



Environmental Exposure and Risk Assessment

Lilian Törnqvist, Helena Parkman and
Johannes Knulst

September 2014

Content

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

Tool for decision making based on predicted environmental effects

- o Hazard assessment – based on basic properties only (e.g. classification)
- o 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.)

Risk assessment (RA)

- Hazard assessment
- Exposure assessment



Risk characterization

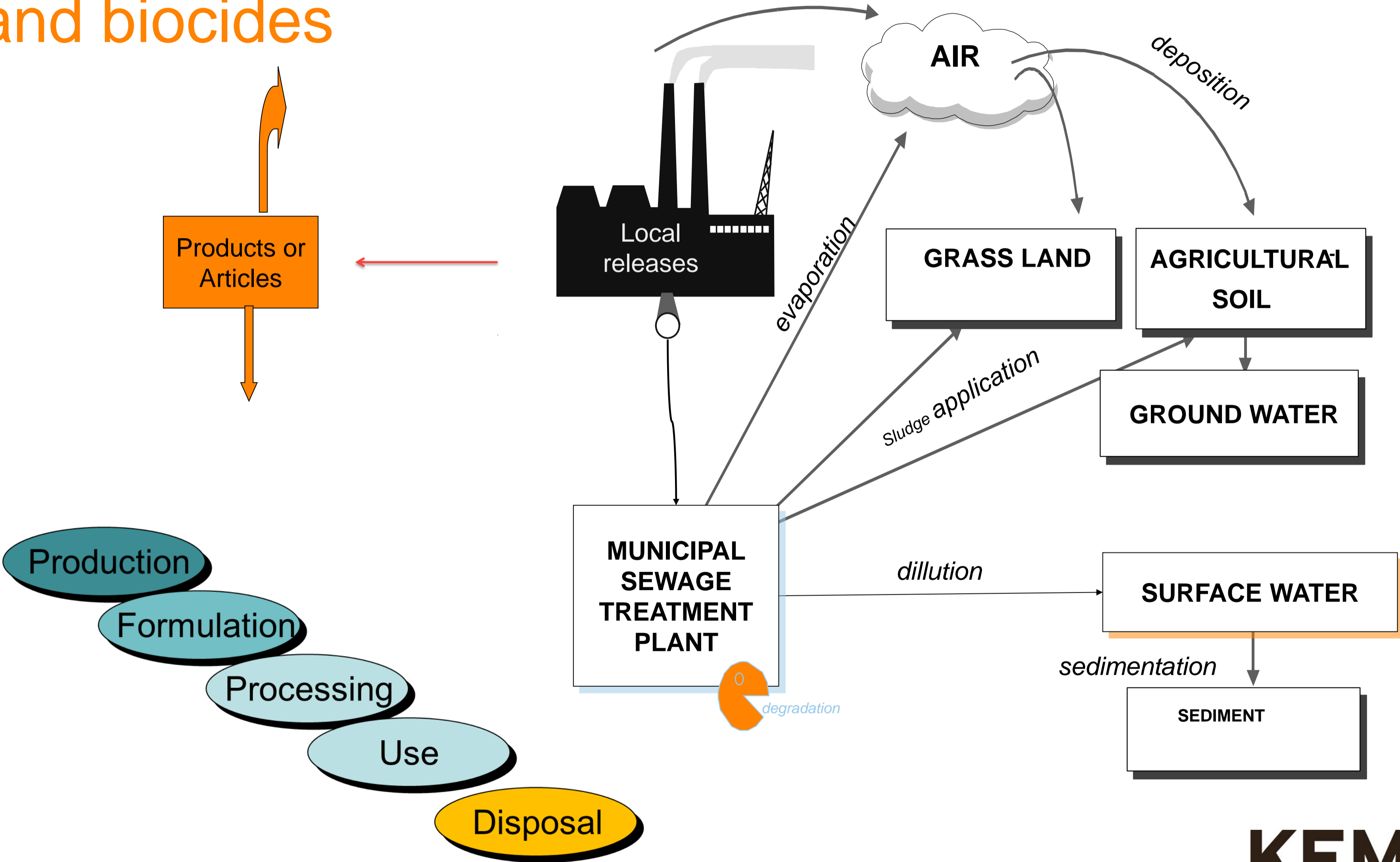
RA for industrial and consumer chemicals (Reach) and biocides versus agro-chemicals: Similar in principle but somewhat different in terms and details

Environmental exposure assessment

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

PEC – Predicted Environmental Concentration

Exposure Assessment – relevant compartments for industrial and consumer chemicals (Reach) and biocides



Spatial Exposure Assessment

– industrial/consumer chemicals and biocides

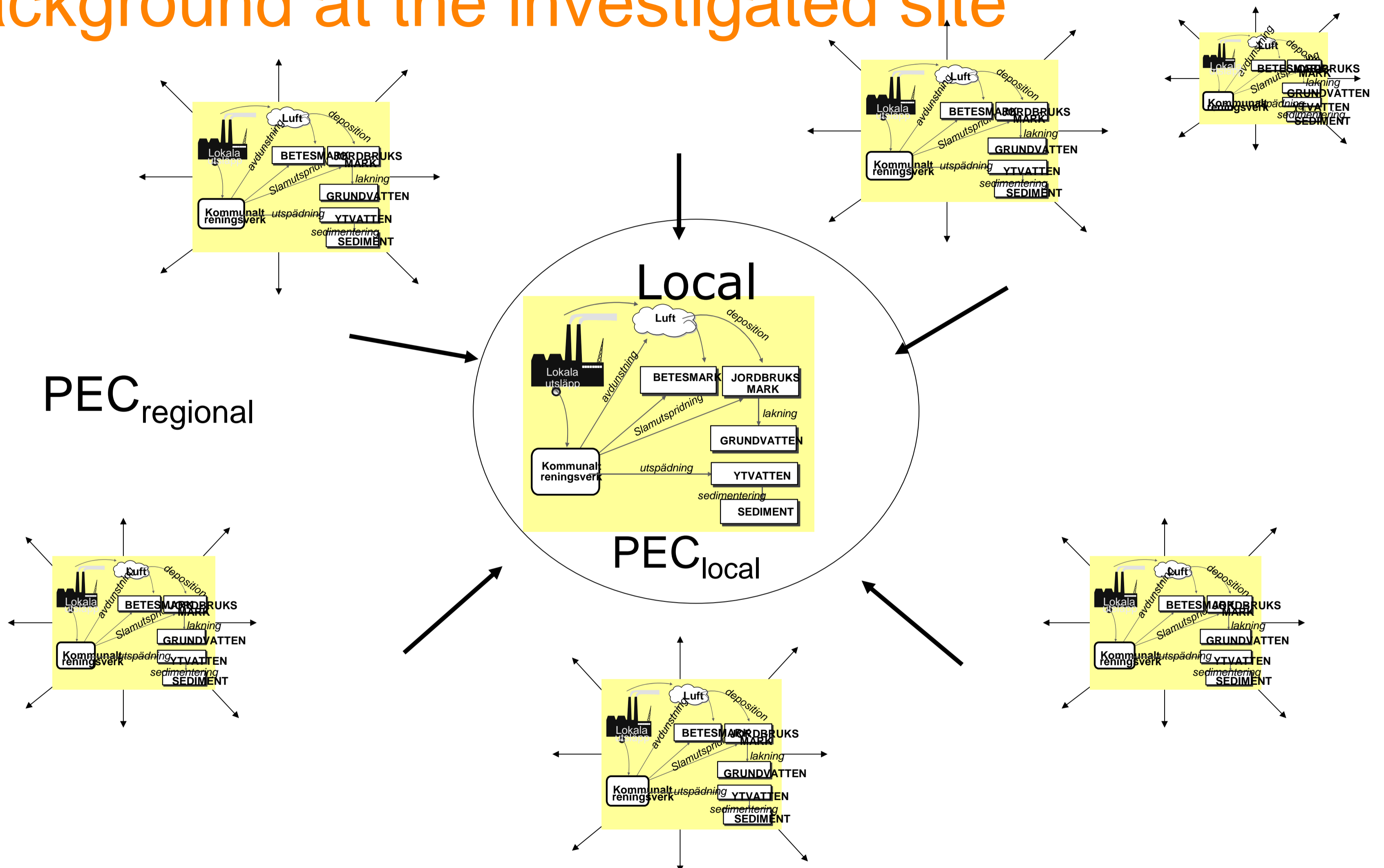
In principle assessed on two spatial scales:

1. locally in the vicinity of point sources \Rightarrow

PEC_{local}

2. regionally for a larger area which includes all point sources and wide dispersive sources in that area $\Rightarrow PEC_{\text{regional}}$

All emitters contribute to the regional background at the investigated site



PEC_{regional}

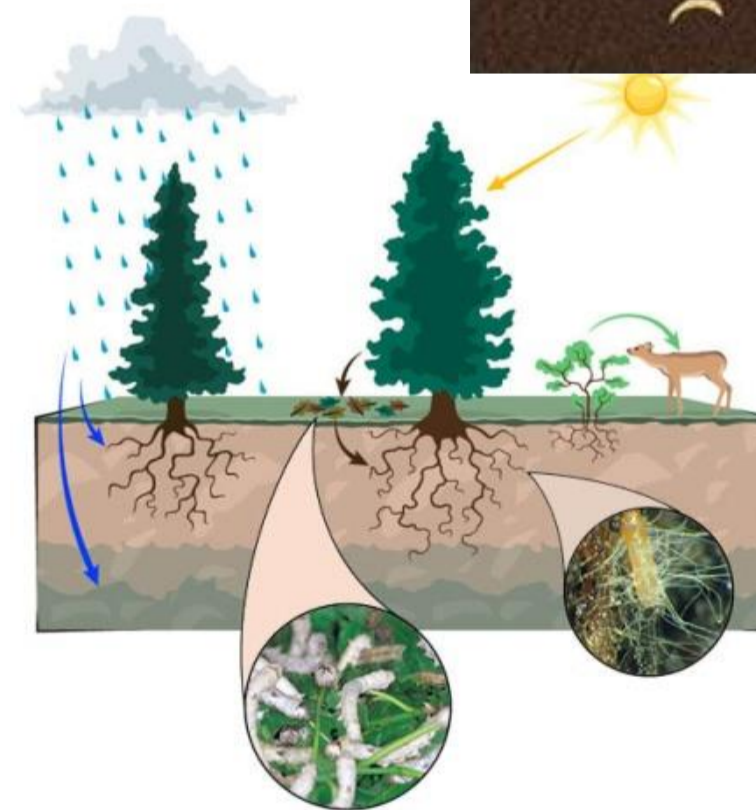
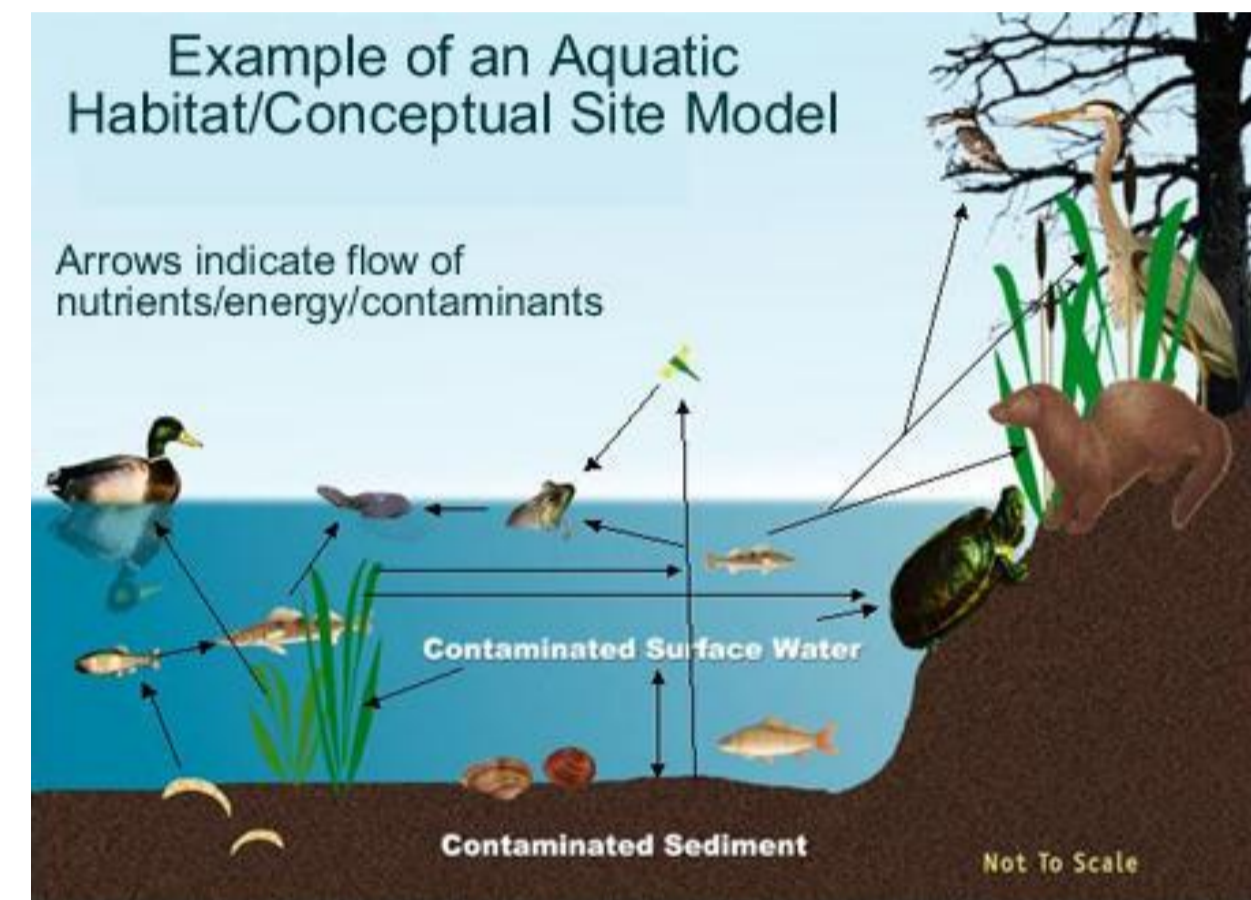
Local

PEC_{local}

$$PEC_{local} = C_{\text{from local emissions}} + PEC_{regional}$$

Administration of a chemical in the environment → different exposure routes

- Water / sediment
- Soil / pore water
- Air
- Via food chain

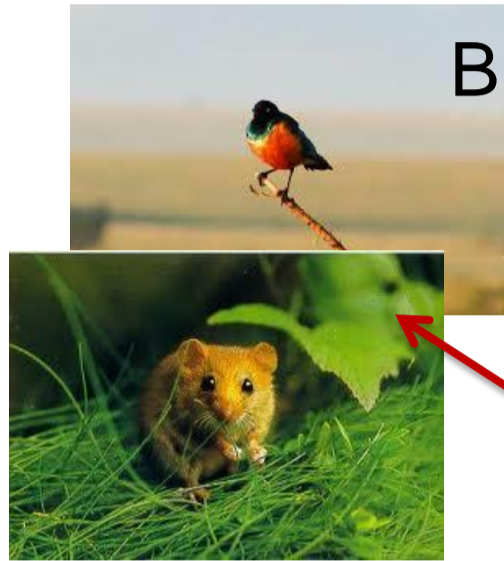


Standard target organisms

- Water organisms
- Sediment organisms
- Soil organisms
- Wastewater treatment organisms
- Top predators 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



