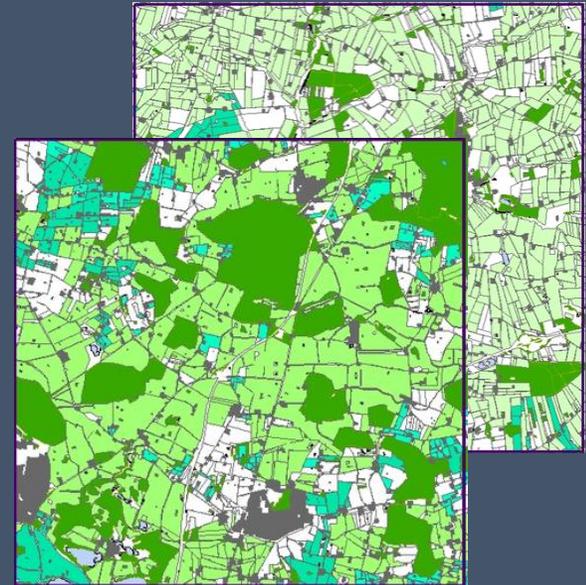
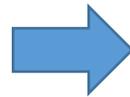
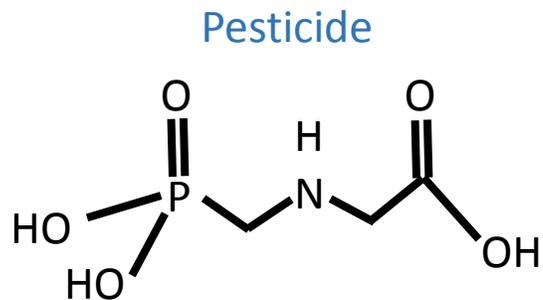


Landscape-scale population-level ERA: Current status and challenges



Focus in ERA is changing

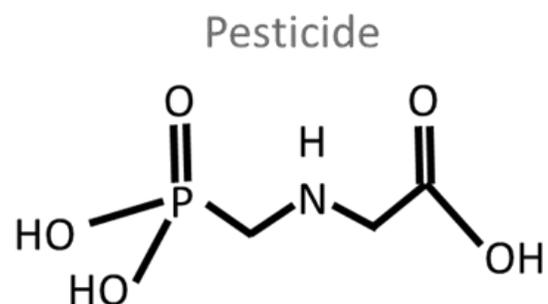
ERA



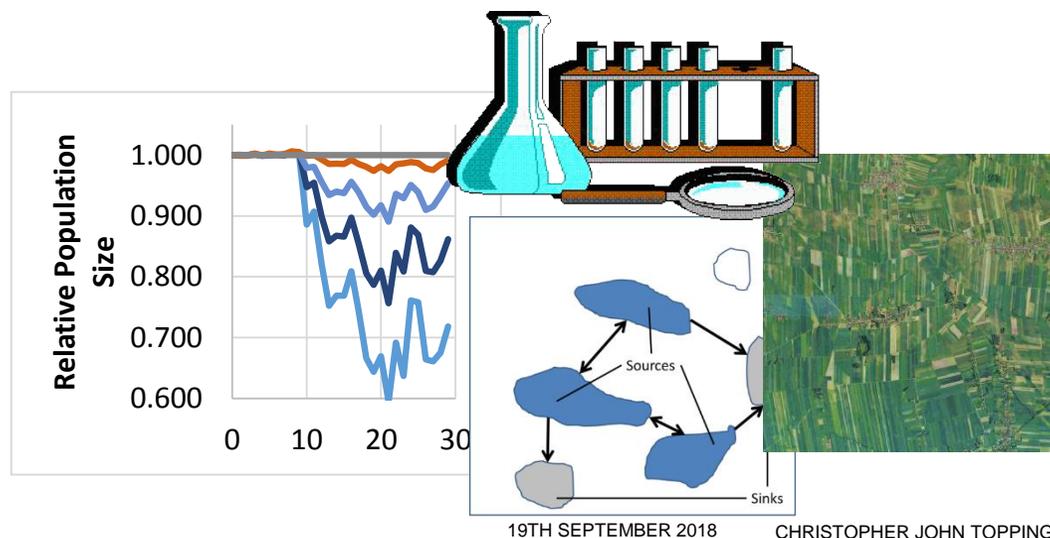
The traditional approach focuses on toxicology and makes generalisations about exposure and fate.

Focus in ERA is changing

ERA



The traditional approach focuses on toxicology and makes generalisations about exposure and fate.



Current and future ERA is much more inclusive of ecology, defines fate and potential exposure in greater detail and takes a **population-level and landscape-scale**.

