



# THE ENVIRONMENTAL RISK ASSESSMENT OF BIOCIDES

REGULATORY CHALLENGES AND  
SCIENTIFIC SOLUTIONS



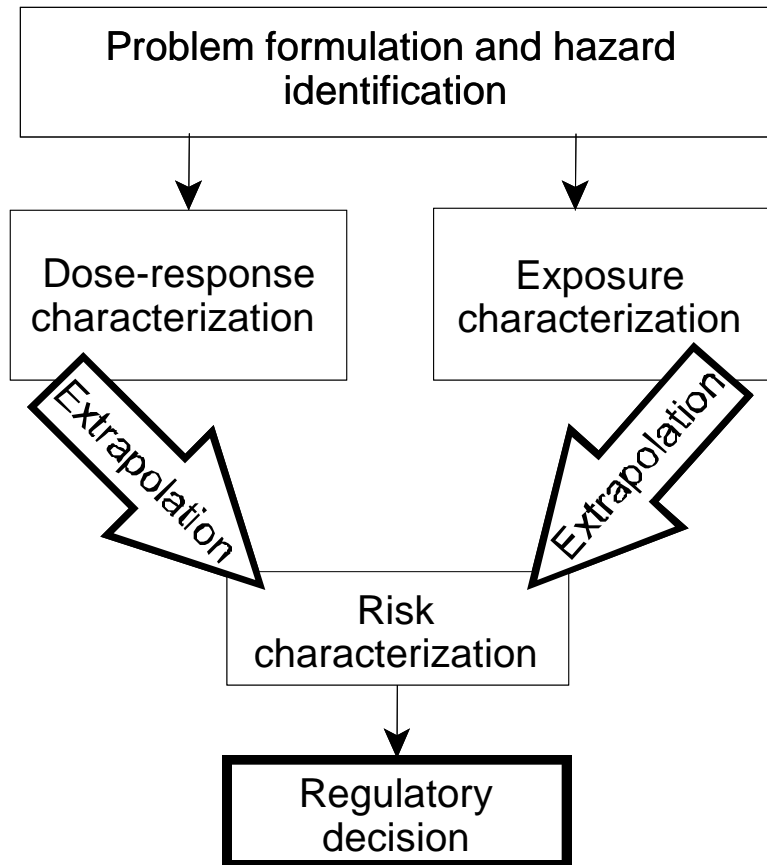
## Protection goals for environmental risk assessment of biocides

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# Protection goals and selected endpoints

## RISK ASSESSMENT



- Clear definition of protection goals is a key step in the problem formulation (*link between risk assessment and risk management process*)
- Assessment and measurement endpoints will vary depending on the protection goals

# Protection goals

For developing RA schemes, we need to know:

- **What** do we want to protect?
- **Where** do we want to protect it?
- Over what **time period** do we want to protect it?



We may not always be able to protect everything everywhere – there is a trade off between economic activities and biodiversity

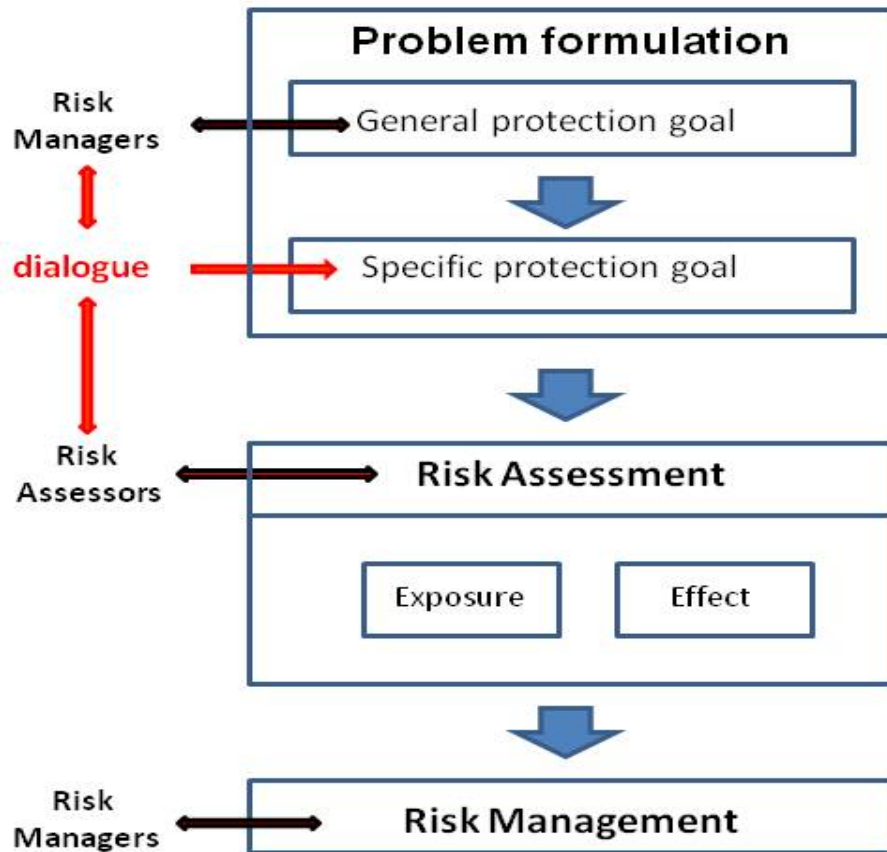
# Protection goals Biocide Directive (98/8/EC)

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- Following the use of a biocidal product *unacceptable effects* on the environment and on non-target organisms should be avoided
- Both the exposure in the environment and the impact on the *viability* of exposed non-target organisms needs to be assessed

