

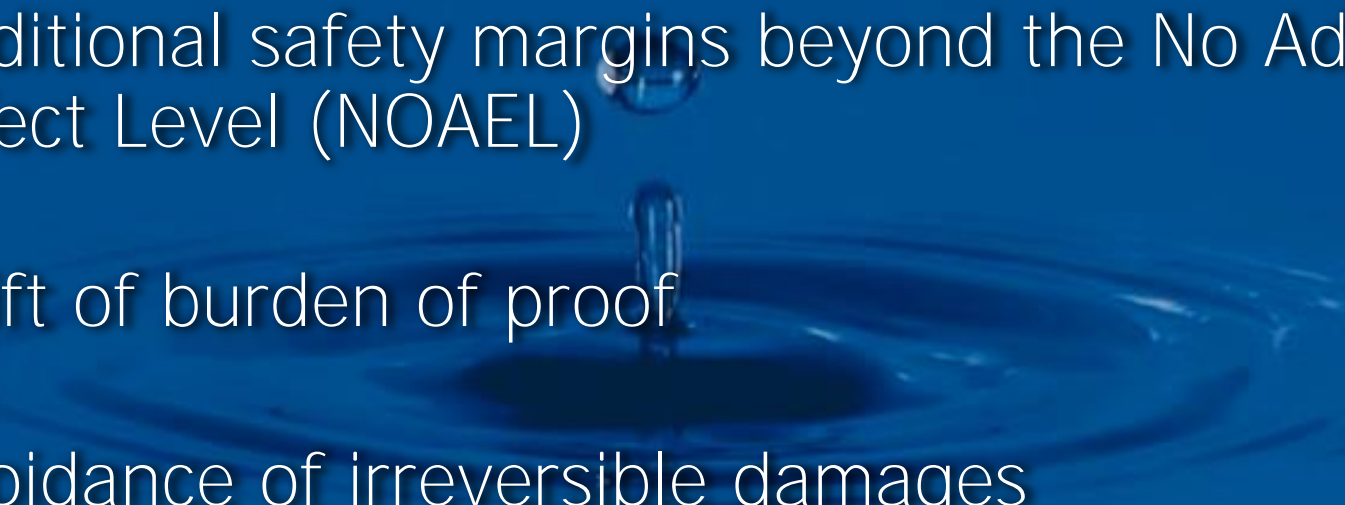
Risk Governance, Precaution, and Policy Making



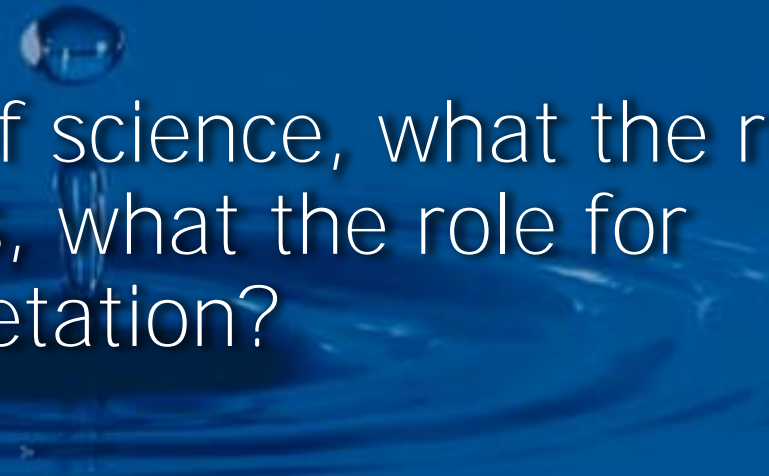
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Definitions of Precaution

- General: Acts of caution in the face of uncertainty
 - Possibility of regulatory action even if conclusive evidence of harm is missing
 - Additional safety margins beyond the No Adverse Effect Level (NOAEL)
 - Shift of burden of proof
 - Avoidance of irreversible damages
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Open Questions

