TOXICITY and ENVIRONMENTAL IMPACT

MARINE RISK ASSESSMENT METHODOLOGY APPLIED IN THE CONTEXT OF ACCIDENTAL SPILLS

An example with the CLARA Project

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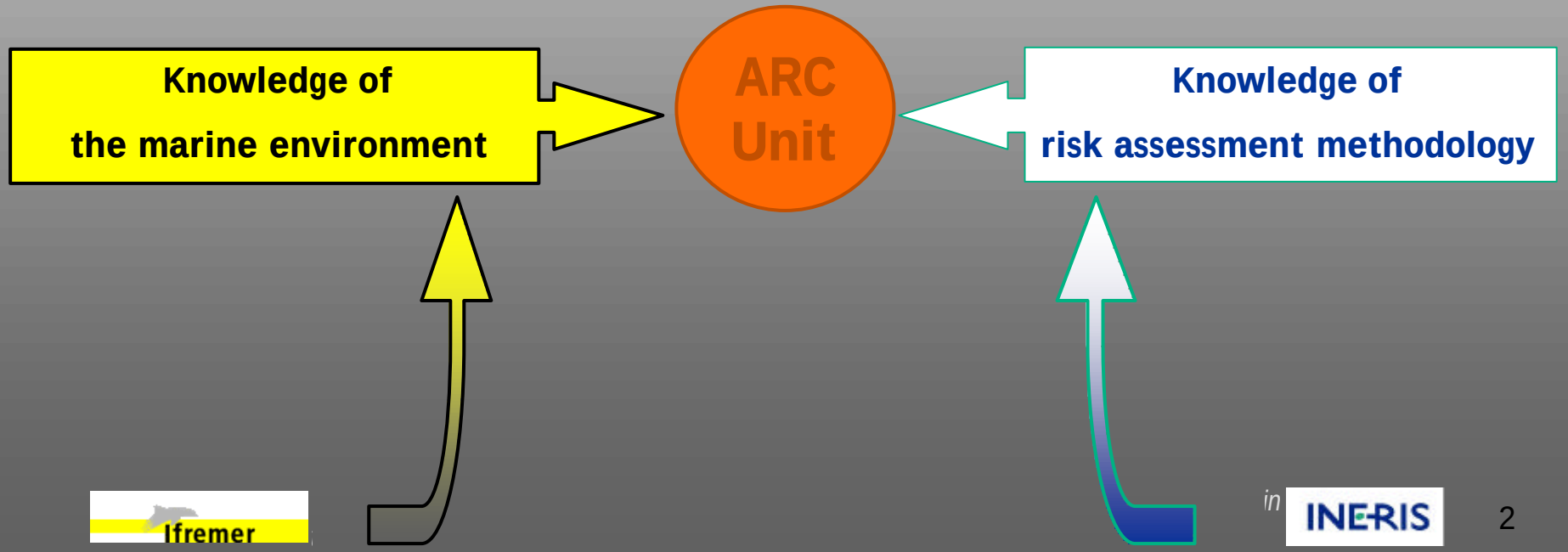
Joint IFREMER/INERIS ARC Unit

- "Analyse des Risques Chimiques (**ARC**) en milieu marin"

  = **Marine Risk Assessment Unit**

  - 2 institutes : IFREMER / INERIS
  - combination of two skills :



INVOLVMENT OF ARC Unit IN THE CLARA PROJECT (1/2)

- In the second phase of the project :

