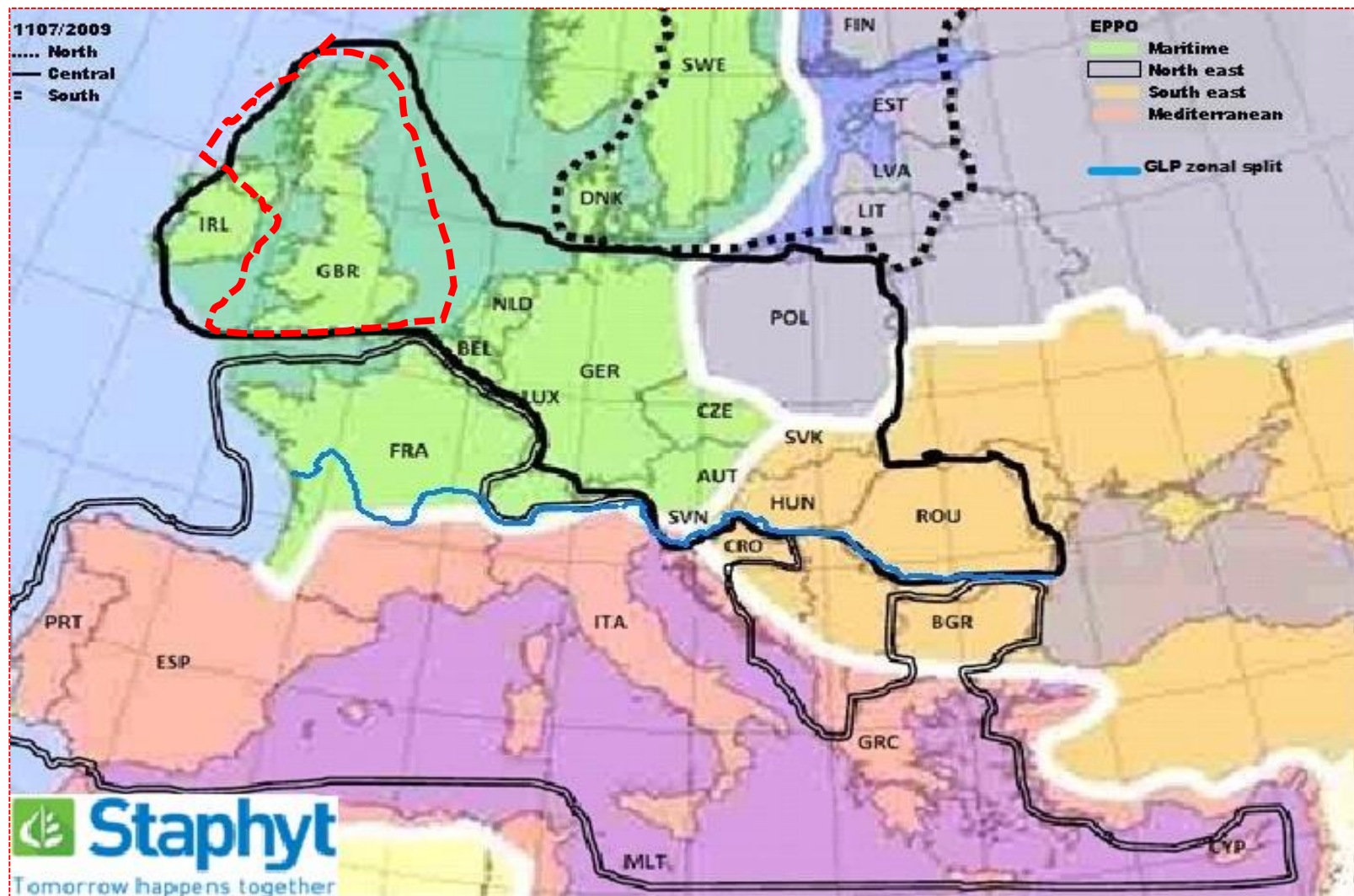


For non protected crops



Map & Zones

depending on Brexit issues, Hard or 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 pachage 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 coordination 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!

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