

Nanoregulering symposium: reuze-oplossingen voor dwergproblemen?
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Nano Risks, Uncertainty and the Precautionary Principle

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Nanotechnologie

- Sterk groeiende sector: *“Since 2001, nanotechnology has grown from little more than a gleam in the eyes of researchers to a technology projected to be worth \$2.6 trillion in manufactured goods in 2014”* (Hansen 2008)
- **Nederland** op 3e plaats kwa investeringen in nanotechnologie (genormeerd naar BNP) (EZ, 2008)

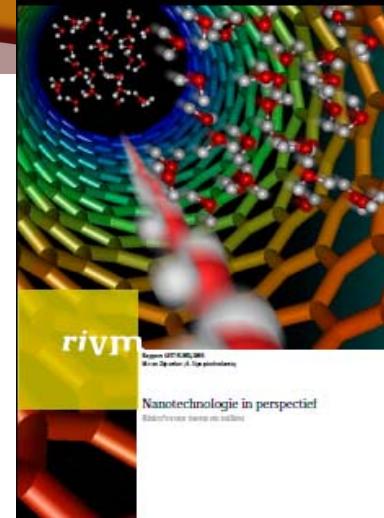


Huidige toepassingen

- Cosmetica
- Wasmiddelen
- Lichtgewicht fietsframes
- Nanocomposieten
- Kleding met antibacteriële eigenschappen
- Medicale toepassingen
- Voedselproducten
- Etc.

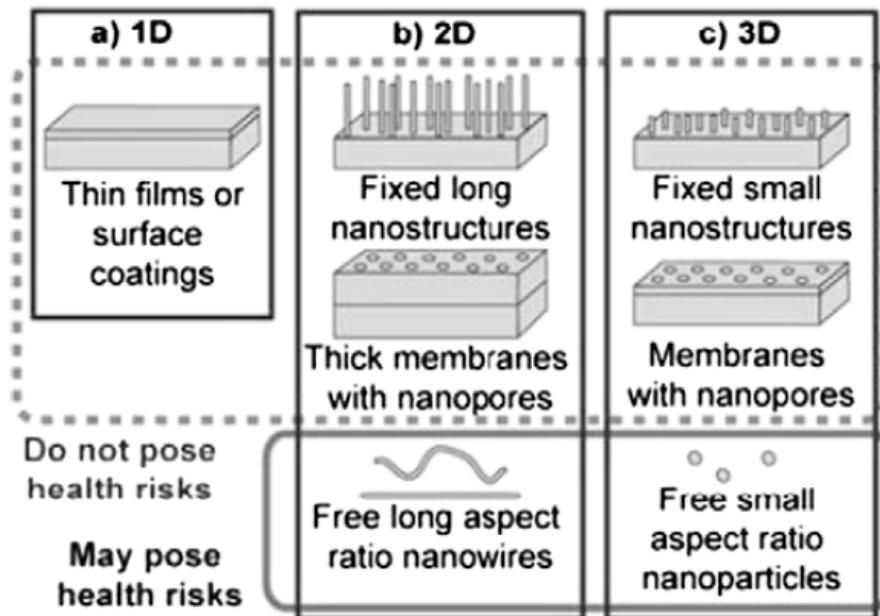
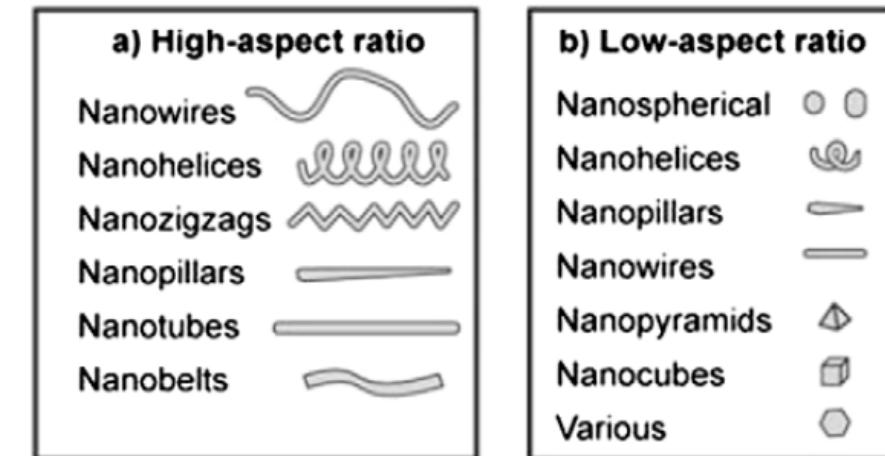
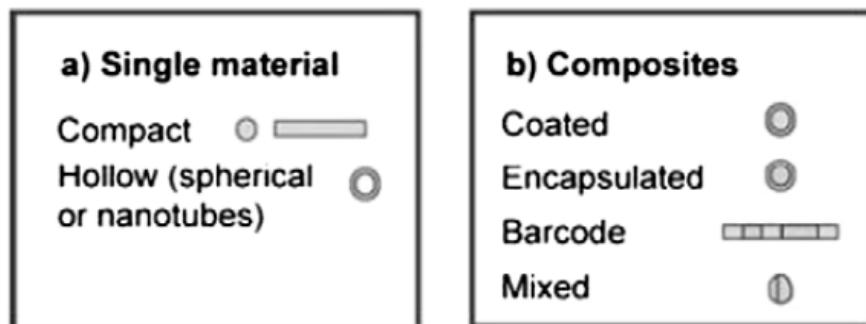
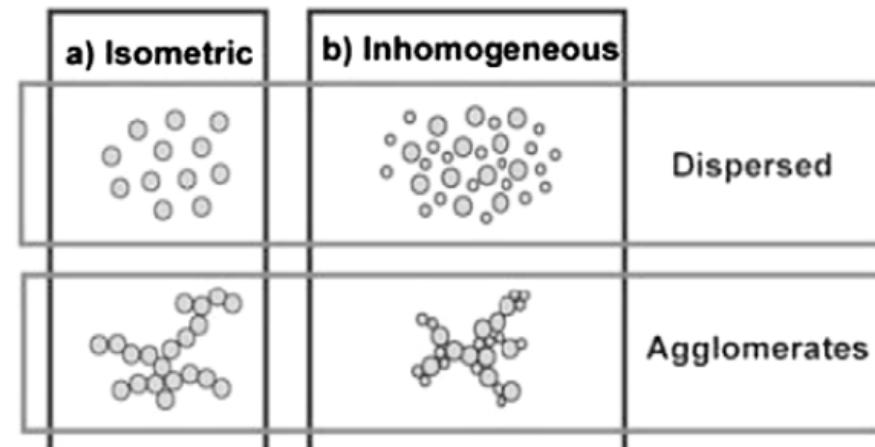


