Optimization Options for Environmental Risk Assessment

G. Peter Dohmen

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Model Building

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Environmental Risk Assessment - Optimization Options
Structure of talk

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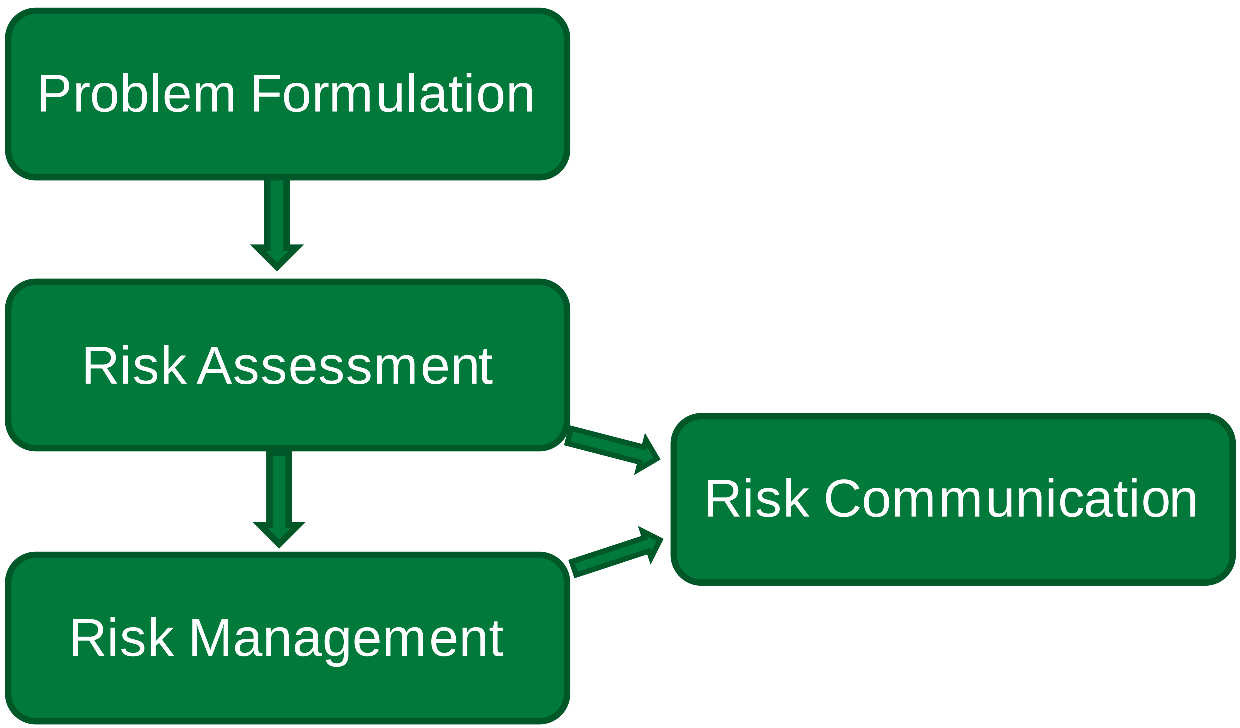
Structure

- Some basic principles
- Protection goals, ecosystem services approaches
- Standard risk assessment models
- Deterministic / probabilistic risk assessment
- Simplicity – complexity; conservatism - pragmatism
- Higher tier options
- Modelling tools
- Landscape scale modelling, risk/landscape management

Environmental Risk Assessment - Optimization Options
Basic Principles

<u>Some basic principles</u>

The risk assessment / management process is generally structured as follows:



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Basic Principles

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Basic principles, general remarks

- ❑ The environment is extremely complex, and we cannot address the full complexity in detail in our assessments

➔ We always use some kind of models to describe risk (model building) starting from very simple TER/RQ calculations
to future landscape level risk assessment models

- ❑ There is always some risk of all or our activities

➔ We need to decide which level of risk we accept and we need risk management to reduce potential risks

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Protection Goals

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- Agricultural food production does necessarily have an impact on the environment; it is a basic principle of agriculture to reduce biodiversity within the cultivated area in order to enhance the yield of the crop we need for food
- This has to be discerned from human risk assessment where a negative impact is not acceptable; however, for the benefit of man we produce food which does impact the environment.

→ Demanding “no effect” from agriculture on the environment is unrealistic. This is equally true for all tools used to support food production, regardless whether for example mechanical or chemical methods are used to reduce weed competition. However, minimize side effects

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Protection Goals

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- Thus robust and efficient regulatory risk assessment procedures **require clear protection goals** specifying what to protect, where to protect it and over what time period.

