Environmental Exposure and Risk Assessment

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Topics

1. Why do an environmental risk assessment?
2. Which parts of the environment?
3. What tools do we have to estimate the exposure?
4. What tools do we have to estimate the risk?

Risk Assessment

Tools for decision making based on predicted environmental effects

- Hazard assessment – based on basic properties only (e.g. classification)
- Estimation of environmental exposure

→ Possibility to do a risk assessment and to make some sort of decision (rejection, request for more data, approval, restrictions, etc.)

Environmental exposure assessment

Estimation of the concentrations/doses which organisms in environmental compartments (aquatic, terrestrial, food) are, or may be exposed to.

Given as:

PEC – **P**redicted **E**nvironmental **C**oncentration

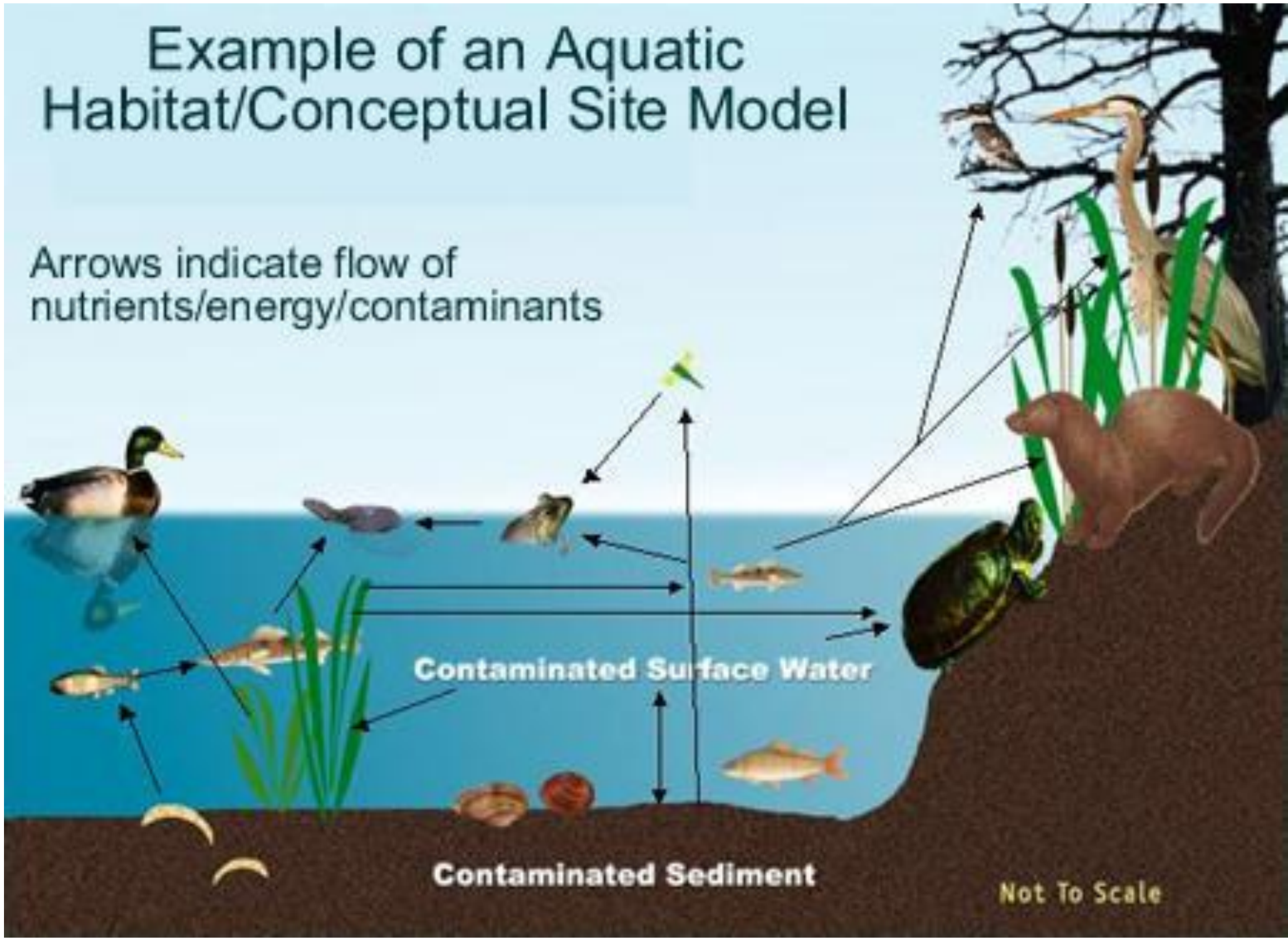
Administration of a chemical in the environment → different exposure routes

