

Environmental Risk Assessment current assessment and methodologies

An Industry point of view

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25-years of ERA in the EU/ = 25-years of ERA for me



The times before 91/414 We have come a long way

- 'Weird' national testing requirements (Grey and Red-legged partridge)
- Confusion between beneficials/IPM and Non-Target arthropods
- Trout, Carp, Bluegill, zebra-fish, sturgeon
- Testing for classification or for risk assessment
- Relevant risk assessments (LD50/square foot) ?
- PEC/PNEC or TER's
- EU-general chemical assessment factors or PPP specific
- Spray-drift, run-off, other exposure pathways

25-years of ERA in the EU / Achievements in harmonization

- Testing requirements
 - OECD test guidelines
 - SETAC and other learned society testing methodologies
- Risk assessment models
- Risk assessment scenarios
- Protection goals (based on ecosystem services)



25-years of ERA in the EU / Achievements in **Quality** and **Relevance**

■ **Animal testing** – (RRR)

Reduced (for vertebrates) and Refined

■ (Scientific-) **Quality**

Including transparency, reproducibility, robustness and predictability (... EPPO experience)

■ **Relevance**

Most of what we do makes sense to me

- Good coverage of theoretical major pathways for environmental risk
- Monitoring data have not identified any large unaddressed risk

– but we maybe doing a bit too much (pages in dossiers)



25-years of ERA in the EU / The struggle with **complexity**

.....unless it is clearly established through an **appropriate** risk assessment that under **field conditions** no **unacceptable** impact on the viability of exposed species occurs

What is appropriate ? what are field conditions ?
how do you judge acceptability ?

My golden rules:

- ▣ Keep it Simple
- ▣ Accept making decisions on representative scenarios



25-years of ERA in the EU / The Tiered testing scheme

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- Start simple, and add relevance where needed = focus

Did I say ... FOCUS ?

- Best practice example: FOCUS scenarios
 - Tiered/flexible
 - Start simple, add reality/complexity when needed
 - Multi-stakeholder approach = true independent science



25-years of ERA in the EU / Accessible for many

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▣ representative scenarios – FOCUS

Where (some of the) national scenarios were only known to a few, and the modelling skill required to run them at times were high, FOCUS has gone a long way in making ERA's accessible to all, whilst keeping relevance and science at high levels

**Dream big,
work hard,
stay focused &
surround
yourself with
good people.**

25-years of ERA in the EU / Risk Assessment vs Risk communication

How good are we about communicating on our ERA work ?

- Pass/fail = poor result

- > 50 standard environmental safety studies
- > 20 million€ investments
- Multi-year review process



- Informative for risk managers (unacceptable question)

To be able to assess risk vs benefits, a risk management needs more than a simple high/low risk statement

- How severe is the impact if a predicted risk occurs ?
- How wide-spread - single hot-spots or landscape size impacts
- How frequent – at every application or once in 20 years

- Societal acceptance

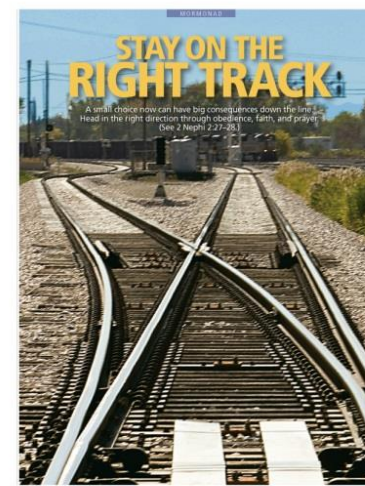
Conclusions?

Many achievements in 25 years of ERA

- Harmonisation of testing
- Tiered Assessment scheme
- Relevant risk assessment scenarios

May need further attention

- Struggle with complexity
- Definition of protection goals
- Risk communication





Thank you!