→ First identify what to protect where and when before developing risk assessment models and testing guidelines (optimization of risk assessment process)

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Protection Goals

- The Ecosystem Services Approach is a useful tool to define the overall and the specific environmental protection goals, trying for an optimal balance between food production and environmental protection.

Dimensions and parameters of ecosystem services to select specific protection goals:

Dimensions	Options
Ecological entity	Individual – (meta)population – functional group – community – ecosystem – habitat
Attribute	Behaviour – survival – growth – reproduction – abundance – biomass – process – within and between species diversity – landscape or habitat structure
Magnitude	Negligible – small – medium – large
Temporal scale	Days – weeks – months – seasons – years – decades – generations – rotations
Spatial scale	In crop/field – edge of field/field margin – nearby off-crop – protected area – watershed – landscape – region – continent

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Protection Goals

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Ecosystem Services

- It is obvious that not all ecosystem services can be fully protected everywhere at the same time
- Thus, one needs to find appropriate balance between the various ecosystem services and implement respective risk management
- This can also include spatial temporal considerations (e.g. restrict agriculture and agricultural chemicals mainly in certain areas (at certain times) and avoid contamination to unintended areas)
- Standardizes models/tools which allow such balanced assessments of the different ecosystem services in a more quantitative way are not yet available

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Standard environmental risk assessment models

- Hazard identification, i.e. the **determination of toxicity**

- **Paracelsus** (1493 – 1541): **The dose makes the poison.**

"Alle Ding' sind Gift und nichts ohn' Gift; allein die Dosis macht, das ein Ding kein Gift ist.“

(“All things are poison, and nothing is without poison; only the dose permits something not to be poisonous.”)

!

Dose/concentration-effect relationship is a basis of (eco)toxicological testing

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- Toxicity, however, is only one part of the equation in Risk assessment and, considered in isolation, does not provide the required information needed for decision making

Risk = **Hazard** (Toxicity) **x** **Exposure**

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Standard Risk Assessment Models

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Toxicity

- In principle is a substance inherent property
  (considering certain system inherent properties)
- Toxicity determination generally done using internationally accepted standardized ecotoxicological guidelines (e.g. OECD) using surrogate, sentinel species
- Results generally expressed using standardized and defined endpoints such as **$L(E)C_{50}$** and **NOEC**

Standard Risk Assessment Models

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Exposure Assessment

In field: direct assessment based on application rate

Off-crop: assuming contamination via
- o Drift
- o Run-off
- o (drainage, dust, volatilization...)

Exposure models generate predicted / estimated environmental concentrations **PEC** **EEC** values for the different environmental compartments

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Standard Risk Assessment Models

- For water exposure calculations the EU uses <u>FOCUS</u> scenarios/models
  The US currently considers the <u>PWC</u> (Pesticide in Water Calculator)

- The overall environment is extremely diverse with all kind of aquatic systems from temporary puddles in the field to large lakes and rivers distant from agricultural uses

- Cannot cover all in detail, thus scenario definition is important

➔ Scenarios should be sufficiently worst to cover most relevant aquatic ecosystems, but also need to be pragmatic
Consider risk management and implementation options when defining the type and the number of different scenarios

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Standard Risk Assessment Models