Crop



Insects



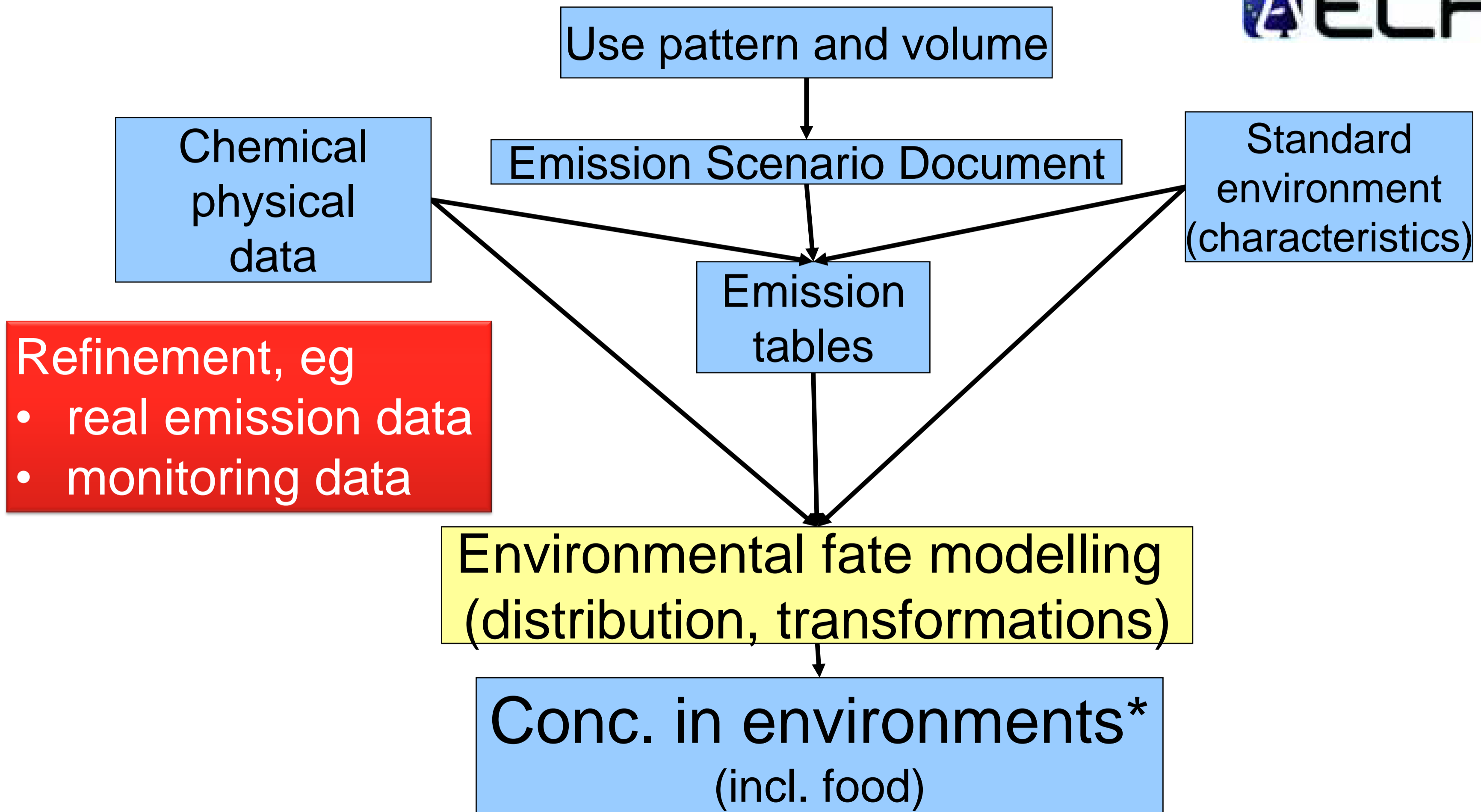
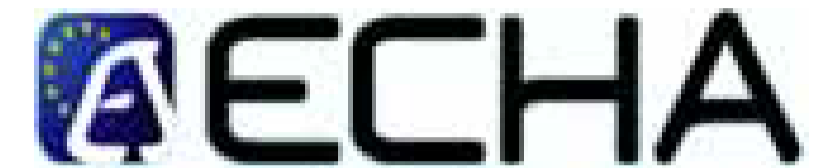
Calculation of Daily Dietary Dose (DDD)



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 estimates, Reach chemicals and biocides - Generic approach



* Predicted Environmental Concentration (PEC)

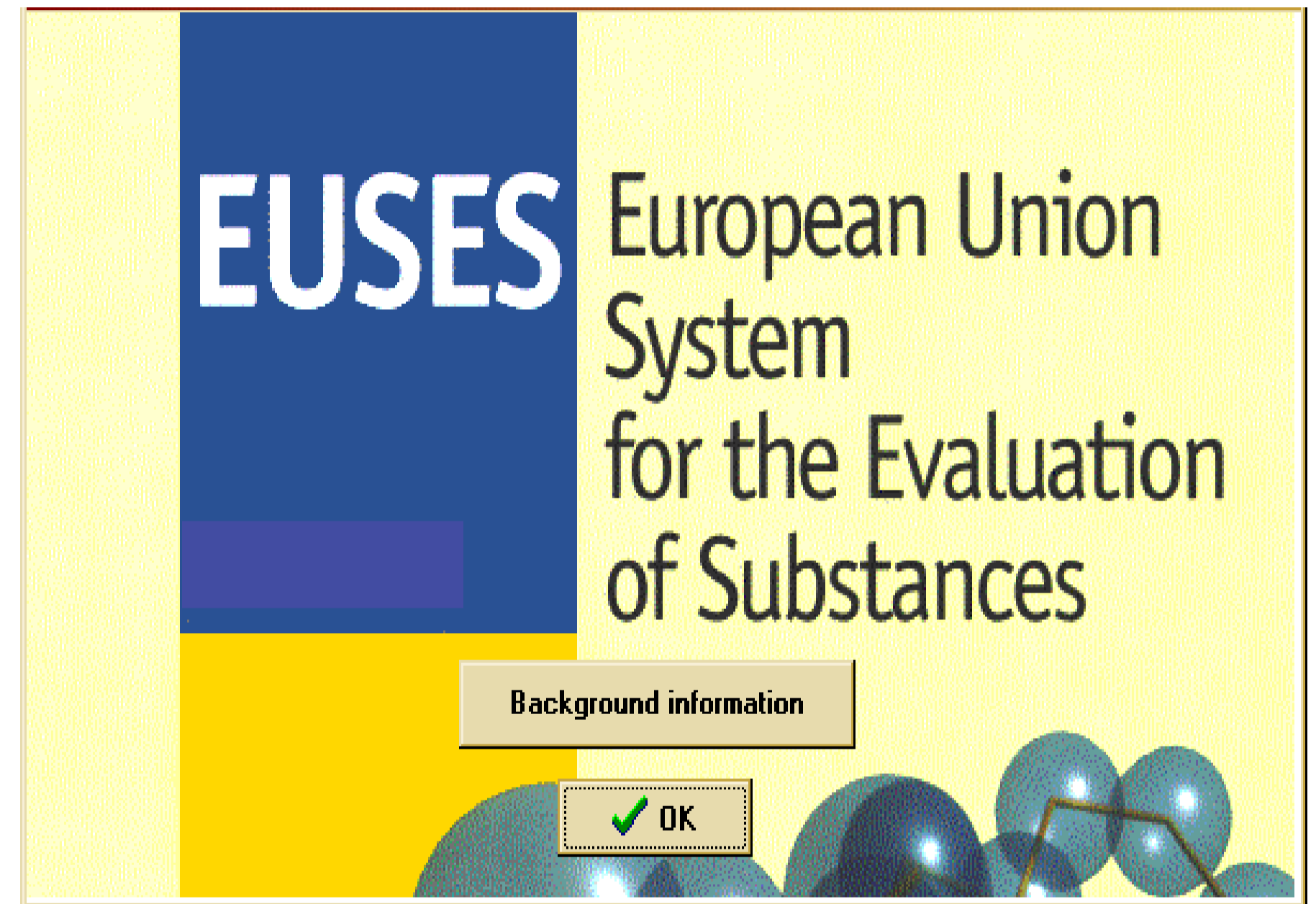


EU model for exposure assessment

Reach chemicals and biocides



- Screening tool
- Computer program
- Environment + Human
- Whole life-cycle
- Generic scenarios
- Emission rates
- Risk characterization

