Workshop New Approach Methodologies for NanoSafety – 30 March 2023

Social and ethical aspects of Nanotechnology

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Senter for vitenskapsteori

RECIPES

Precaution • Innovation • Science

Nanotechnology

- High variability, widely used, rapid growth
- Key Enabling Technology (KET)

  a group of six technologies:
  - micro and nanoelectronics
  - **nanotechnology**
  - industrial biotechnology
  - **advanced materials**
  - photonics
  - advanced manufacturing technologies

  that increase industrial innovation to address societal challenges and are believed to create advanced and sustainable economies.

- Converging Technology

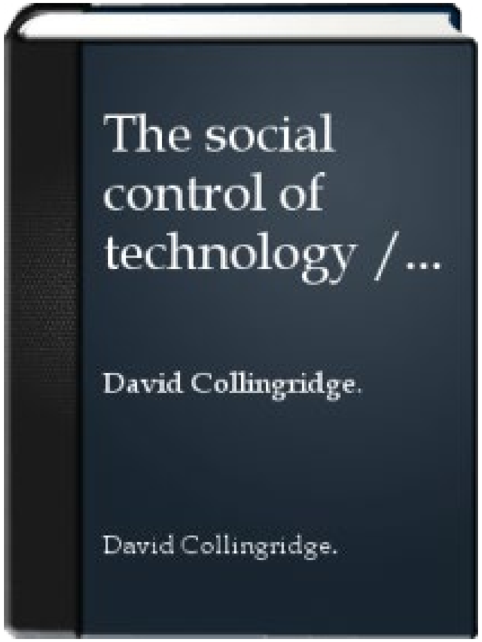
  with biotechnology, information technology, robotics, AI

Collingridge Dilemma

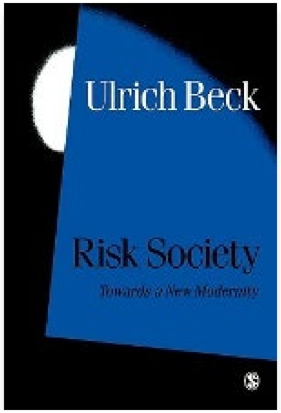
"The social consequences of a technology cannot be predicted early in the life of the technology.

By the time undesirable consequences are discovered, however, the technology is so much part of the whole economics and social fabric that its control is extremely difficult.

This is the *dilemma of control.*"



1980



Risk Society
Ulrich Beck 1986/1992

- Failure of the industrial society to manage the risks it has manufactured
- Disasters such as BSE, Tsjernobyl, etc. are presented as unique events, while in fact they are intrinsic products of the way we have organised our modern industrial society
- Focus of societal conflict shifts from ‘distrubution of goods’ to ‘distribution of bads’

Risk Society - continued

- “Unhoped failure” vs “Normal accidents”
- Largest risk is not physical explosiveness of technology by “societal explosiveness”: loss of trust in institutions
- Who is responsible for uncontrollability of developments? **Organised irresponsibility**
- Symbolic policy to create the (false) expression that risks are under control
- **More and more key decisions on technological development are made in the laboratory; the societal debate lags behind.**

Responsible Research and Innovation (RRI)

- *Responsible Research and Innovation is a* ***transparent, interactive process*** *by which* ***societal actors and innovators*** *become* ***mutually responsive*** *to each other with a view on the (ethical)* ***acceptability, sustainability and societal desirability*** *of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).*

R. von Schomberg (ed.): *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields. A report from the European Commission Services*, 2012, p. 9.
https://publications.europa.eu/en/publication-detail/-/publication/60153e8a-0fe9-4911-a7f4-1b530967ef10/language-en

Table 1
Lines of questioning on responsible innovation.