– Water / sediment

– Soil / pore water

– Air

– Via food chain



Standard target organisms

- Water organisms
- Sediment organisms
- Soil organisms
- Wastewater treatment organisms
- Top predators, exposed via the food chain (secondary poisoning)

Exposure Assessment - relevant compartments PPP

Birds and mammals

Bees

Surface water

Groundwater

Soil

Exposure Assessment – birds and mammals
Food chain

Treated seeds

Crops

Insects

Calculation of Daily Dietary Dose (DDD)

Predicted Environmental Concentration

- Surface water (PEC_{sw})
- Sediment ($PEC_{sediment}$)
- Soil (PEC_{soil})
- Groundwater (PEC_{gw})
- Food chain (PEC_{oral})

- Sewage Treatment Plant (PEC_{STP})
- Marine water (PEC_{marine})

Exposure models

Model calculations in FOCUS:

Groundwater, surface water, persistence in soil

FOCUS Home *MACRO in FOCUS

In English “Safe plant protection”

PEC groundwater in EU

PEC_{gw} should not exceed 0.1 µg/l.

- Is the same value for all substances, and for relevant metabolites (RM) i.e. that have a biological activity)
This is a politically decided endpoint

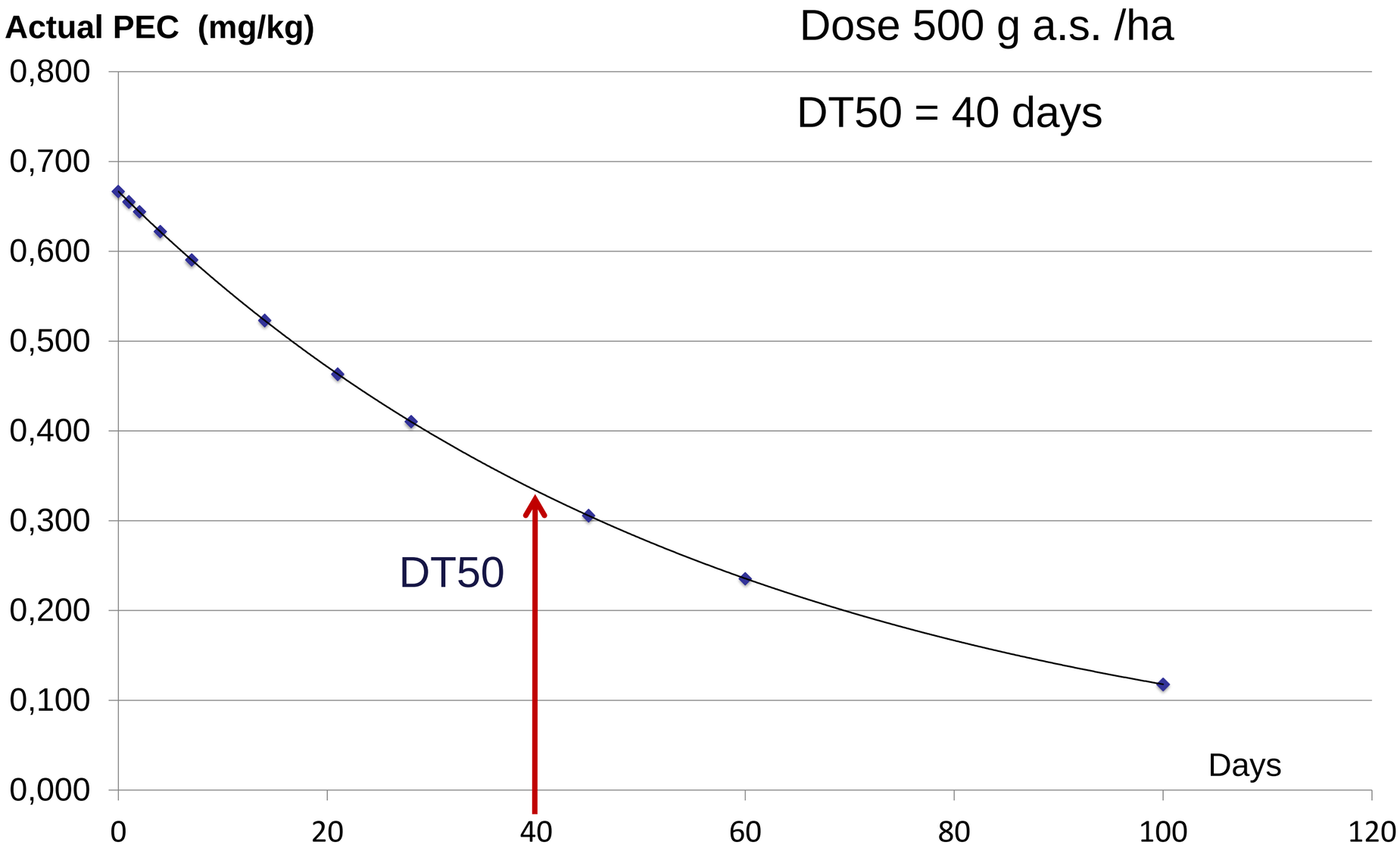
- this means that this value is not compared with ADI