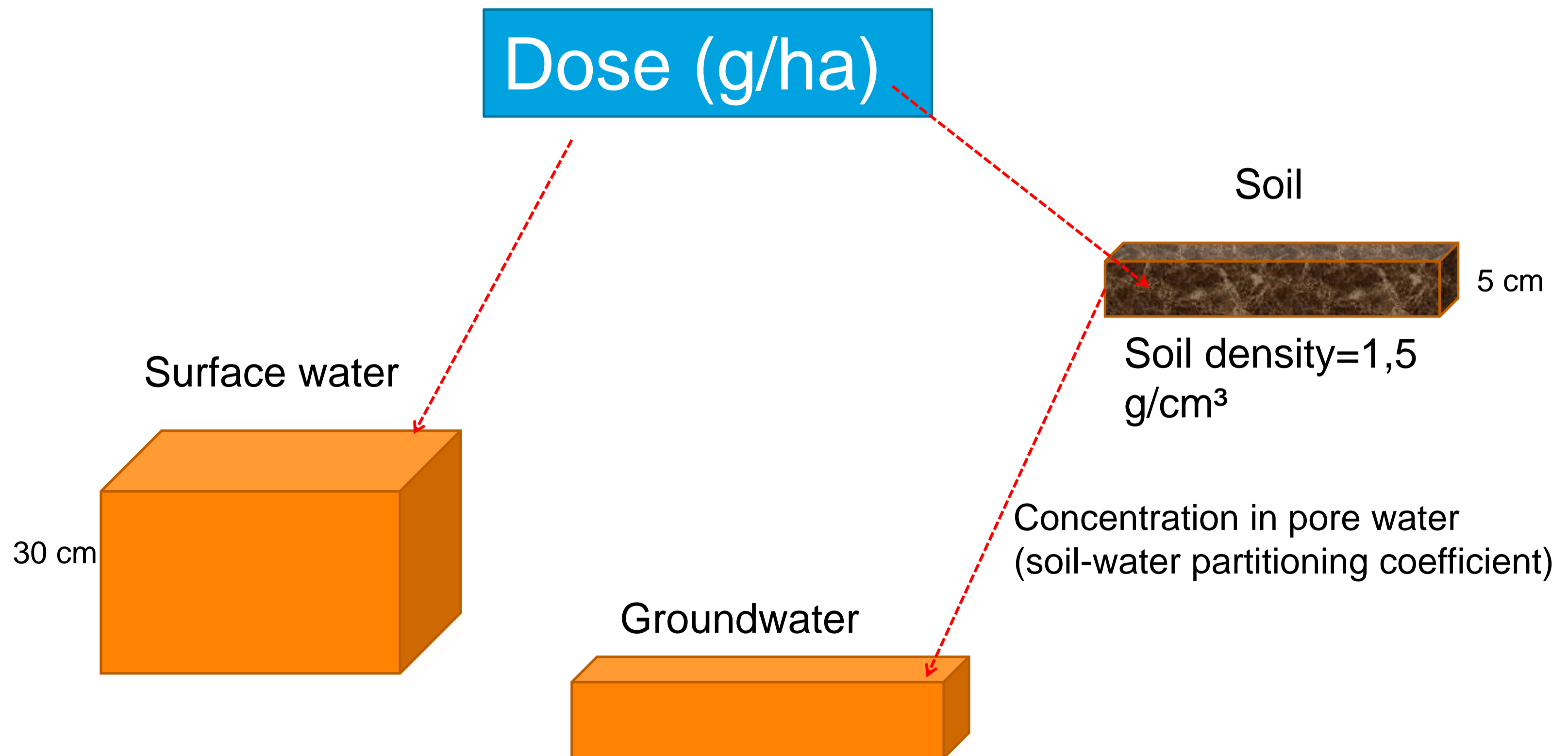


EUSES (2.1) and a manual to the program can freely be downloaded from the internet:

http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/euses/euses

Exposure Assessment (pesticides)– estimate concentrations

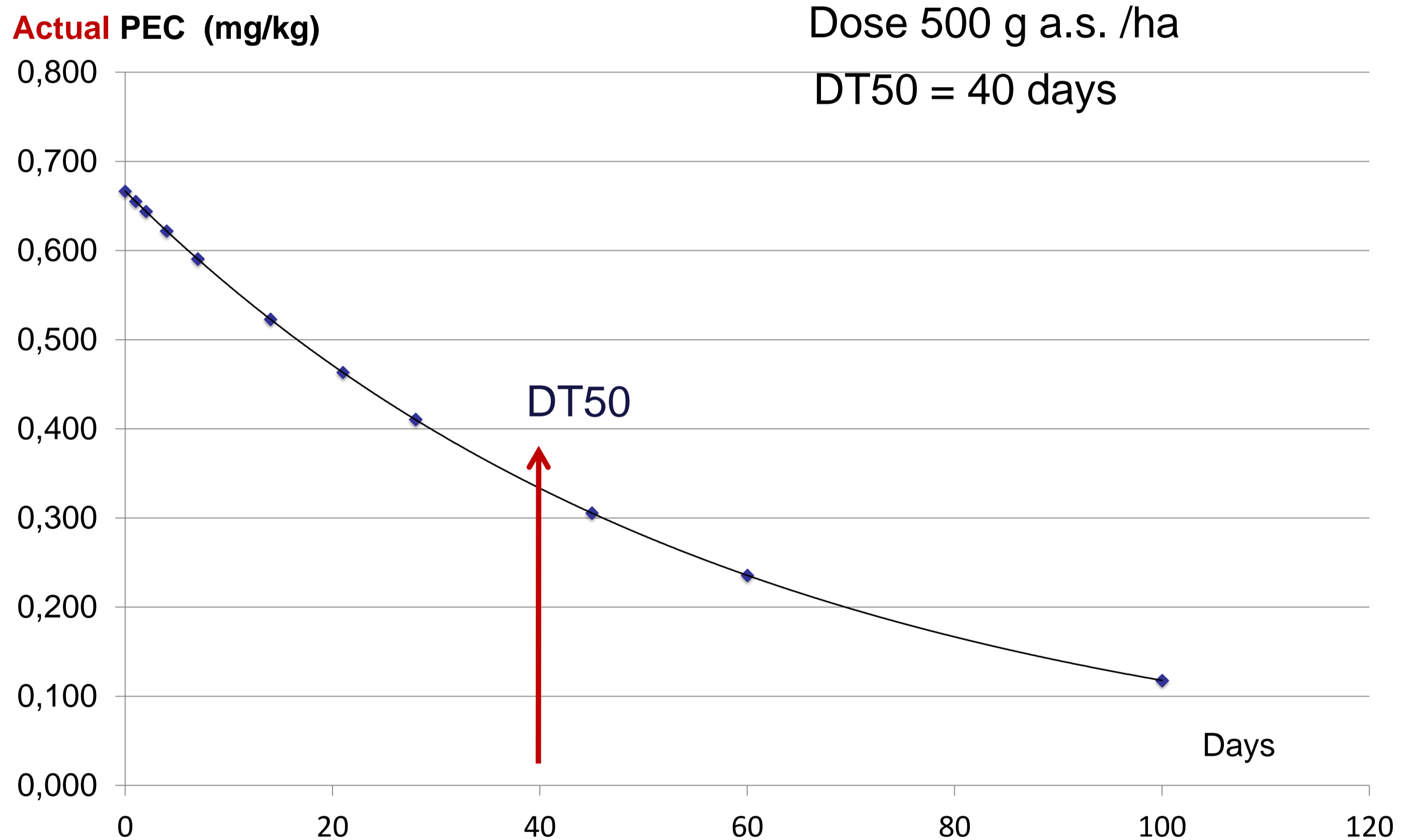
START SIMPLE!!!



Exposure of soil, ground- and surface waters/ Exposure models

- Model calculations FOCUS: groundwater, surface water, persistence in soil; [FOCUS Home](#)
- [In English](#) “Safe plant protection”

Transformation: Example degradation in soil, (one dose)