The 'systems approach'

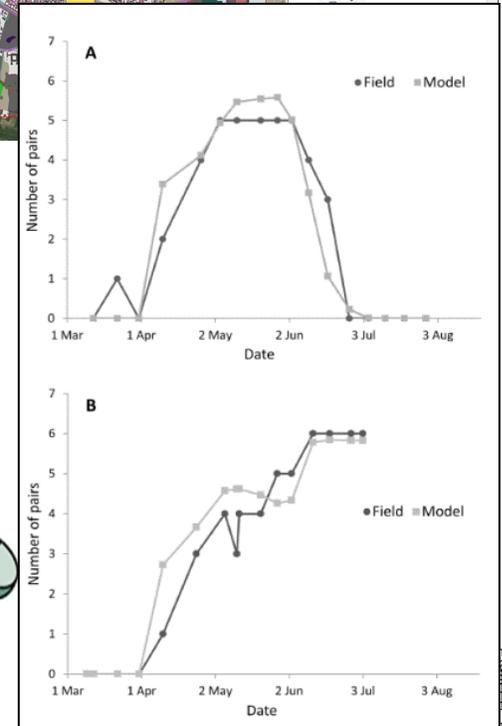
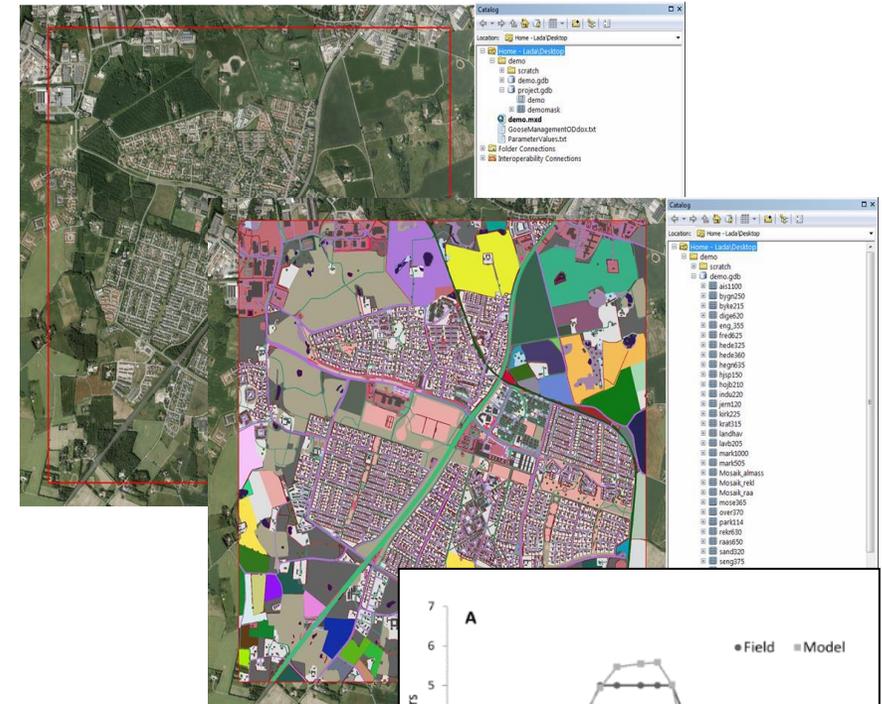
- Views the receiving environment at a larger spatial scale than usual (**landscapes**)
- Includes **multiple stressors** – not just regulated ones
- Has **longer temporal perspective**, includes year-on-year effects
- Is a **spatial** assessment as well as a population-level assessment
- Includes the **connections** between elements of the system



The systems approach will require a fundamental change to the way we carry out ERA

Current capability

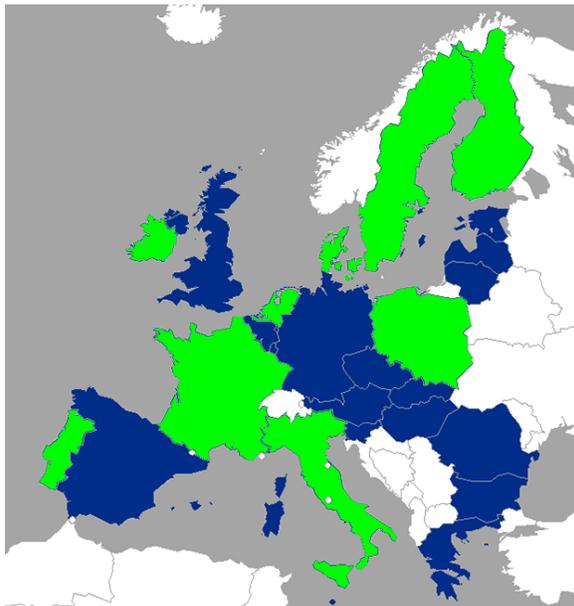
- We have the tools to make fully integrated landscape and population-level assessments
- This includes highly detailed dynamic landscape modelling and agent-based models for animal species



