

“Capacity Building and Strengthening Institutional Arrangement”

Workshop: “Hazardous Substances and Wastes”

The Technical Guidance Document on Risk Assessment

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1. The Manual

Technical Guidance Document for Risk Assessment

in support of:

- Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC
- Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93
- Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market



Institute for Health and Consumer Protection

European Chemicals Bureau

Technical Guidance Document on Risk Assessment

in support of

Commission Directive 93/67/EEC

on Risk Assessment for new notified substances

1. The Manual

Manual contents:

How to calculate a PEC/PNEC ratio

How to conduct a PBT assessment

How to judge which of the possible administrative decisions on risk assessment need to be taken

How to decide on testing strategies

1. The Manual

Environmental Exposure Assessment

Production

Transport and storage

Formulation (blending and mixing of substances in preparation)

Industrial/Professional use

Private or consumer use

Service life of articles

Waste disposal

Effects Assessment

Hazard identification

Dose (concentration)-response(effect) assessment

1. The Manual

Directive 93/67EECon risk assessment for new notified substances

Article 2 defines risk from a chemical substance as the “*incidence and severity of adverse effects [i.e. harm] likely to occur... due to actual or predicted exposure to a substance*”

Predicted Environmental Concentration (PEC)

Predicted No-Effect- Concentration (PNEC)

2. The PBT Criterion

PBT Criterion

(Technical Guidance Document – risk assessment for new and existing substances, chapter 4)

- : half-life > 60 days in seawater
 - > 40 days in freshwater
 - > 180 days in marine sediment
 - > 120 days in freshwater sediment

- : Bioconcentration factor > 2000

- : NOEC (derived from chronic tests) < 0,01 mg/L
- CMR
- proven endocrine disruptor effects

3. The PNEC/PEC

Assessment factors to derive PNEC_{freshwater}

Available ecotoxicological data	Assessment Factor
At least one short-term L(E)C ₅₀ from each of the three trophic levels of the base set (fish, <i>Daphnia</i> , alga)	1000
One long-term NOEC (fish or <i>Daphnia</i>)	100
Two long-term NOEC from species representing two trophic levels (fish and/or <i>Daphnia</i> or alga)	50
Long-term NOECs from at least three species (fish, <i>Daphnia</i> or alga) representing the three trophic levels	10
Species sensitivity distribution (SSD) method	5-1 to be fully justified by case
Other evidence, including field data or model ecosystems, allowing to evaluate and implement more precise security factors	Reviewed on a case by case basis

3. The PNEC/PEC

Assessment factors to derive PNEC_{marine}

Available ecotoxicological data	Assessment Factor
Lowest short-term L(E)C ₅₀ from freshwater or saltwater representatives of the three taxonomic groups (algae, crustaceans and fish) of the three trophic levels	10000
Lowest short-term L(E)C ₅₀ from freshwater or saltwater representatives of the three taxonomic groups (algae, crustaceans and fish) of the three trophic levels + 2 additional marine taxonomic groups (e.g. echinoderms, molluscs)	1000
One long-term NOEC (from freshwater or saltwater reproduction or fish growth studies)	1000
Two long-term NOEC from three freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and /or fish)	500
Lowest long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and /or fish) representing three trophic levels	100
Two long-term NOEC from three freshwater or saltwater species representing two trophic levels (algae and/or crustaceans and /or fish) + 1 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 + 2 long-term NOECs from additional marine taxonomic groups (e.g., echinoderms, molluscs)	10

PROTECTION OBJECTIVES	METHODOLOGY
Pelagic Community (internal waters)	Acute and chronic tests Implementation of security factors
Pelagic Community (marine waters)	Acute and chronic tests Implementation of security factors/TGD scheme
Benthic community (internal waters)	Implementation of partition equilibria – benthos toxicity data
Benthic community (marine waters)	Implementation of partition equilibria – benthos toxicity data
Aquatic super-predators	Toxicity studies of aquatic birds diet – use of BCF and BMF
Human (consumption of fish products)	Admissible daily dose- use of BCF
Human (drinking water consumption)	EU Directive 75/440/EC Drinking Water Directive 98/83/EC Treatment level

3. The PNEC/PEC

Source screening: lead

“Expert advisory forum for priority substances and pollution control”

Source	Source relevance
Atmospheric deposition onto surface waters	XXX
Infiltration into groundwater	X
Farming	X
Hunting/Fisheries	XXX
Built-up area runoff	XX
Household discharges (batteries, wastewater, solid waste...)	XX
<u>Industrial activities</u> : Small and Medium enterprises (directly or via a treatment plant)	XX
<u>Industrial activities</u> : Large industrial plants (directly or via a treatment plant: Zn production, mines)	XXX XX
Solid waste management	XX
Leaching from soils/sediments – historical pollution	XX

3. The PNEC/PEC

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- Marine Effects Assessment -

- Greater taxonomic diversity (especially invertebrates) in seawater in comparison to freshwater
- Some taxonomic groups live exclusively in seawater
- In some cases species sensitivity differs by a factor 10
- The three taxa model (algae-crustaceans-fishes) is not protective of the marine environment
- Lack of ecotoxicological data about echinoderms and molluscs