- WHO has set other values for individual substances, based on ADI

During monitoring of drinking water, the limit is set to:

- 0.1 µg/L for a single active substance and RM
- 0.5 µg/L when you have more than one substance or RM

Transformation: Example degradation in soil, (one dose)



Exposure Assessment (pesticides)

To estimate concentrations;

Realistic worst case scenario

START SIMPLE!!!

Dose (g/ha)

Soil density=1.5g/cm³

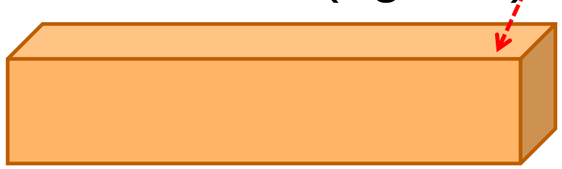
Soil (mg/kg dw)

5cm depth

Surface water (mg/liter)

30cm depth

Groundwater (ug/liter)

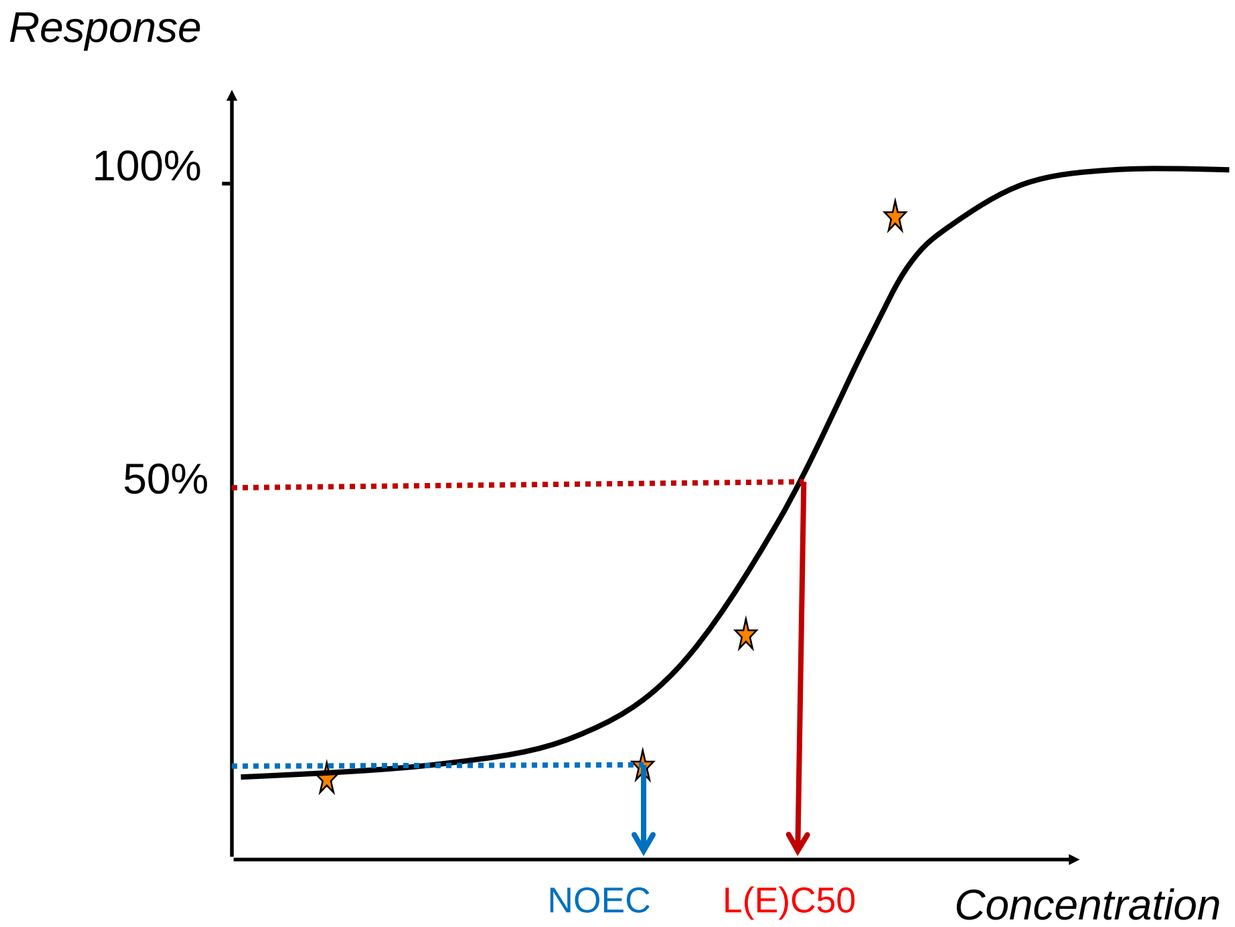


Concentration in pore water (calculated with soil-water partitioning coefficient)

Environmental effects assessment: General principle

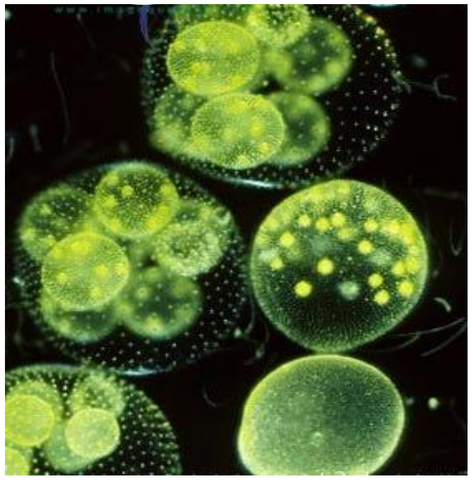
Estimate a concentration below which effects are not expected

1. Identify critical effects