Current tool development status

Focal species models available and ready to use:

- Skylark (*Alauda arvensis*), hare (*Lepus europeaus*), field vole (*Microtus agrestis*) and a carabid beetle (*Bembidion lampros*)
- In development: honey bee, solitary bee, bumblebee, spider, great crested newt, and partridge



National coverage, dynamic landscape models for:

Denmark, Poland, The Netherlands, and underway for Portugal and a further 5 EU countries

Challenges and Opportunities

Opportunities

- **Ecologically realistic** assessment
- **Long-term** perspective
- **Options to tailor** the procedure to local conditions
- **Mitigation** options can be integrated directly

Challenges

- **Conceptual** - ERA process definition
- **Acceptance/use** of the new approaches
- **Technical** - developing the tools
- **Logistical** - resourcing and data provision

Ecological realism brings with it challenges for definition of the ERA process



Opportunities - ecology

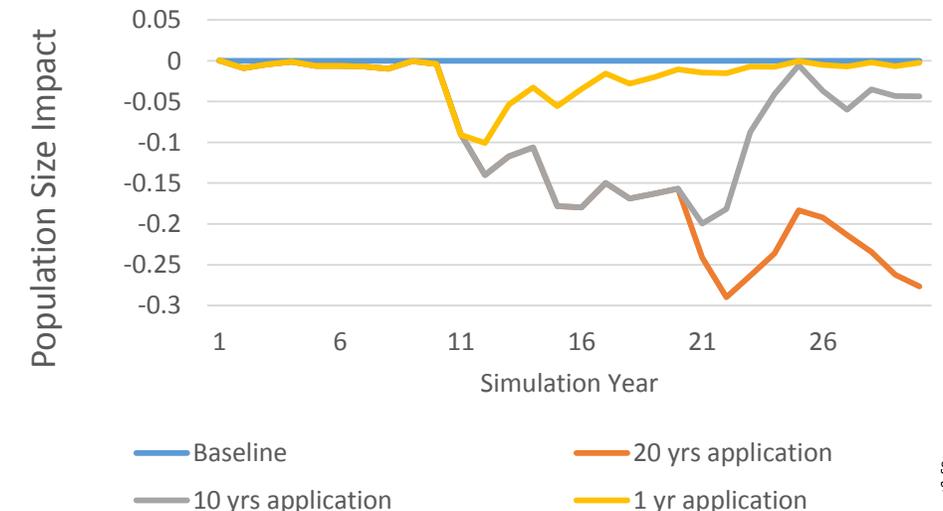
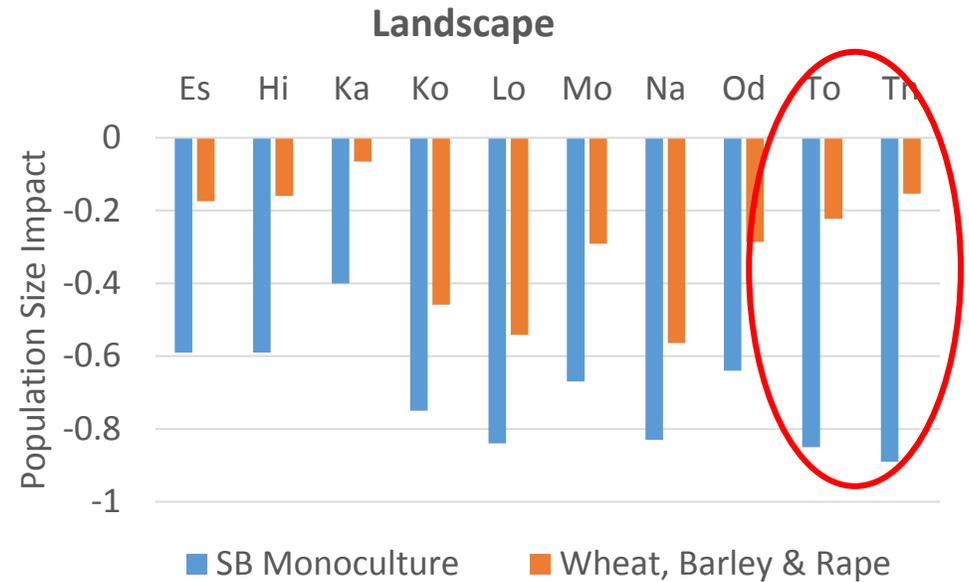
Ecology means including the interactions between components and the context into the ERA.