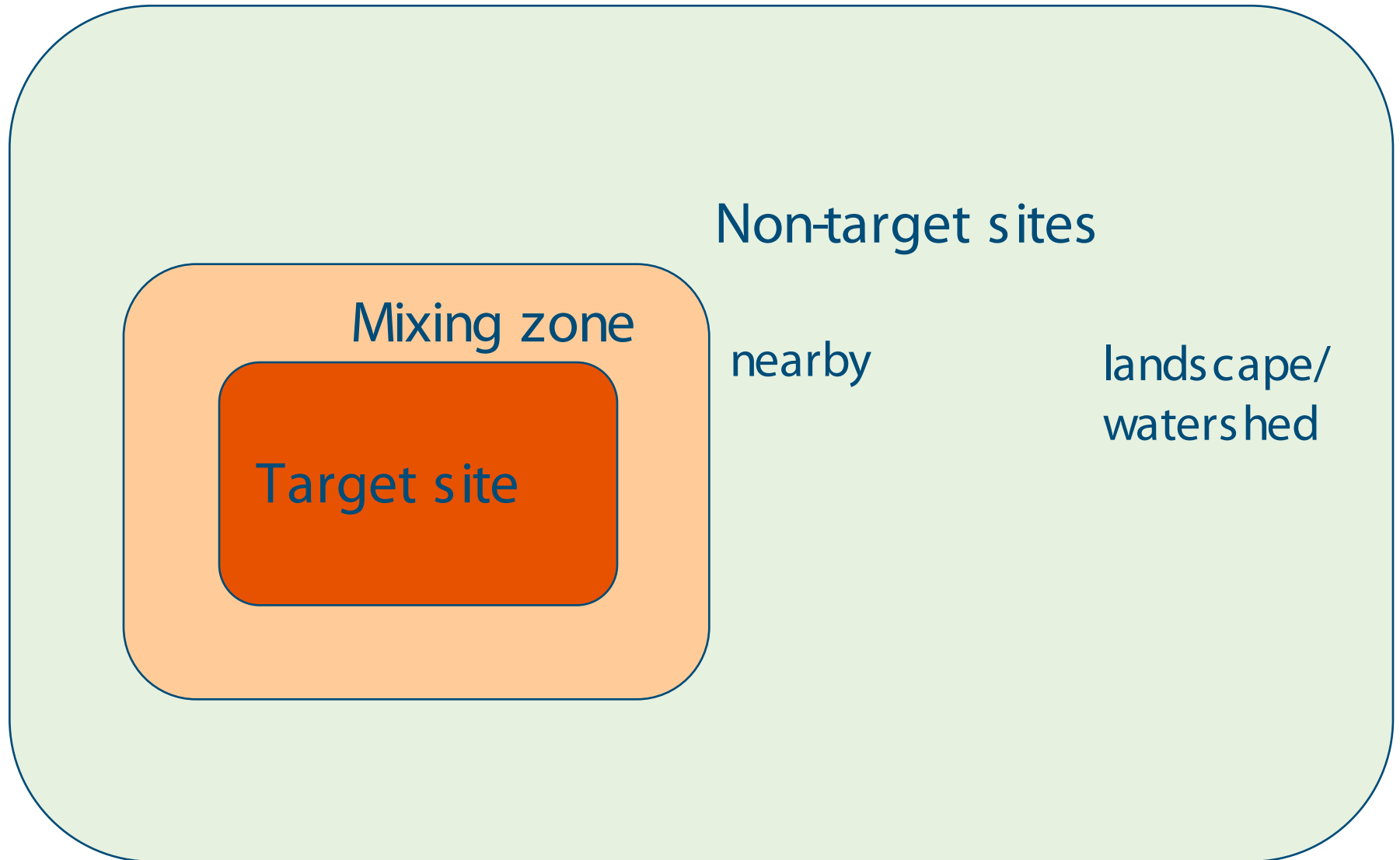
It is not operationally defined what is an unacceptable environmental effect and which level of effect violates the viability of non-target organisms

# The Risk Assessment process



**The general protection goals need to be made operational**

# Concepts for differentiation in protection goals



# Concepts for differentiation in protection goals

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**Essential information is missing:**

## ***The Precautionary Principle***

Precautionary action since uncertainty of risk is too high

**Essential information available:**

## ***The Pollution Prevention Concept***

Pollution should be prevented as much as technologically and socio-economically feasible (*EQS standards for priority (hazardous) substances*)

## ***The 'Ecological Threshold' Concept***

Communities and sensitive populations are hardly impacted below a certain threshold level (*ERA for biocides at non-target sites ?*)

## ***The 'Ecological Recovery' Concept***

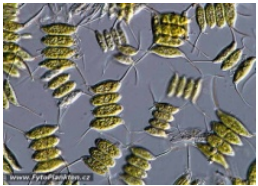
Ecosystems can endure a certain amount of pollution because of ecological recovery (*ERA for biocides in mixing zone/nearby non-target sites ?*)

## ***The 'Functional redundancy' Concept***

Decrease in biodiversity needs not to be dramatic due to redundancy in functions of surviving species (*ERA of biocide at target site ?*)

# Protection goals for aquatic and terrestrial organisms?

- Is a spatial differentiation in protection goals required?
- Choice of tested species governed by practicality (needs link to protection goal)

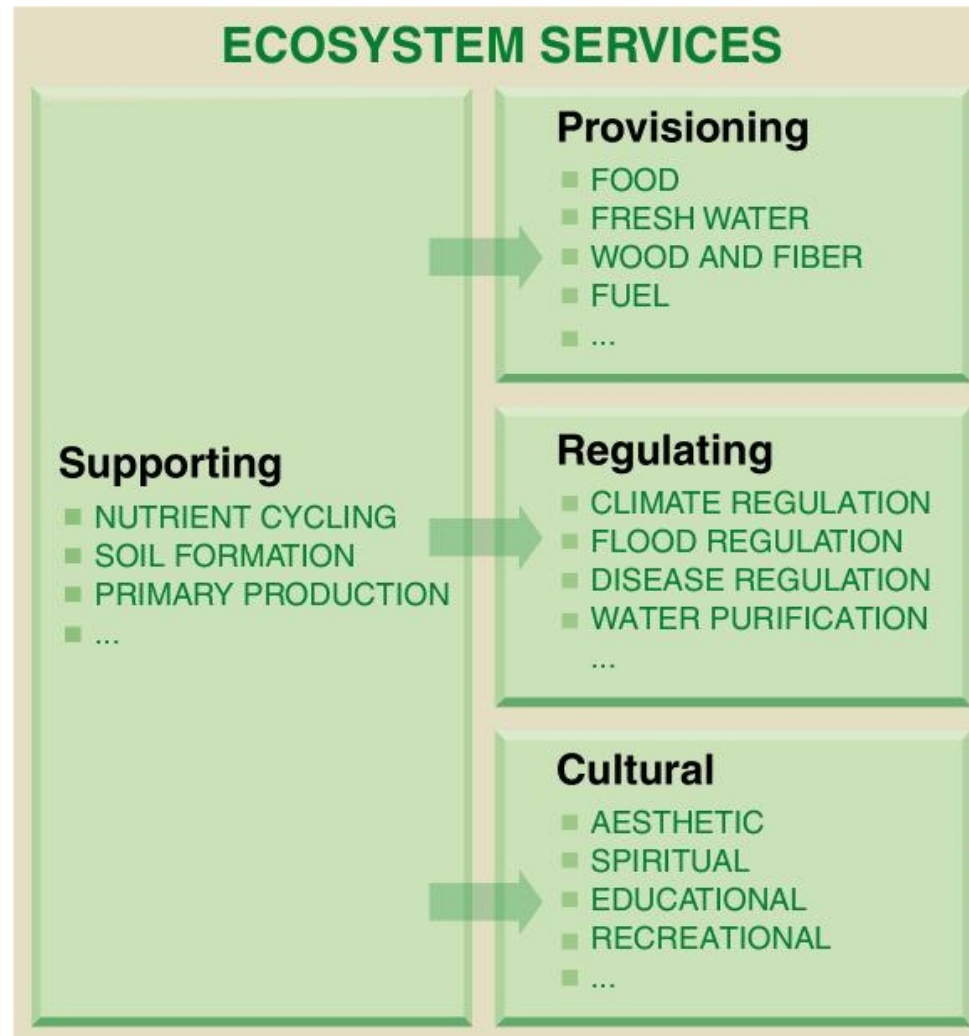


- **Ecosystem services concept**
  - Functions of and provisions from ecosystems that are useful for and available to humans
  - Allows to address trade-offs, societal demands and spatio-temporal scales



# Why use the ecosystem services concept?

- Can be applied to all ecosystems (and all environmental compartments)
- Can be applied at different spatial and temporal scales
- Strong communication tool
- Allows systematic and transparent assessment for detecting all important key drivers



Millennium Ecosystem Assessment (2005) Ecosystems and Human Well-being: Synthesis. Island Press, Washington DC, 160 pp

# Steps in the procedure (developed for PPPs by EFSA)

List of Ecosystem Services  
(Millennium Ecosystem Assessment)