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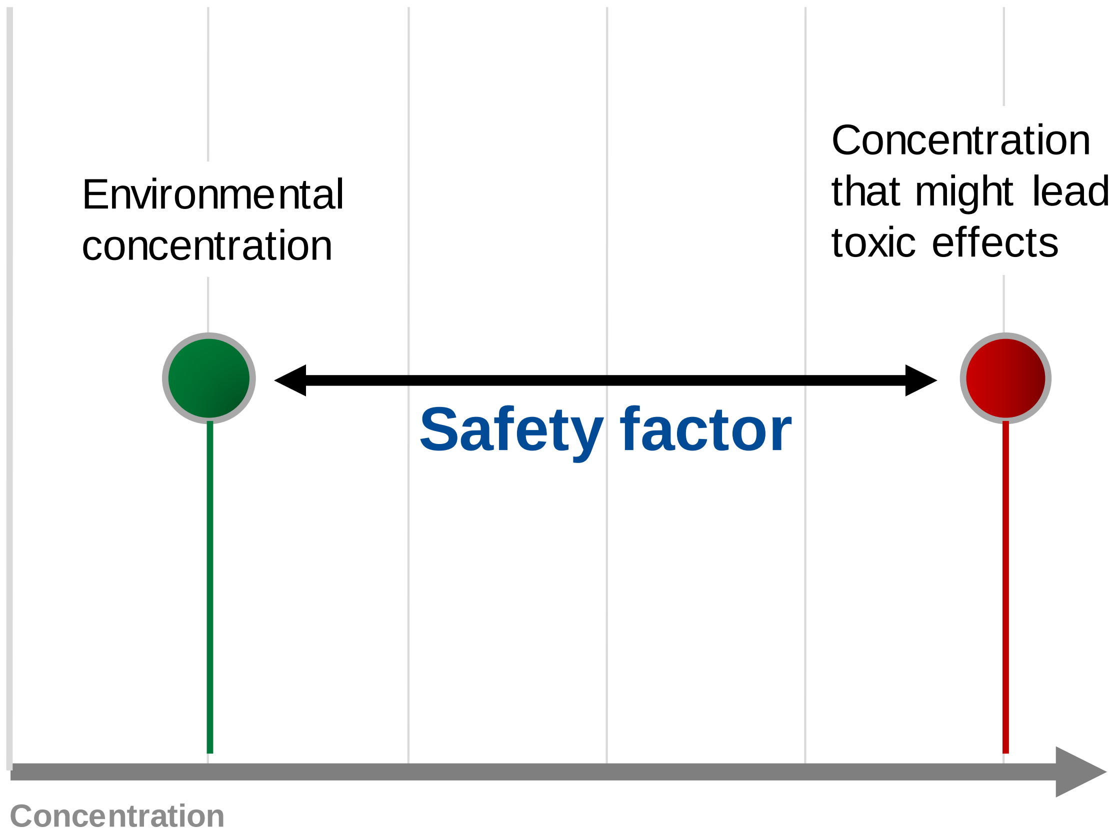
Risk Assessment (deterministic)



Toxicity Exposure Ratio

$$\mathbf{TER} = \frac{\textbf{Toxicity}}{\textbf{Exposure}}$$

$$\frac{\text{LC50/NOEC [mg/L]}}{\text{PEC [mg/L]}}$$

Risk Quotient

$$\mathbf{RQ} = \frac{\textbf{Exposure}}{\textbf{Toxicity}}$$

$$\frac{\text{EEC [mg/L]....}}{\text{LC50/NOEC [mg/L]}}$$

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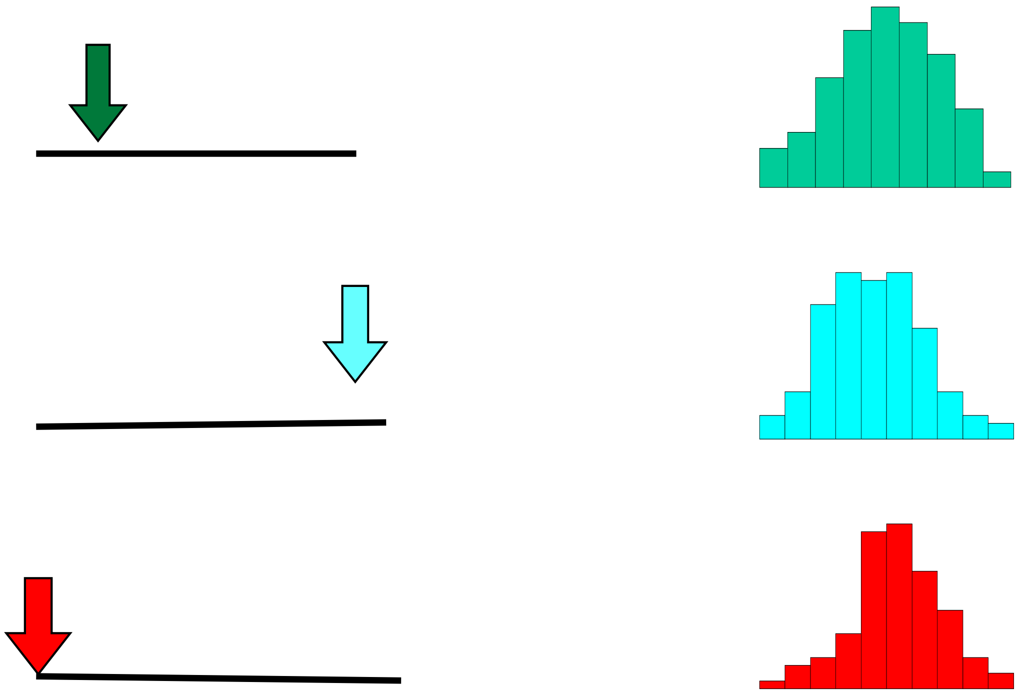
Deterministic / probabilistic risk assessment