Here we see simulated impacts of pesticide impacts on newt populations in 10 different landscapes and 2 scenarios.

Landscape composition alters impact and interacts with the scenario.

An example of year-on-year effects and recovery.

Impacts increase with time, recovery can take a long time!



Opportunities - utility

We just saw that landscapes and agricultural systems alter the predicted impact

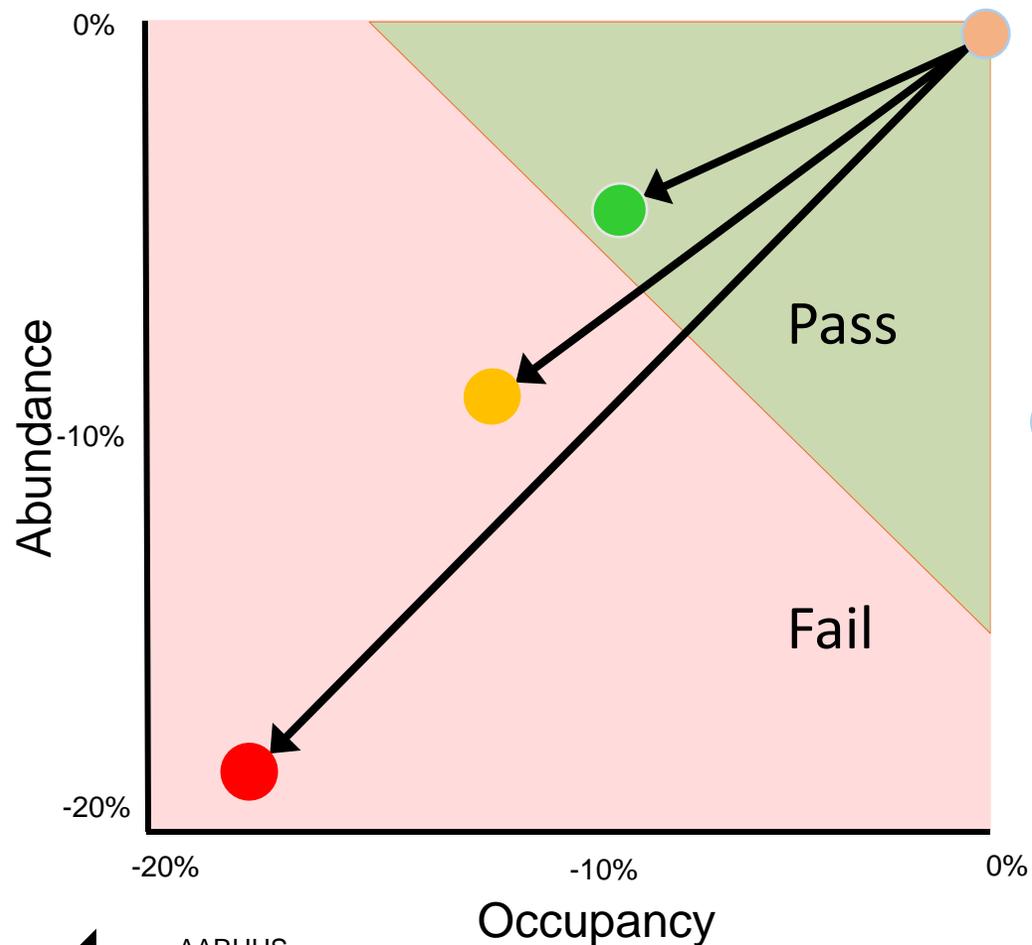
...but this means we can use this fact to tailor ERA to the specific requirements of member states

Systems or locations of particular concern can be simulated directly



Both landscapes are the same size, but otherwise have very different properties

Opportunities - utility



We can also combine the ERA with risk mitigation options using the same tool.

- No pesticide
- With pesticide
- With pesticide + 1m sown field margin
- With pesticide + 5m sown field margin