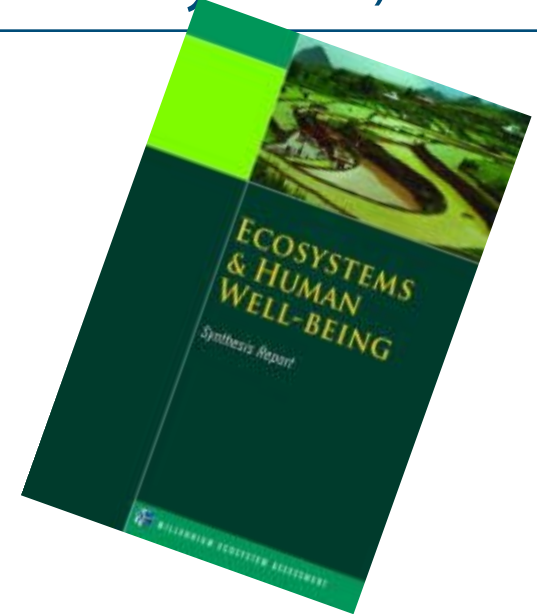
Identify **ES affected by biocides**



Identify **key drivers** for these ES (i.e. representative taxa or functional groups)



Development of **specific protection goals**: identify  
“**6 dimensions**” for the key drivers / ES  
combinations



Ecosystem services and relevant key drivers should be assessed for different types of ecosystem at risk (e.g. freshwater, marine, terrestrial)

## Example: Identification of important key drivers for biocide ERA

Ecosystem service	Organisms	Legal requirement	Desired protection goal
Pollination	Honey bee, wild bees, hover-flies, butterflies	No unacceptable lethal and sublethal effect. No effects on ongoing behaviour	No to small effects on biodiversity, abundance and foraging behaviour
Soil formation	Soil invertebrates, microbes, vascular plants	No unacceptable lethal and sublethal effects.	No to temporary impacts on functional groups
Water purification	Microbes, algae, aquatic vascular plants	No unacceptable lethal and sublethal effects.	No to temporary impacts on functional groups
Genetic resources	All microbes, plants, invertebrates, vertebrates	No unacceptable lethal and sublethal effects.	No decline in biodiversity

The organisms potentially affected by biocides and that perform the ecosystem services can be grouped in key drivers

# Key drivers identified by EFSA for PPP risk assessment

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- Microbes
- Algae
- Vascular plants (aquatic and terrestrial)
- Aquatic invertebrates
- Terrestrial non-target arthropods (incl. honey bees)
- Terrestrial non-arthropod invertebrates
- Vertebrates (aquatic and terrestrial)

Most likely the key drivers (main taxonomic groups) identified by EFSA can be used for biocide risk assessment as well

For each key driver and ecosystem type representative standard test species and “vulnerable” field taxa should be identified

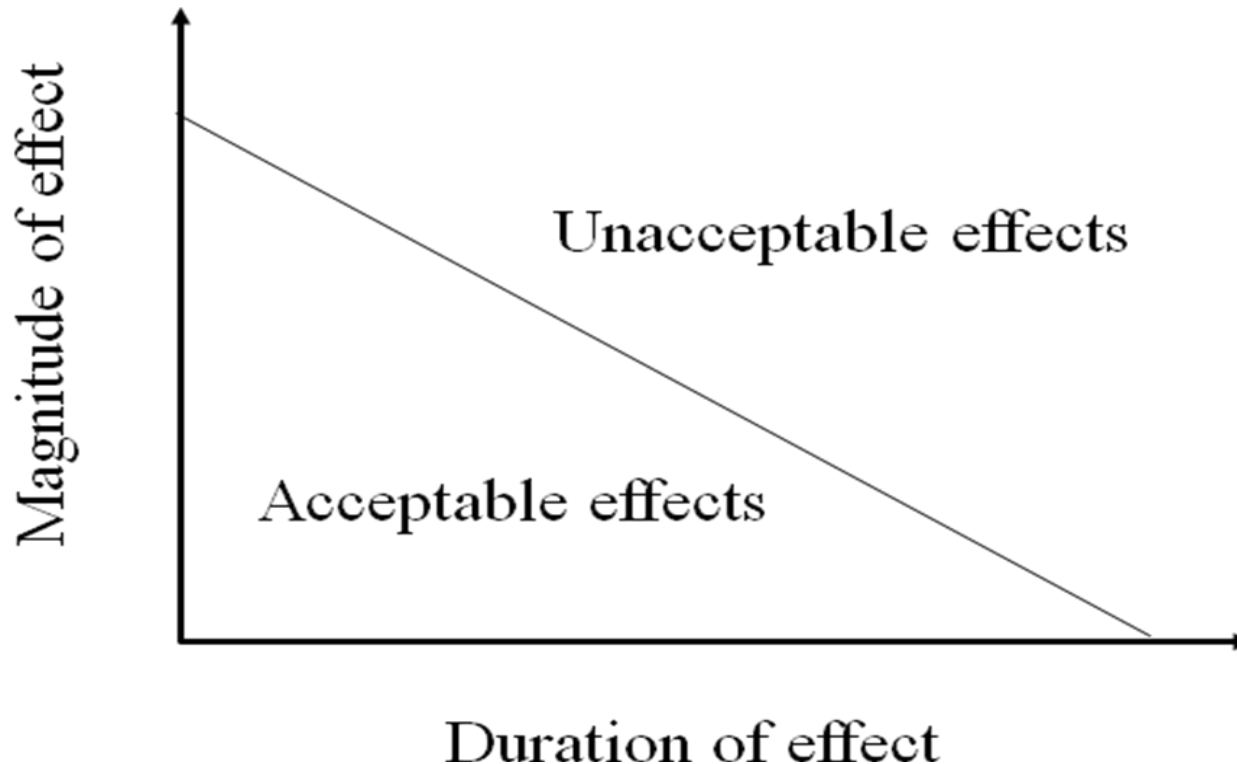
# Specific Protection Goal-dimensions for each key driver

<b>Ecol. entity:</b>	<b>individual – (meta)population – functional group – ecosystem</b>
<b>Attribute:</b>	<b>behaviour – survival/growth – abund./biomass – process – biodiversity</b>
<b>Magnitude:</b>	<b>negligible effect – small effect – medium effect – large effect</b>
<b>Duration:</b>	<b>&lt;days – days – weeks – months – seasons – &gt; 1 year</b>
<b>Spatial scale:</b>	<b>target site – mixing zone – nearby non-target site – watershed/landscape</b>
<b>Degree of certainty:</b>	<b>low – medium – high</b>

For each SPG option one (range of) point(s) on each dimension must be chosen, and then defined in precise enough terms to be measurable

# Multi-dimensional nature of SPG

## Example of interdependency of dimensions



- relationship may be unknown
- some potential relationships could be possible
- most simple relationship is given as example