   (e.g. reproduction, behaviour, immobilisation, growth)
2. Calculate dose – response endpoint
   (L(E)C_{50} or NOEC)
3. Add an Assessment/Safety Factor

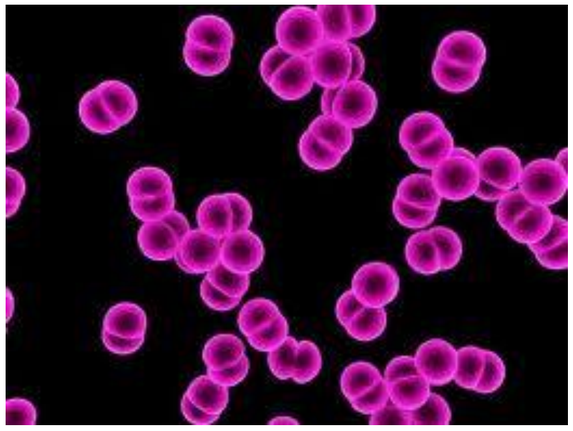


Standard organisms used for testing

Surface water: Algae, arthropods, fish



Soil: Earthworms, Micro-organisms



Refinement – toxicity data

Laboratory tests with additional species of animals or plants

More realistic tests

field tests (mesocosm)

Assessment/safety factor

- Reflects the degree of uncertainty in extrapolation from laboratory toxicity test data for a limited number of species to the 'real' environment.

- AF applied for long-term tests are lower than for short-term tests.

Why? → reduced uncertainty of extrapolation from laboratory data to the natural environment.

Therefore long-term data are preferred over short-term data.