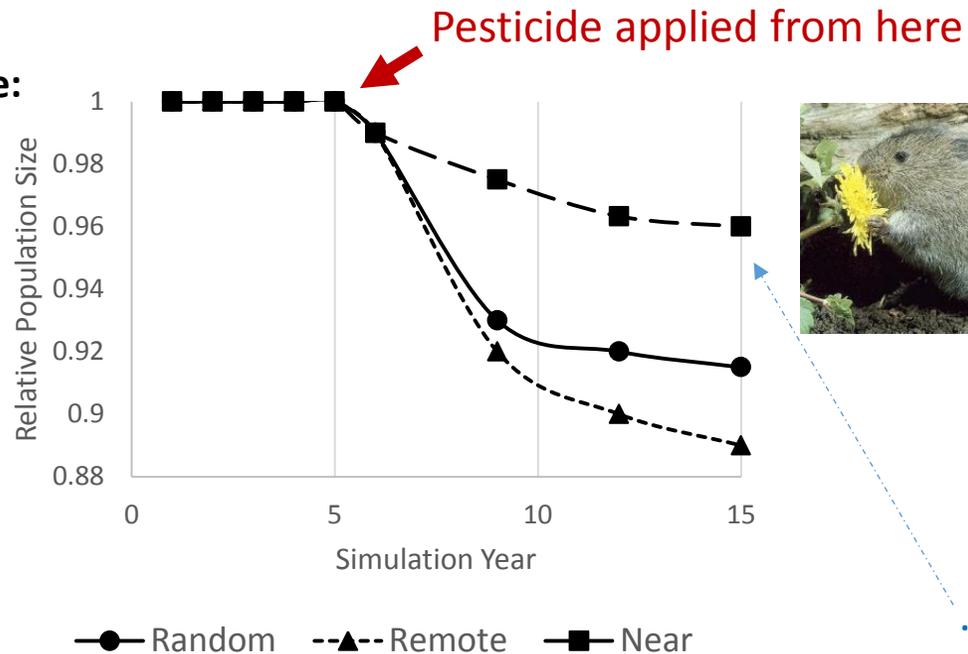
Challenges - conceptual

Protection goal definition

1. What is the metric used to assess impact, what is acceptable?

- Population size change – how much is OK, % or absolute numbers?

An example:



Vole simulation on 10 x 10 km landscape, orchard application of an endocrine disruptor.

Optimal vole habitats randomly distributed, moved near to orchards or moved away from orchards.

Impact as a proportion of the population was greatest when optimal habitat was *furthest* from the orchards

...but the **actual net** population impact was largest in 'Near'

Challenges - conceptual

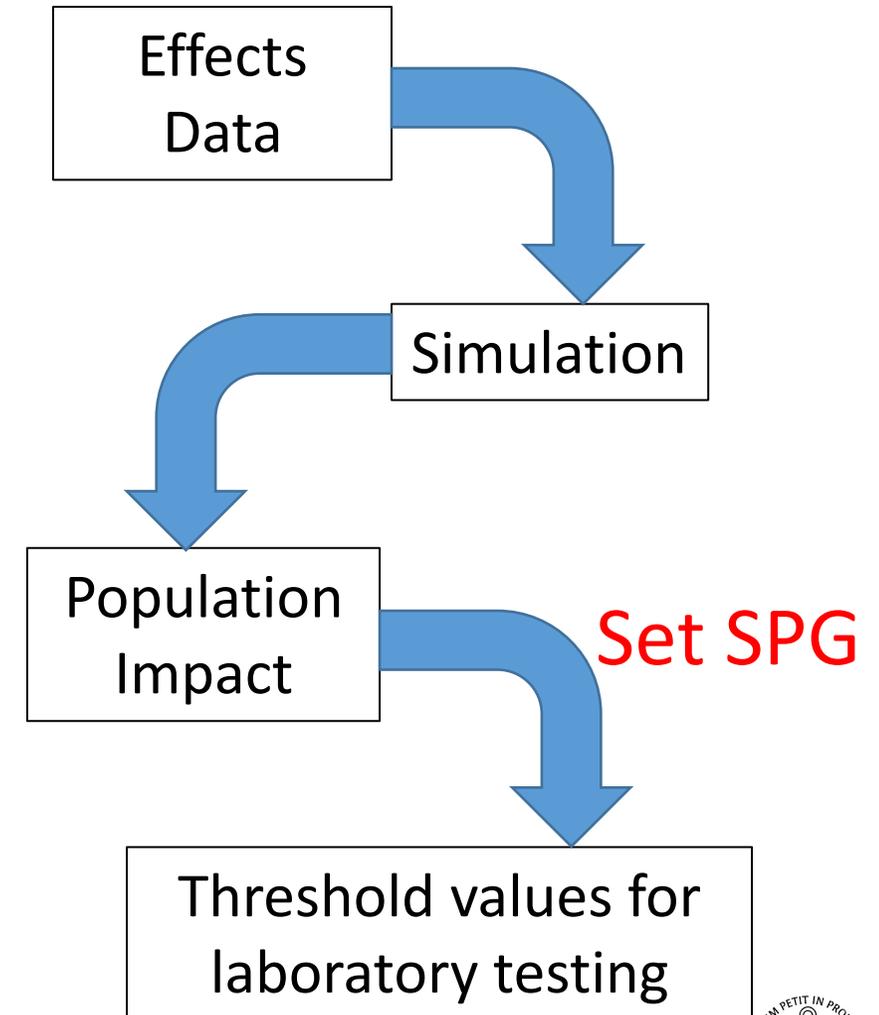
Protection goal definition

1. What is the metric used to assess impact, what is acceptable?
 - Population size change – how much is OK, % or absolute numbers?
2. What species to use – the most vulnerable?
3. What to include in the scenarios – assumptions about agricultural systems other pesticides & which landscapes