# Specific Protection Goal-dimensions for each key driver

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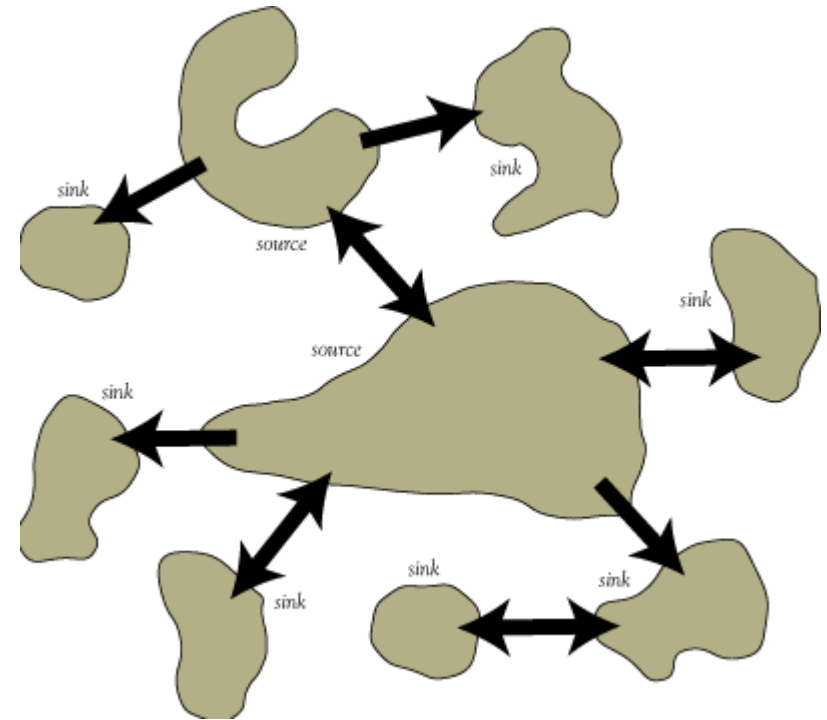
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# Individual, population and metapopulation

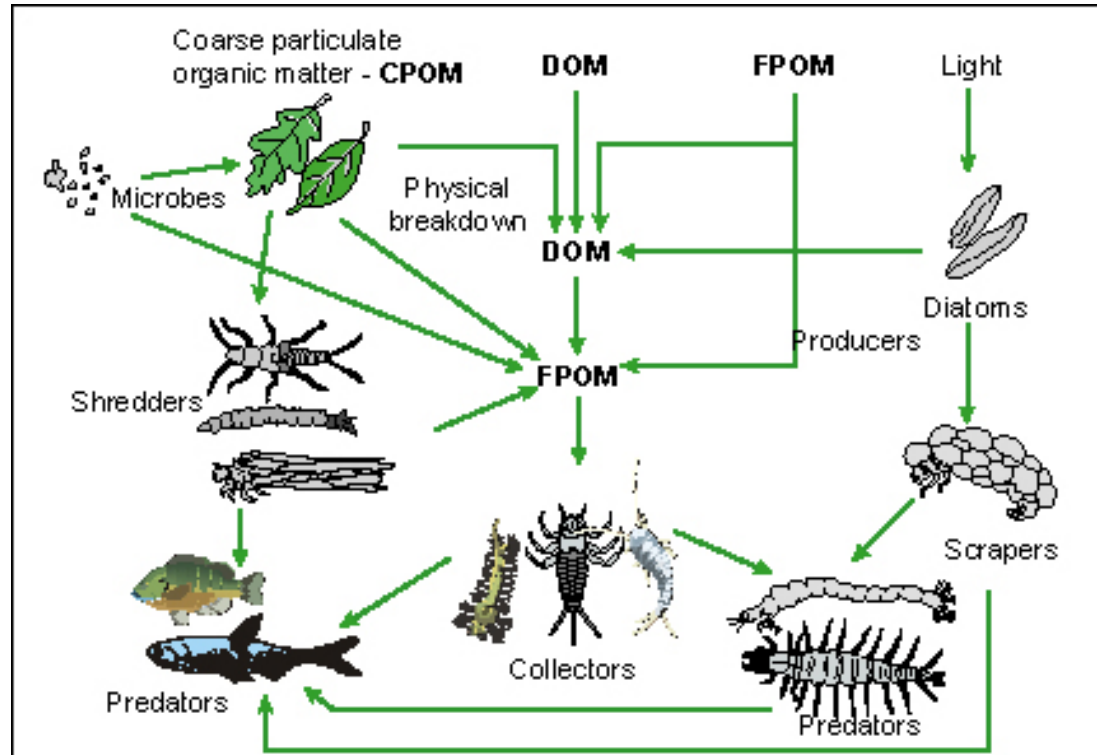
A **population** is an aggregate of interbreeding individuals of a species, occupying a specific location in space and time



A **metapopulation** is a 'population of populations' of the same species connected through immigration and emigration (*important for external recovery after biocide-stress*)



# Functional group, community and ecosystem



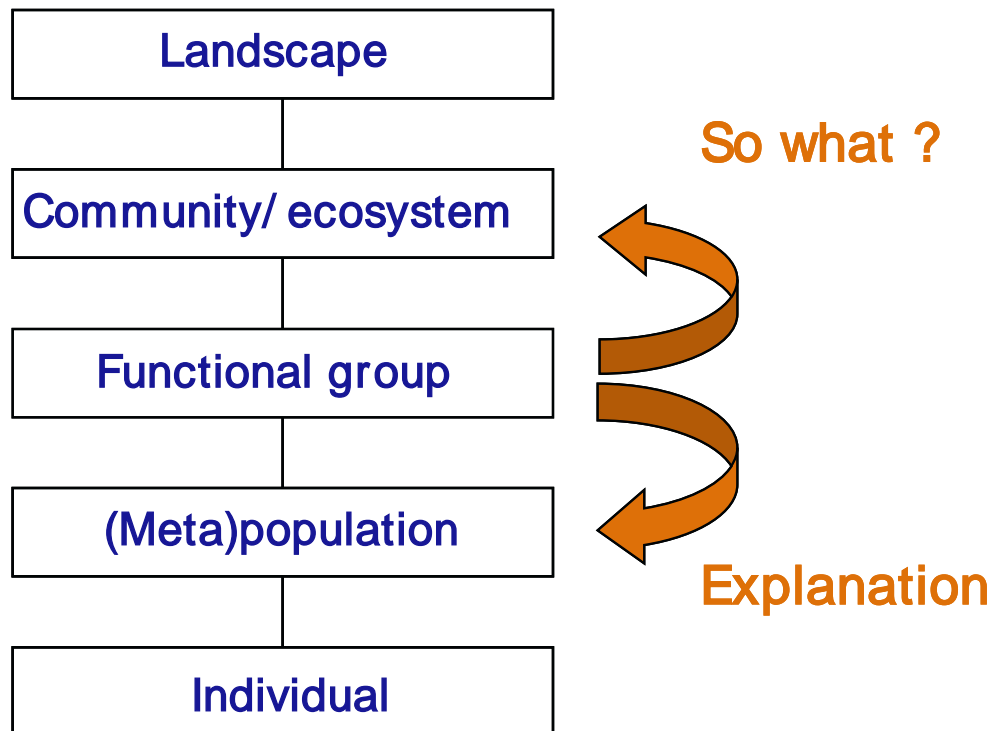
**Functional group** is a collection of different species in a biological community that perform the same functions in the ecosystem (*also providing the same ecosystem service*)

A **biological community** consists of different species of plants, animals and microbes occupying the same area at the same time (*together with its abiotic environment it forms the basis of an **ecosystem***)

# Multi-dimensional nature of SPG

What is the ***ecological entity*** of the key driver (taxa) to be protected?

