


Providing high quality services in the field of risk assessment


Uncertainty and Precaution under current and future EU chemical risk assessment

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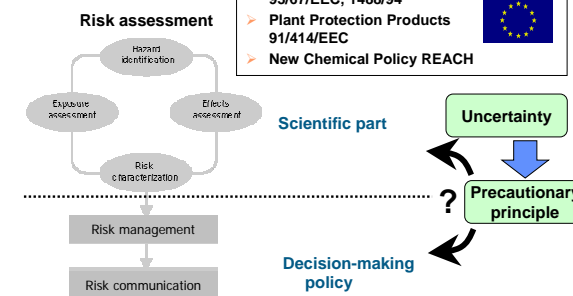

Outline

- Introduction
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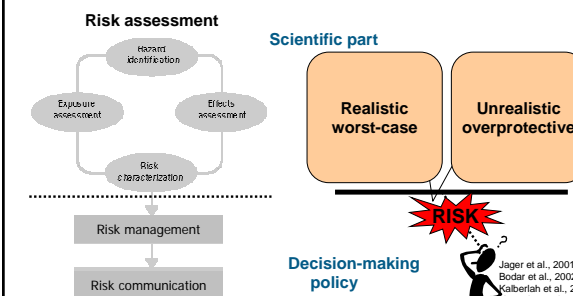


Introduction


- New & Existing Substances 93/67/EEC, 1488/94
- Plant Protection Products 91/414/EEC
- New Chemical Policy REACH

Introduction




Jager et al., 2001;
Bodar et al., 2002;
Klaberlah et al., 2003
Vermere et al., 2001

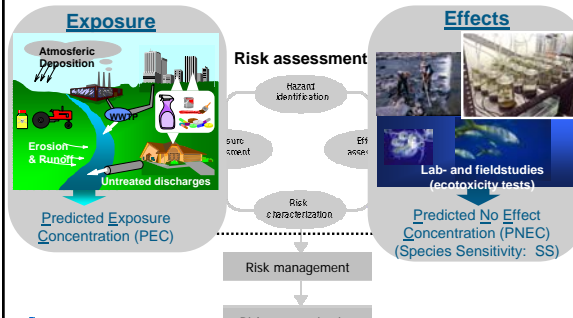



Introduction

- Degree of uncertainty/conservatism is not transparent enough because hidden in the risk quotient through
 - Worst-case assumptions
 - Safety/assessment factors
- This complicates decision-making when social, economic, ethical and other consequences have to be deliberated
- Precautionary Principle (prudential/cautionary measures) part of risk assessment?



Chemical Risk Assessment

History Uncertainty EU RA

Uncertainty is not explicitly quantified, only arbitrarily considered in **worst-case assumptions**

E.g. A/B-tables EUSES: **emission factors can be 3-4 orders of magnitude conservative**

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History Uncertainty EU RA

Uncertainty is not explicitly quantified, only arbitrarily considered in **safety/assessment factors**

E.g. effects assessment for PNEC derivation:
Divide smallest toxicity value by **10-100-1000** to account for

- interlaboratory variation
- intra- and interspecies variation
- lab to field extrapolation
- etc...

Risk assessment process diagram showing exposure assessment, risk characterisation, risk management, and risk communication.

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Historical Perspective

- Milestones in the evolution of scholarly thinking about uncertainty.
 - Medieval religious thinking
 - Enlightenment or the Age of Reason (17th-18th-century thinkers in Europe):
 - science as the 'provider of certainty'
 - uncertainty = unscientific
 - systematic inquiry using mathematical and quantitative methods will lead to certain knowledge about reality generally referred to as '**positivism**' paradigm
- Safety factors and worst case assumptions can be seen as concepts from the positivism paradigm as a way to avoid or hide uncertainty in order to obtain **deterministic, certain worst-case risk estimates**.