	Deterministic	Probabilistic
Toxicity		
Exposure		
TER		



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Deterministic / probabilistic risk assessment

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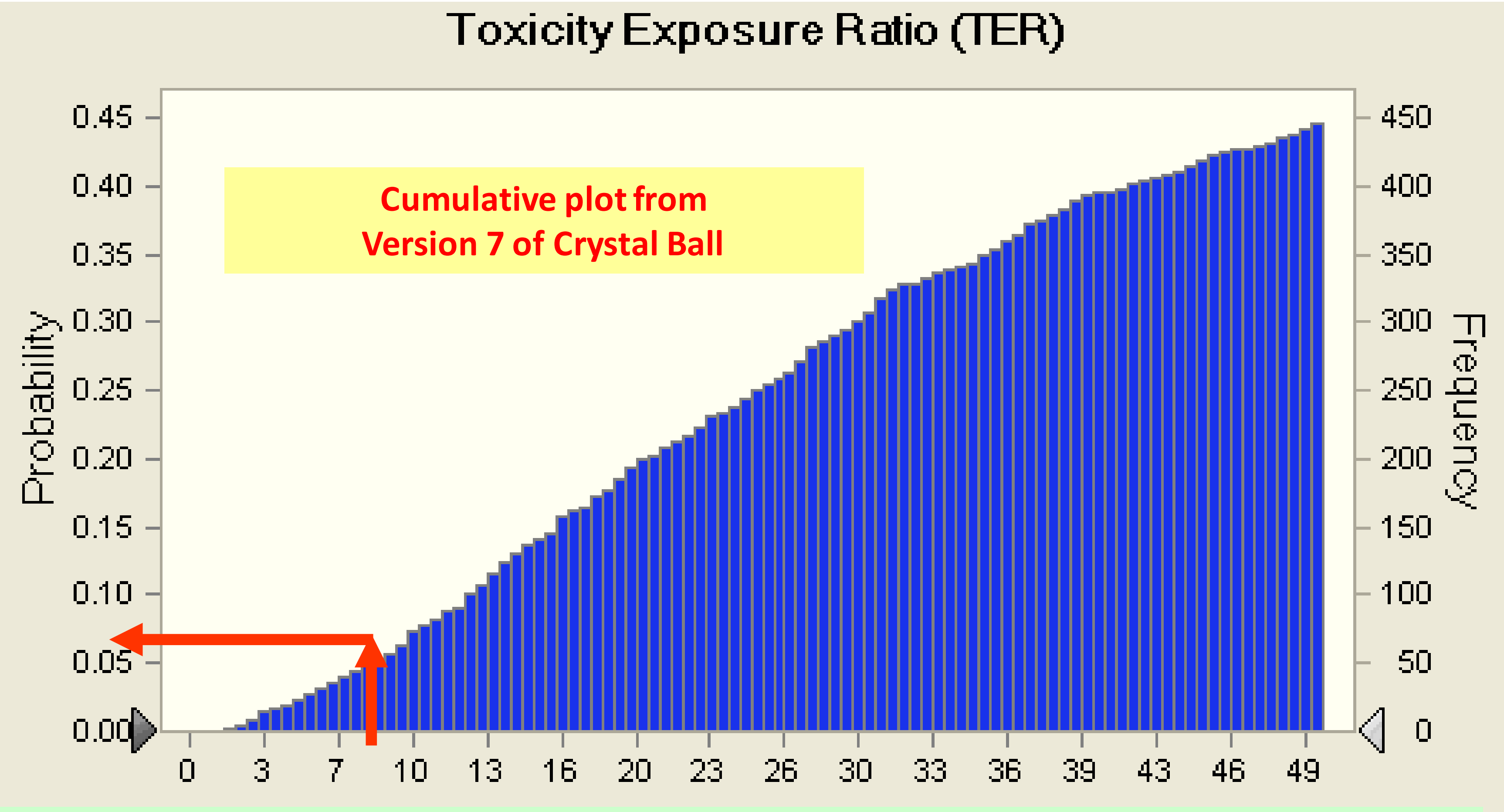

7% of exposure/species combinations give TERs below 10

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Deterministic / probabilistic risk assessment

Deterministic risk assessment

- Compares 2 values, e.g. lowest NOEC and highest PEC, providing a single TER, RQ
- Does not really allow a proper quantification of risk
- Is easy to use and communicate

Probabilistic risk assessment

- Uses all data (not only a single NOEC and single PEC)
- Quantifies variability and to some extent uncertainty
- Allows a better risk quantification (more realistic assessment)
- But does not provide simple (yes/no) answers
- Generally needs more data and expertise

