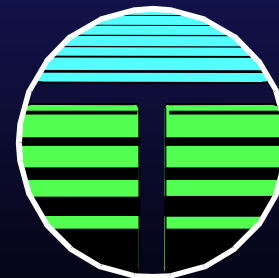


BIOSOLIDS, ESTROGENS AND THE DEVELOPMENT OF THE PRECAUTIONARY PRINCIPLE

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- Chair of SETAC workgroup on the Precautionary Principle since 2001.
- Worked with aspects of PP and ecotoxicology since 1995.
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Outline – Section 1

Precaution

- From Rio to Ottawa
- EU and Canadian perspectives
- Certainty of uncertainty
- Type I, II & III error

Outline – Section 2

Science

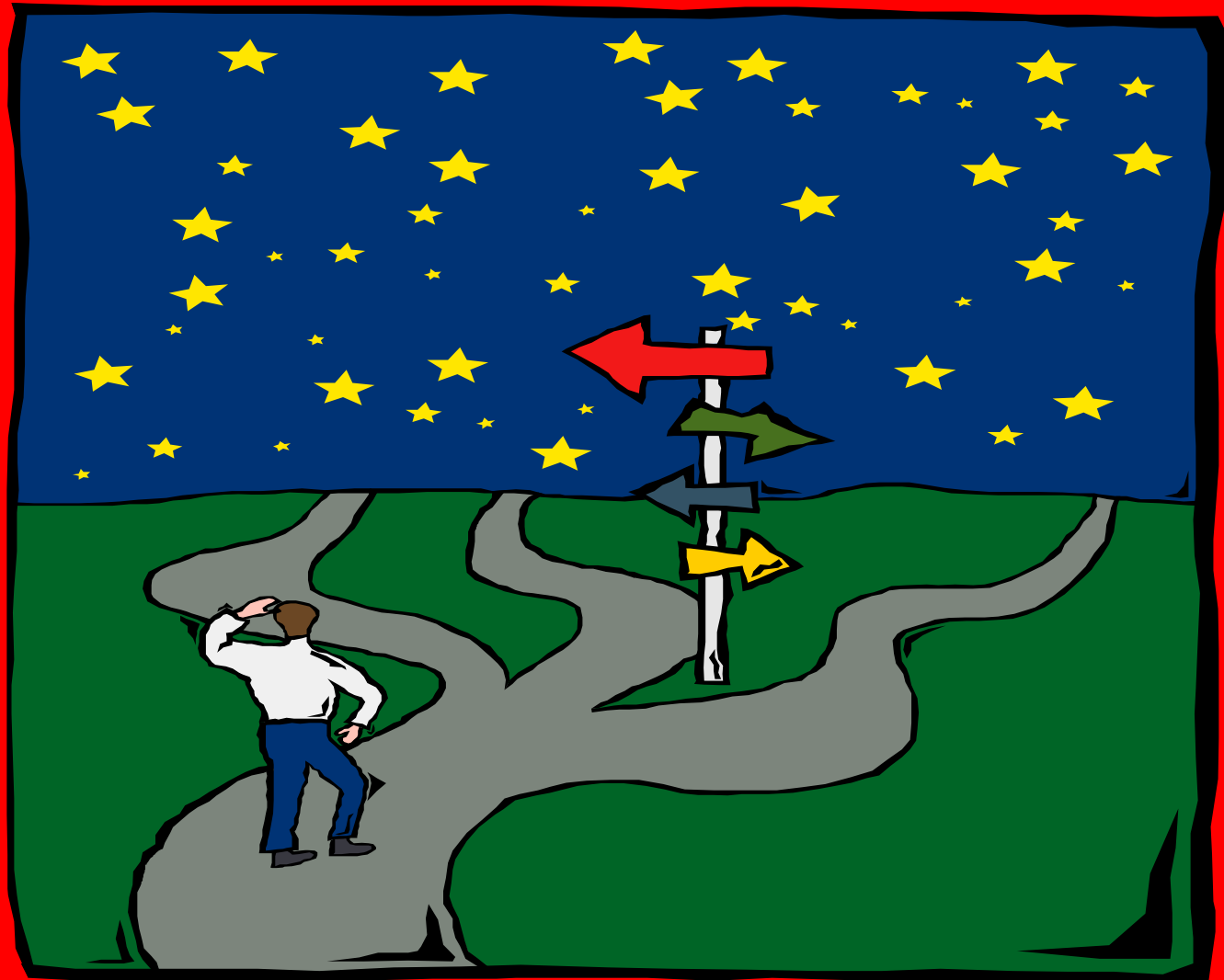
- From 1850s to 2004
- From determinism to social constructivism
- Falsification to paradigms

Outline – Section 3

Biosolids

- Switzerland – BSE
- Denmark – EDC's
- Canada – *E. coli*
- Biosolids, science and precaution – how do they mix?