ecological entity = level of biological organisation



# Specific Protection Goal-dimensions for each key driver

**Ecol. entity:** individual – (meta)population – functional group – ecosystem

**Attribute:** behaviour – survival/growth – abund./biomass – process – biodiversity

**Magnitude:** negligible effect – small effect – medium effect – large effect

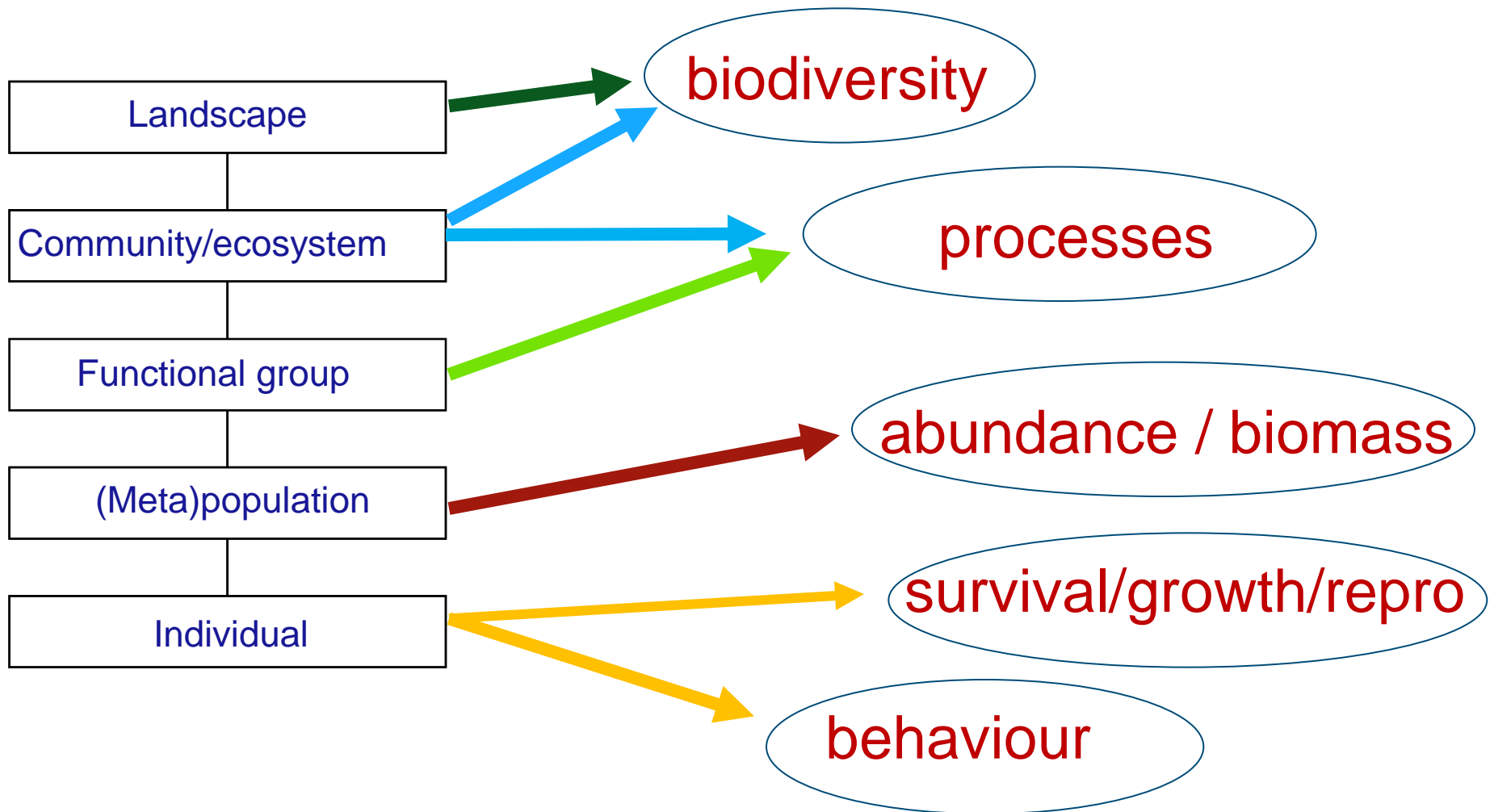
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**Spatial scale:** target site – mixing zone – nearby non-target site – watershed/landscape

**Degree of certainty:** low – medium – high

# Multi-dimensional nature of SPG

Which **attribute(s)** to select as endpoint?



# Specific Protection Goal-dimensions for each key driver

**Ecol. entity:** individual – (meta)population – functional group – ecosystem

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**Magnitude:** negligible effect – small effect – medium effect – large effect

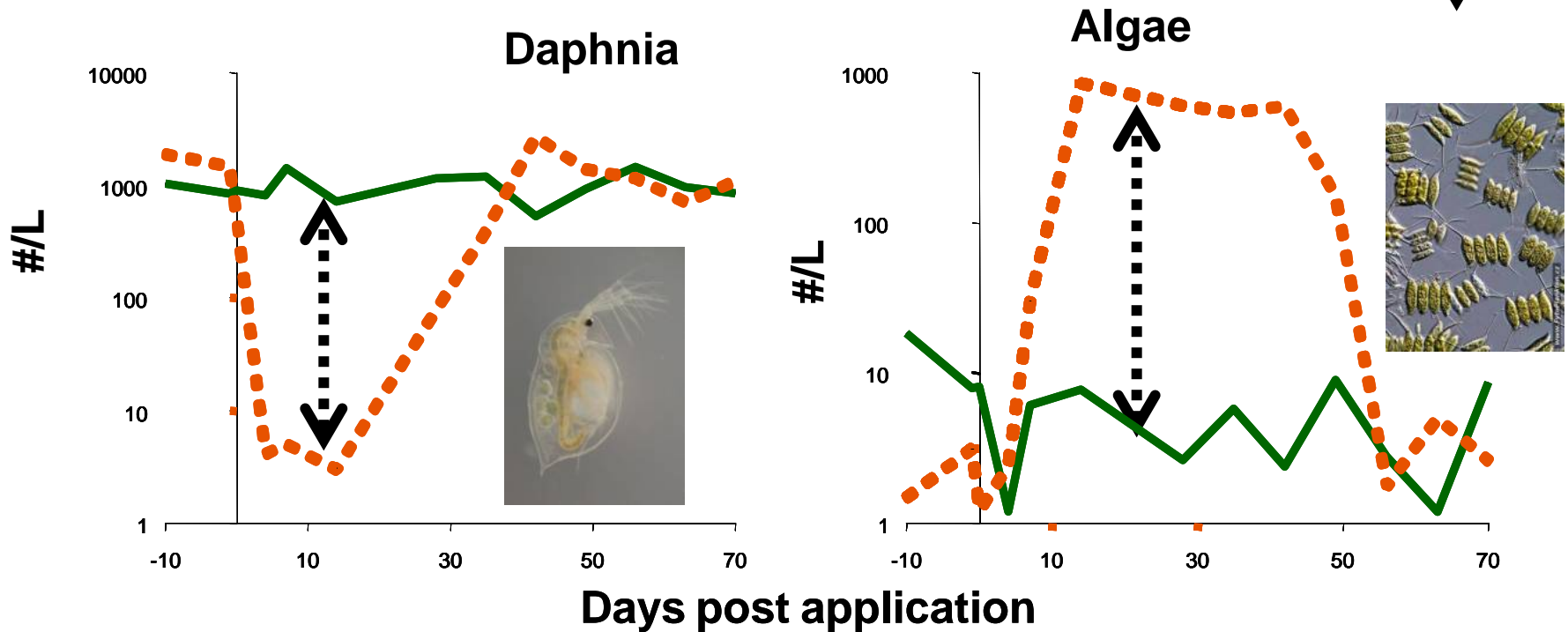
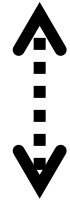
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**Degree of certainty:** low – medium – high

# Multi-dimensional nature of SPG

Which *magnitude of effect* can be tolerated?