RIVM 2008



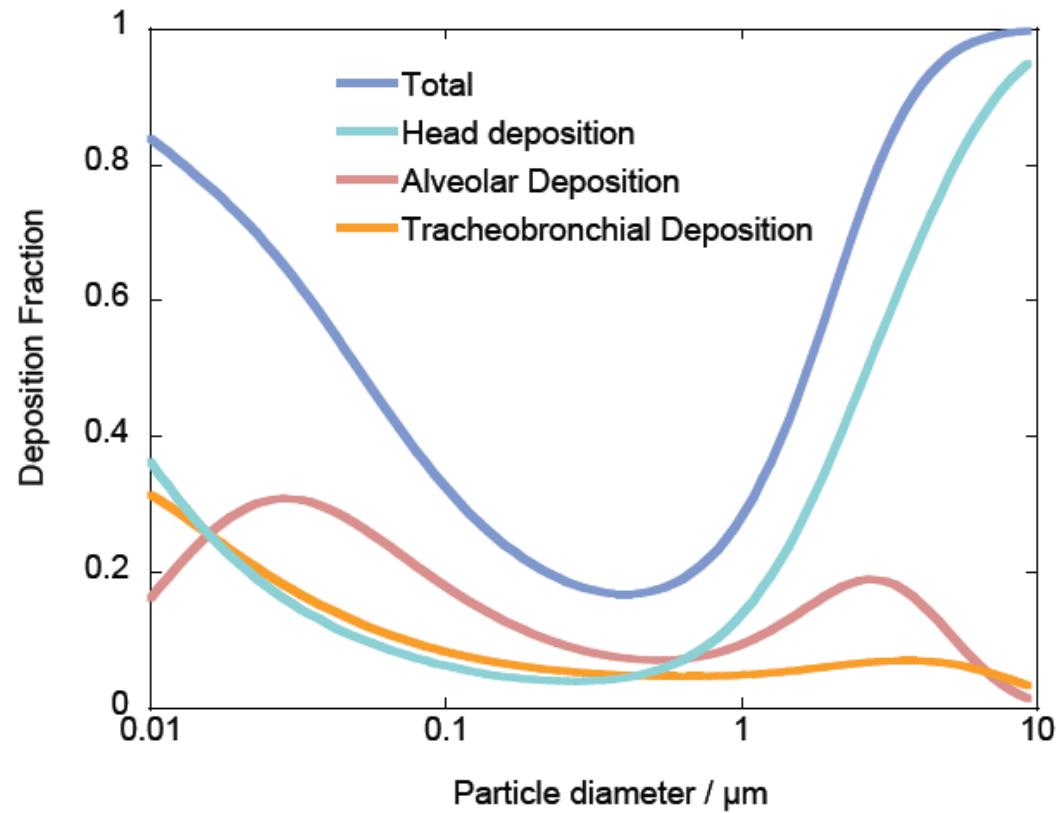
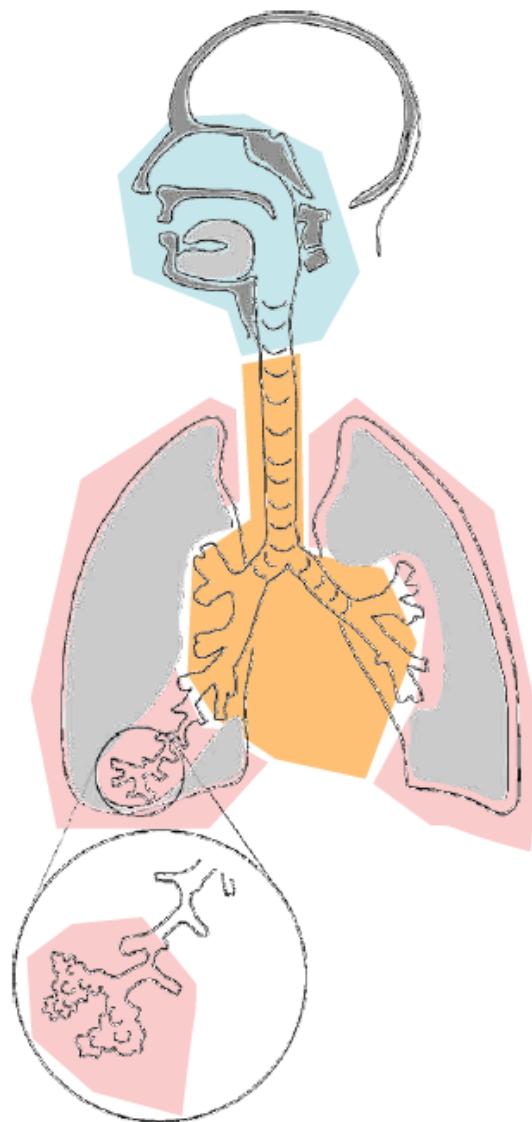
- Risico's niet uit te sluiten
- Veel kennis ontbreekt over gedrag chemische stoffen in nanovorm
- Toch zijn er al honderden producten met nanomaterialen op de markt
- Onderzoek naar blootstelling en toxiciteit dringend gewenst