Collection of valid **ecotoxicity data**

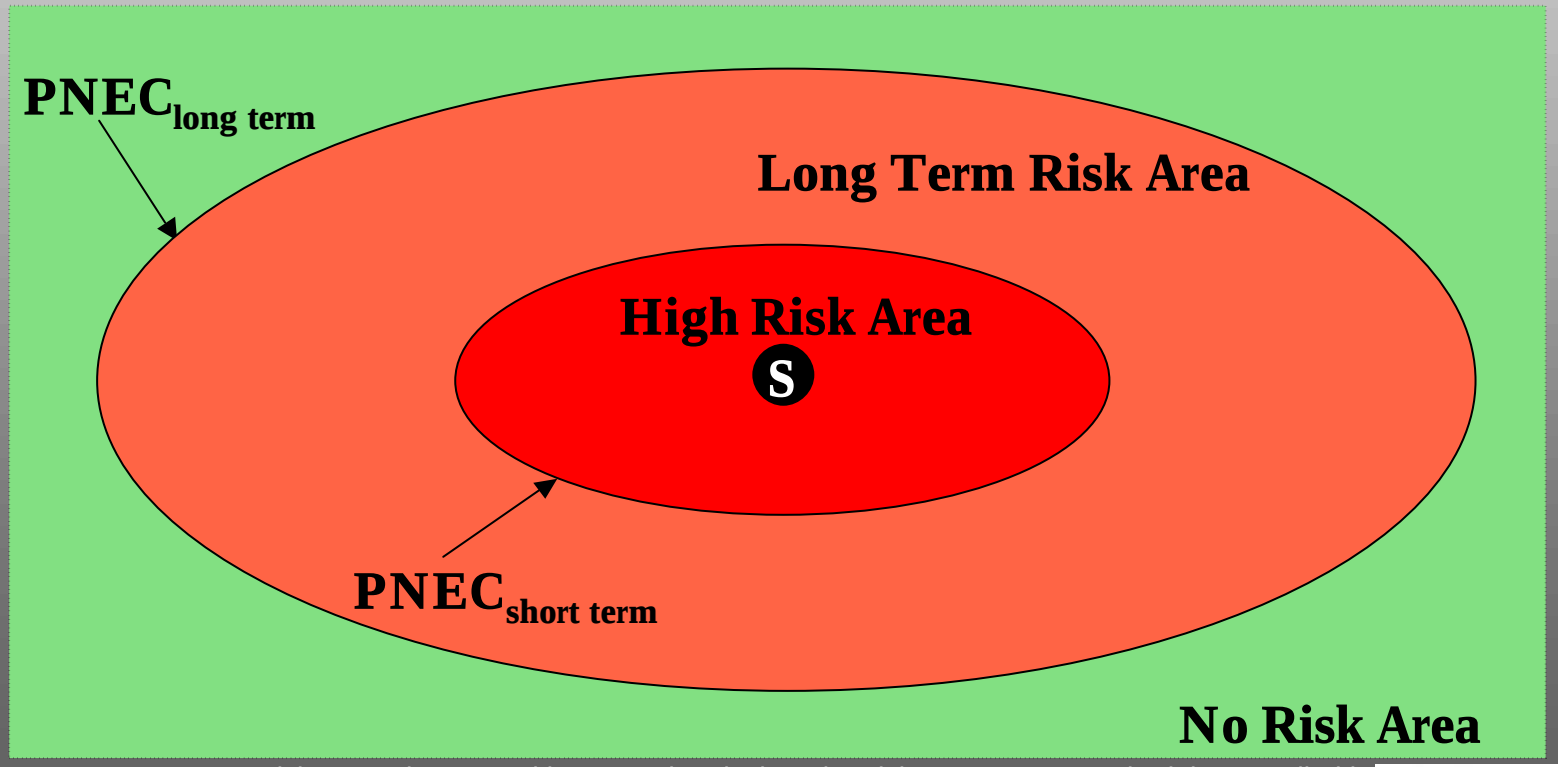
…to derive…

Predicted No Effect Concentrations (PNECs)

- for short term exposure
- for long term exposure

INVOLVMENT OF ARC Unit IN THE CLARA PROJECT (2/2)

- **Derivation of PNECs : what for ?**
  - Aim : definition of risk areas



RISK ASSESSMENT METHODOLOGY DERIVATION OF PNEC$_{marine,\ long\ term}$

- **TGD : Technical Guidance Document** in support of Commission Directive 93/67/EEC on **risk assessment for new notified substances** and Commission Regulation EC No 1488/94 on **risk assessment for existing substances** and Commission Directive (EC) 98/8 on **biocides.**

Chapter 3. Environmental Risk Assessment - **Marine**

DERIVATION OF $PNEC_{long\ term}$

2 methods available for derivation

Bioassays

→ Effect Concentrations (LC_{50}, EC_{50}, NOEC)

Assessment factors method

Statistical extrapolation method

Predicted No Effect Concentrations ($PNEC_{long\ term}$)

DERIVATION OF PNEC$_{long\ term}$

2 methods available for derivation extrapolation factors method

Bioassays

→ Effect Concentrations (LC_{50}, EC_{50}, NOEC)