Product questions	Process questions	Purpose questions
How will the risks and benefits be distributed? What other impacts can we anticipate? How might these change in the future? What don't we know about? What might we never know about?	How should standards be drawn up and applied? How should risks and benefits be defined and measured? Who is in control? Who is taking part? Who will take responsibility if things go wrong? How do we know we are right?	Why are researchers doing it? Are these motivations transparent and in the public interest? Who will benefit? What are they going to gain? What are the alternatives?

http://dx.doi.org/10.1016/j.respol.2013.05.008

Nano risk assessment some challenges

- Particle toxicology is fundamentally different from classic toxicology
- Speed with which nanomaterials hit the market >> pace at which knowledge on their risks develops
- REACH is too slow and leaves major data gaps, especially for substances below 1 ton/yr production volume

Known Knowns

- Confirmed results
- Reproduced studies
- Protocolls
- guidelines

Unknown Knowns

- Results we do not have access to
- „grey literature“
- Data requests

Known Unknowns

- Questions following from research
- Further research
- Research gaps

Unknown Unknowns

- We don‘t know what we don‘t know
- Irregularities
- unexpected phenomena

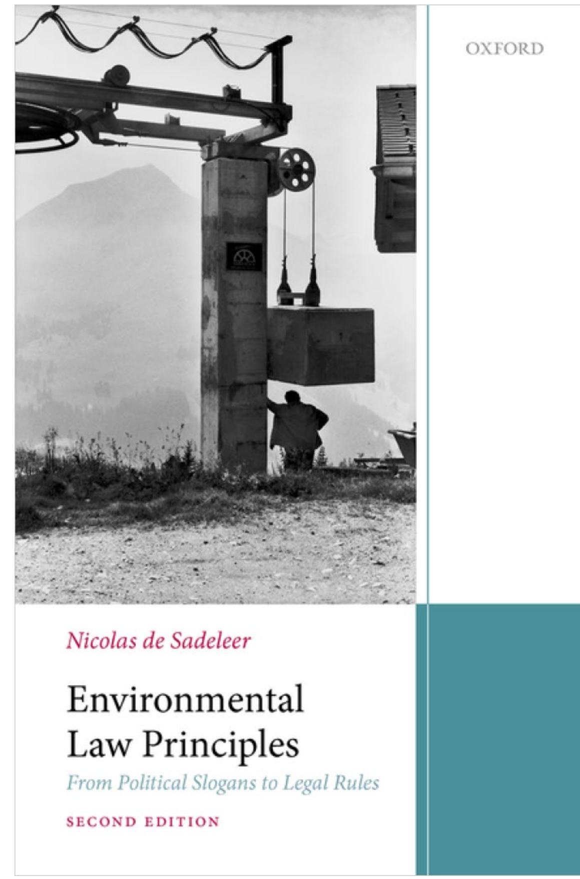
Traditional risk assessment approach fails for nano-risk because:

- Impossible to quantify the probabilities
- Impossible to quantify the likelihoods(?)
- Impossible to quantify the severity of the consequences
- = No trustworthy risk assessment (in the European / orthodox tradition)
- Uncertainty
- Ignorance (unforeseen effects may emerge)
- Indeterminacy (open-ended causal systems)
- Ambiguity (plurality of interpretations of data)

Principles in Environmental Policy

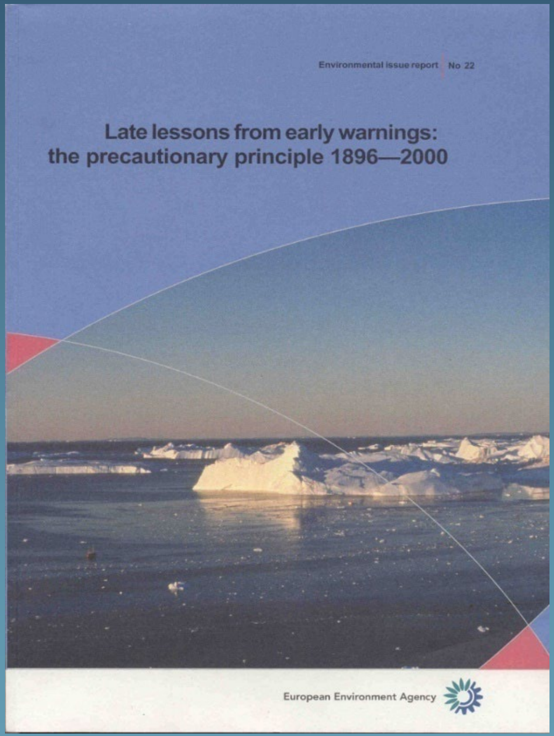
- *curative* model
  Polluter Pays Principle
- ‘prevention is better than cure’ model
  Prevention Principle
- ‘better safe than sorry’ model
  Precautionary Principle

paradigmatic shift from ***a posteriori*** control (civil liability as a curative tool) to the level of ***a priori*** control (anticipatory measures) of risks