However, if we could determine '1' to '3' then we could use the simulation to help with setting the laboratory toxicity thresholds

Opportunities - simulation to set toxicity thresholds

- Simulation, taking the environmental context into account enables prediction of the population impact
- The lab toxicity threshold can then be determined by finding the toxicity level that results in the desired limit of population effects (SPG).

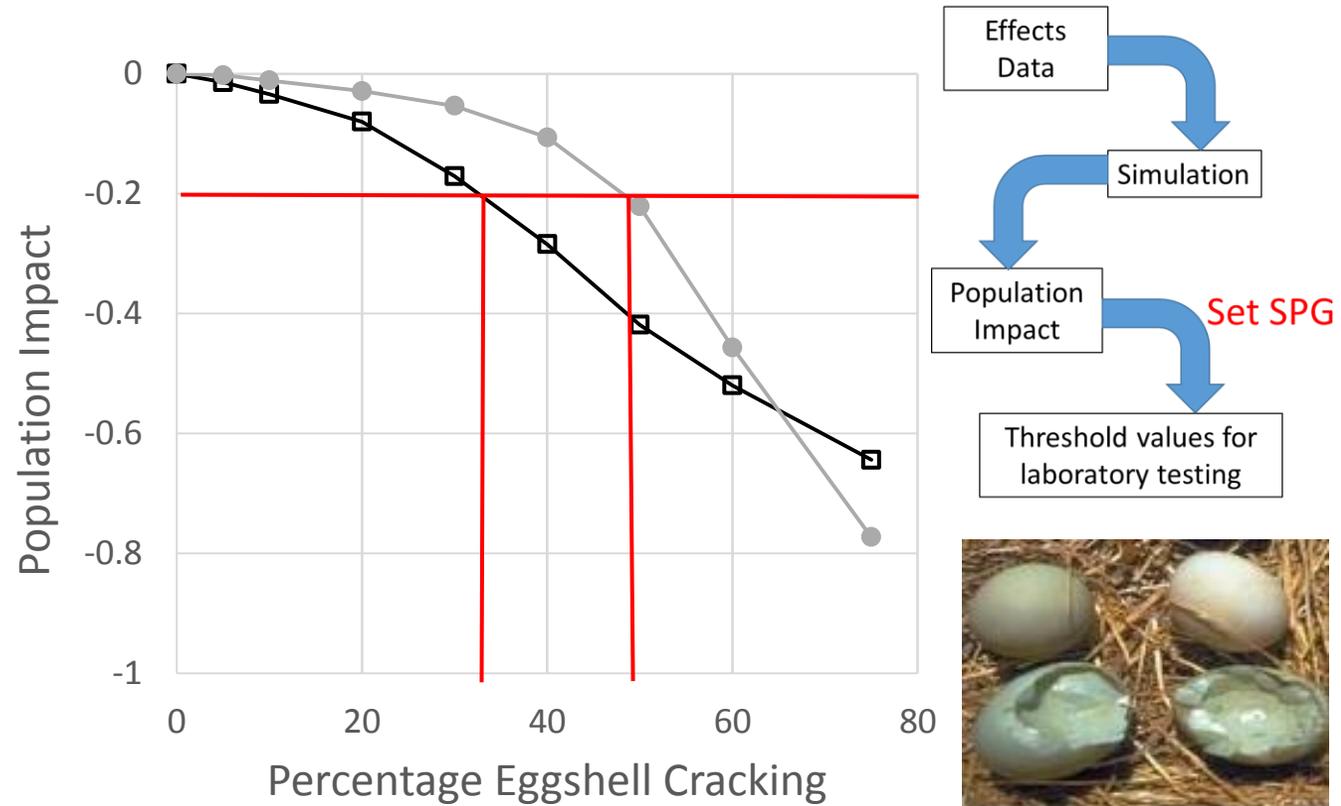


Opportunities - simulation to set toxicity thresholds

Using a realistic worst case scenario including landscape selection, pesticide application timing and two assumptions of distribution of effect.

The toxicity threshold can be set by determining the acceptable population effect.

In this example a 20% impact level translates to a eggshell cracking of 33% assuming the most conservative distribution of effect.