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

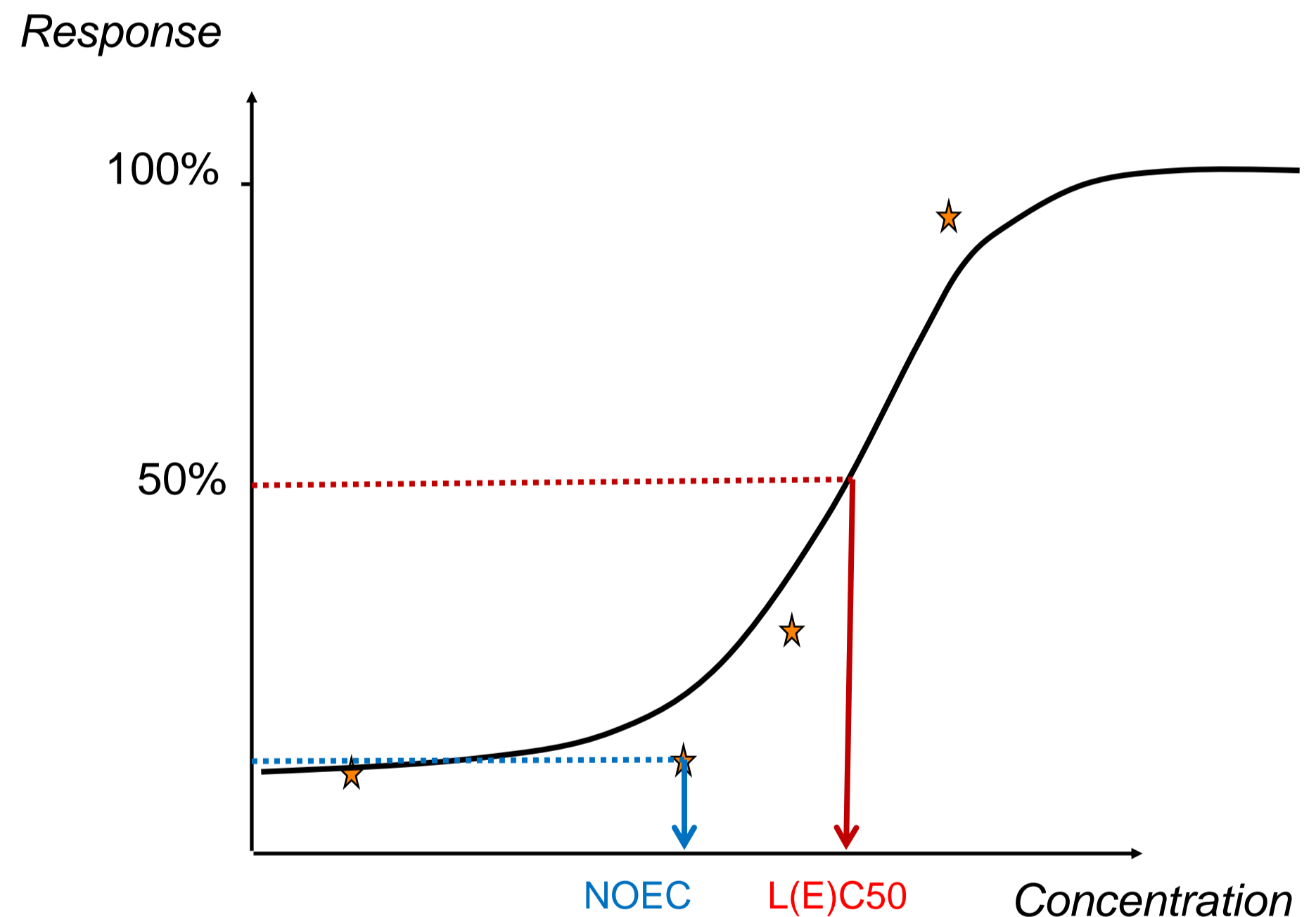
- this means that this value is not compared with ADI
- WHO has set other values for individual substances based on ADI

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

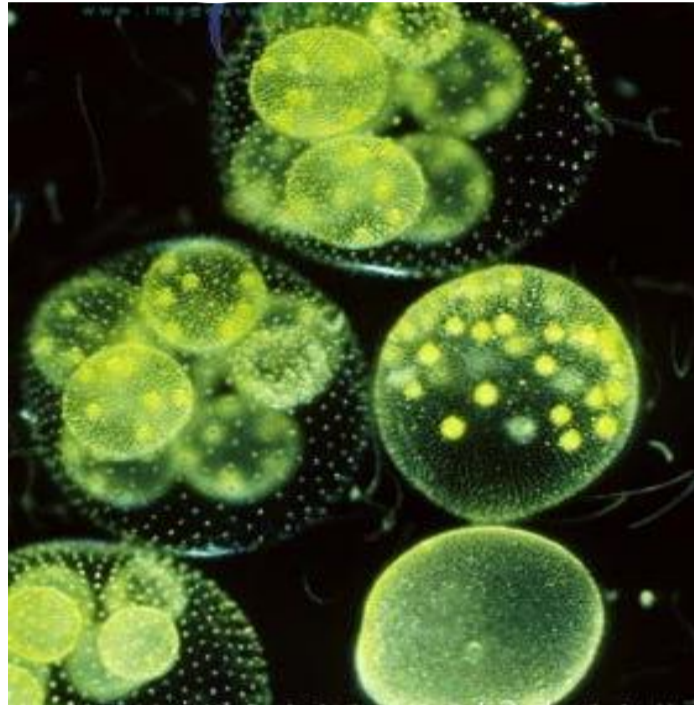
Environmental effects assessment – general principle

1. Identify critical effects (e.g. reproduction, behaviour, immobilisation, growth)
2. Calculate dose – response endpoint (L(E)C₅₀ or NOEC)
3. Add an Assessment/Safety Factor

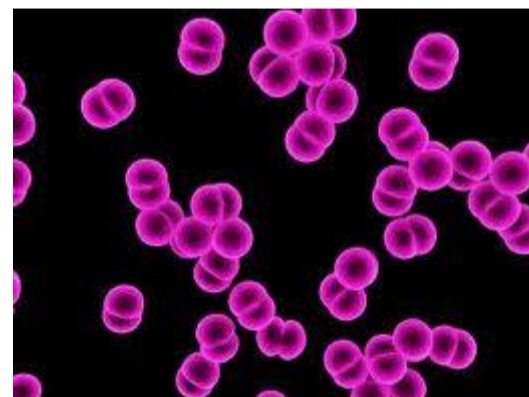


Standard organisms used for testing

Surface water



Soil



Refinement – toxicity data

Laboratory tests with more species



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.
- Assessment/safety factors applied for long-term tests are smaller than for short-term test, as the uncertainty of the extrapolation from laboratory data to the natural environment is reduced. For this reason long-term data are preferred to short-term data.

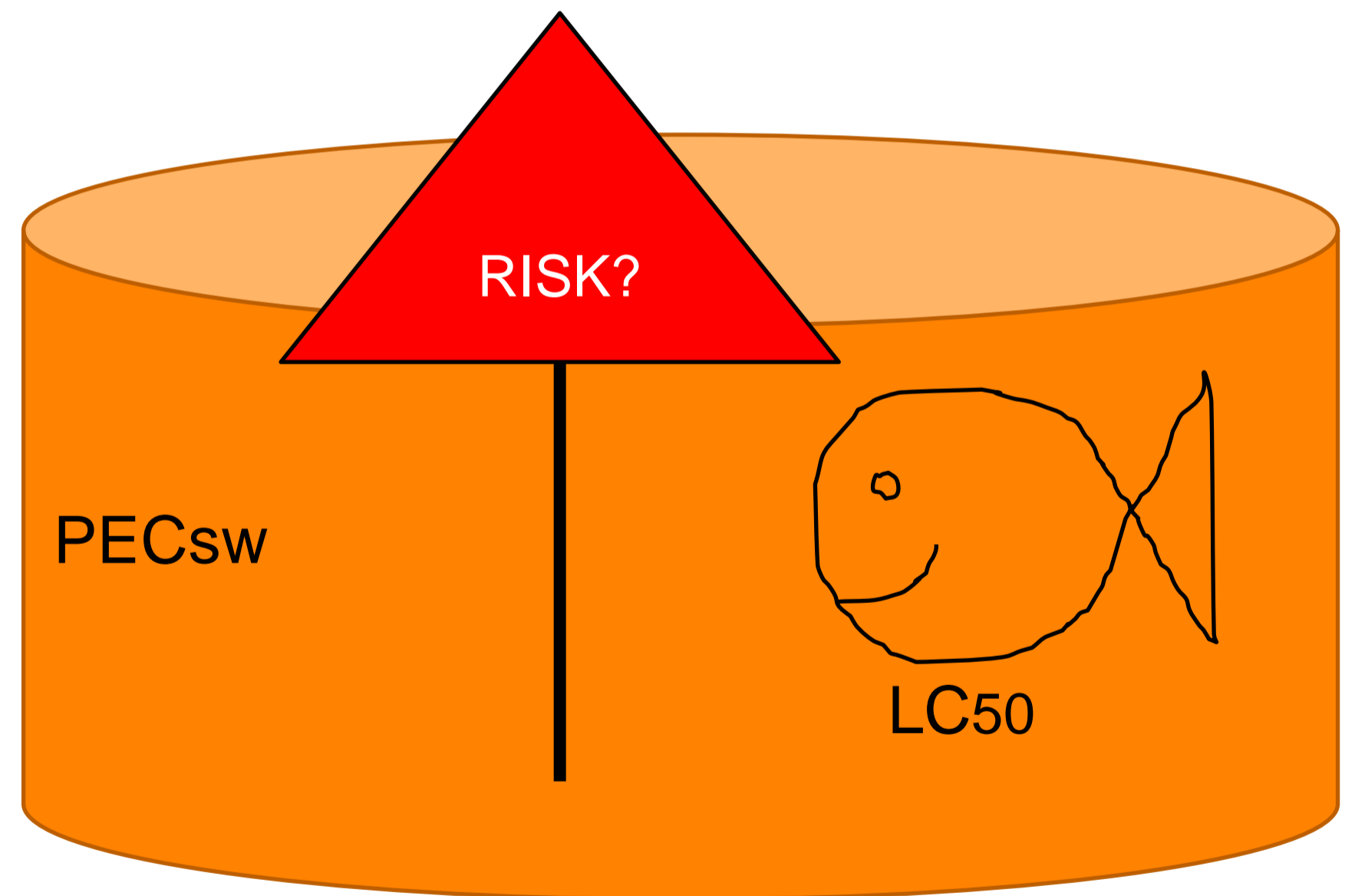
Risk assessment - plant protection products