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Simplicity – complexity; conservatism - pragmatism

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<u>Tiered Approach</u>

Most efficient way for environmental risk assessment

- Start with a limited set of data and assumptions and apply required assessment factors and only need to proceed to higher tiers if the first tier does not allow to exclude a relevant risk
- Thus uncritical compounds, areas, can be early identified with limited efforts in lower tiers
- However, initial tiers do not provide a realistic indication of an actual risk, i.e. they should be protective, but they are not predictive

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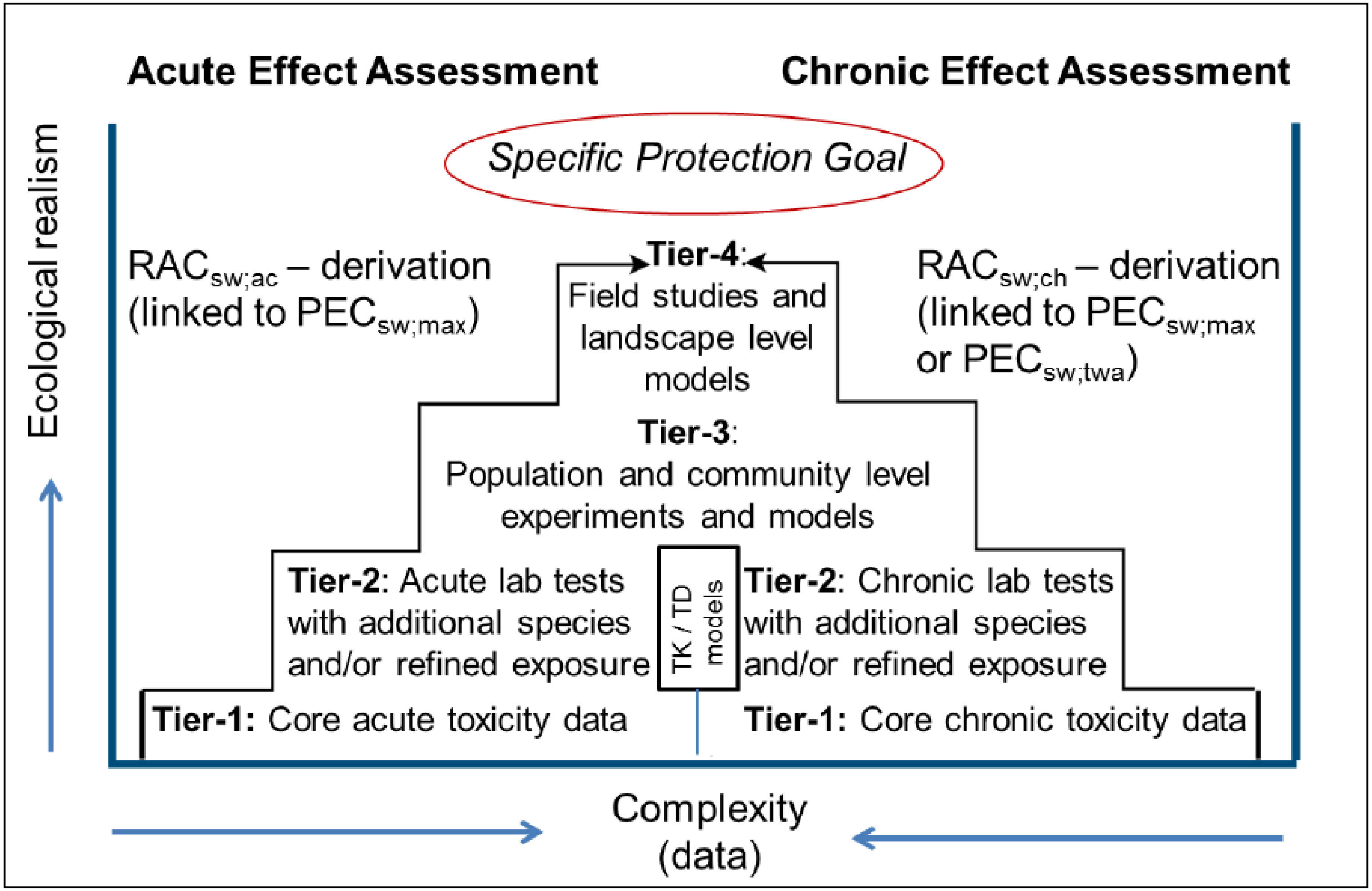
Simplicity – complexity; conservatism - pragmatism