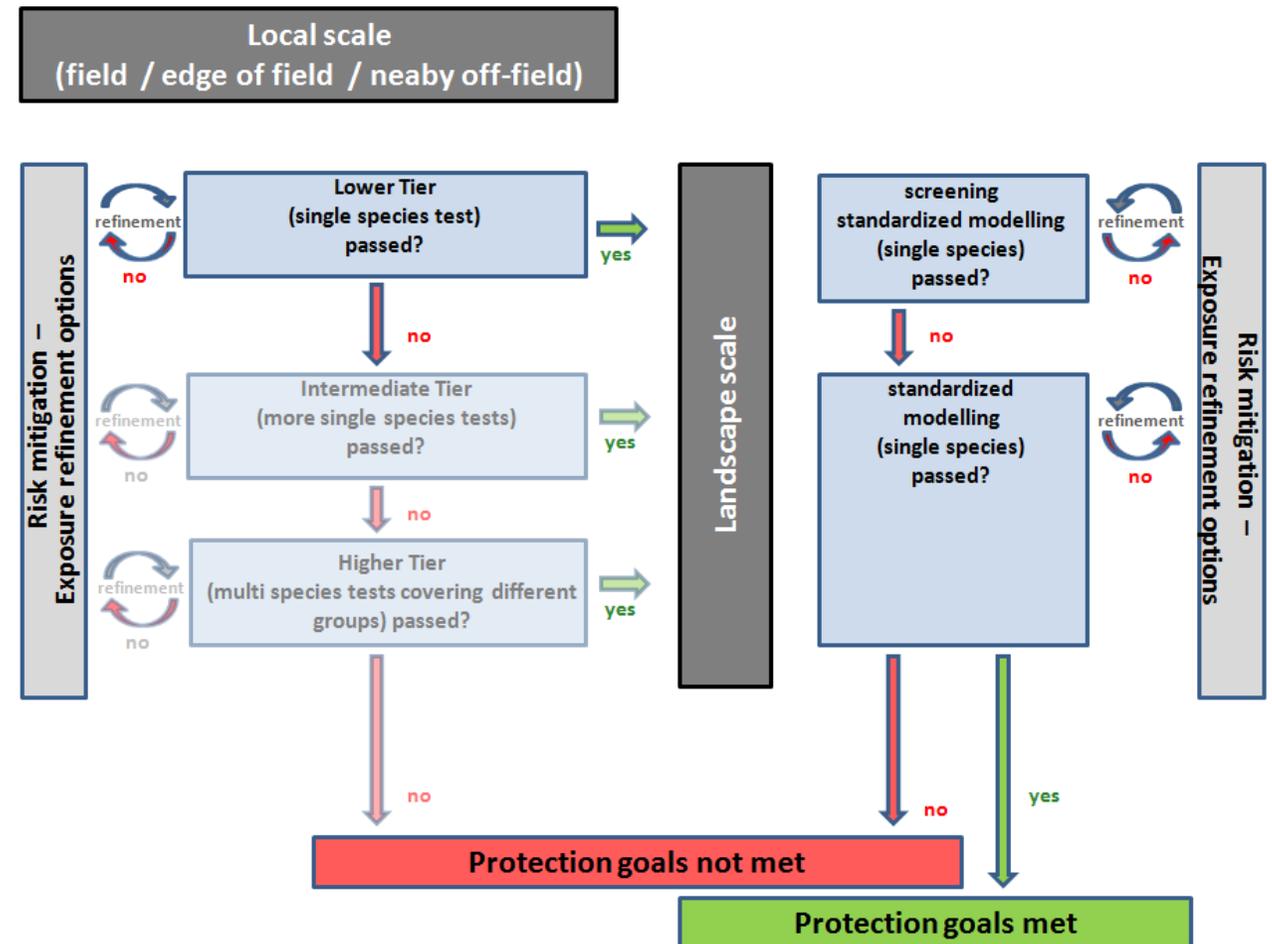


From Topping & Lutik 2017. Regulatory Toxicology and Pharmacology: 89, 40-49

Challenges – acceptance/use

Landscape and systems modelling approaches are recommended in 4 recent EFSA scientific opinions.

However, tools and guidance are not yet provided.