May include decreases and increases due to indirect effects

# Specific Protection Goal-dimensions for each key driver

**Ecol. entity:** individual – (meta)population – functional group – ecosystem

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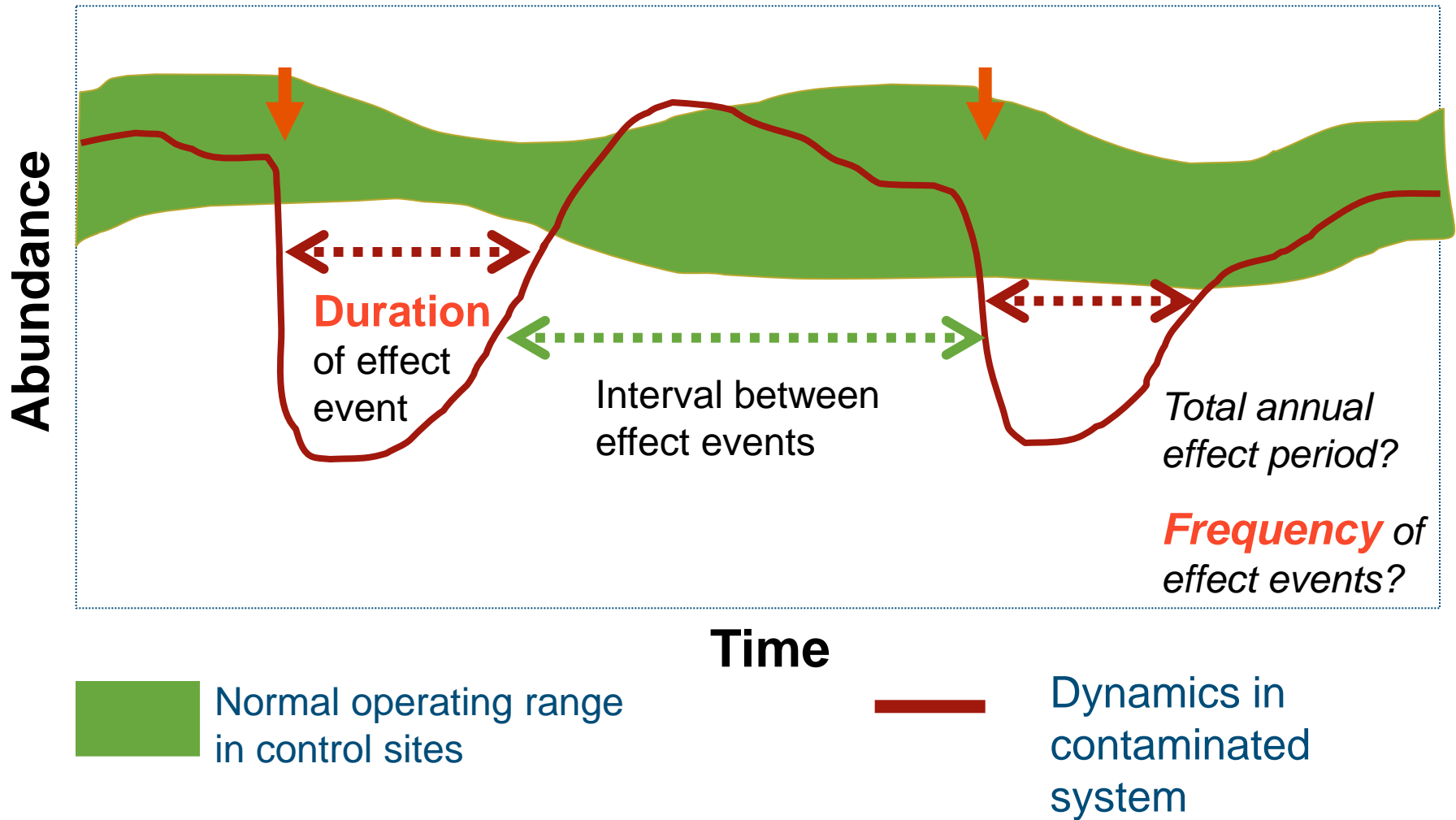
**Duration:** <days – days – weeks – months – seasons – > 1 year

**Spatial scale:** target site – mixing zone – nearby non-target site – watershed/landscape

**Degree of certainty:** low – medium – high

# Multi-dimensional nature of SPG

Which *temporal scale of effect* can be tolerated?





# Specific Protection Goal-dimensions for each key driver

**Ecol. entity:** individual – (meta)population – functional group – ecosystem

**Attribute:** behaviour – survival/growth – abund./biomass – process – biodiversity

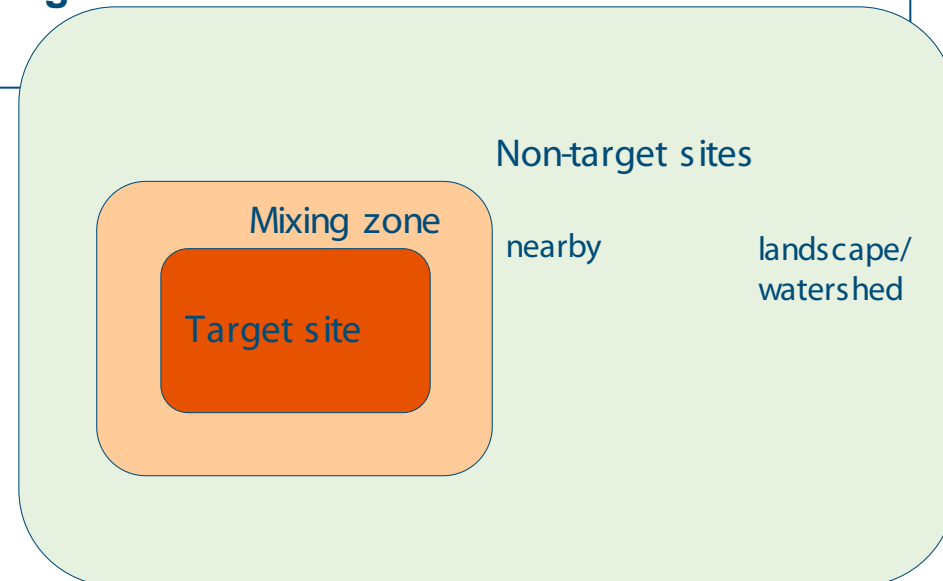
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**Spatial scale:** target site – mixing zone – nearby non-target site – watershed/landscape

**Degree of certainty:** low – medium – high

Exposure and effect scenario's may need to be developed that allow spatial differentiation in risk assessment



# Specific Protection Goal-dimensions for each key driver

<b>Ecol. entity:</b>	individual – (meta)population – functional group – ecosystem
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<b>Degree of certainty:</b>	low – medium – high