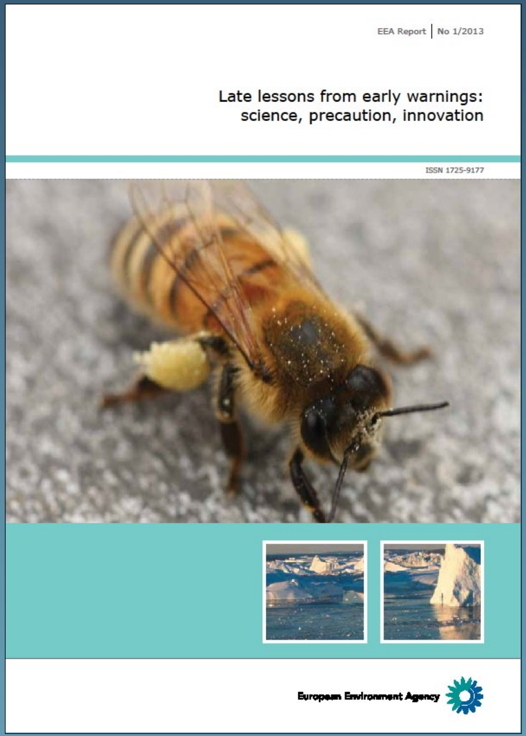


Homo Sapiens (tragicus?) as slow learners
Two volumes

2001



2013



https://www.eea.europa.eu/publications/environmental_issue_report_2001_22
https://www.eea.europa.eu/publications/late-lessons-2

34 case studies: *20 in vol 2-2013*

'Environmental chemicals'

- ***Beryllium***
- **PCBs**
- **CFCs**
- **TBT antifoulants**
- ***Mercury***
- ***Tobacco-environmental***
- ***Perchlorethylene***
- ***Booster biocides***
- ***DBCP***
- ***DDT***
- ***Vinyl chloride***
- ***Bisphenol A***

Ecosystems

- ***Ecosystems resilience***
- **Great Lakes pollution**
- **Fish stock collapse**
- **Acid rain**
- ***Bee decline, France***
- ***Invasive alien species***
- ***Floods***
- ***Climate change***

Transport fuel additives

- **Benzene**
- **MBTE**
- ***Leaded petrol***

'Micro technologies'

- ***Nano***
- ***GMOs***

Animal feed additives

- **BSE/mad cow disease**
- **Beef hormones**
- ***Antibiotic growth promotors***