Safety/Assessment factors and PNEC: Industrial/ consumer chemicals and biocides

Predicted No Effect Concentration (PNEC)
is calculated from NOEC or EC_x
divided by an assessment factor

Example $PNEC_{surface\ water}$

Available data	Assessment Factor
At least one short-term LC_{50} from each of 3 trophic levels (base dataset)	1000
One long-term NOEC	100
Two long-term NOECs from different trophic levels	50
Long term NOECs from at least 3 species in three different trophic levels	10

Safety factors - plant protection products

TER (Toxicity Exposure Ratio) values are ”political values”, agreed in Regulation EU1107/2011, not scientifically based

Examples:

- Acute toxicity to aquatic organisms: TER 100
- Acute toxicity to earthworm: TER 10
- Long-term toxicity to birds: TER 5

Risk assessment - plant protection products

1. Compare estimated concentration in the environment with compartment effect concentations

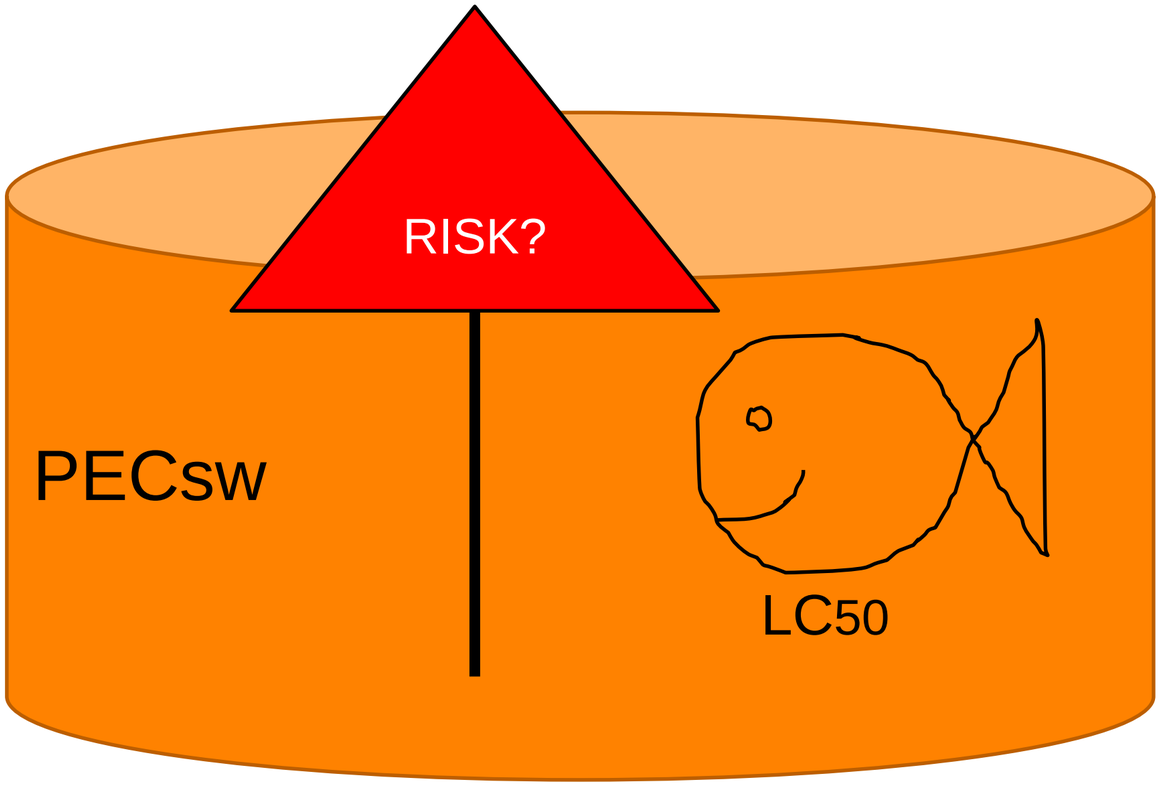
is calculation of Toxicity Exposure Ratio (TER)

2. Compare with safety factor

Generally:

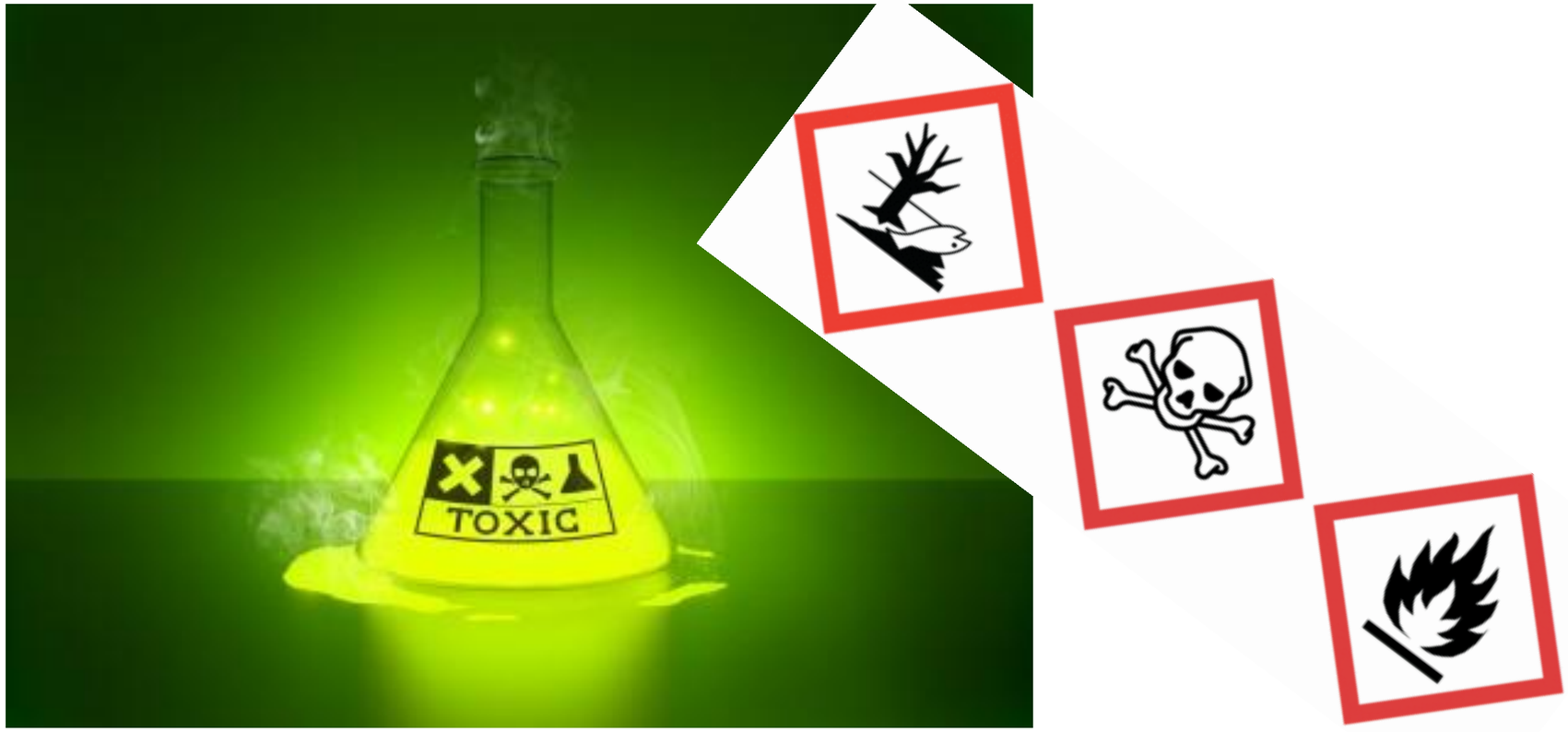
TER > safety factor → OK

TER < safety factor → RISK



Substances of Very High Concern (SVHC)