- Problem of arbitrariness
 - Problem of predictability of regulatory outcome
 - Problem of adjustments over time
 - Who can use the discretionary power to what extent?
 - What is the role of science, what the role of legal provisions, what the role for subjective interpretation?
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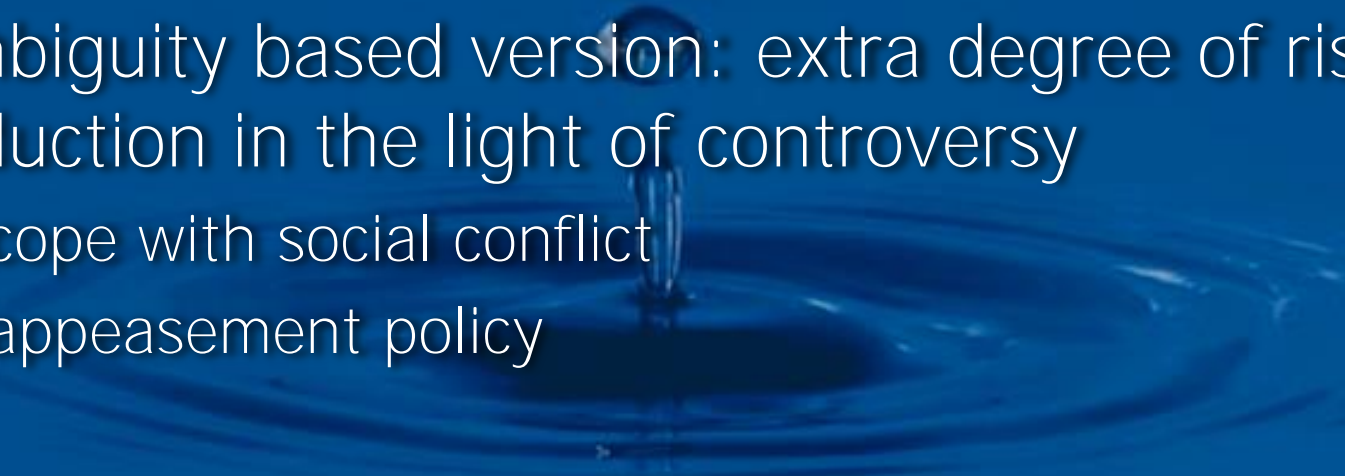
Principles of the EU (Communication 2000)

- Sound scientific expertise
 - Burden of proof
 - Consistence and coherences
 - Non-discrimination
 - Proportionality
 - Cost-Benefit- Analysis
 - Predictability for all actors (within reason)
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Different Concepts of Precaution I

- Original German Version: precaution is the space between intervention point and residual risk
 - Not related to coping with uncertainty
 - Provides discretion for regulatory action beyond legally prescribed intervention point
- Assessment based version: conservative assessments within scientifically (or statistically) determined confidence intervals
 - worst case estimates within reason
 - xy percent of confidence interval
 - safety factor for threshold risk levels

Different Concepts of Precaution II

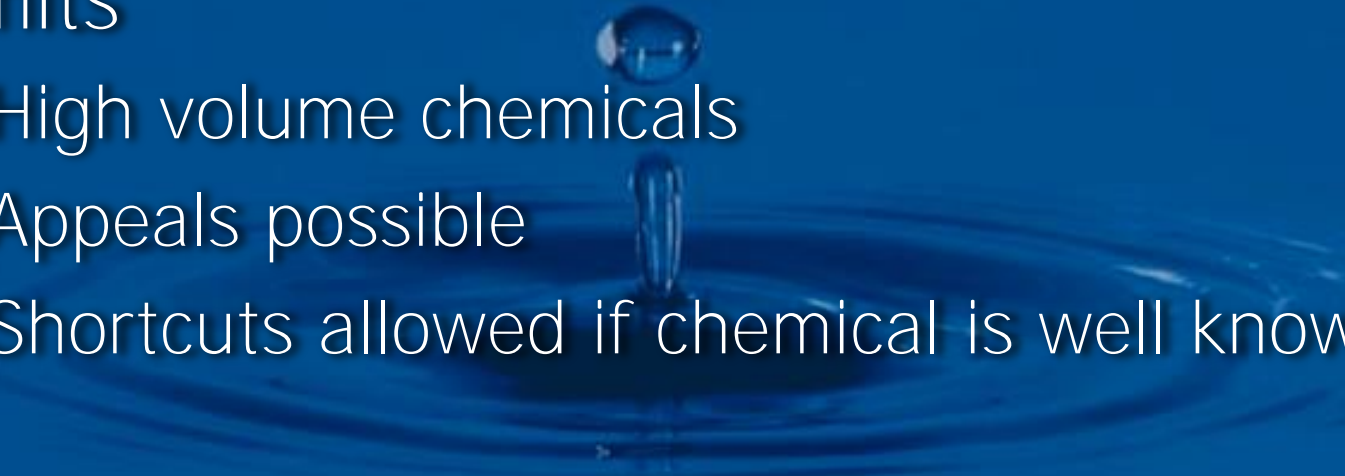
- Management based version: extra degree of safety in the light of ignorance
 - acknowledgement of systems boundaries
 - securing of reversibility of decisions
 - **“better safe than sorry” attitude**
 - Ambiguity based version: extra degree of risk reduction in the light of controversy
 - cope with social conflict
 - appeasement policy
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European Version of Precaution