SECTION 1: PRECAUTION



RIO 1992



- PP is a tool for sustainable development. Rio declaration § 15:

“Where there are threats of serious irreversible harm lack of full scientific certainty should not postpone effective measures to prevent environmental degradation”.

European Union

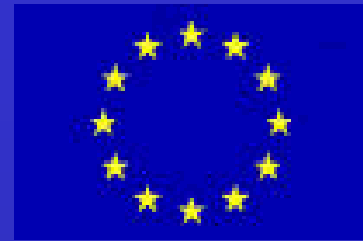


- 2000: EU Commission communication on interpretation of PP
- 2000: Future chemicals policy paper
- 2001: Nice treaty implements the communication definition and future chemicals policy must be based on PP
- 2003: Canadian Perspective



EU COM(2000)1

- Issued 1. February 2000 by the EU Commission as a White Paper (EU COM (2000)1)
- Precaution = Prevention
- Redundant Precaution \neq Prevention
- Prevention = reduce *known* risk
- Precaution = reduce unknown risk



EU COM(2000)1

- Strictly a political tool to cover whole policy areas - not individual cases
- Integration in the risk assessment paradigm
- Precaution = more data



Canadian Perspective

- Based on a the Discussion Document “*A Canadian perspective on the precautionary principle*”, Sept. 2001 + public peer review and conclusions based on meetings. Final version fall of 2003.
- General principles of application:
Distinguishing features of decision making, when risk of serious or irreversible harm + significant scientific uncertainty

General principles



- PP is a legitimate and distinct decision making tool
- Guided by society's chosen level of protection (Δ)
- Sound science is the basis for applying PP and PP measures
- Evidence relative to (Δ) and burden of proof may shift
- Mechanisms for reevaluation – adaptive management
- Greater; transparency, accountability and public participation

Precautionary measures



- Purposes specific characteristics that apply once a decision on PP measures:
- Reconsideration new level (Δ), science & technology
- Proportionality – severity and (Δ)
- Non-discriminatory (trade issues)
- Cost-effective
- Least trade-restrictive option when more than 1 of above are meet

Key Issues



- Public peer review 1-2 years main comments:
- Further analysis of PP and economy
- Scientific vs. legal proof – harmonization
- Proportionality principle (action relative to problem/severity)
- Scientific peer review alone does not secure quality
- International tools and PP
- Reflects Canadian values
- Greater transparency and public participation (Δ)
- Positive feed backs from the public
- Severe concerns over trade regulation and barriers

Uncertainty vs. Certainty

- Which should we focus on from a regulatory perspective relating to biosolids?
- Chemical mixtures
- Extrapolation of effects:
- Across levels of biological organization
- Across temporal and spatial scales
- = Certainty of uncertainty

POWER ANALYSIS

Tool for management of
precaution?

Statistical power analysis

- Given EU COM 2000 (1) and Canadian interpretation:
- Acceptable risk of Type I and II errors
- Type I error is “the *producers* risk” of false positive (e.g toxic when not) (5%)
- Type II error is “the *recipients* risk” of false negative (e.g not toxic when in fact toxic) (20%)

Type I & II errors

Relationship	H_0 True	H_0 False
Accept H_0	Good ✓	Type II error/ False negative/ Over-selective
Reject H_0	Type I error/ False positive/ Over-protective	Good ✓

Type I & II error analogies

- Type I error = over-protective. Or fishing with too small mesh size and thus catching too many small fish
- Type II error = over-selective. Or fishing with too large mesh size and thus not catching many good size fish

Power analysis

- Simple statistical method
- Define the entities: α , β and Δ (effect size), background variance (σ^2) number of replicates (n) must be determined from a pilot study – *a priori*
- Define Δ from probability distributions of ecological effects, cost-effectiveness and ethics
- Define α & β from societal cost-benefit analysis (environmentally focus on β)

Type III error

- A qualitative type of error, can't be *a priori* assessed quantitatively
- Right answer – wrong question! (misdirected or fishing where there are no fish – or not fishing where there are lots of fish) wrong management decisions
- Increased risk of Type III error due to ignorance of Type II error and the significance of non-significant results
- Type I and II are just a question of sampling, and often qualitatively trivial, without information on acceptable effects!