Assessment factors method

Statistical extrapolation method

Predicted No Effect Concentrations (PNEC$_{long\ term}$)

DERIVATION OF $PNEC_{long\ term}$
extrapolation factors method

Definition of extrapolation factors :
they are divisor coefficients of effect concentrations

$$PNEC = \frac{\text{effect concentrations } (EC(L)_{50}, NOEC)}{\text{extrapolation factor}}$$

DERIVATION OF PNEC$_{long\ term}$
extrapolation factors method

Why we apply extrapolation factor : to take account, if necessary, of

Extrapolation of data :
- laboratory → field
- acute toxicity → chronic toxicity
- freshwater → saltwater

Uncertainties of data, due to
- intra- and inter-specific variations
- intra- and inter-laboratories variations .

Lack of data (marine and estuarine waters)

DERIVATION OF PNEC freshwater, long term
extrapolation factors method

Table 16 Assessment factors to derive a $PNEC_{aquatic}$

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]

DERIVATION OF PNEC$_{marine,\ long\ term}$
extrapolation factors method

Marine environment

Lack of ecotoxicity data on marine organisms

DERIVATION OF PNEC$_{marine,\ long\ term}$
extrapolation factors method

Adaptation of the TGD to the marine environment

When it seems that there are no significant differences between freshwater data (FW) and marine data (SW)

Use of the whole data set
(FW and SW) to derive PNEC

Higher biodiversity and
Specific taxa in the marine environment

Precaution : application of an additional extrapolation factor of 10 (FW -> SW)

DERIVATION OF PNEC marine, long term
extrapolation factors method

Table 25 Assessment factors proposed for deriving $PNEC_{water}$ for saltwater for different data sets

Data set	Assessment factor
Lowest short-term L(E)C50 from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels	10,000 [a]
Lowest short-term L(E)C50 from freshwater or saltwater representatives of three taxonomic groups (algae, crustaceans and fish) of three trophic levels, + two additional marine taxonomic groups (e.g. echinoderms, molluscs)	1000 [a]
One long-term NOEC (from freshwater or saltwater crustacean reproduction or fish growth studies)	1000 [a]
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish)	500 [a]
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels	100 [a]
Two long-term NOECs from freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and/or fish) + one long-term NOEC from an additional marine taxonomic group (e.g. echinoderms, molluscs)	50
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels + two long-term NOECs from additional marine taxonomic groups (e.g. echinoderms, molluscs)	10

DERIVATION OF $PNEC_{long\ term}$

2 methods available for derivation

statistical extrapolation method

Bioassays

→ Effect Concentrations (LC_{50}, EC_{50}, NOEC)

Assessment factors method

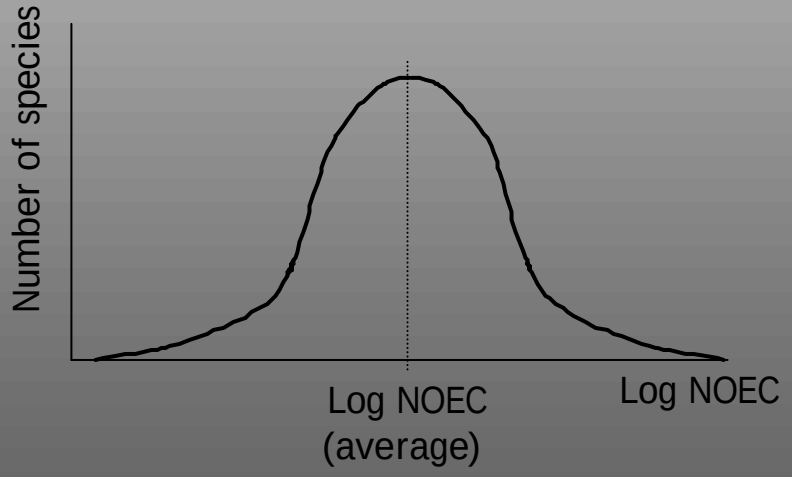
Statistical extrapolation method

Predicted No Effect Concentrations ($PNEC_{long\ term}$)