1) Dimensionality**2) Morphology****3) Composition****4) Uniformity & agglomeration state**

Buzea et al. (2007); Bystrzejewska-Piotrowska et al, 2009

Particle Deposition in the Lungs



Modeled lung deposition. Mouth and nose breathing, person at rest.

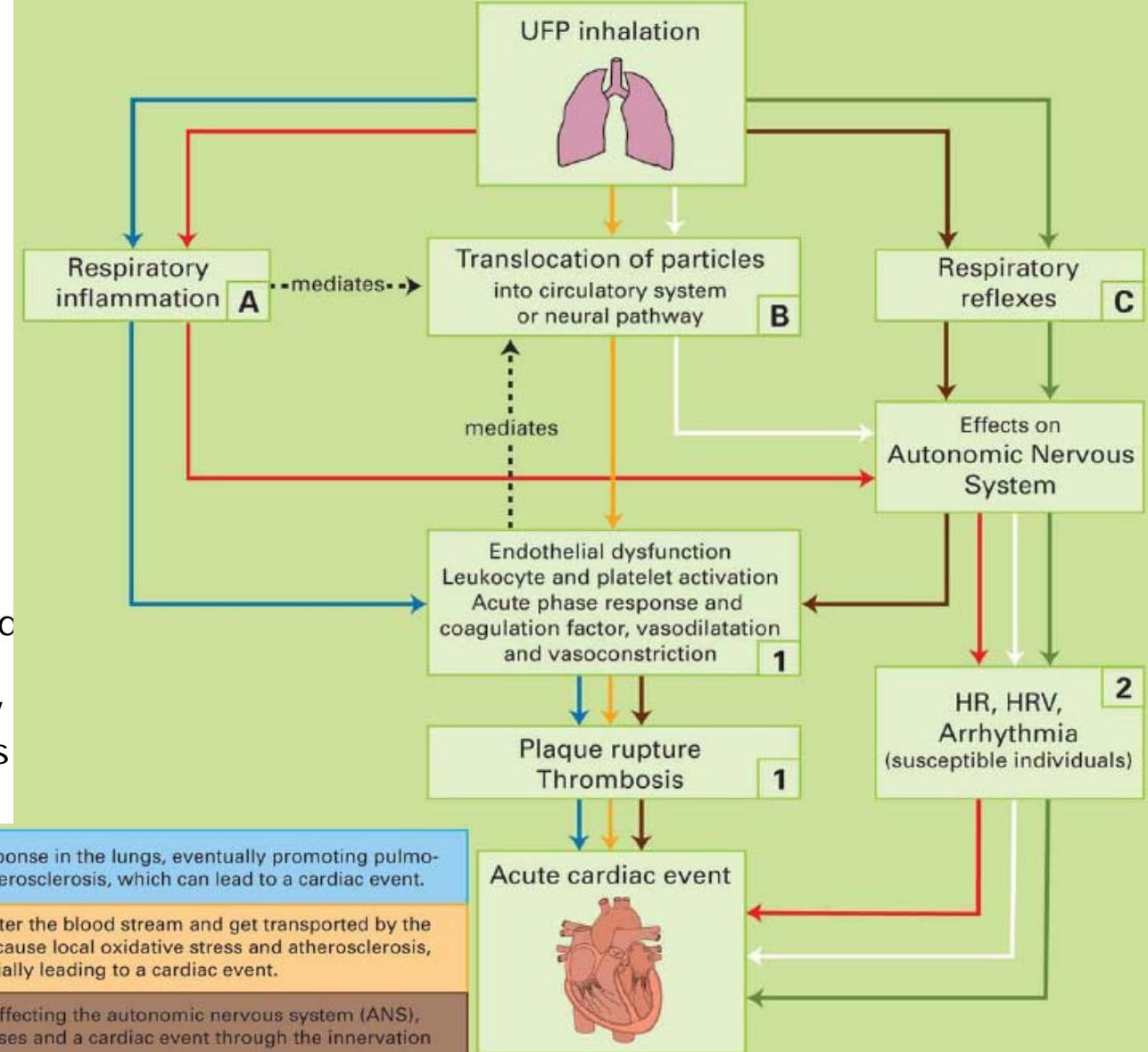
UFP health risks

Expert Workshop

Likelihood of causal relation between **short-term** UFP exposure and all-cause mortality, hospital admissions for cardiovascular and respiratory diseases, aggravation of asthma symptoms and lung function decrements was rated **medium to high**.