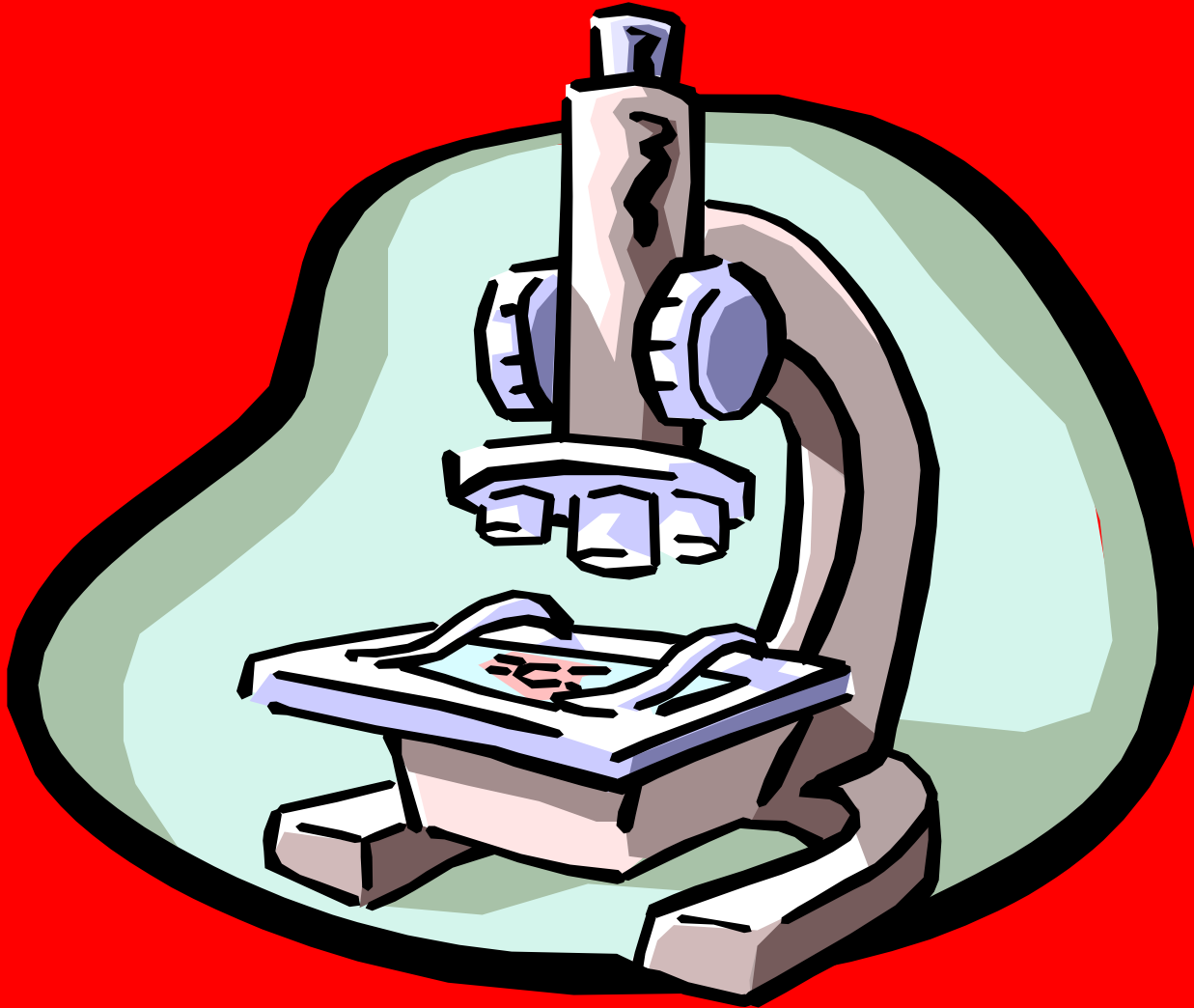
PP In short

- PP is a tool taken out of context applied for sustainability – not an aim in itself:
- Optimize resource allocation + transparency
- Change env. science epistemology
- May be abused in trade and as a political catch-word
- Sustainability: Resources for future generations and right to relative or informed risk freedom vs. corporate rights to profit

How did we get here?