DERIVATION OF PNEC$_{long\ term}$
statistical extrapolation method

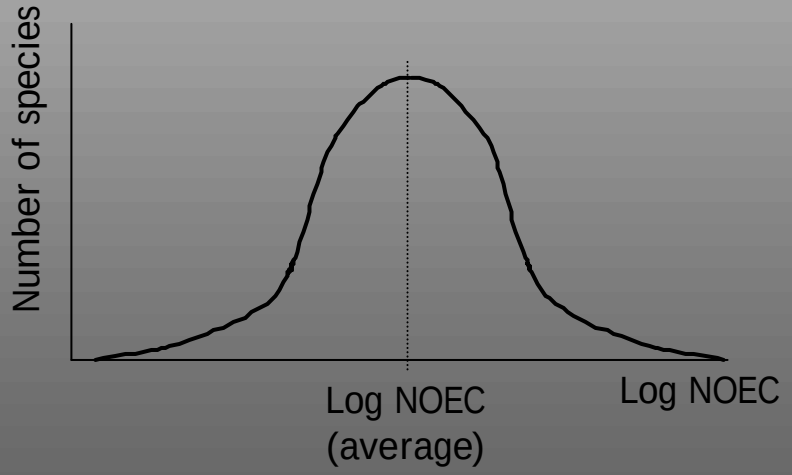
Assumptions :

- the distribution of species sensitivities follows a theoretical distribution function
- the group of species tested in the laboratory is a random sample of this distribution



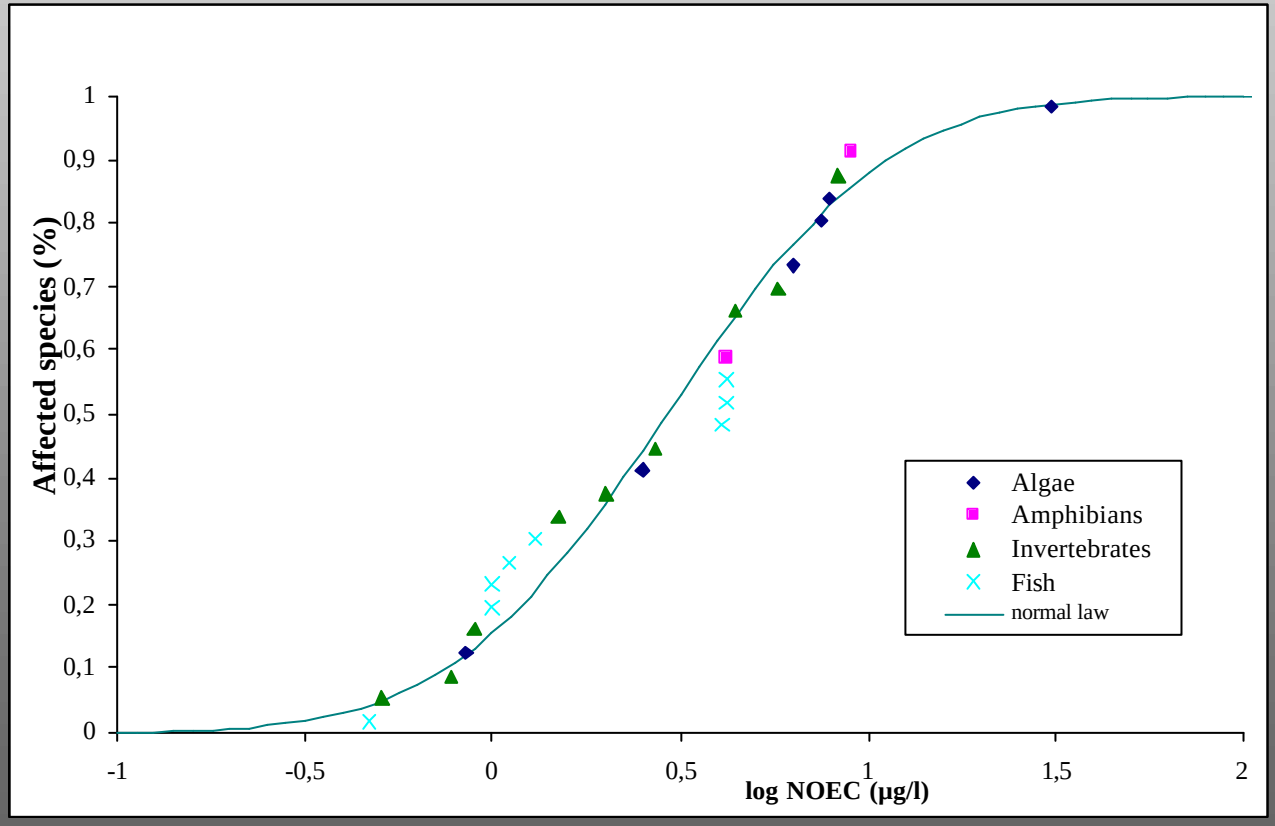
DERIVATION OF $PNEC_{long\ term}$
statistical extrapolation method