The degree of certainty in the ERA of biocides probably needs to be fixed at high (legal requirement)

# Possible SPG definition for non-target algae and invertebrates



*Ecological threshold option  
for non-target sites*



Ecol. entity:	individual – <b>(meta)population</b> – functional group – ecosystem
Attribute:	behaviour – survival/growth – <b>abund./biomass</b> – process – biodiversity
Magnitude:	<b>negligible effect</b> – small effect – medium effect – large effect
Duration:	<b>&lt;days – days</b> – weeks – months – seasons – > 1 year
Spatial scale:	target site – mixing zone – <b>nearby non-target site – watershed/landscape</b>

## Potential vulnerable taxa:

- algae with a low growth rate and limited dispersal ability
- uni-/ semivoltine invertebrates (long life cycles) with a low dispersal ability

# Possible SPG definition for non-target algae and invertebrates



*Ecological recovery option for  
target site and mixing zone*



**Ecol. entity:** individual – (meta)population – functional group – ecosystem

**Attribute:** behaviour – survival/growth – abund./biomass – process – biodiversity

**Magnitude:** negligible effect – small effect – medium effect – large effect

**Duration:** <days – days – weeks – months – seasons – > 1 year

**Spatial scale:** target site – mixing zone – nearby non-target site – watershed/landscape

*Magnitude and duration of effects cannot  
be considered in isolation*



## Possible SPG definition non-target vertebrates



**Ecol. entity:** individual – (meta)population – functional group – ecosystem

**Attribute:** behaviour – survival/growth – abund./biomass – process – biodiversity

**Magnitude:** negligible effect – small effect – medium effect – large effect

**Duration:** <days – days – weeks – months – seasons – > 1 year

**Spatial scale:** target site – mixing zone – nearby non-target site – watershed/landscape

For aesthetic reasons it may be decided that non-target vertebrates should not suffer visible mortality due to biocide exposure

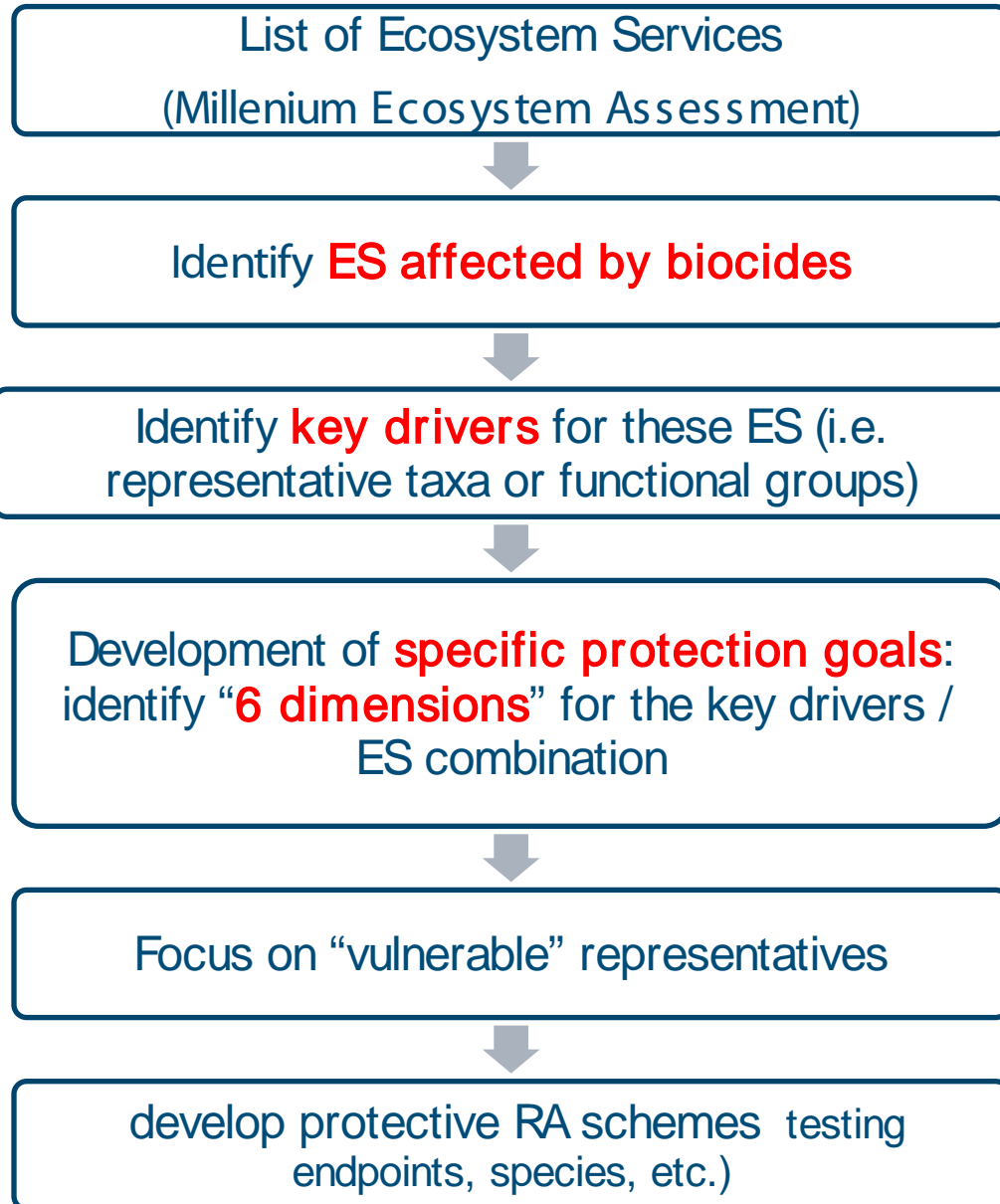
Risk managers have the final responsibility in setting SPGs, the role of risk assessors is to provide and evaluate options

# Possible SPGs for biocides

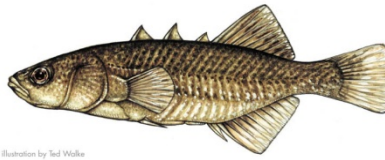
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- The ecological entity to be protected for non-target organisms usually is the (meta)population
- Vertebrates may be protected at the individual level (aesthetic considerations)
- For certain services provided by microbes, algae and invertebrates the ecological entity of concern may be the functional group at target sites (and mixing zone ?)
- Maintenance of biodiversity at the landscape/watershed level for all key drivers
  - Temporal effects on local populations may under certain well-defined conditions be acceptable