- Certainly political and economic reasons; most prominent PP case was BSE (France, Germany against UK and Thatcher's anti-EU)
- What was science role and public perception?

SECTION 2: SCIENCE

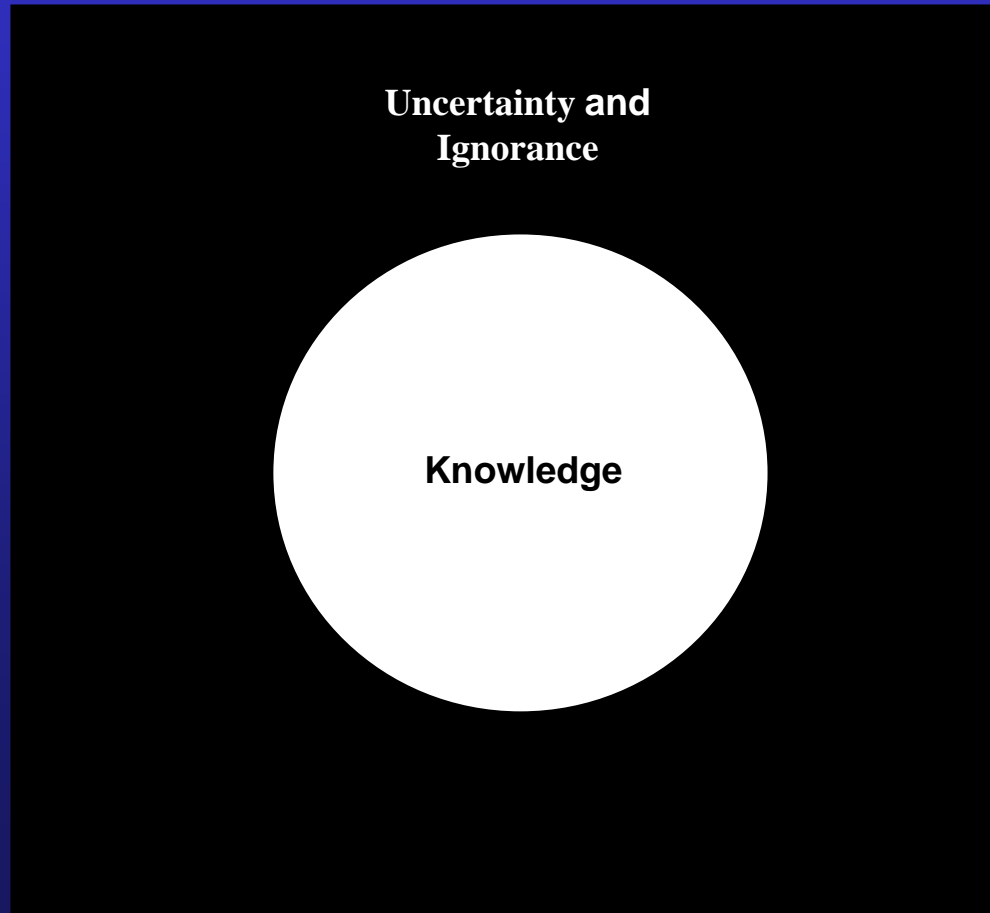


Determinism



- Everything is quantifiable (mid 1800s)
- Science can positively assess and predict all events
- Comte (1798-1857)