- Toxic
- Persistent
- Bioaccumulating

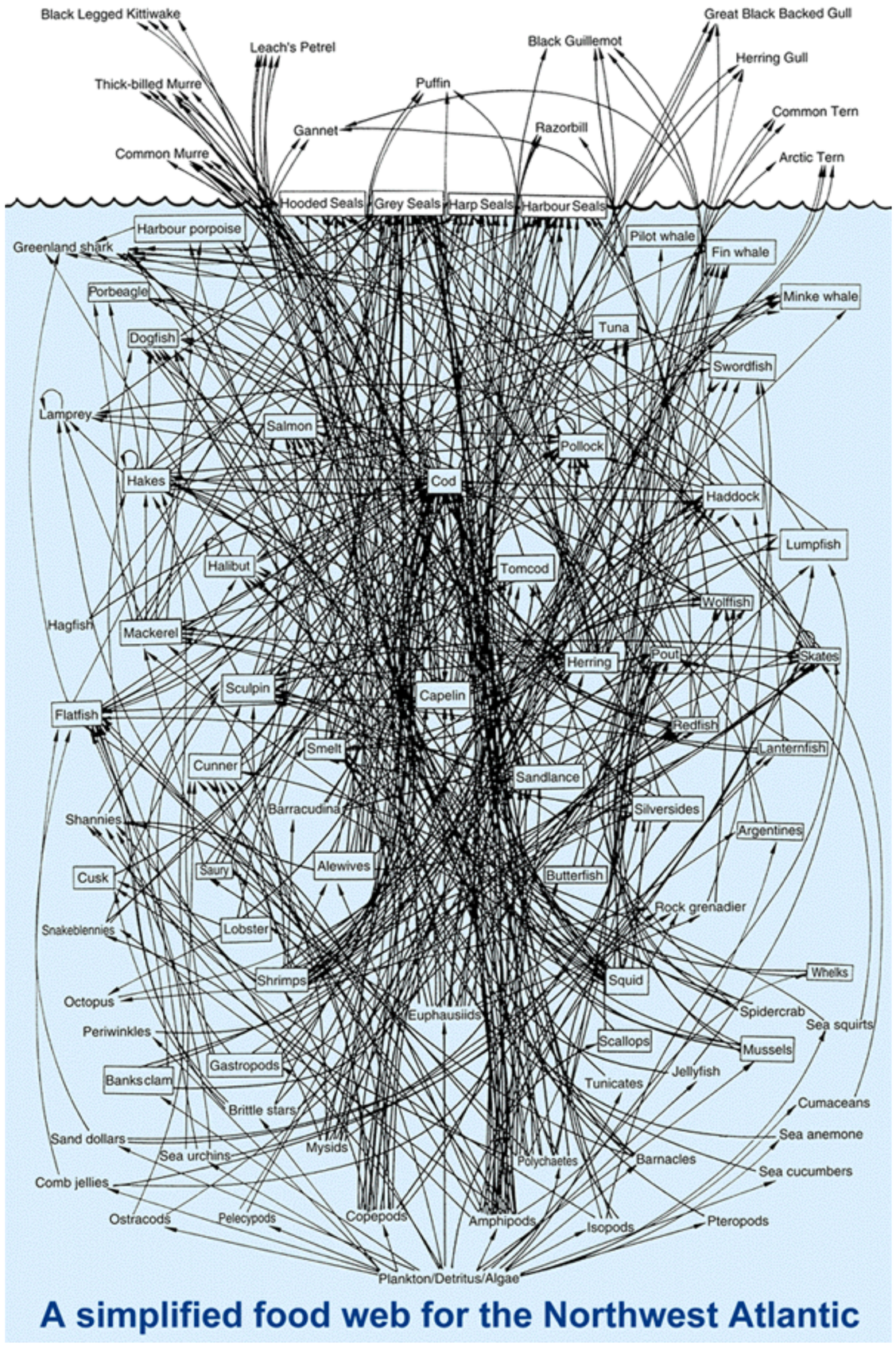


A few species from different levels in the food web representing the whole ecosystem

