



# Environmental Exposure and Risk Assessment cont.


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# Today

- Some repetition
- Finding data on biocides
- Exercises on Risk Assessment

# Risk assessment (RA)

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- Hazard assessment
  - Exposure assessment

***Risk characterization***

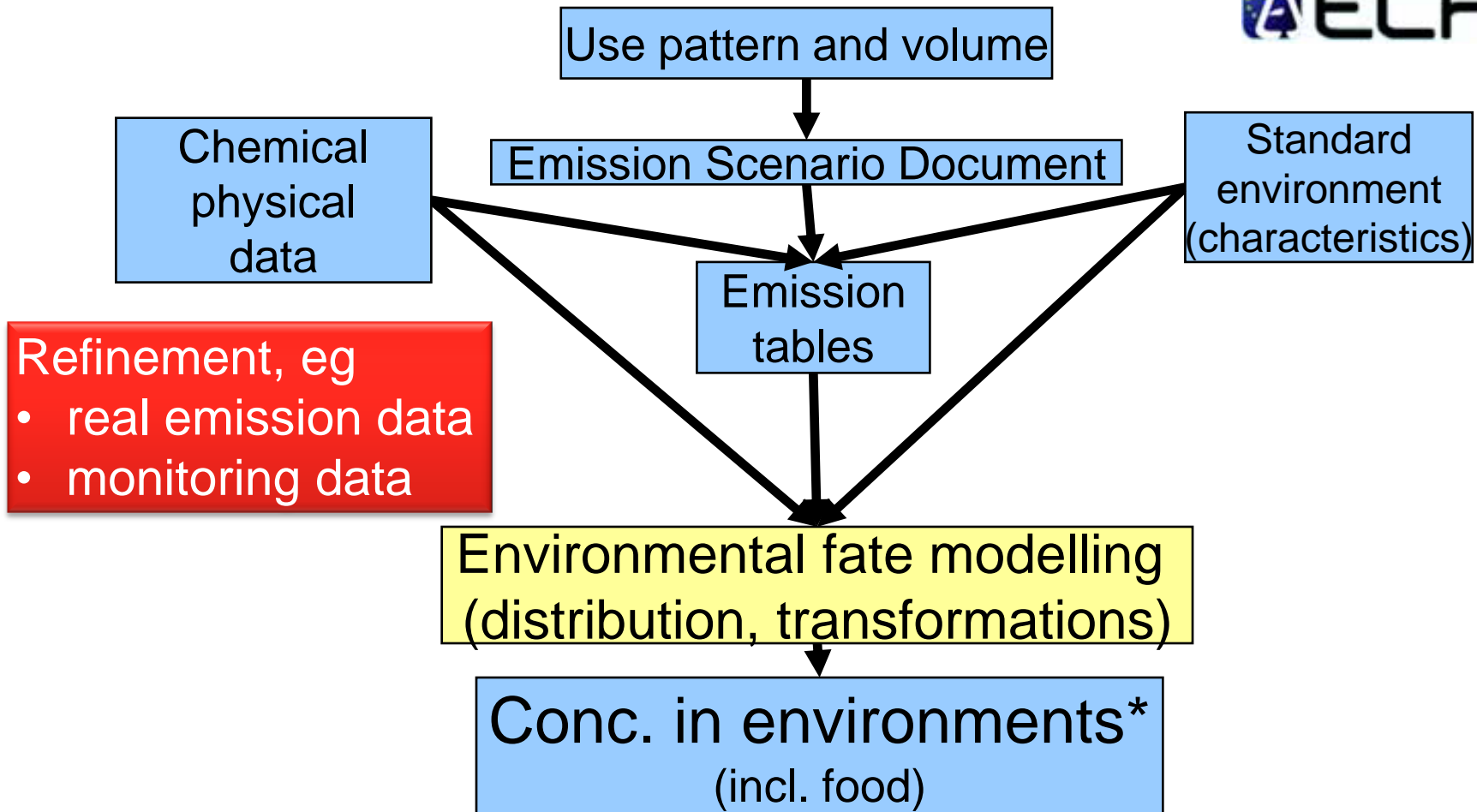
RA for industrial and consumer chemicals (Reach) and biocides versus agro-chemicals: Similar in principle but somewhat different in terms and details