Likelihood for **long-term** UFP exposure to be causally related to all cause mortality, cardiovascular and respiratory morbidity and lung cancer was rated **medium**.

| | |
|--|---|
| | Pathway 1A UFP trigger an acute inflammatory response in the lungs, eventually promoting pulmonary or systemic inflammation and atherosclerosis, which can lead to a cardiac event. |
| | Pathway 1B UFP penetrate the lung interstitium, enter the blood stream and get transported by the blood to other organs. There they can cause local oxidative stress and atherosclerosis, or directly affect the heart, both potentially leading to a cardiac event. |
| | Pathway 1C UFP affect direct respiratory reflexes, affecting the autonomic nervous system (ANS), leading to acute cardiovascular responses and a cardiac event through the innervation of the heart. |
| | Pathway 2A UFP trigger an acute inflammatory response which in turn may affect the ANS, resulting in changes in cardiac rhythm, which could lead to cardiac events. |
| | Pathway 2B UFP are translocated to the brain and affect the ANS directly through the nerves, changing cardiac rhythm and as such causing a cardiac event. |
| | Pathway 2C UFP cause direct respiratory reflexes, affecting ANS and subsequently causing disruption of the cardiac rhythm resulting in (fatal) arrhythmia. |



Highest likelihood: pathway involving respiratory inflammation and subsequent thrombotic effects.
 Knol e.a. 2009
www.particleandfibretoxicology.com/content/6/1/19

Kennis gezondheidseffecten ultrafijn stof versus synthetische nanodeeltjes (Borm e.a. 2008)

Onopzettelijke emissies:

- Verbranding (diesel)
- Natuurlijk (branden, nucleation)

Extrapolatie mogelijk?

Synthetische NP:

- Bestaande NP (uf CB, TiO₂)
- Afbreekbare NP
- Nieuw ontwikkelde NP voor speciale toepassingen.

| Effect ultrafijn stof | Status voor synthetische Nanodeeltjes (type) |
|---|---|
| Ontsteking in de luchtwegen & longen | Bevestigd in proefdieren (CNT). |
| Hartritmestoornissen (diesel) | Bevestigd in proefdieren (CNT, CB) |
| Ontregeling vasoregulatie | Bevestigd in proefdieren (TiO ₂ , CB) |
| Inflammatie/Verstoring hersenfunctie | Bevestigd in proefdieren (Au, MnO ₂ , C) |
| Exacerbatie asthma-COPD | Onbekend |
| Effect op bloedstolling (bloedplaatjes) | Bevestigd in vitro en vivo (CNT) |
| Effect niet bekend of gevonden | Granuloma vorming in peritoneaal mesotheel (MWCNT > 20 µm) ¹ |

"carbon nanotubes toegelaten op de markt omdat ze chemisch gezien voor 100 % uit koolstof bestaan"

Hazard assessment vuistregel

Hoe hoger op de lijst, hoe meer maatregelen moeten worden genomen om de blootstelling te voorkomen

- i. Vezelvormig en onoplosbaar;
- ii. Stoffen waarvan het 'uitgangsmateriaal' bijzondere eigenschappen heeft (carcinogeen, mutageen, reproductietoxisch, sensibiliserend);
- iii. Onoplosbaar (en niet in één van de voorgaande categorieën);
- iv. Oplosbaar en niet in één van de voorgaande categorieën).

(Borm et al, 2008)



Late lessons from early warnings EEA 2001 rapport

“False Negatives”

Structured around 4 questions:

- When were first scientifically based early warnings ?
- When and what were the main actions, or inactions by society's actors ?
- What were the costs and benefits (all kinds) of the actions/inactions; and
- What lessons can be drawn that may help improve decisionmaking and reduce overall costs ?