Perception of scientific certainty



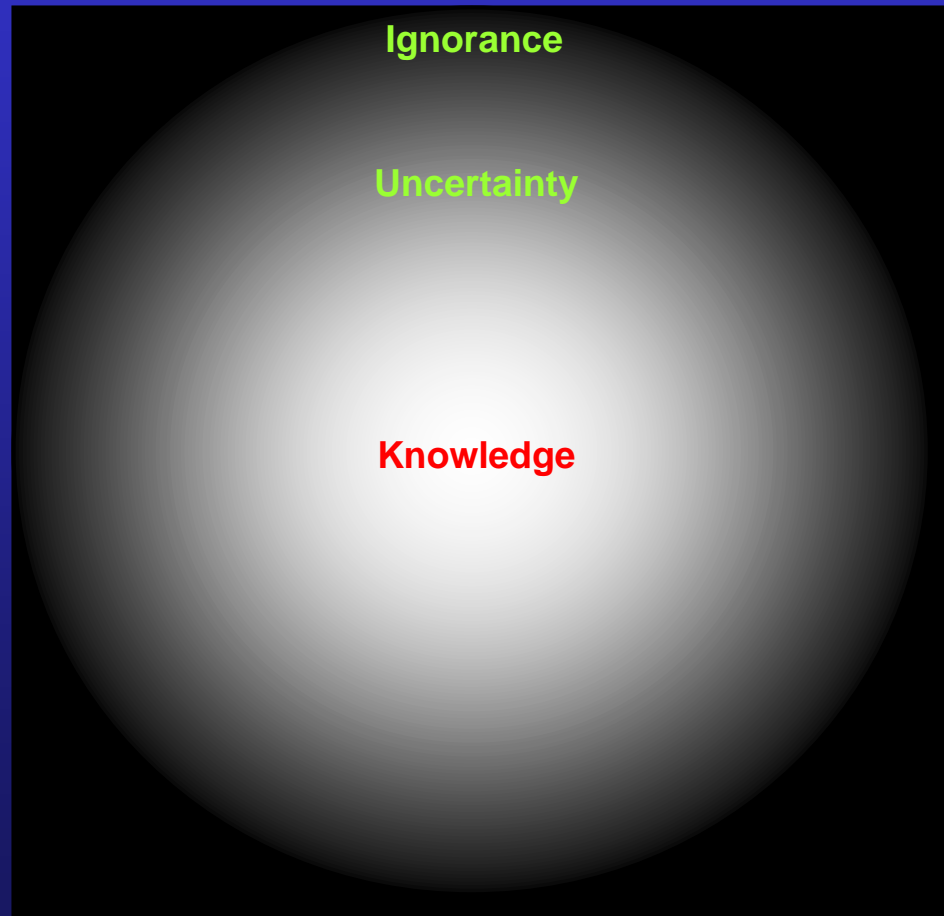
Quantum Mechanics



- Bohr (1885-1962)

- There are randomness in nature, one can never describe natural states 100%
- Predictions must be tested, conclusions expressed as probabilities (1920s)

Perception of scientific certainty



Falsification



- Popper (1902-1994)

- Science has to be testable and falsifiable
- Hypothesis must be tested and sought falsified through experimentation
- 99% of science devoted to full force of falsification of the 1% (1930s)

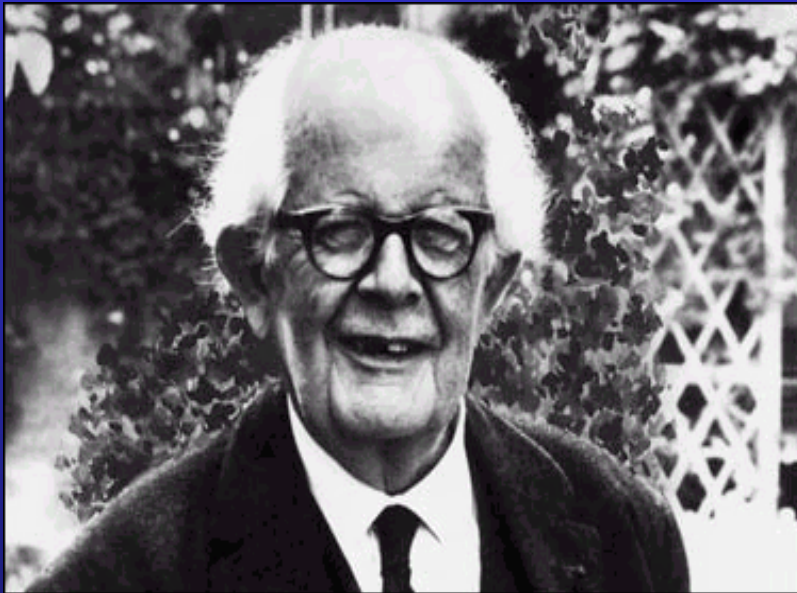
Paradigms



- Kuhn (1922-1996)