1. Compare estimated concentration in the environment with effect concentrations = calculation of Toxicity Exposure Ratio (TER)

2. Compare with safety factor

$TER > \text{safety factor} \rightarrow \text{OK}$

$TER < \text{safety factor} \rightarrow \text{RISK}$



Safety factors - plant protection products

TER (Toxicity Exposure Ratio) values are "political values", agreed in the Regulation 1107/2011,- not scientifically based

Examples:

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

(Safety) Assessment factors - 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 L(E)C50 from each of three trophic levels of the base-set (fish, Daphnia and algae)	1000 ^{a)}
One long-term NOEC (either fish or Daphnia)	100 ^{b)}
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 ^{c)}
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 ^{d)}
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) ^{e)}
Field data or model ecosystems	Reviewed on a case by case basis ^{f)}

Risk characterization

Risk characterization ratio

$$RCR = PEC/PNEC$$

In principle:

$RCR < 1$, risk controlled (Reach)/ acceptable (biocides)

$RCR > 1$, risk not controlled/ not acceptable =>

Risk management measures

Example, risk characterization

Concentration in water (estimated or measured); PEC _{water}	0.5 mg/L
<i>Daphnia magna</i> reproduction test (21 days), NOEC	10 mg/L
Fish long-term test, NOEC	50 mg/L
Assessment Factor (AF)	50
PNEC	0.2 mg/L
Risk characterization ratio PEC/PNEC	2.5

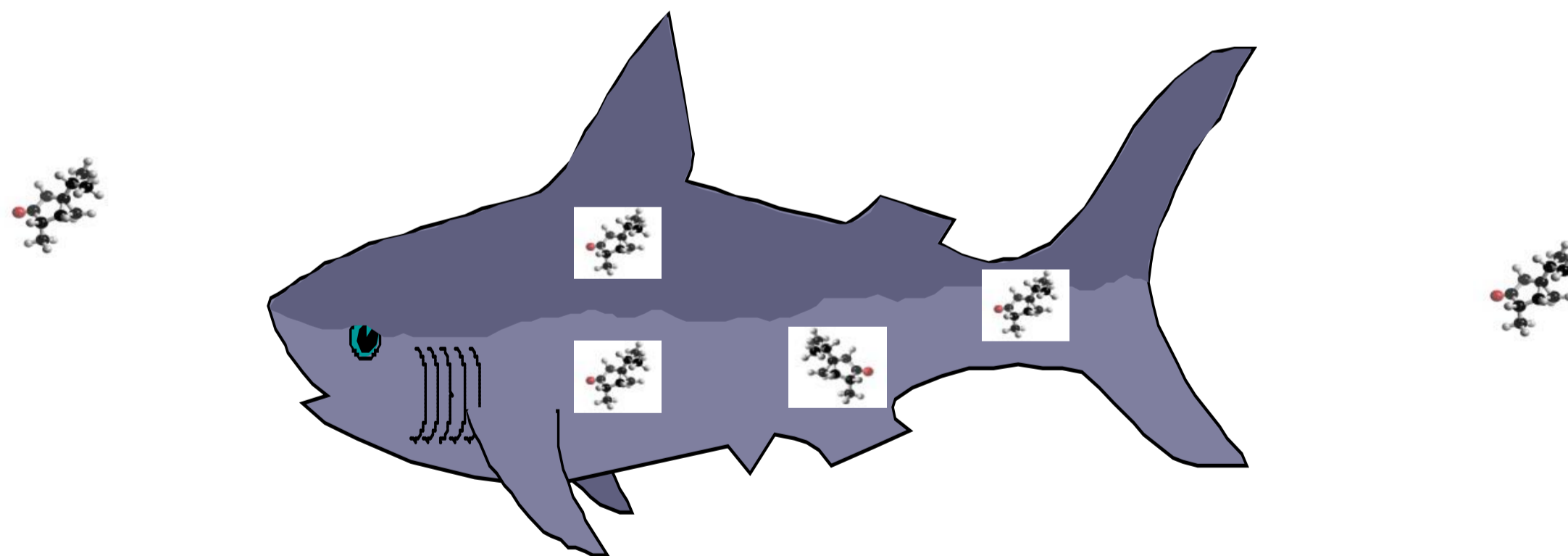
Substances of Very High Concern (SVHC)

- Toxic
- Persistent
- Bioaccumulating

Bioaccumulation

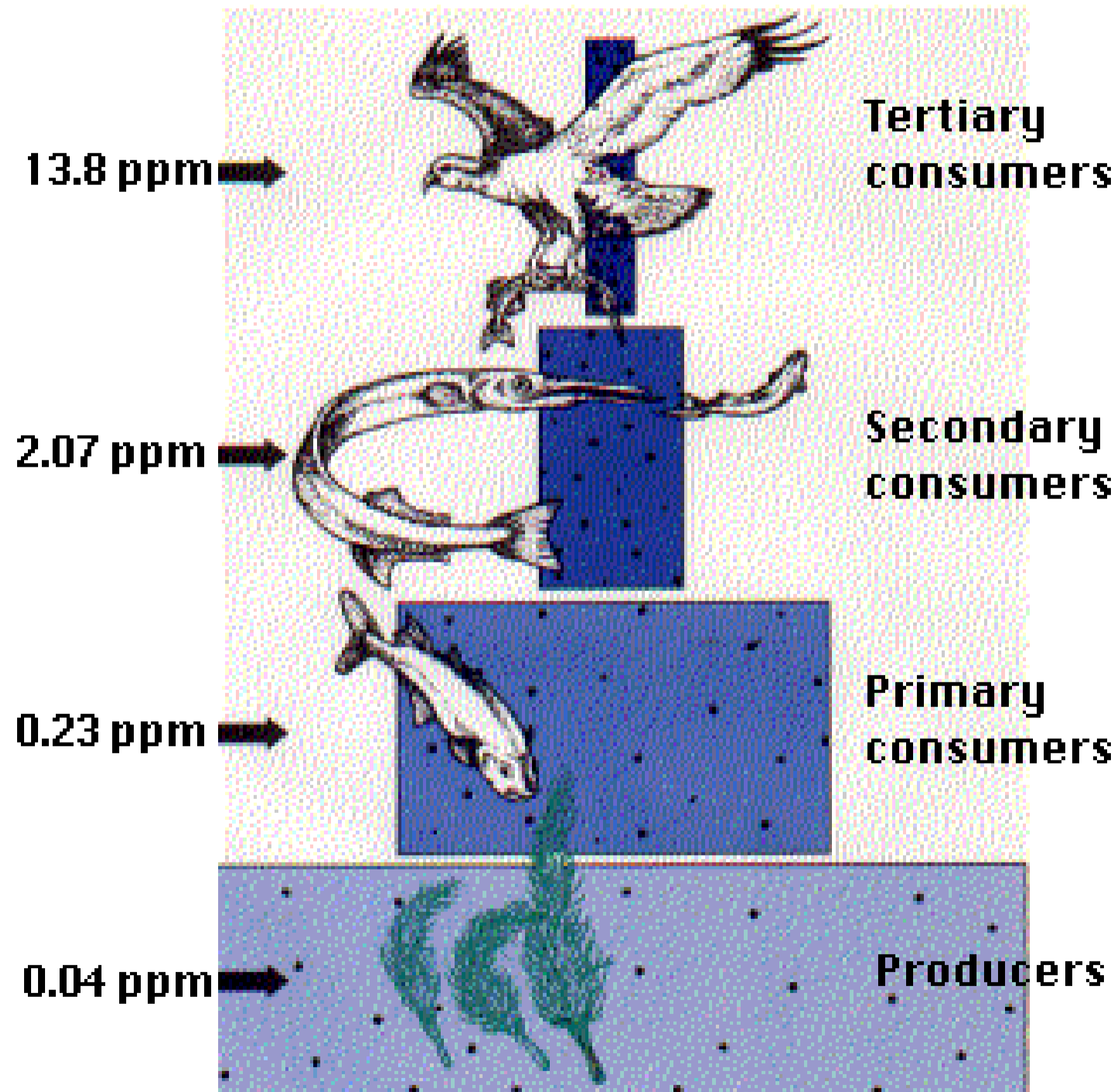
The balance between uptake and excretion.