Late lessons from early warnings

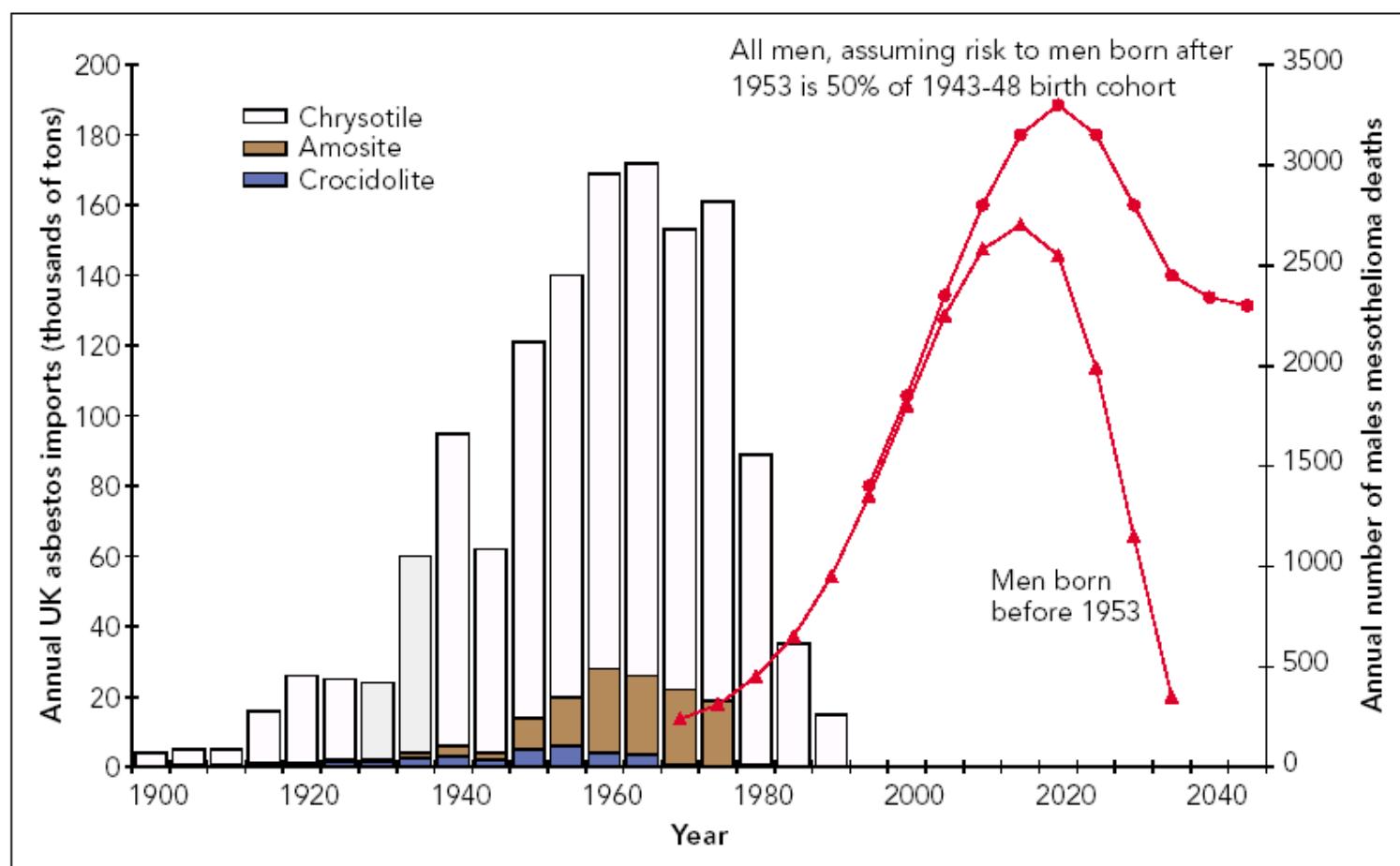
- Example Asbestos: (roofs, building materials)
- 1880 introduction of Asbestos
- 1900 First warnings
- 1920 first signals of cancer related to asbestos
- 1930 first scientific proof of negative effects
- 1965 first steps to reduce asbestos
- 1993 ban in Netherlands
- 2000 still negative effects and financial costs (42.500 effected persons, costs 67 Mrd NLG)
- 34.000 lifes could have been saved in the Netherlands with immediate reactions to early warnings



Figure 5.1.

UK asbestos imports and predicted mesothelioma deaths

Source: Peto, 1999



Precautionary Principle:

When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.

Morally unacceptable harm refers to harm to humans or the environment that is

- threatening to human life or health, or
- serious and effectively irreversible, or
- inequitable to present or future generations, or
- imposed without adequate consideration of the human rights of those affected.

The judgment of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.

Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.

Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.



(UNESCO COMEST 2005)

Late Lessons from Early Warnings

01. Acknowledge and respond to ignorance, as well as uncertainty and risk, in technology appraisal and public policy-making.
02. *Provide adequate long-term environmental and health monitoring and research into early warnings.*
03. Identify and work to reduce blind spots and gaps in scientific knowledge.
04. *Identify and reduce interdisciplinary obstacles to learning.*
05. Ensure that real world conditions are adequately accounted for in regulatory appraisal.
06. *Systematically scrutinize the claimed justifications and benefits alongside the potential risks.*



Late Lessons (continued)

07. Evaluate a range of alternative options for meeting needs alongside the option under appraisal, and promote more robust, diverse and adaptable technologies so as to minimize the costs of surprises and maximize the benefits of innovation.
08. *Ensure use of 'lay' and local knowledge, as well as relevant specialist expertise in the appraisal.*
09. Take full account of the assumptions and values of different social groups.
10. *Maintain regulatory independence from interested parties while retaining an inclusive approach to information and opinion gathering.*
11. Identify and reduce institutional obstacles to learning and action.
12. *Avoid 'paralysis by analysis'; act to reduce potential harm when there are reasonable grounds for concern.*



Nanotech in European public policy

Inspired by:

- EU Lisbon agenda for growth and competitiveness ("Europe needs knowledge intensive innovation")
- +- Recent experiences with new technologies ("avoid another GMO controversy" ; but : various interpretations of 'what went wrong' in the case of GMO's)

Consensus about three functions of governance :

- Promoting innovation (for growth and benefits for society)
- Controlling impacts (anticipate adverse health and environmental effects)
- Facilitating debate and democratic decision-making

'An integrated, safe and responsible approach to nanotechnology'
(EU Action Plan on Nanotechnology : 'as agreed by all stakeholders')

(Craye 2008, RiskBridge)



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'lessons learnt' in European public policy

What has been learned ?

- Transparency and communication
- Increased attention to risks and safety
- Focus on ethics as avoiding misuse of NTs
- Partial attention to socially desirable technological development (knowledge of stakeholder views ; acknowledgement of non-risk aspects related to nanotechnology, but no real integration of this in innovation decision making)

What has not/hardly changed ?