# Further steps in the procedure (developed for PPPs by EFSA)



# Ecological vulnerability

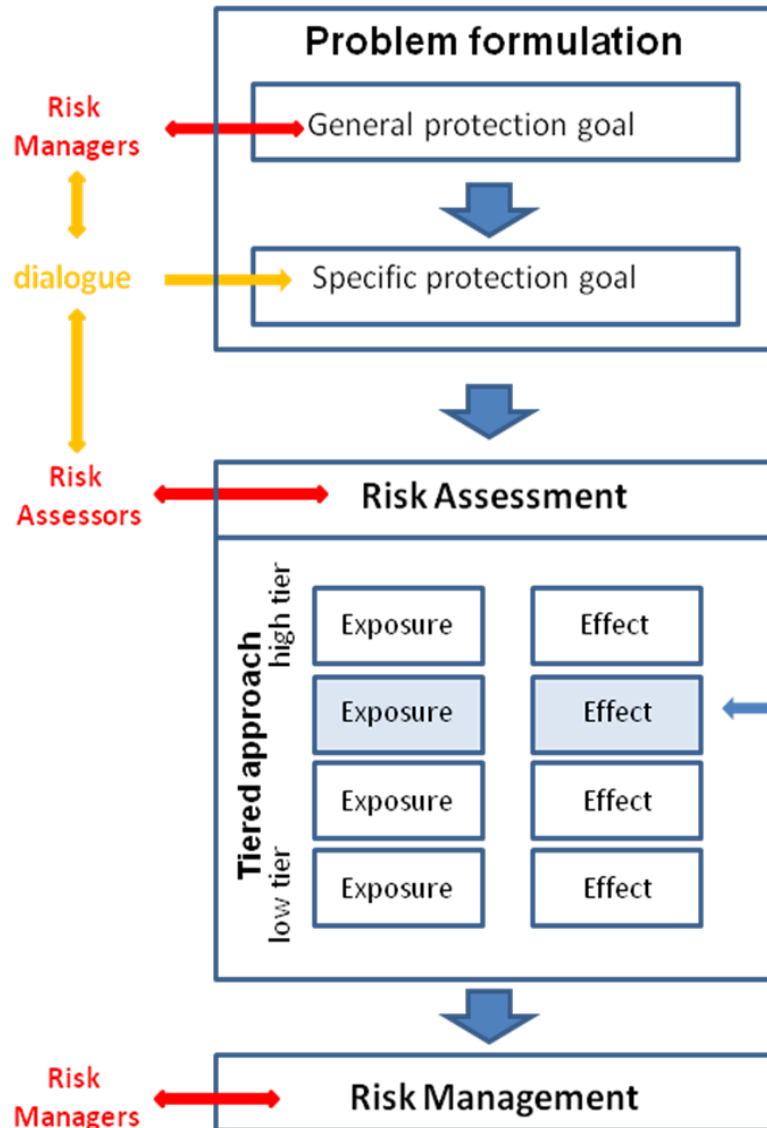


In ecosystems the vulnerability of populations to toxicants is influenced by:

1. Exposure and sensitivity to direct toxic effects
2. Indirect effects due to shifts in species-interactions
3. Recovery potential
  - *Life cycle characteristics*
    - Number of generations per year
    - Resistant life stages
    - Dispersal ability
  - *Ecological infrastructure* (connectivity between stressed and non-stressed ecosystems)



# SPGs and tiered risk assessment schemes

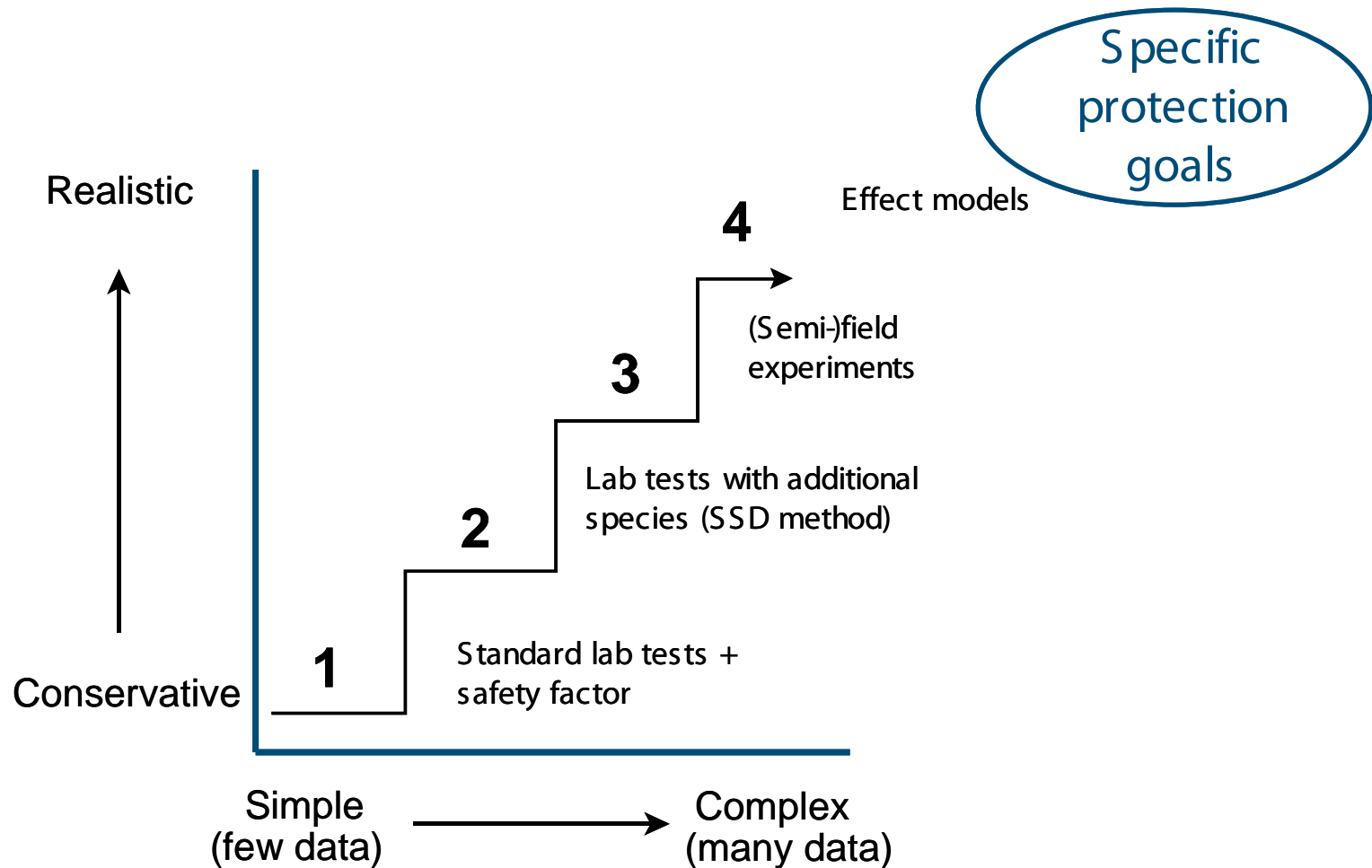


After SPGs are clear, **tiered risk assessment schemes** can be developed that are:

- Appropriately protective
- Internally consistent
- Cost-effective
- More accurate and precise when going from lower to higher tiers

For each SPG a **reference tier** needs to be identified based on the most practical and sophisticated experimental/modeling risk assessment method.

# SPGs and tiered risk assessment schemes



For all tiers the same specific protection goal is applicable but higher tiers address the problem with a higher degree of realism and complexity

# Conclusions

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- Ecosystem services concept is suitable to develop specific protection goals
  - helps in deciding what, where, and at what scale to protect; helps to decide in case of trade offs; includes different societal demands
- A methodology is proposed for the development of SPG-options
  - Allows to identify alternative levels of protection for key drivers of concern
  - Overarching approach for aquatic and terrestrial compartments
  - Systematic check of potentially important key-drivers/ecosystem services to be protected
- The SPG-options can be used in the 'acceptability' debate
  - Transparent communication between stakeholders
  - Decision making by risk managers

# Thank you for your attention

## Questions ?





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