Tiered approach in the EU aquatic guidance document



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Tiered Approach

- The tiered system requires sufficiently conservative assumptions / assessment factors in lower tiers to exclude false negatives with a high level of certainty
- The relevant factors were partially derived empirically
- There are trends to make lower tiers more (over)conservative based on theoretical combinations of a number of worst case situations
- Instead, the applicability of the tiered system should be calibrated against realistic environmental scenarios

➔ Avoid unnecessary overconservative assumptions in tier 1 else it becomes meaningless

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Simplicity – complexity; conservatism - pragmatism

Tiered Approach

- Lower tiers are based on a limited data set; thus, large uncertainties remain, for example
  - Sensitivity differences between species
  - Sensitivity and relevance of other endpoints (next to mortality, growth, reproduction)
  - Effects under more realistic variable exposure conditions
  - Combinations with other stressors
- Higher tier studies target to address these uncertainties
- Reduction of uncertainties allows reducing assessment factors

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Tiered Testing Scheme

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Tier I

Higher Tier

Realism
Complexity
Cost

Uncertainty

Laboratory

Extended Laboratory

Semi-Field

Field/ Mesocosm

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Higher tier options

- Higher tier options to reduce uncertainties should generally consider the main uncertainties remaining (problem formulation)
- Frequently utilized higher tier options include:
  - Testing of more species
    - 2-4 species to calculate a geomean endpoint
    - $\geq$ 5 species to provide a species sensitivity distribution
  - Testing under more realistic test conditions
  - Population, community level studies
  - Ecosystem, mesocosm, field studies

→ Process is fostered if the problem is clearly formulated and solutions are agreed together with the evaluating authority

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Simplicity – complexity; conservatism - pragmatism

Simple, practical versus laborious, complex

- Complexity requires high level of expertise
- Lack of expertise leads to uncertainties
  ➔ additional requirements, safety margins

" IT LOOKS LIKE THEY'RE BRINGING IN THE NEW REGULATIONS MANUAL."

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Simplicity – complexity; conservatism - pragmatism

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Simplicity - complexity

- The tiered testing approach starts rather simple, only if needed moves to more complex steps
- Similarly risk assessment guidelines should be sufficiently easy to use and should restrict itself to the necessary level
- There are already many data, guidelines, methodes available, make use of those unless there is a clearly justified need to deviate

Principle: Keep risk assessment process simple when possible and proceed to more complex assessment only if needed
- utilize available data / information methods; avoid redoing

Environmental Risk Assessment - Optimization Options
Modelling tools

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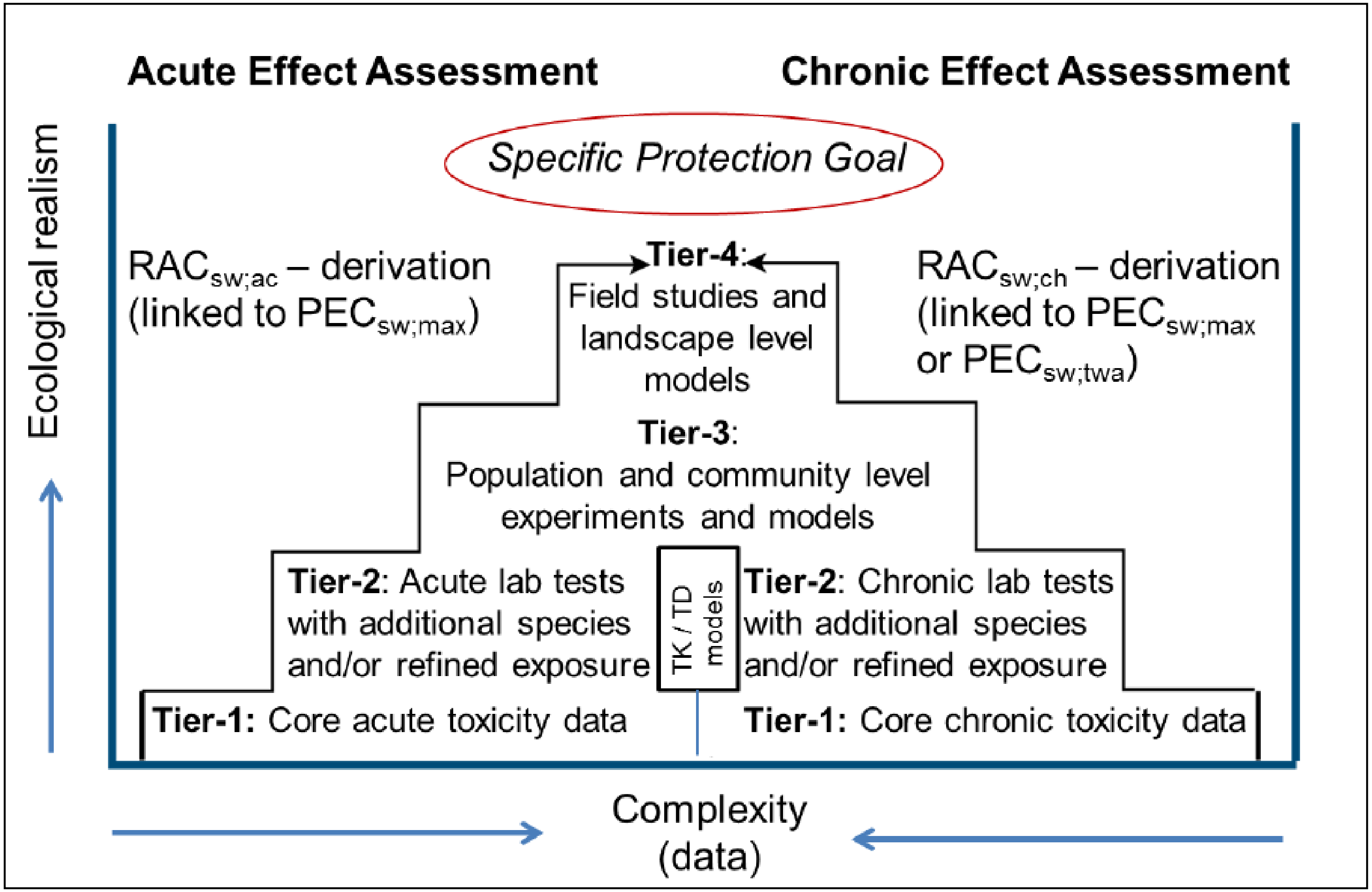