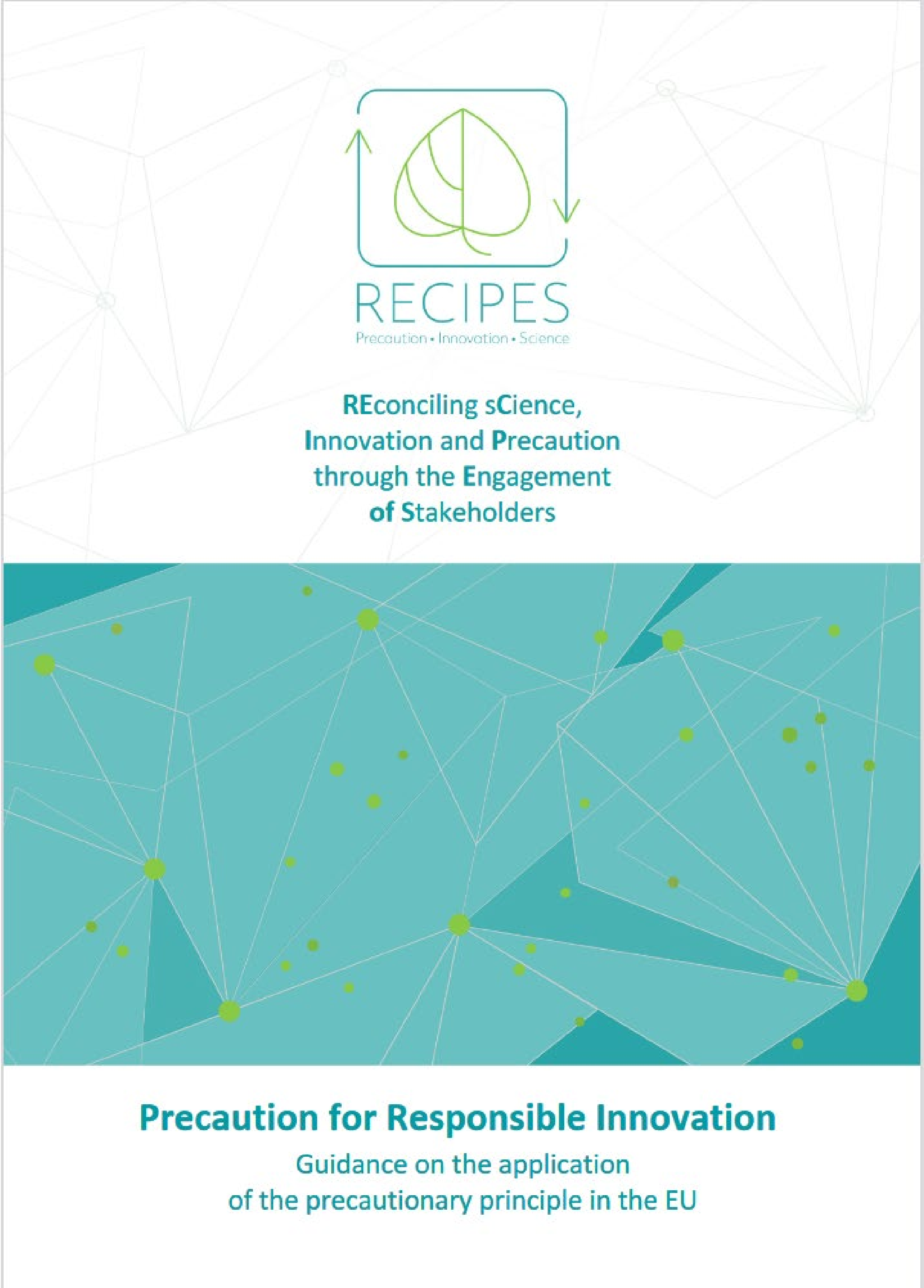
- **Asbestos**

Pharmaceuticals

- ***Contraceptive pill pollution***
- **DES**

Radiations

- **X-rays**
- ***Mobile phones-head cancers***
- ***Nuclear accidents***



Three parts:

- Scope of application
- Organisation of expertise
- Participation

https://recipes-project.eu/results/guidance-future-application-precautionary-principle

two-way use of the precautionary principle

- **Compass:**
  - Guide innovation towards more societally acceptable, clean and safe directions.
  - Responsible innovation: Anticipation, reflexivity, inclusion, responsiveness (Stilgoe e.a).
- **Legal safeguard:**
  - Justify early policy or regulatory action to manage uncertain risks.
  - Appeal to prudence.

Scope of application of PP

- Precautionary action requires scientifically underpinned grounds for concern, not certainty, nor an exhaustive risk assessment.
- The use of cost-benefit analysis is of limited value in cases that require the precautionary principle
- The choice who or what gets the benefit of the doubt is a policy issue and should be made explicitly

PP not only in risk management!