- Popper is too ideal. We use imperfect theories ad hoc, despite falsification, as they might work within its realm
- In doing so we construct paradigms, that change when they no longer work (1960s)

Social and Radical Constructivism



- Piaget (1896-1980)

- All knowledge is a human construction and reality is not accessible to rational human knowledge
- Knowledge is the product of the particular context or setting to which the learner belongs

Risk Society



- Ulrich Beck

$f(x)$: Social constructivism
+ Information-society +
Uncertain science +
Threats of severe
environmental risk
= RISK SOCIETY
(1990s) → Reflexive,
adaptive decision-
making. Science is part
of the problem – not the
solution!

Global Market

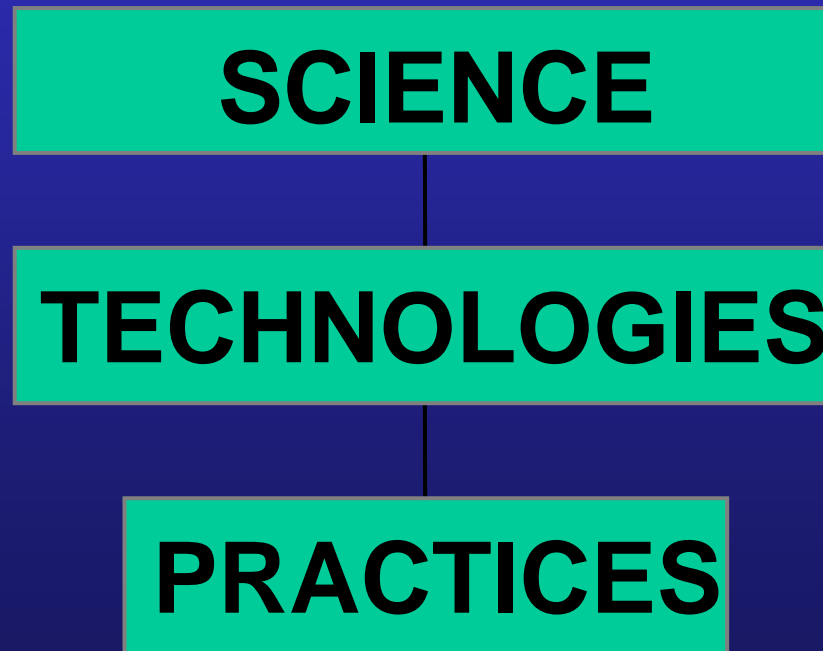
- Following globalization, expansion of markets occur primarily within organizations like: EU, NAFTA, ASEAN, regulated by WTO. Environmental and safety issues becomes “legal” barriers to trade, based on PP. Why WTO will not accept PP without science, risk assessment and intelligible guidelines.
- PP also becoming increasingly important PR tool for industries

Complex questions yield complex answers

- Science is by nature uncertain (Popper's falsification)
- Since the discovery of quantum mechanics and uncertainty theorem in the 1920s not even physics is expected to provide PROOF in a judicial sense
- Biology and ecology are "impaired" by historicity (DNA), "irrational" behavior, and generally lacking pristine reference sites

Science?