Environmental Risk Assessment - Optimization Options
Modelling tools

Models

- In a broader sense, standard RA procedures like the use of TER or HQ for decision making are assessment models
- In a narrower sense, mechanistic, statistical models provide information beyond the data derived from ecotoxicological testing
- It is neither possible nor meaningful to consider each and every option in ecotoxicological studies.
  Models can be used to extrapolate experimental results to a whole range of different conditions, such as impact and recovery under different temperatures or combinations of stressors.
  They can inform risk managers on the need/ appropriateness of risk management options.

Modelling tools

There are a number of models available / in development, serving different purposes

- Statistical methods/models
  - Simple such as use of mean or geomean (base RA not on lowest endpoint, but on geomean since more species tested)
  - Species sensitivity distribution (SSD)
    reduces significantly a main uncertainty, i.e. the representativity of the endpoint of the tested species for other species

    Two standard accepted models/methods
    - E_TX 2.2 http://rivm.nl/rvs/Risicobeoordeling/Modellen_voor_risicobeoordeling/ETX
    - MOSAIC http://pbil.univ-lyon1.fr/software/mosaic/ssd/
  - Probabilistic assessments, JPC (e.g. E_TX)

Environmental Risk Assessment - Optimization Options
Modelling tools

Models available / in development

- ❑ Eco(toxico)logical models
  - o QSARs

    Quantitative structure activity relations, e.g. USEPA ‘ECOSAR’
  - o TK/TD models

    Toxicokinetic-toxicodynamic (TKTD) models quantify the time-course of internal concentration (uptake, elimination, metabolism TK), and processes leading to toxic effects (TD). TKTD models show potential in predicting pesticide effects in fluctuating concentrations.
  - o GUTS, DEBtox

    The General Unified Threshold model for Survival (GUTS) integrates previously published toxicokinetic-toxicodynamic models and estimates survival with explicitly defined assumptions taking time-variable exposure to the stressor into account. DEBtox is also a TKTD approach, but deals with a whole range of organism responses (not only mortality but e.g. growth, reproduction).