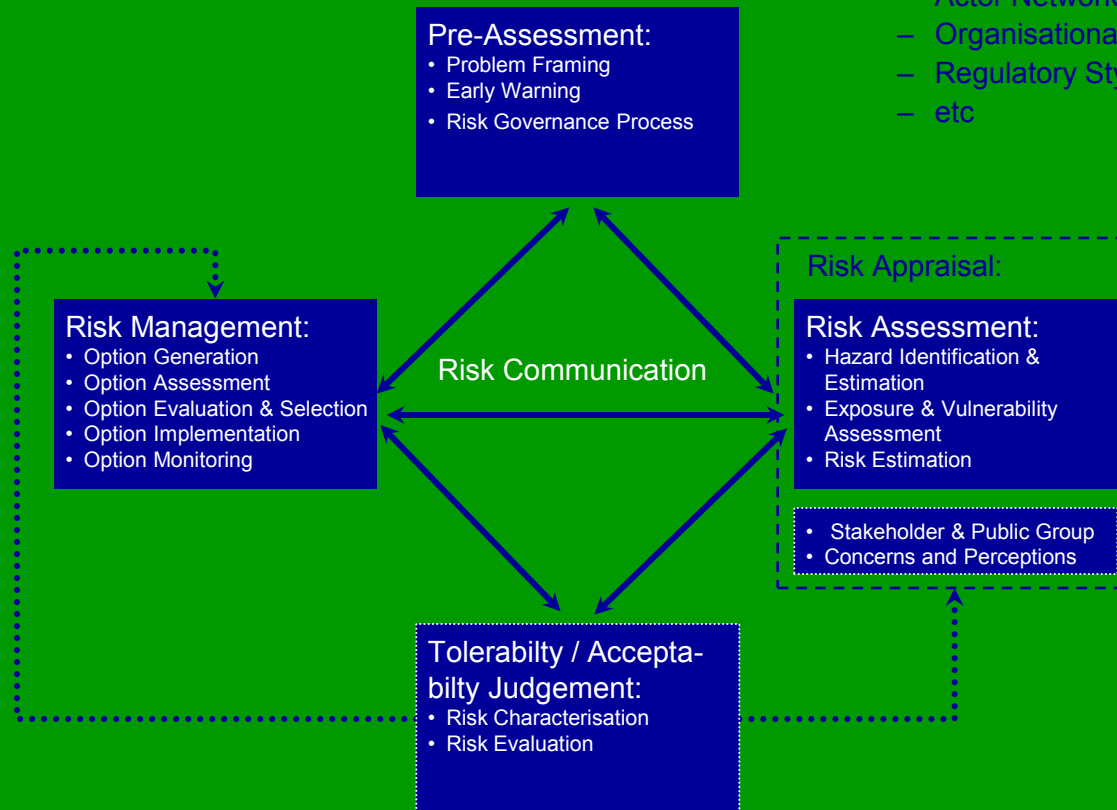
- Management based version:
 - Condition: scientific uncertainty prevalent
 - Rationale: avoid irreversibility
 - Method:
 - Investment in more research
 - Containment methods
 - Strict monitoring
 - Limits:
 - Proportionality
 - Strong social or economic interest
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Application to REACH

- Application to new and old chemicals
 - Characterization by hazard properties
 - Full reporting and traceability
 - Discretionary power for agencies
 - Limits
 - High volume chemicals
 - Appeals possible
 - Shortcuts allowed if chemical is well known
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Risk Governance Framework

Risk Governance Framework (Components and Contextual Aspects)



The Risk Management Escalator

(from simple via complex and uncertain to ambiguous phenomena)

			<p><i>Risk Tradeoff Analysis and Deliberation Necessary</i></p> <p>Risk Balancing Necessary</p> <p>Risk Assessment Necessary</p> <p>Types of Conflict:</p> <p>cognitive</p>
		<p><i>Risk Balancing Necessary</i></p> <p>Risk Assessment Necessary</p> <p>Types of Conflict:</p> <p>cognitive</p> <p>evaluative</p> <p>Actors:</p> <p>Risk Managers</p>	<p>evaluative</p> <p>normative</p> <p>Actors:</p> <p>Risk Managers</p>
	<p><i>Scientific Risk Assessment Necessary</i></p> <p>Types of Conflict:</p> <p>cognitive</p> <p>Actors:</p> <p>Risk Managers</p> <p>External Experts</p> <p>Discourse:</p> <p>cognitive</p> <p>Complex</p>	<p><i>Risk Balancing Necessary</i></p> <p>Risk Assessment Necessary</p> <p>Types of Conflict:</p> <p>cognitive</p> <p>evaluative</p> <p>Actors:</p> <p>Risk Managers</p> <p>External Experts</p> <p>Stakeholders such as Industry, Directly Affected Groups</p> <p>Discourse:</p> <p>reflective</p> <p>Uncertain</p>	<p>External Experts</p> <p>Stakeholders such as Industry, Directly Affected Groups</p> <p>Representatives of the Public(s)</p> <p>Discourse:</p> <p>participatory</p> <p>Ambiguous</p>
<p><i>Routine operation</i></p> <p>Actors:</p> <p>Risk managers</p> <p>Discourse:</p> <p>internal</p> <p>Simple</p>			

Conclusions

- Precaution is still a fuzzy concept that has different meanings in different concepts
- There is an agreement among all risk professionals that a precautionary approach in risk assessment is prudent
- There is clear disagreement about the role of precaution in risk management (US versus Europe)
- The most controversial issues are avoidance of arbitrary regulation and dismissal of scientific evidence