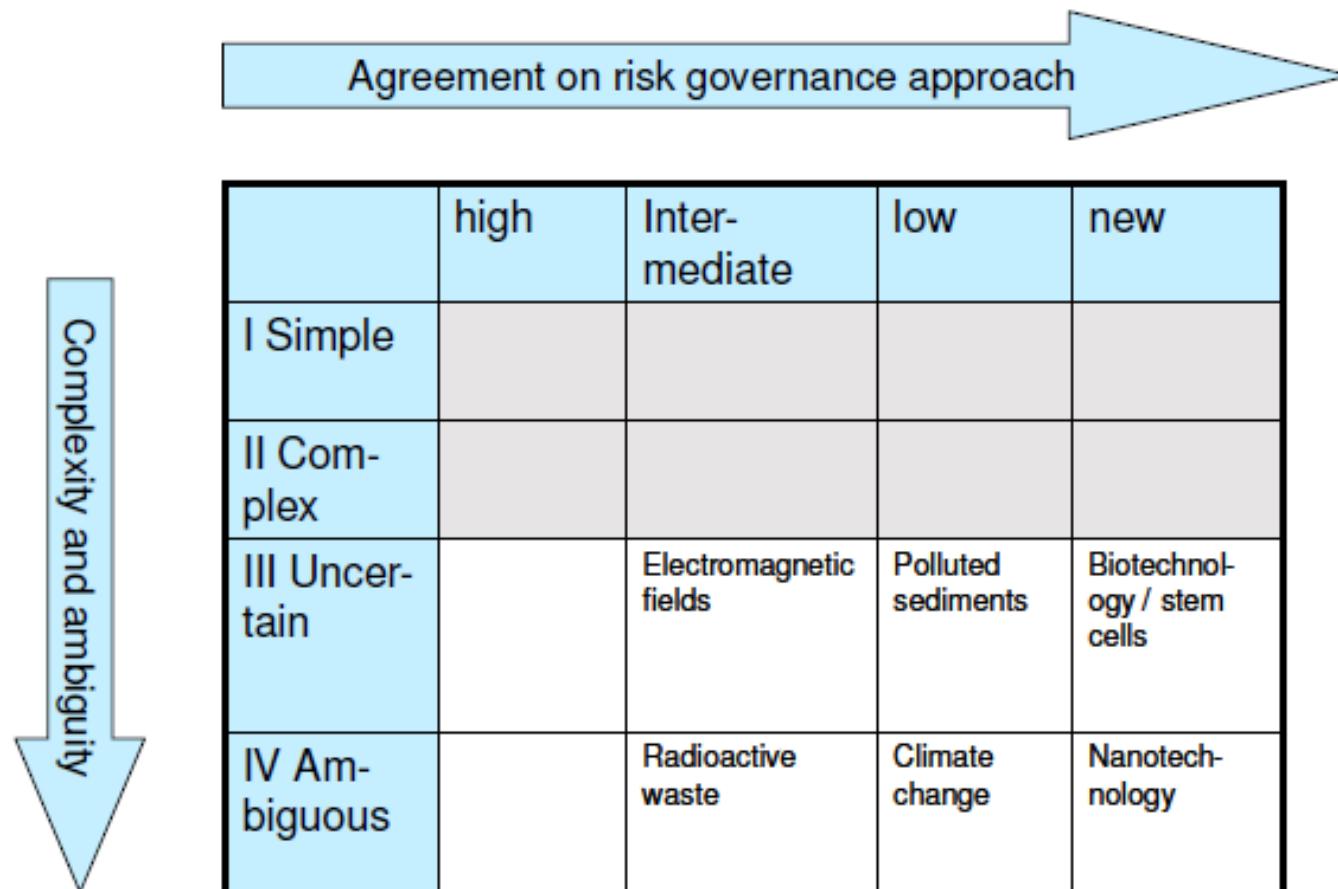
- No profound questioning of innovation
- View of technological innovation as mainly a linear process (no collective co-responsibility for innovation)
- Safety as legitimate concern (but very narrow view on 'precaution')
- No open acknowledgement of the possibility of surprise
- Institutionalized processes and structures of decision-making

(Crayx 2008 – RiskBridge)



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Risk typology



Source: Risk Bridge project



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)



Daily practice of dealing with uncertain science in policy making

Two dominant strategies: uncertainties are either

- **downplayed** to promote political decisions (enforced consensus), or
- **overemphasised** to prevent political action
- Both promote decision strategies that are **not fit for meeting the challenges** posed by the uncertainties and complexities faced.
- This delays a transition to sustainability.
- We need a theory of uncertainty, scientific dissent & **plurality** in sustainability science.



3 framings of uncertainty (van der Sluijs, 2006)

'deficit view'

- Uncertainty is provisional
- Reduce uncertainty, make ever more complex models
- *Tools:* quantification, Monte Carlo, Bayesian belief networks

'evidence evaluation view'

- Comparative evaluations of research results
- *Tools:* Scientific consensus building; multi disciplinary expert panels
- focus on robust findings

'complex systems view'

- Uncertainty is intrinsic to complex systems: permanent
- Uncertainty can be result of new ways of knowledge production
- Acknowledge that not all uncertainties can be quantified
- Openly deal with deeper dimensions of uncertainty
- *Tools:* Knowledge Quality Assessment

"*speaking truth to power*" vs "working deliberatively within imperfections"



Modern Model of Science & Policy

Perfection and perfectibility

- Facts determine correct policy
 - The true entails the good
 - No limits to progress of control over environment
 - No limits to material & moral progress
 - Technocratic view
-
- Science informs policy by producing ***objective***, ***valid*** and ***reliable*** knowledge:

"Speaking truth to power"

(Funtowicz, 2006; Funtowicz & Strand, 2007)



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Modern model assumes that:

- Uncertainty can be eliminated or controlled
- Only one correct system description
 - *system and problem are not complex*
- Ethical question “is this new technology good for us?” can be reduced to Rational Cost Benefit Analysis

(Funtowicz, 2006; Funtowicz & Strand, 2007)



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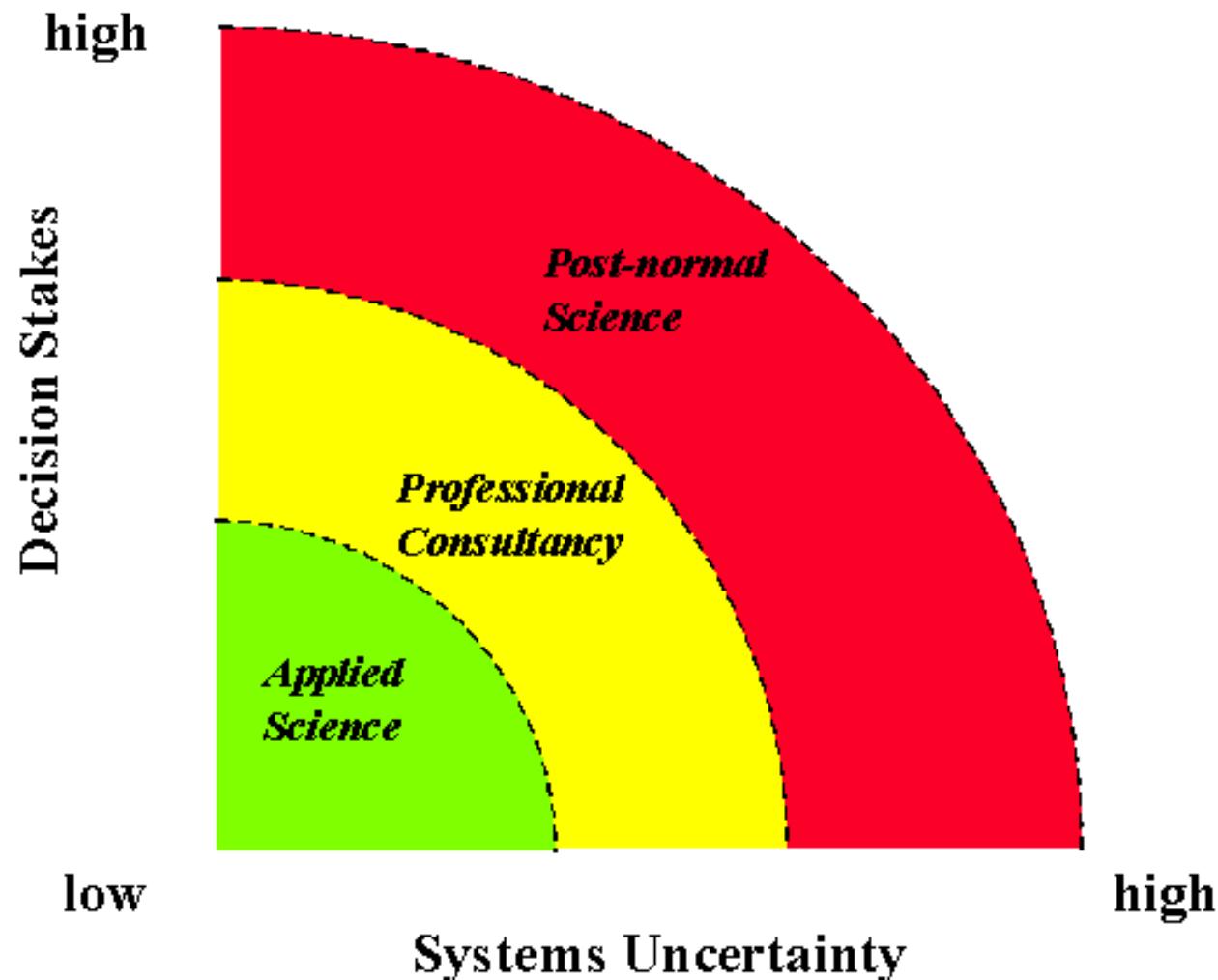
Complex - *uncertain* - risks

Typical characteristics (Funtowicz & Ravetz):

- Decisions will need to be made before conclusive scientific evidence is available;
- Potential impacts of 'wrong' decisions can be huge
- Values are in dispute
- Knowledge base is characterized by large (partly irreducible, largely unquantifiable) uncertainties, multi-causality, knowledge gaps, and imperfect understanding;
- More research ≠ less uncertainty; unforeseen complexities!
- Assessment dominated by models, scenarios, assumptions, extrapolations
- Many (hidden) value loadings reside in problem frames, indicators chosen, assumptions made

Knowledge Quality Assessment is essential





Funtowicz and Ravetz, **Science for the Post Normal age, *Futures*, 1993**



Post Normal Science

Extended participation: working deliberatively within imperfections

- Science (the activity of technical experts) is only one part of relevant **evidence**
- Critical dialogue on strength and relevance of evidence
- Interpretation of evidence and attribution of policy meaning to a given body of evidence is democratized
- Tools for Knowledge Quality Assessment empower all stakeholders to engage in this deliberative process

(Funtowicz, 2006; Funtowicz & 2007)



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GR advies 2006

G

- Moeilijk afbreekbare synthetische Nanodeeltjes vragen om voorzorgprincipe
- In kaart brengen vrijkomen deeltjes in levenscyclus: afvalstadium
- nanovormen bestaande stoffen behandelen als nieuwe stoffen onder REACH
- Internationale coordinatie toxiciteitstests
- Risk governance en dialoog met publiek



Is huidige afvalverwerking toegerust op nanoafval?