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Current Trends

- Dominance of positivism but also criticism:
 - Early 20th century: contradictions at the foundations of mathematics
 - 1905 'new physics' of Einstein
 - Emergence of statistics
 - Mid 20th century: post-modernism and social-constructivism partly due to many mistakes with respect to human health and environmental risks:
 - Knowledge is not equivalent with truth and certainty
 - Uncertainty is not simply the absence of knowledge
 - New information can either decrease or increase uncertainty
 - Uncertainty can still prevail in situations where a lot of information is available
- also recognition within risk assessment community
- Currently: mix of uncertainty recognition and positivism

Boder et al., 2002
Hart, 2003
Jager, 1998, 2001
Kalberlahn et al., 2002
Matthies et al., 2004
Moore et al., 1999
Vermeire et al., 2001

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Current Trends

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Current Trends


- Large uncertainties, which may rise to PP,
- Further research may lead to
- Increased uncertainty "The more we know, the more we know we don't know"
- Different decision consequences

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Back to the Future

> So, what is the alternative?

- Separate **variability** from **uncertainty** ("separating preventive measures versus precautionary measures")
- Risk and uncertainty are two independent concepts
- Uncertainty should be explicitly communicated to risk managers



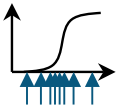

Variability

Definition:

- real variations, describes the **entire** distribution
- can **not** be reduced

Forms:

- Inter-species, intra-species
- Temporal
- Spatial



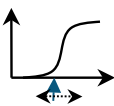
Uncertainty



Definition:

- describes **1 value** from the entire distribution
- can be **reduced** by extra info


Forms:



- "Sampling" uncertainty
- Measurement error
- Model uncertainty
- Unknown ignorance



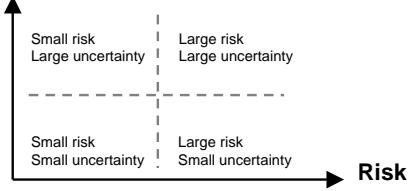


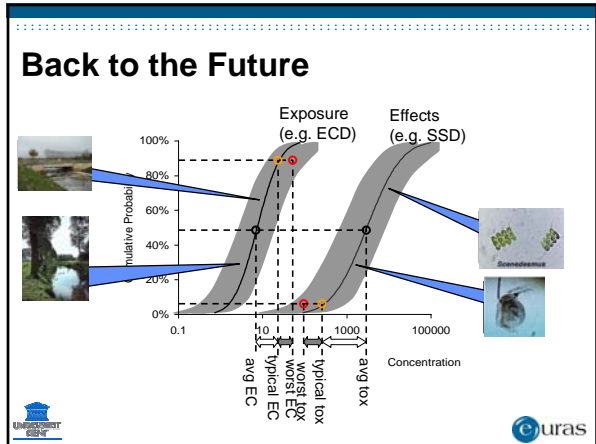
Sources

	Variability	Uncertainty
Exposure	<ul style="list-style-type: none"> • Temporal variability of emission, effluent concentration, flow... • Spatial variability of environmental characteristics 	<ul style="list-style-type: none"> • E-USES model structure uncertainty • Parameter uncertainty: physico-chemical properties, partition coefficients, removal rates,... • Spatial variability of environmental characteristics,... in local assessment
Effects	<ul style="list-style-type: none"> • Inter-species sensitivity  • Intra-species sensitivity • Inter- and intra-laboratory Endpoint differences 	<ul style="list-style-type: none"> • Probability distribution uncertainty (e.g. threshold versus non-threshold distribution) • Diversity & representativeness • Sampling uncertainty

Back to the Future

Uncertainty and risk are independent



Back to the Future

Uncertainty analysis: methodology

> Data-rich substances: conduct **many** scenarios (e.g. 10000)

- Best-case scenarios
- **Typical scenario**
- Any intermediate scenario...
- **Worst-case scenario**
- Unrealistic worst-case scenarios

} Uncertainty distribution
Confidence interval

Conclusions

- Current EU risk assessments deal with **uncertainty as a technical construct** under the format of worst-case assumptions and safety factors as if these **'certain uncertainties'** can lead to certain risk estimates. Thus, uncertainty is hidden in the risk estimate.
- **Uncertainty analysis is a useful process** (not a goal) for risk assessors and managers:
 - quantifies to the extent possible the **uncertainty and variability** for both data-poor and data-rich substances.
 - separates uncertainty from risk allowing an objective and resource-efficient risk assessment and a better risk management in the application of the precautionary-principle.