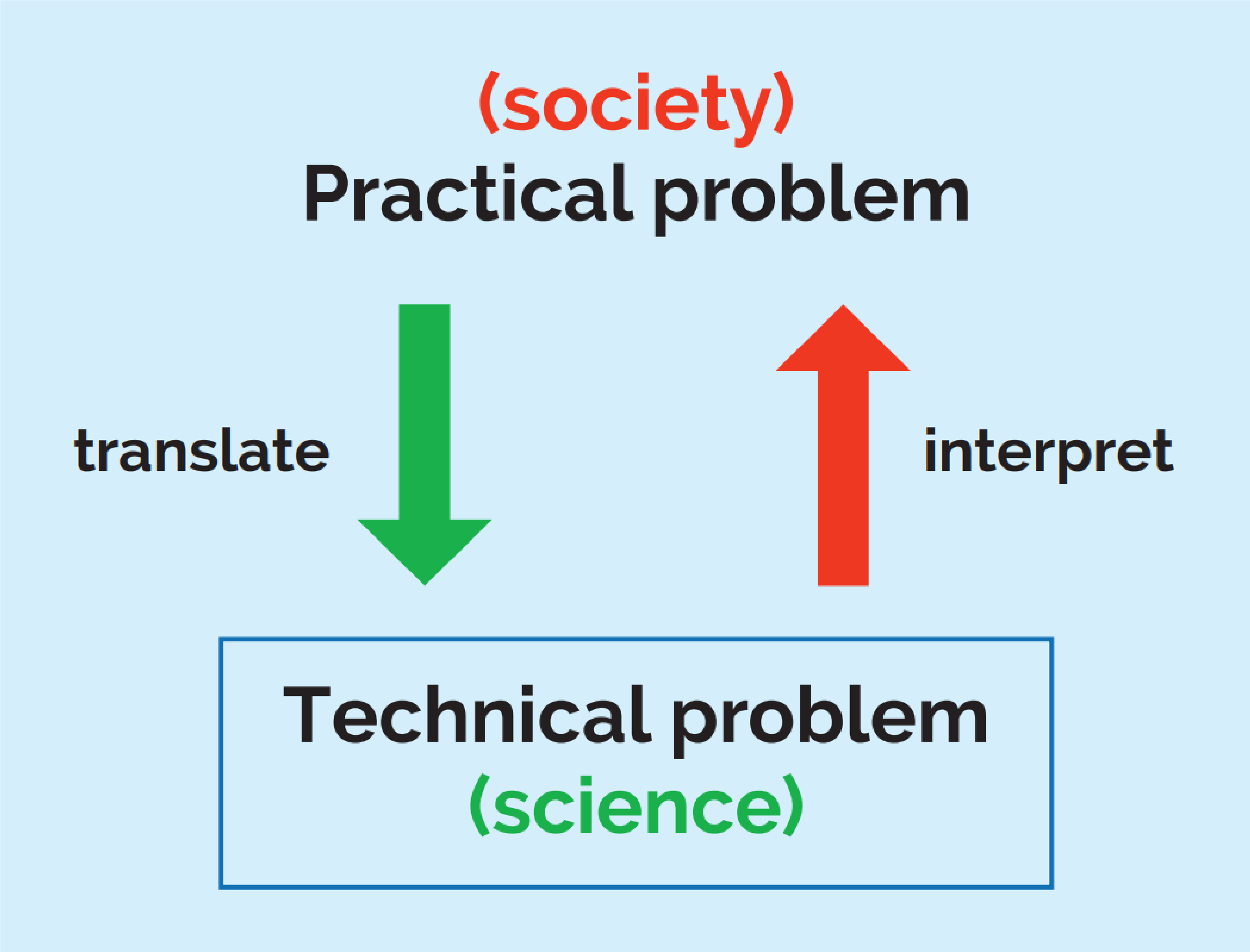
- Risk assessment needs to be well-informed by the precautionary principle
  - so that situations that require precautionary action can be detected more adequately and timely
  - well-organised and timely collection of ***actionable knowledge*** is key for dealing prudently with uncertain risks
    - Actionable knowledge for the PP includes knowledge on the **severity and nature** of potential adverse effects, the nature of the **uncertainties** on **risks and proclaimed benefits**, knowledge **gaps**, knowledge on **alternatives**.
  - Pluralization of expert knowledge in scientific assessment: **engage wider range of knowledge holders**

Uncertainty

- Policy makers should require that risk assessment includes systematic and transparent appraisal of scientific uncertainties, knowledge gaps and ignorance.
- Explicit and transparent problem scoping
  - What are relevant aspects of the problem?
  - Set problem boundaries wide enough to include the concerns of those affected by the risks and the risk regulation.