- Nanodeeltjeshoudend afval wordt nog niet als aparte afvalstroom beschouwd
- Nanocomposit kan bulkproduct worden dus grote afvalstroom mogelijk
- Huidige filtertechnieken **afvalverbrandingsovens** kunnen niet overweg met <100nm deeltjes
- Deeltjes met smeltpunt >300 graden kunnen ongewijzigd in het milieu komen
- Ondermeer: Silica, Titaniumoxide wit, Zinkoxide, Zirconia, Goud, Zilver en Kobalt.
(Roes en Patel, forthcoming)
- Is **rioolwaterzuivering** toegerust op grote stromen van nanodeeltjes uit cosmetica, wasmiddelen, persoonlijke verzorgingsproducten? (Titaanoxide, zilver, etc)



Aanbevelingen

- Extended participation
- Diversificeer risicoanalysemethoden (te vroeg voor harmonisatie -> anchoring)
- Implementeer 12 late lessons
- Monitoring!!!
- Meer kritische reflectie op nano-innovatie: nano-ethiek
- Classificering
- Labeling
- Aparte verwerking nano-afval?

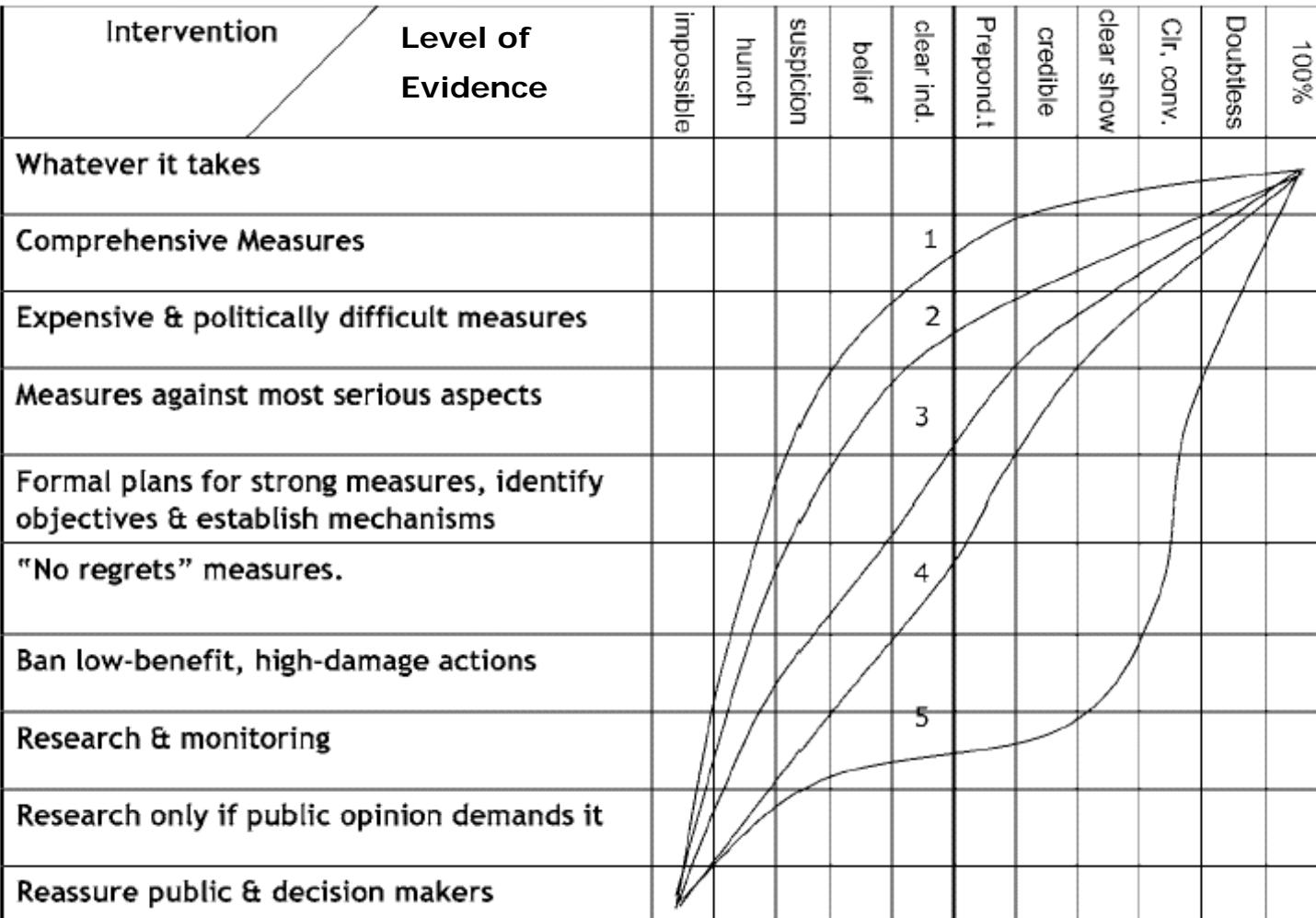


Weiss 2003/2006 evidence scale

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



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**



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