- **Chronic ecotoxicological data available :** NOEC
- At least 10 NOEC (preferably more than 15) among 8 different taxa
- **log-normal** distribution, log-logistic distribution…



DERIVATION OF PNEC$_{long\ term}$
statistical extrapolation method

- **SSD : « Species Sensitivity Distribution**



DERIVATION OF PNEC$_{long\ term}$
statistical extrapolation method

- **Chronic ecotoxicological data available :** NOEC
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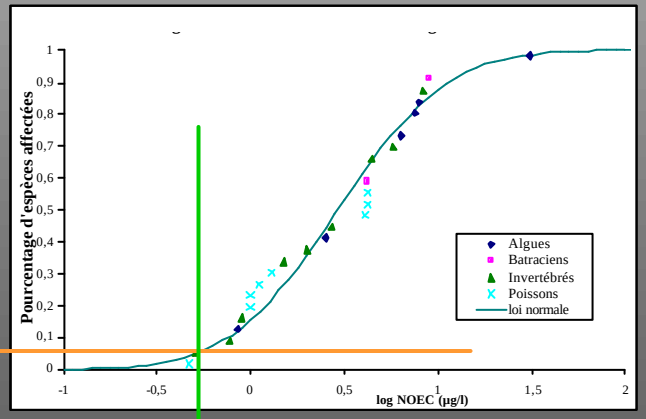
- **log-normal** distribution, log-logistic distribution…
- HC5 estimation : 5th percentile of SSD

5% species affected



DERIVATION OF PNEC$_{long\ term}$
statistical extrapolation method

- **Chronic ecotoxicological data available :** NOEC
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- **log-normal** distribution, log-logistic distribution…
- HC5 estimation : 5th percentile of SSD