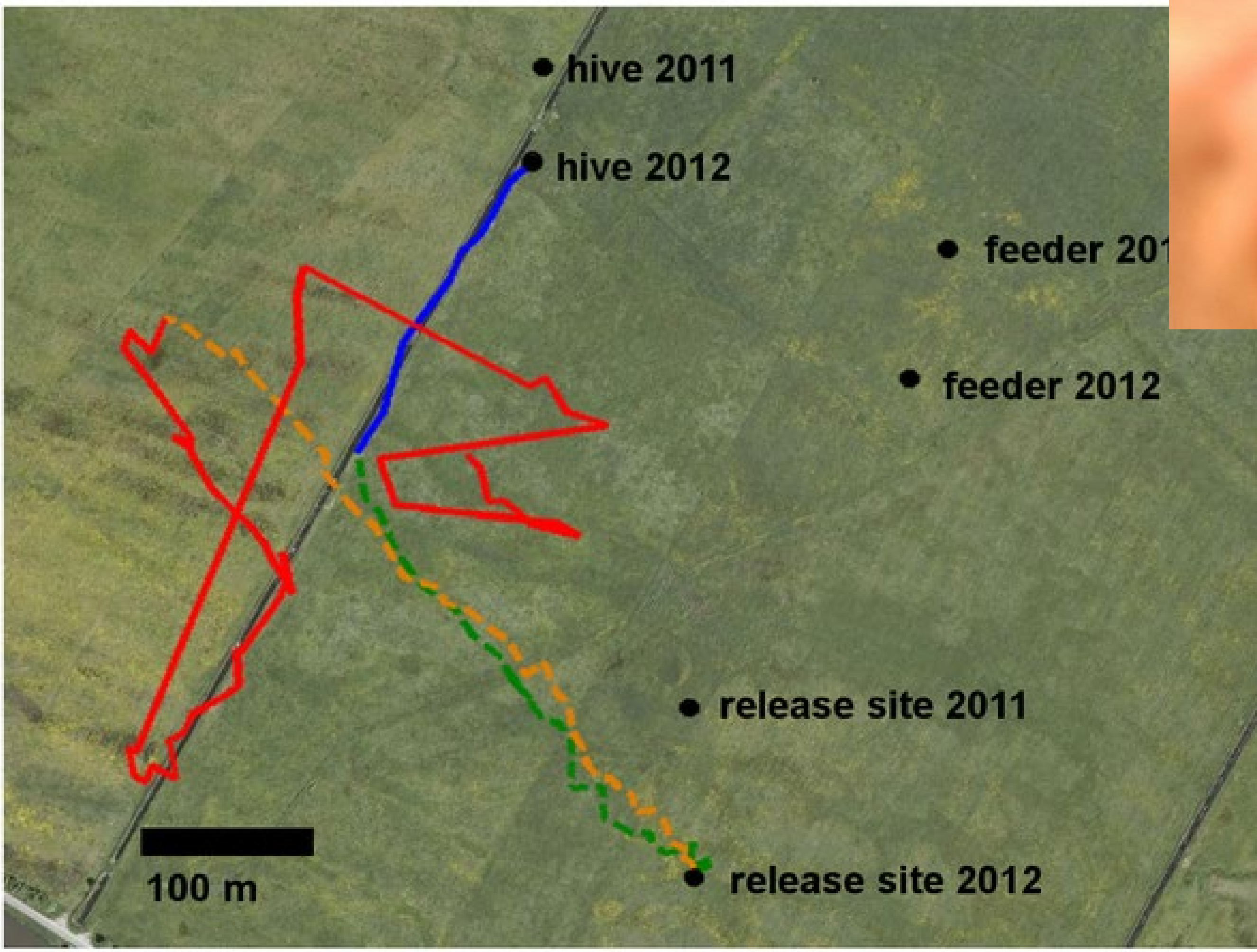
risk assessment must be open to ‘non-standard’ knowledge

- Blind spots in overly reductionist risk assessment protocols.
- Overly specific protection goals can undermine PP
- Knowledge that do not fit in such protocols (e.g. knowledge regarding end-points not covered by the protocols) is often downplayed, marginalised or ignored.
- Too often, it is necessary that coalitions of concerned scientists and societal actors step in and ‘break the script’ of routinised assessment and management processes in order to recognise key uncertainties and potential harm.