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Modelling tools

Models available / in development

- ❑ Eco(toxico)logical models
  - o IBMs, MEMs

    Individual based (IBM), mechanistic effect models (MEMs) enable the integration of population-level effects beyond exposure and effects, thus increasing the ecological relevance of risk assessments as well as providing vital understanding of how chemicals interact with ecosystems; this is impossible to fully address empirically
  - o MASTEP

    An individual based model to assess impact and recovery of aquatic invertebrates following pesticide stress
  - o Chaoborus model, IDamP – *Daphnia magna* model

    Individual based models to assess impact and recovery of *Chaoborus crystallinus* and *Daphnia magna*

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Modelling tools

Models available / in development

- ❑ Eco(toxico)logical models
  - o BEEHAVE
    BEEHAVE is a mechanistic effect model to simulate the development of a honeybee colony in different landscapes. It allows multiple stressors of honeybee colonies within a hive and in the landscape to be represented, either alone or in combination, and pesticide-induced losses of honey bees.
  - o ALMaSS
    A landscape-scale simulation for terrestrial population modelling and environmental risk assessment (a complex spatially and temporarily explicit mechanistic IBM considering many parameters in a realistic landscape)

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Modelling tools

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- Many models are available
- However, in practice so far still of limited use in the EU due to
  - Lack understanding (and thus trust) of models by risk assessors
  - Need for additional competences
  - Difficult to “validate” models
    full validation as such not possible, however, testing of models to show their applicability
- Therefore, authorities in the EU request the development and ‘validation’ of an accepted modelling tool box and training in its uses

➔ Modelling provides many promising tools for environmental risk assessment; some models are ready to be used; further co-operation needed to establish more extensive tool box in future

Next level:

Landscape scale modelling, risk/landscape management

- The current risk assessment is quite generic
- The landscape, on the other hand, is very diverse
- Its vulnerability to agriculture and pesticide impact differs in space and time
- There are also different levels of protection needed in different places and at different times
- Since computation options are large, this may also be used to optimize agricultural production and to improve risk assessment and management of pesticides

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Landscape scale modelling, risk/landscape management

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What is needed for LRA:

- High resolution maps including all relevant spatial elements
  - Landscape structure
  - Soil structure / surface water information (depths, width, flow etc.)
  - Climatic data
  - Application scenarios for different crops and regions
- Information on the biology (growth, reproduction, feeding, movement patterns etc.) of vulnerable key driver species and their distribution within the landscapes
- Spatially explicit mechanistic models integrating exposure and population modelling
- Specific protection goals for landscape level assessments

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Landscape scale modelling, risk/landscape management

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What is available for LRA:

- High resolution maps partially available
- Information on the biology of relevant species and their distribution within the landscapes is rather limited
- Some models being developed; however, need testing and reality checks
- To start it will be helpful to have environmental scenarios as prerequisite of model application
- We are at an early stage of development and full scale landscape level risk assessment will take many years before becoming operational

LRA is a promising tool in future and will help to optimize agricultural production and improve risk assessment and management of pesticides; Chinese scientists could get involved early and adapt to Chinese situations and needs

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Summary and Conclusions

- The production of sufficient high quality food as well as the protection/ improvement of environmental quality are top priorities also in China
- These goals have been endorsed in the recently released guidelines on "green development in agriculture, setting goals for resource conservation and environmental protection"
- I am convinced that it will be possible to achieve both targets, if agricultural practices are regulated / managed wisely
- Considering principles of integrated crop management, this encompasses the use of all available tools including chemical tools in an optimized way
- Ecosystem services provide a unifying framework for risk assessment and management and are a basis for setting respective protection goals.

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Summary and Conclusions

- Next to appropriate Risk Assessment, this will equally require Risk Management, the implementation of those measures and communication
- In addition to environmental risk assessment and management there is the urgent need for
  Landscape management
- Not each area is equally suited for efficient crop production and for high biodiversity spots
- Actually, often areas most interesting for biodiversity (wet areas, dry nutrient limited areas) are least suitable for agriculture.
- Using land in an optimized way (e.g. set aside some area for biodiversity) allows to combine high crop production and a more biodiverse and beautiful countryside

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<u>Summary and Conclusions</u>

- To optimize ERA, learn from what is available and learn from mistakes, but don't repeat similar mistakes, and don't re-invent the wheel (e.g. use available data, guidelines, information)

As previously stated:

- First identify what to protect where and when before developing risk assessment models and testing guidelines to optimize risk assessment process
- Be sufficiently protective, but avoid unnecessary overconservative assumptions in tier 1, else it becomes meaningless

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Summary and Conclusions

- Risk assessment process is fostered if the problem is clearly formulated and solutions are agreed together with the evaluating authority
- Don’t overcomplicate; keep risk assessment process simple when possible and proceed to more complex assessment only if needed
- Modelling provides many promising tools for environmental risk assessment; co-operation needed to establish appropriate tool box
- LRA is a holistic approach beyond just looking at pesticide ER requiring also more competencies; but it is a promising and important tool in future and will help to optimize agricultural production and improve risk assessment and management of pesticides


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Thank you
for your attention