# Environmental exposure assessment

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

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

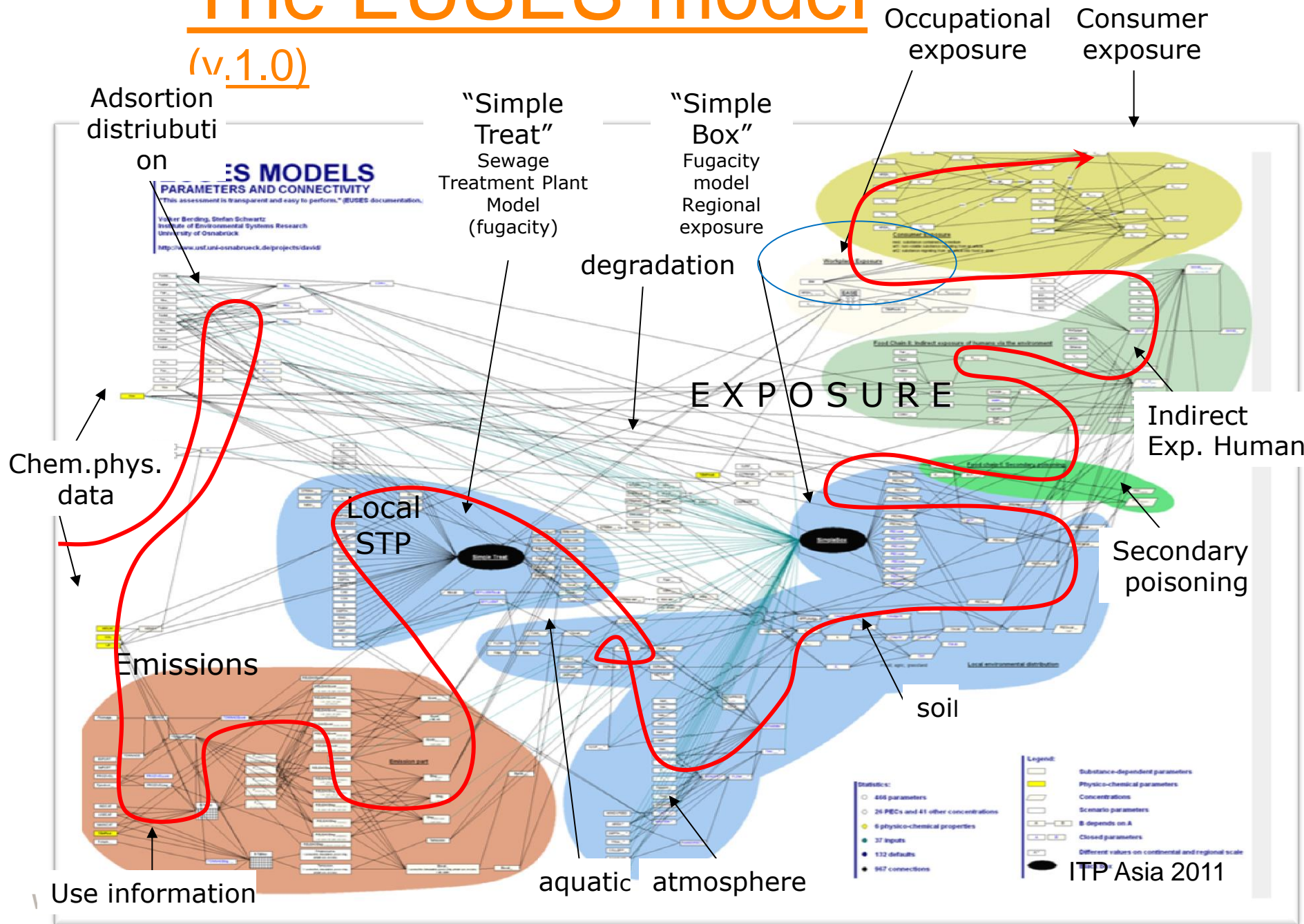
# Exposure estimates, Reach chemicals and biocides - Generic approach



\* Predicted Environmental Concentration (PEC)

# The EUSES model

(v.1.0)



# (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<sub>surface water</sub>



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 <sup>a)</sup>
One long-term NOEC (either fish or Daphnia)	100 <sup>b)</sup>
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 <sup>c)</sup>
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 <sup>d)</sup>
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) <sup>e)</sup>
Field data or model ecosystems	Reviewed on a case by case basis <sup>f)</sup>

# 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 <sub>water</sub>	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	<b>2.5</b>

# cadmium

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- 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

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

# Take home message:

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

# Exercise, search Echa website

Use your own monitoring data or i propose

Dibutyltin dilaurate, Cas No: 77-58-7

Trixylyl phosphate, Cas No: 25155-23-1

- Look at information on use. Is there consumer use?
- Volume (tonnage band)?
- Is the chemical/compound (self) classified?
- Assess your own data, or for the two proposed chemicals use
  - $PEC_{\text{aquatic (fresh water)}} = 1 \mu\text{g/L}$
  - $PEC_{\text{sediment (fresh water)}} = 1 \mu\text{g/kg}$
- Is risk controlled?
- How can the assessment be refined?

$$RCR = PEC/PNEC$$