Differentiation of Science



SECTION 3: BIOSOLIDS



Switzerland



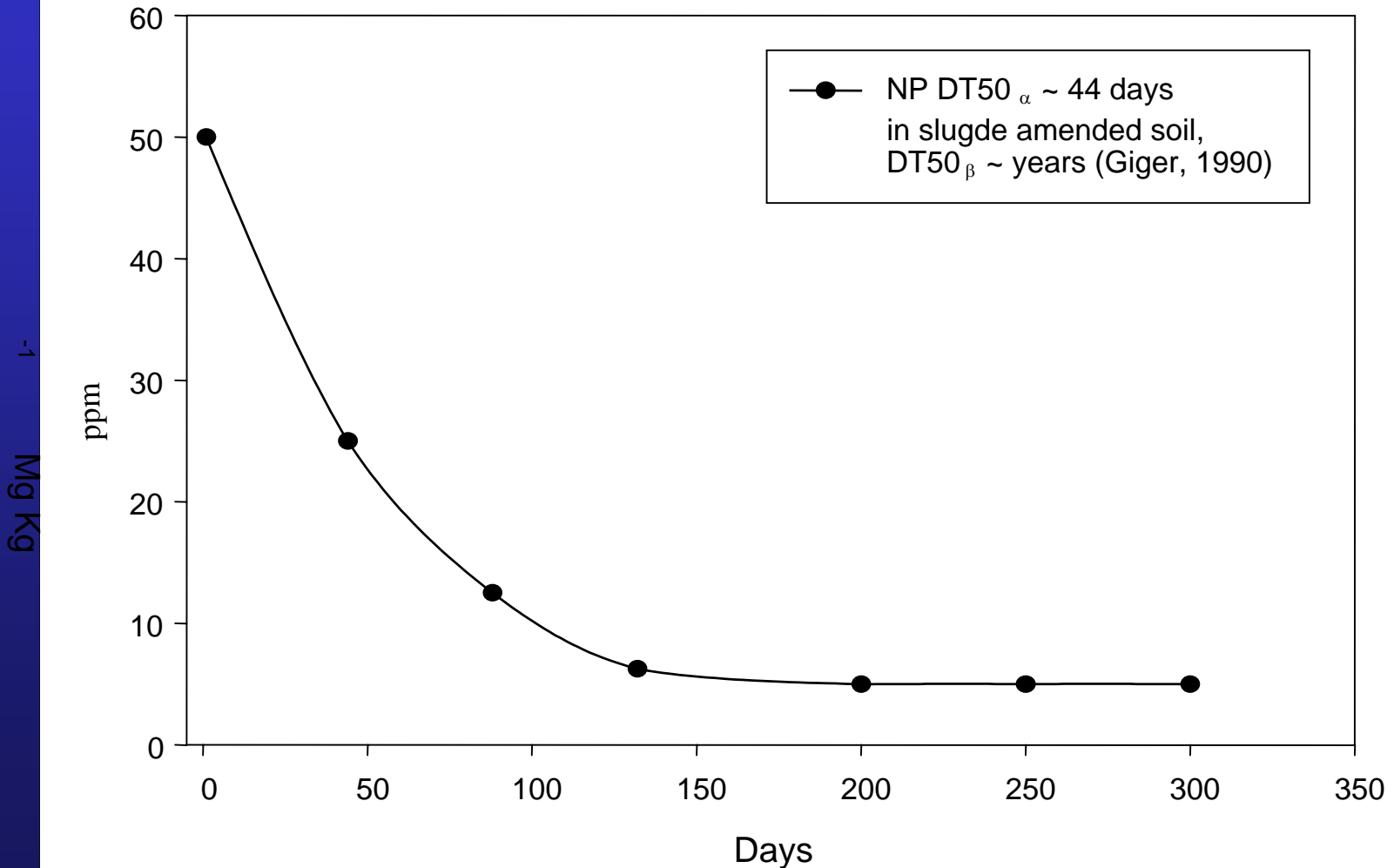
- As of May 1, 2003 ban against biosolids from meat processing plants
- As of 2006 ban all use of biosolids on farmland
- Based on the precautionary principle – concerns of BSE (mad cow)
- Incineration of all biosolids - extra cost estimated at < 40 million CDN\$/yr

Denmark



- Trigger value of 10 mg Kg^{-1} NP in biosolids – the main limiting factor!
- In 1997: ~ 40% of all biosolids more than 10 mg Kg^{-1} → voluntary phase out of NP
- In 2000: ~ 75% of all biosolids were under 10 mg Kg^{-1} , the rest incinerated and stored
- Concerns of endocrine disruption → precaution principle
- NP degrades aerobically – often only degrade on the surface of the biosolids

Nonylphenol





Canada

- Biosolids regulated with focus on metals, where Cu & Pb are most often the limiting parameters
- Organic xenobiotics assumed removed by biosolid digestion prior to application
- Public concern primarily *E. coli* and emerging pharmaceuticals (antibiotics)

Public perception, PP and Biosolids – how do they mix?

- Do biosolids fulfill the 3 main tenets for application of precaution: a) need for a decision; b) risk of serious or irreversible harm; c) lack of scientific certainty? Probably; yes to all three
- What are the consequences:
 - Reversed burden of proof = the party that markets the product must generate data to mitigate risk (polluter pays), and determine Δ
 - Consider use and monitor potential effects and risks.