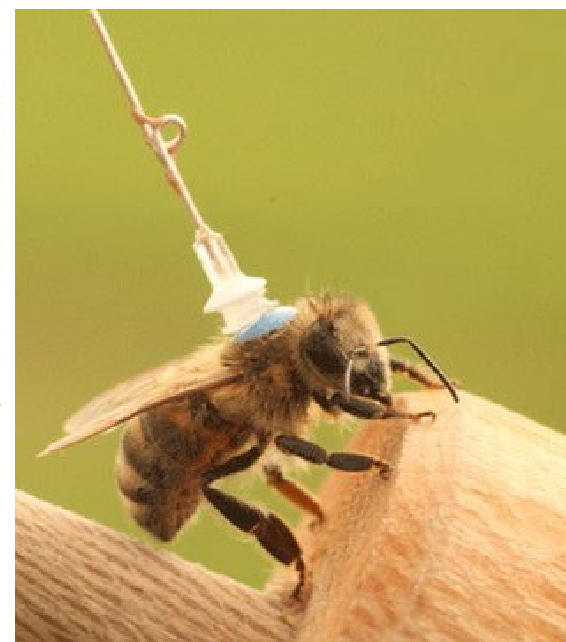
Ravetz, J., 1971, Scientific Knowledge and its Social Problems, Oxford University Press.

Radar-tracking experiment Randolf Menzel:
Bees exposed to neonicotinoids loose orientation



Yellow-Red Thiacloprid-bees

Green-Blue Control bees



Fischer J, Müller T, Spatz A-K, Greggers U, et al. (2014) Neonicotinoids Interfere with Specific Components of Navigation in Honeybees. PLoS ONE 9(3): e91364. doi:10.1371/journal.pone.0091364
http://www.plosone.org/article/info:doi/10.1371/journal.pone.0091364

PLOS ONE

Is present day waste treatment ready for nano waste?

- Waste that contains nano-particles not yet treated as a separate waste stream
- Nanocomposite polymers can become bulk product: big waste streams possible
- Present day filtering techniques in waste incinerators cannot handele particles <100nm (20% not captured by filter)
- Particles with melting point >300 °C might be emitted unchanged
- E.g.: Silica, Titaniumoxide white, Zinc Oxide, Zirconium, Gold, Silver en Cobalt.

(Roes en Patel, 2012)

- Is **waste water treatment** ready to handle high fluxes of nanoparticles from cosmetics, washing powder and personal care products? (Titanium oxide, silver, etc.)
  - Based on **bacterial** decomposition of organic substances in waste water
  - nano silver and titanium oxide inhibit bacterial growth…

Recommendations

- Extended participation in RA / upstream engagement
- More critical reflection on nano-innovation: nano-ethics / RRI
- Diversify risk analysis methods (too early for harmonization -> avoid anchoring)
- "Keep it complex" (Andy Stirling 2010: *When knowledge is uncertain, experts should avoid pressures to simplify their advice.*)
- Keep RA open to non-standard knowledge and proactively include emerging end-points of concern
- Monitoring!!!
- Labelling
- Classify nano particles and products according to potential risk (*water soluble? persistent? melting point?, biocidal properties, etc.*)
- Separate collection and treatment of nano waste.

…. if time allows:

In case of uncertain risks, What Level of intervention is justified? ...

- Reassure public and decision makers
- Research only if public opinion demands it
- Research and monitoring
- Ban low benefit high damage actions
- "no regrets" measures
- Formal plans for strong measures, identify objectives and establish mechanisms
- Measures against most serious aspects
- Expensive & potentially difficult measures
- Comprehensive measures
- What ever it takes.

(evidence scale by Weiss, 2003)

... this depends on two factors:

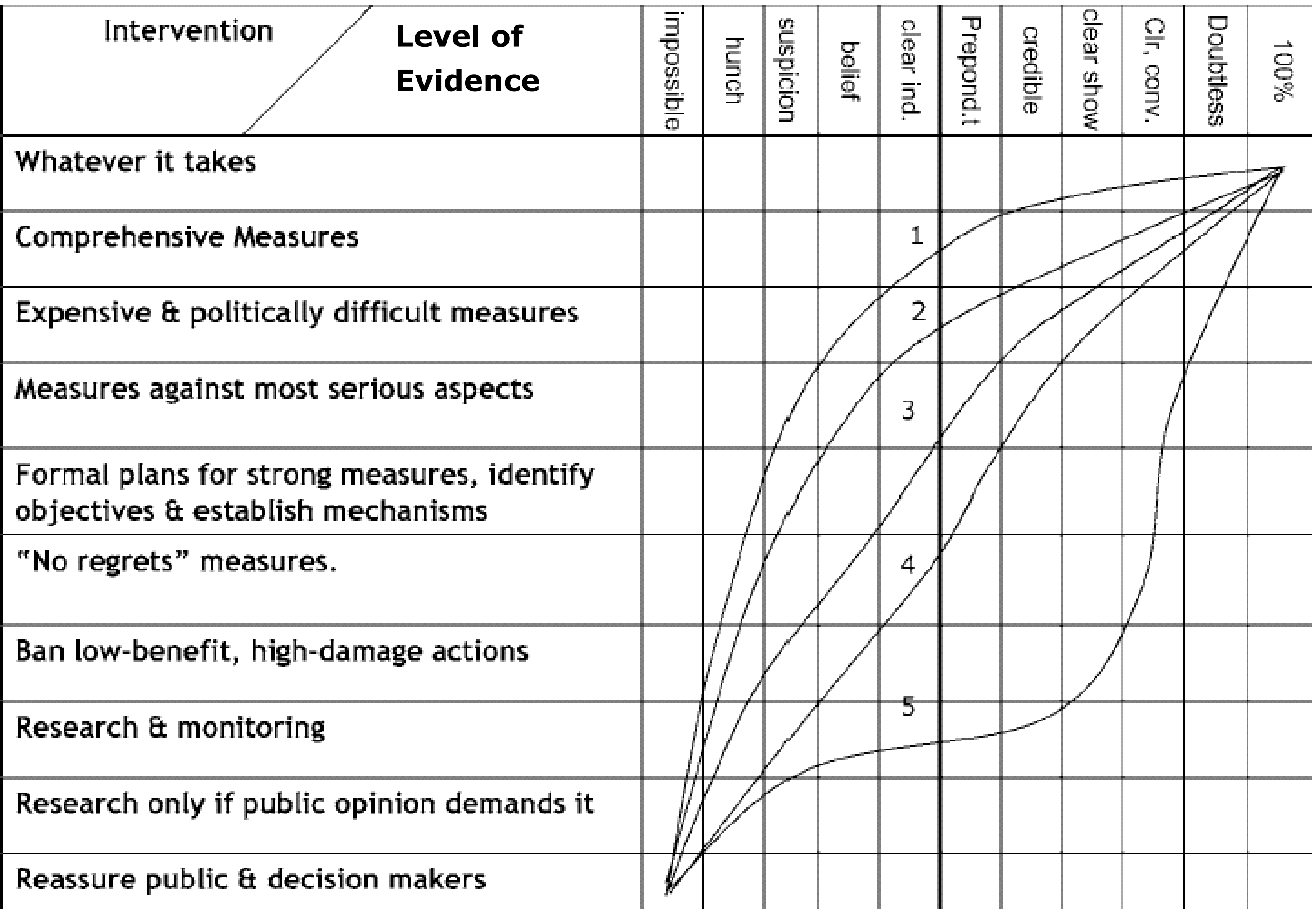
1. How strong is the evidence of unacceptable harm?

Weiss 2003/2006 evidence scale:

10. Virtually certain
9. Beyond a reasonable doubt
8. Clear and Convincing Evidence
7. Clear Showing
6. Substantial and credible evidence
5. Preponderance of the Evidence
4. Clear indication
3. Probable cause: reasonable grounds for belief
2. Reasonable, articulable grounds for suspicion
1. No reasonable grounds for suspicion
0. Insufficient even to support a hunch or conjecture

2. One’s risk-attitude:

Even where there is agreement on “level of evidence”, there usually is substantial societal disagreement on what level of intervention is justified.



Attitudes according to Weiss 2003:

1. Environmental absolutist

2. Cautious environmentalist

3. Environmental centrist

4. Technological optimist

5. Scientific absolutist

Refs and further reading

- **Guidance on the application of the precautionary principle in the EU:** https://recipes-project.eu/sites/default/files/2022-07/2814_RECIPIES_Guidance_Book_final.pdf
- **RECIPES Case study Nanotechnology:** https://recipes-project.eu/results/case-study-5-nanotechnologies.html
- **EEA Late Lessons from Early warnings volume 2:** https://www.eea.europa.eu/publications/late-lessons-2
- **EEA Late Lessons from Early warnings volume 1:** https://www.eea.europa.eu/publications/environmental_issue_report_2001_22