- assessment factor (AF) = 1 - 5
- PNEC = HC5 / AF

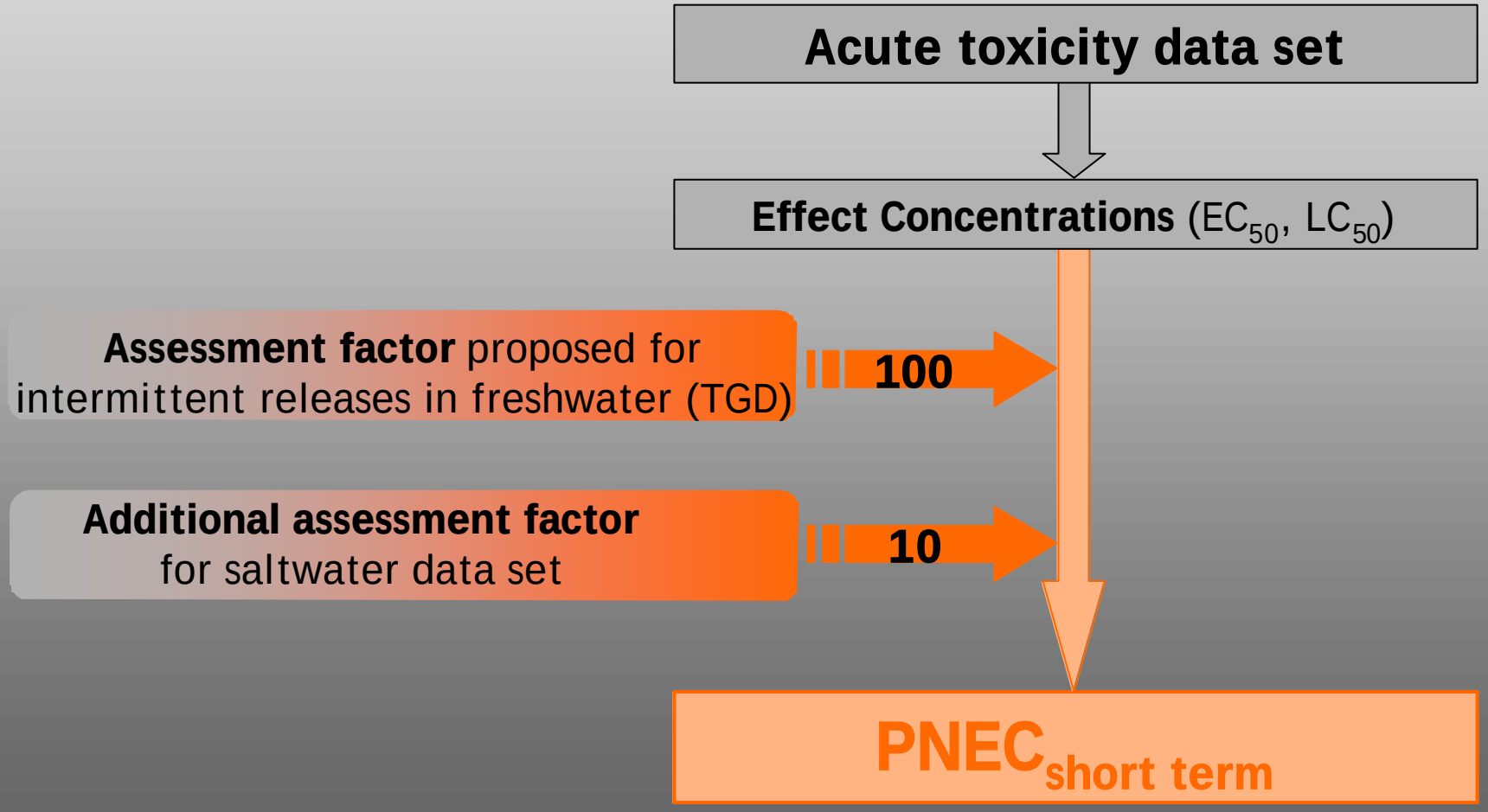
DERIVATION OF PNEC$_{marine,\ short\ term}$

- **hazard assessment for long term exposure :**
  - for saltwater : clear guidance in the TGD (Part 4.3.1)

- **hazard assessment for intermittent release :**
  - for freshwater : guidance in the TGD (Part 3.3.2)
  - for saltwater : **no clear guidance** in the TGD

Methodology proposed by ARC Unit

DERIVATION OF PNEC$_{marine, short\ term}$

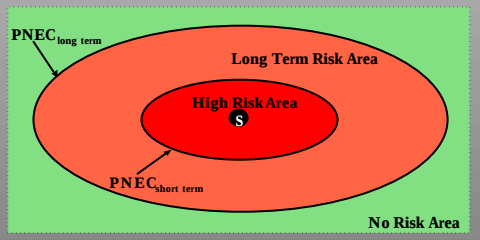


Chemicals	CAS Number	Short term PNEC ($\mu g.L^{-1}$)	Long term PNEC ($\mu g.L^{-1}$)
Methanol	67-56-1	1 200 000	12000
Ethylene glycol	107-21-1	10000	6000
Dichloromethane	75-09-2	9700	825
1,2-Dichloroethane	107-06-2	8500	1060
MTBE	1634-04-4	1360	260
MDI	26447-40-5	1000	100
Ethyl acetate	141-78-6	130	2.4
1,1,2-Trichloroethane	79-00-5	60	6
Benzene	71-43-2	53	8
Acetic acid	107-13-1	51.6	4
Phenol	108-95-2	42	0.544
Toluene	108-88-3	38	7.4
Ethyl benzene	100-41-4	18	2
Ortho cresol	95-48-7	8.4	0.84
Naphtalene	91-20-3	8	1.2
Styrene	100-42-5	4.02	0.402
Vinyl acetate	108-05-4	2.5	1.1
Xylenes	1330-20-7	1	0.14
Biphenyl	92-52-4	0.36	0.17
Nonylphenols	25154-52-3	0.17	0.039

RESULTS : PNECs

To define

risk areas



Thank you for your attention

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