Assessment of bioaccumulation Bioconcentration factor, BCF: the concentration of the compound in aquatic biota relative to the concentration in the surrounding water



Biomagnification

Increased concentration of a substance with increasing trophic level (accumulation via food chain)



The numbers are representative values of the concentration in the tissues of **DDT** and its derivatives (in parts per million, ppm)

PBT / vPvB assessment

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

very **P**ersistent and **v**ery **B**ioaccumulating have the potential to build up in organisms. Long-term effects (e.g. reduced fertility) could present themselves in the future

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

The PBT / vPvB criteria

Property	PBT-criteria	vPvB-criteria
Persistence*	<ul style="list-style-type: none"> • $T_{1/2} > 60$ days in marine water, or • $T_{1/2} > 40$ days in fresh- or estuarine water, or • $T_{1/2} > 180$ days in marine sediment, or • $T_{1/2} > 120$ days in fresh- or estuarine sediment, or • $T_{1/2} > 120$ days in soil. 	<ul style="list-style-type: none"> • $T_{1/2} > 60$ days in marine, fresh- or estuarine water, or • $T_{1/2} > 180$ days in marine, fresh- or estuarine sediment, or • $T_{1/2} > 180$ days in soil.
Bioaccumulation	BCF > 2000 L/kg	BCF > 5000 L/kg
Toxicity	<ul style="list-style-type: none"> • 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 	Not applicable

* $T_{1/2}$ is the half-life of the chemical in the specific environment

If PBT or vPvB

- Risk reduction measures should be performed
- Exposure assessment not needed
- Substance is put on candidate list for SVHC substances => limitations/ authorisation
- Any supplier of an article containing SVHC in a concentration above 0.1 % by weight shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article.

Take home message:

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

Finding information:

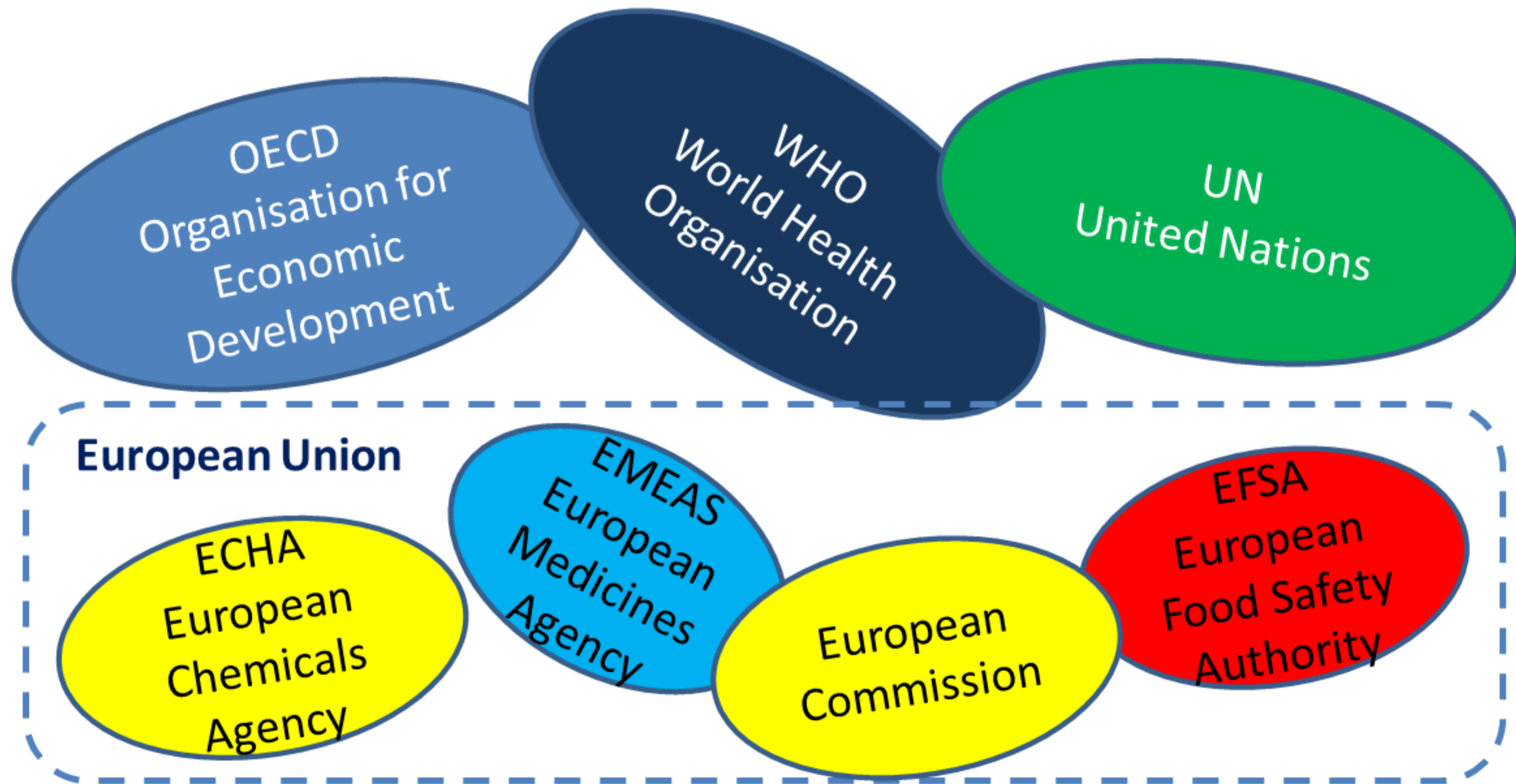
The key to finding things is knowing where to look...

This is simplified by ...

understanding who **OWNS** the information you are looking for.

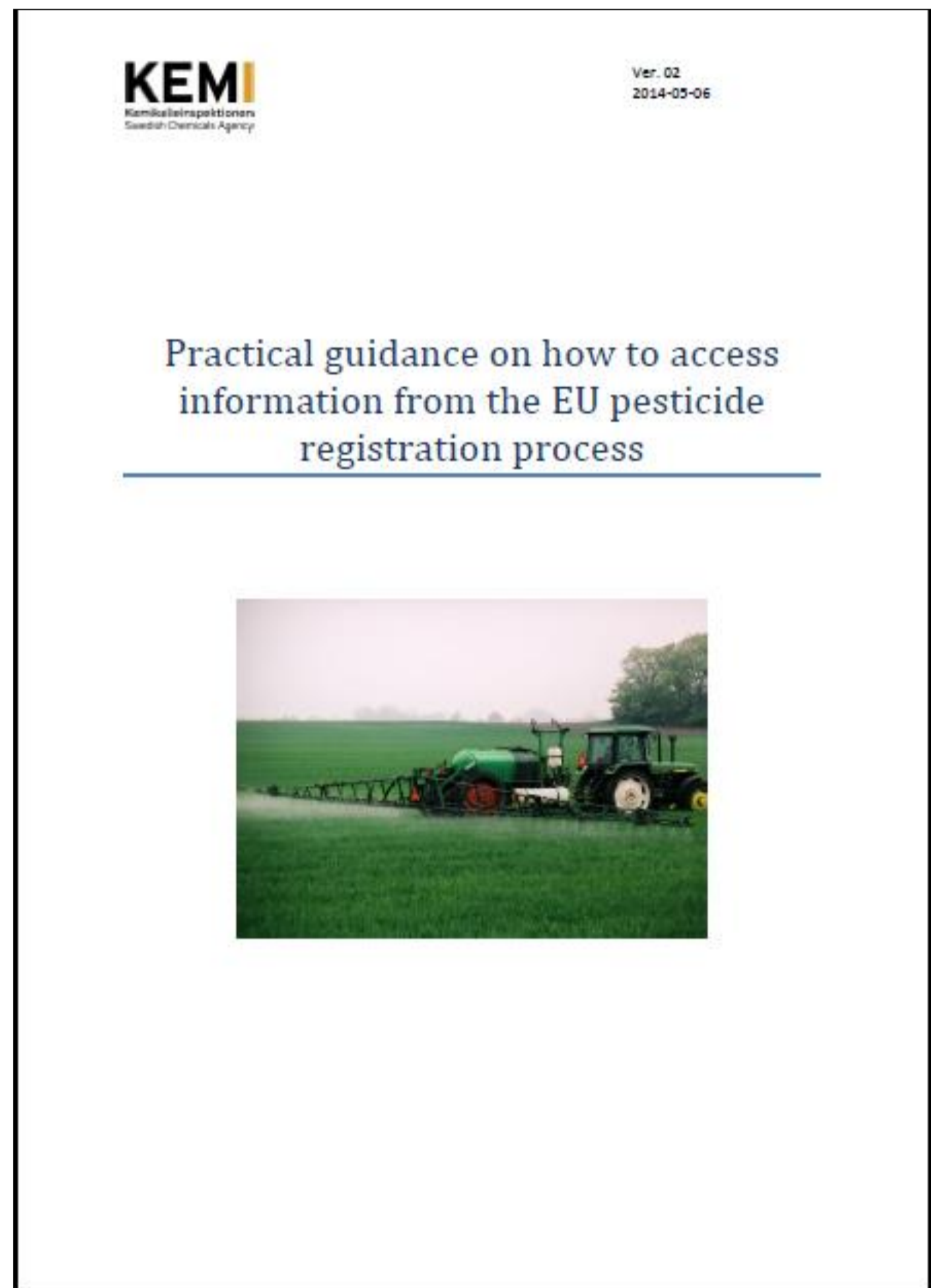
Finding information:

understanding who owns the information you are looking for.



Find information about plant protection products

http://ec.europa.eu/food/plant/index_en.htm



Finding information:

European Commission:

1. Legislation
2. Documentation
3. Data to support decisions
4. Other

Finding information:

European Chemicals Agency:

1. Information about data requirements
2. Handling applications
3. Assessment reports
4. Other

Find information about biocides

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Practical guidance on how to access
information from the European Union
biocides registration process

August, 2014



Data search for industrial and consumer (Reach) chemicals and biocides

ECHA web site

<http://echa.europa.eu/>



Search the ECHA Website

- About Us
- Regulations
- Addressing Chemicals of Concern
- Information on Chemicals**
- Chemicals in our Life

ECHA > Homepage



01 September 2014 - Press release
ECHA's proposal to add new substances to the Authorisation List is now in public consultation

ECHA has launched a public consultation on its draft recommendation of new substances to be included in the Authorisation List. Comments can be submitted by 30 November 2014. In parallel, ECHA facilitates a call by the European Commission on the possible socio-economic consequences of the inclusion of these substances in Annex XIV.

Search for Chemicals

I have read and I accept the

Name, EC or CAS No

CLP 2015: ACT NOW!

Biocides Stakeholder
 24 September 2014, Helsinki, F

News

18 September 2014 - News alert
ECHA calls for a new round of comments on the reproductive toxicity of acetochlor

ECHA is launching an additional public consultation on the harmonised classification and labelling (CLH) for reproductive toxicity of acetochlor (EC No 251-899-3, CAS No 34256-82-1). New comments on this hazard class are welcome.

17 September 2014 - News alert

> REACH IT

> IUCLID 5



Search the ECHA Website

About Us

Regulations

Addressing Chemicals of Concern

Information on Chemicals

Chemicals in our Life

ECHA > Information on Chemicals



Information on Chemicals

This is unique source of information on the chemicals manufactured and imported in Europe. It covers their hazardous properties, classification and information on how to use them safely. It is generated by industry in line with their responsibilities under the EU chemicals legislation. This information is a valuable resource for advancing the safe use of chemicals and for the replacement of the most hazardous ones by safer alternatives.

Search for Chemicals

I have read and I accept the terms and conditions

Name, EC or CAS No

REACH



> [Registered substances](#) ←

> [EC Inventory](#)

> [Pre-registered substances](#)

> [Testing Proposals](#)

> [Transitional Measures](#)

> [Community Rolling Action Plan \(CRAP\)](#)

> [Candidate List substances in article 18](#)

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances to be registered by 31

Last updated 14 August 2014. Database contains 12636 unique substances and contains information from 48801 Dossiers.

EC / List number	<input type="text"/>	Registration Number	<input type="text"/>
CAS Number	<input type="text" value="7440-43-9"/>	Registrant	<input type="text"/>
Name	<input type="text" value="Cadmium"/>	Total tonnage band (min)	<input type="text"/>
Total tonnage band (min)	<input type="text"/>	Total tonnage band (max)	<input type="text"/>
Last update date (min)	<input type="text"/>	Last update date (max)	<input type="text"/>
Country in which registered	<input type="text"/>	Registration type	<input type="text"/>
PBT Assessment outcome	<input type="text"/>	Submission type	<input type="text"/>
Product Category	Sector of Use	Process Category	Environmental Release Category
<input type="text" value="Select"/>	<input type="text" value="Select"/>	<input type="text" value="Select"/>	<input type="text" value="Select"/>
<input checked="" type="checkbox"/> I have read and I accept the legal notice			
<input type="button" value="Search"/> <input type="button" value="Reset"/>			

EC / List No.	CAS No.	Name	Registration type	Submission type	Tonnage band	View
208-168-9	513-78-0	cadmium carbonate	Full	Joint Submission	100 - 1,000 tonnes per annum	
215-146-2	1306-19-0	cadmium oxide	Full	Joint Submission	1,000 - 10,000 tonnes per annum	
215-147-8	1306-23-6	cadmium sulphide	Full	Joint Submission	10 - 100 tonnes per annum	
215-149-9	1306-25-8	cadmium telluride	Full	Joint Submission	100 - 1,000 tonnes per annum	
231-152-8	7440-43-9	cadmium	Full	Joint Submission	1,000 - 10,000 tonnes per annum	
232-466-8	8048-07-5	cadmium zinc sulfide yellow	Full	Joint Submission	100 - 1,000 tonnes per annum	
233-296-7	10108-64-2	cadmium chloride	Full	Joint Submission	1 - 10 tonnes per annum	
233-331-6	10124-36-4	cadmium sulphate	Intermediate	Joint Submission	Intermediate Use Only	
233-710-6	10325-94-7	cadmium nitrate	Full	Joint Submission	10 - 100 tonnes per annum	
244-168-5	21041-95-2	cadmium hydroxide	Full	Joint Submission	1,000 - 10,000 tonnes per annum	
261-218-1	58339-34-7	cadmium sulfoselenide red	Full	Joint Submission	100 - 1,000 tonnes per annum	
273-707-7	69011-69-4	Cadmium, dross	Intermediate	Joint Submission	Intermediate Use Only	
273-721-3	69012-21-1	Wastewater, cadmium sulfate electrolytic, acid	Intermediate	Joint Submission	Intermediate Use Only	
273-809-1	69029-67-0	Flue dust, lead-refining	Full	Joint Submission	1,000 - 10,000 tonnes per annum	
202 200 7	91053-	Leach residues, cadmium cake	Intermediate	Joint Submission	Intermediate Use Only	

cadmium

Use of this information is subject to copyright laws and may require the permission of the owner of the information
ECHA [Legal Notice](#).

- Exposure**
- PBT assessment**
- Physical and chemical properties**
- Environmental fate and pathways**
- Ecotoxicological Information**
 - > Ecotoxicological Information.001
 - > **Aquatic toxicity**
 - > **Sediment toxicity**
 - > **Terrestrial toxicity**
- Toxicological**

Ecotoxicological Information.001

Hazard for aquatic organisms Hazard for terrestrial organisms Haza

Hazard for aquatic organisms

Freshwater

Hazard assessment conclusion	PNEC aqua (freshwater)
	0.19 µg/L
Assessment factor	2
Extrapolation method	statistical extrapolation

Thank you for your attention!



Useful links

Risk assessments:

Pesticide risk assessments (EFSA conclusions):

http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection

Or Google search "EFSA conclusion + name of the active substance"

Risk assessments for biocides (assessment report):

<http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

Risk assessments for substances on Annex III, Rotterdam convention (Decision Guidance documents):

<http://www.pic.int/TheConvention/Chemicals/DecisionGuidanceDocuments/tabid/2413/language/en-US/Default.aspx>

Guidance document on exposure and risk assessments:

Pesticides:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm

Biocides:

<http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

<http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents>

Industrial and consumer chemicals (REACH):

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>

Homework for Monday

- Look for monitoring data from your country (e.g. metal concentrations such as cadmium, lead) in water.
- Try to find data close to local sources and at reference stations.