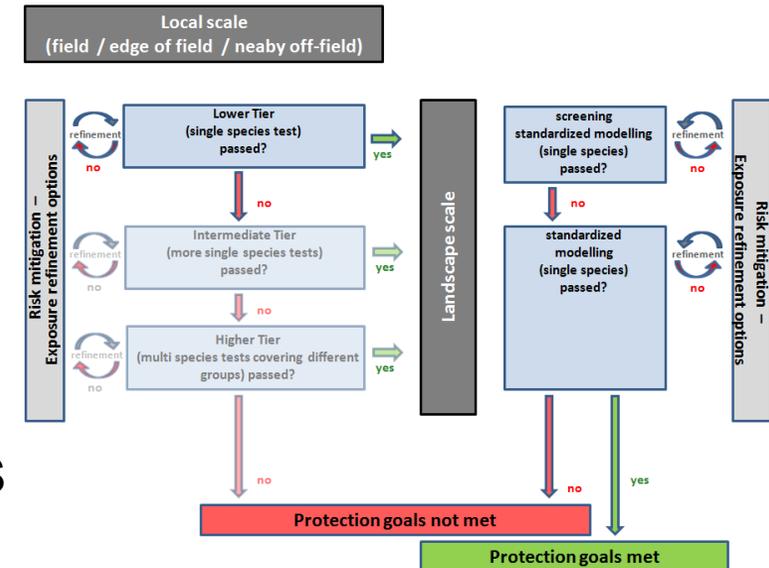
Challenges – acceptance/use

EFSA Implementation strategy

- EFSA PPR panel activity
- Aims to provide **standard** tools for landscape-scale ERA
- This will be done based on what is currently available
 - existing available data through co-operation with JRC
 - existing modelling and concepts e.g. from PERSAM, FOCUS and other ERA models

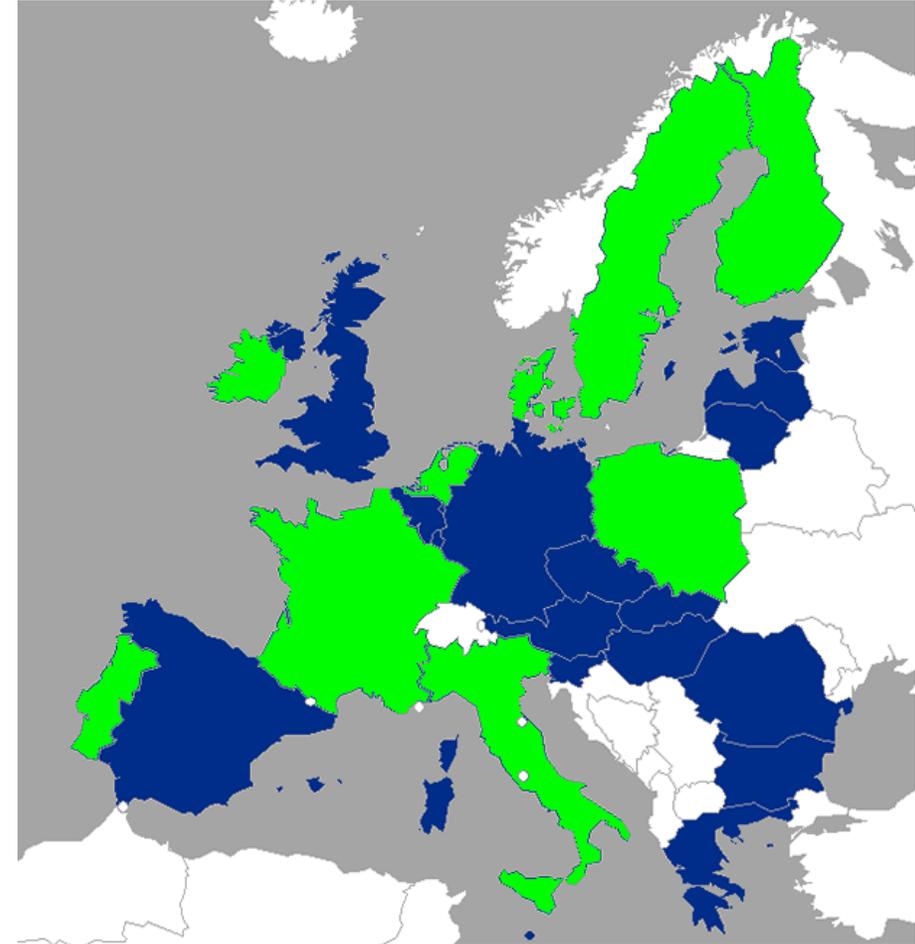
Benefit and anticipated outcome

- To provide risk managers in EC and MSs with tools for landscape-scale ERA for active substance approval and authorisations of PPP
- Develop landscape conditions for use by applicants and MSs in support of higher tier ERA



Future steps

- Development of landscape modelling for the missing EU countries & development and testing of further focal species models
- Expansion to include aquatic systems – requires supporting development of dynamic landscape-scale fate modelling as well as organism models
- Active participation of MSs and other potential users, hopefully part of the EFSA process





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