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Background

- Registration of Plant Protection Products (PPPs) in the EU falls under Regulation 1107/2009
- This Regulation recommends a tiered approach to assess the risk to non-target terrestrial plants (NTPPs)
- Little information is available on:
 - How to perform higher tier studies or
 - How to use them in the risk assessment (RA)
- EFSA will develop a Guidance Document on NTPP RA within two years after the finalisation of the Protection Goals for NTPP by the EU Commission
- In July 2014 EFSA published a Scientific Opinion on the state of the science on the RA for NTPPs

Overall aims of the workshops

- Two SETAC endorsed workshops were organized in April 2014 and in September 2015
- Workshop aims:
 - Discuss higher-tier approaches to assess the risk of PPPs to NTPPs in off-crop areas
 - Promote better understanding among different stakeholders of the state-of the art scientific knowledge relevant to NTPP RA and the sustainable use of PPPs
 - Apply cross-stakeholder understanding to agree on suitable risk management strategies
 - Consolidate scientific, technical and regulatory expertise as input for the further development of robust, reliable and usable NTPP testing and assessment procedures in the EU

Main scientific questions discussed at the workshops

- Is the sensitivity of crop plants protective of wild plants?
- Are vegetative growth endpoints protective of effects on sexual reproduction?
- What options are available for higher-tier NTPP testing?
- How to mitigate risks for NTPPs?



Specific Protection Goals (SPGs) and Ecosystem Services (ES)

- SPGs applied to the in-field/off-crop area depend on the primary purpose of this area:
 - In-crop SPGs for areas whose primary purpose is mitigation of risks of PPPs (e.g. no-spray buffer zones)
 - Off-crop SPGs for areas whose primary purpose is enhancement of biodiversity
- NTPP entity to be protected is the population or higher. Transient effects at a local scale are acceptable for some ES, but there should be negligible effects at either the landscape scale or in protected areas
- "Food web support" is an important ecological function to be protected. No consensus among participants on how to classify "food web support" in the context of ES

Compensation

- Potential role of in-crop NTPPs for sustainability of the food web and provision of habitat acknowledged, but the majority of participants thought that compensation for these ES was not part of PPPs RA
- Compensation for in-crop effects should be defined by risk managers in light of the SPGs
- Several pieces of legislation may be relevant in concert with the PPP EU Regulation 1107/2009 when considering compensation (e.g. sustainable use directive; CAP; habitat directive)

Is the sensitivity of crop plants protective of wild plants?



- The extent to which the species currently tested are protective of wild species was evaluated by comparing the sensitivity of standard and wild species
- Based on an initial analysis of sensitivities of wild versus crop species (Christl, 2015a), testing with standard crop species appears to be protective of wild species
- Additional analyses, performed in response to discussions at the second workshop, have confirmed these initial results (Christl, 2017a)

YES

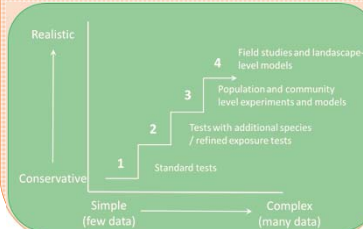
Are vegetative growth endpoints protective of effects on sexual reproduction?

- The extent to which current regulatory endpoints are protective of population effects was evaluated
- Preliminary analysis indicated that reproductive endpoints (R) are on average a factor <2 more sensitive than the vegetative endpoints (V) when comparing the same point estimate (i.e. ER₁₀, ER₂₅ or ER₅₀ each) (Christl, 2015b)
- Analyses on a larger dataset (Christl, 2017b), indicated that extrapolation factors (EFs) from V for young plants to R, maintaining the same point estimate, range from 0.74 to 1.43. Additionally EFs from an ER₅₀ for V for young plants to ER₁₀ or ER₂₅ for R were 6.25 – 8.68 and 2.32 – 3.69, respectively
- Hence R may be covered by applying an appropriate EF to V. However, in cases where R are expected to be much more sensitive than V, reproduction studies may be necessary
- A tiered approach is proposed to cover potential effects on reproduction:
 - Tier 1: V and EF (unless MoA analysis indicates that reproduction is particularly sensitive for that MoA)
 - Higher tier: seed production/germination of annuals and bi-annuals
- Surrogate assessment endpoints for vascular plant reproduction are flowering, seed production and seed germination. Vegetative reproduction is addressed via the biomass tests

- EF from vegetative ER₅₀ can be mostly used
- Reproductive studies may be needed for certain MoA

What options are available for higher-tier NTPP testing?

- Little guidance and experience on field or multispecies studies with NTPPs. Available information was collated.
- Potential higher tier approaches include:
 - Single species tests with refined exposure
 - Test additional species (SSD approach) and/or growth stages
 - Single species, multispecies or plot experiments (greenhouse, semi-field or field-testing)
 - Population/community modelling
- Experimental studies can be in greenhouse or outdoors at semi-field or field level
- Need criteria to evaluate and interpret field studies in the context of SPGs
- Need to define a (surrogate) reference tier to calibrate the tiered approach
 - Some participants suggested that traits could be used. These can be linked to the ES provided by NTPP
- Below approach appropriate for NTPPs effect assessment



How to mitigate risks for NTPPs?

- Need to collate and review available information on different exposure pathways to NTPPs
- Mitigations from MAgPIE toolbox appropriate for NTPPs. Mitigations considered in the context of surrounding landscape
- RA indicates required amount of risk reduction. Individual MS can decide how to achieve this reduction



- Vegetated strips need to be managed for, e.g.
 - Run-off reduction to protect annual/perennial NTPP or
 - Habitat provision for other species
- Management of vegetated strips should be related to SPGs and needs to be regulated in a broader context
- Management of vegetated strips can be part of landscape management for which a broader context of landscape is needed

- MAgPIE toolbox
- Vegetated strips to be managed at landscape level

Outputs

- Report from the 1st workshop: Arts et al. (2015a)*
- Publication with recommendations of the 1st workshop: Arts et al. (2015b)
- Report from the 2nd workshop: Arts et al. (2017)*
- Report comparing sensitivity of crop and wild species: Christl (2017a)**
- Report comparing sensitivity of vegetative and reproductive endpoints: Christl (2017b)**

*: Soon available on SETAC Plant Expert Group webpage
 **: Soon available on Tier 3 homepage

References

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