Secondary consumers

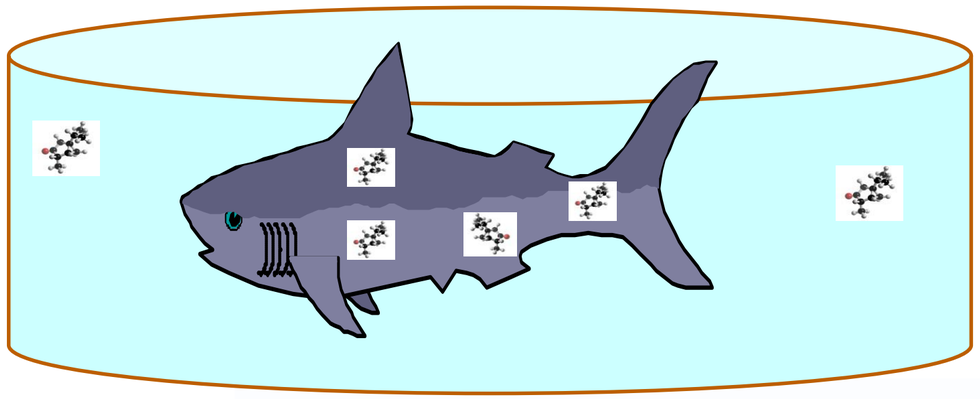
Primary consumers

Producers



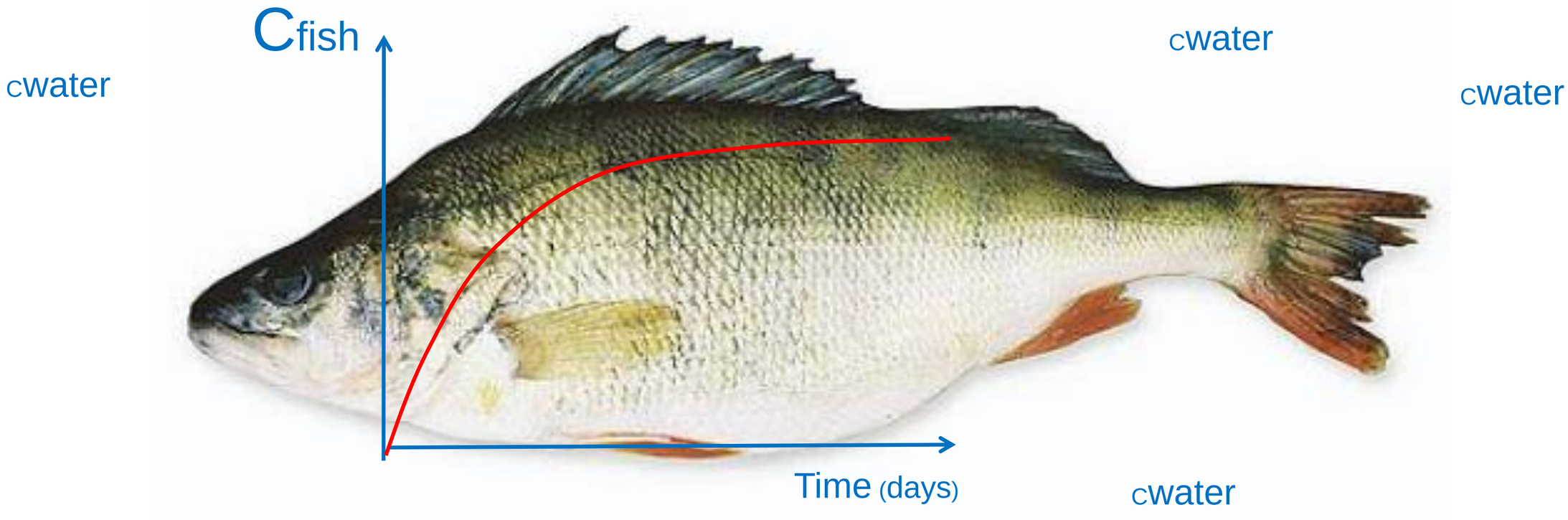
A simplified food web for the Northwest Atlantic

Bioaccumulation



The net result of uptake, transformation and elimination of a substance in an organism

- Assessed with the Bioconcentration factor (BCF)



BCF= C_{fish}/C_{water} at steady state

(OECD GD 305: Bioconcentration: Flow-through Fish Test)

Substances of high concern

PBT - Persistent, **B**ioaccumulating, and **T**oxic substances are substances of high concern

vP/vB - Very **P**ersistent and **v**ery **B**ioaccumulating substances have potential to build up in organisms Long-term effects (e.g. reduced fertility) can cause problems in the future

PBT/vPvB assessments are carried out to protect systems where risks are difficult to estimate, e.g. long range transport of persistent substances

The PBT / vPvB criteria

P

Property	PBT-criteria	vPvB-criteria
Persistence*	$T_{1/2}$ > 60 days in marine water, or	$T_{1/2}$ > 60 days in marine, fresh- or estuarine water, or
	$T_{1/2}$ > 40 days in fresh- or estuarine water, or	$T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment, or
	$T_{1/2}$ > 180 days in marine sediment, or	$T_{1/2}$ > 180 days in soil.
	$T_{1/2}$ > 120 days in fresh- or estuarine sediment, or	
	$T_{1/2}$ > 120 days in soil.	

* T1/2 is the half-life of the chemical in the specific environment

B and T

The PBT / vPvB criteria

Property	PBT-criteria	vPvB-criteria
Bio-accumulation	BCF > 2000 L/kg	BCF > 5000 L/kg
Toxicity	NOEC < 0.01 mg/L for marine or freshwater organisms, or	
	substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or	
	there is other evidence of chronic toxicity	

Take home message:

1. Do a stepwise risk assessment!
2. Start simple! Realistic worst case scenario.
3. Use information that is already available!